PSS INSIGHT

A Tool for Measuring Progress in Pharmaceutical Systems Strengthening

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PSS Insight: A Tool for Measuring Progress in Pharmaceutical Systems Strengthening

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About SIAPS

The goal of the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is to ensure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. Toward this end, the SIAPS result areas include improving governance, building capacity for pharmaceutical management and services, addressing information needed for decision-making in the pharmaceutical sector, strengthening financing strategies and mechanisms to improve access to medicines, and increasing quality pharmaceutical services.

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Key Words

Pharmaceutical system, pharmaceutical system strengthening, definition, framework, measurement, metrics, indicator, indicators, indicator-based, assessment, tool, web-based, portal, dashboard, repository, comparative, longitudinal, score, composite

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CONTENTS

ACRONYMS

MSH	Management Sciences for Health
PIRS	performance indicator reference sheets
PSS	pharmaceutical systems strengthening
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
USAID	US Agency for International Development
WHO	World Health Organization

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INTRODUCTION

In 2012, when the US Agency for International Development (USAID) awarded the SIAPS Program, it tasked the program with developing a measurement framework and corresponding indicators for determining whether investments in pharmaceutical systems strengthening are contributing to the development of stronger, more sustainable pharmaceutical systems. At that time, there were no widely accepted definitions for a pharmaceutical system or pharmaceutical systems strengthening. Furthermore, there was no standardized approach for measuring progress toward stronger, more sustainable pharmaceutical systems.

In 2014, SIAPS conducted a series of literature reviews and held a consultative meeting of SIAPS partners and experts[1] in the field to propose definitions for a pharmaceutical system and pharmaceutical systems strengthening. Participants in the meeting set out to identify the critical system components, primary system outcomes, and key system attributes that are essential to measure and capture progress in pharmaceutical system strengthening over time and across countries (figure 1). Once these key parameters for measurement were identified, SIAPS arranged them within a framework for measurement to guide the selection of indicators and determine a basis to guide the measurement process.[2] Once the framework was in place, an extensive review process of existing indicator-based assessment tools and manuals was undertaken to develop an indicator bank from which to select measures for the PSS Insight tool.[3] Working with experts from Boston University School of Public Health, SIAPS selected key indicators that form the basis of a tool to measure progress in pharmaceutical systems strengthening, using defined indicator selection criteria.[4] The resulting tool, called *PSS Insight*, is a web-based data management system comprising 117 indicators intended to measure progress in pharmaceutical systems strengthening, both across countries and over time.

[1] Please refer to annex A for the consultative meeting report. The report includes the meeting objectives; results of the literature reviews for development of definitions of a *pharmaceutical system* and *pharmaceutical systems strengthening*; identification of the components and elements for measurement; and the proposed definitions, components, and elements.
[2] Please refer to annex B for the framework and accompanying definitions of components, elements, and system attributes and outcomes.
[3] Please refer to annex C for the complete list of reviewed indicator sources.
[4] Please refer to annex D for the indicator selection criteria used to guide the selection of indicators.

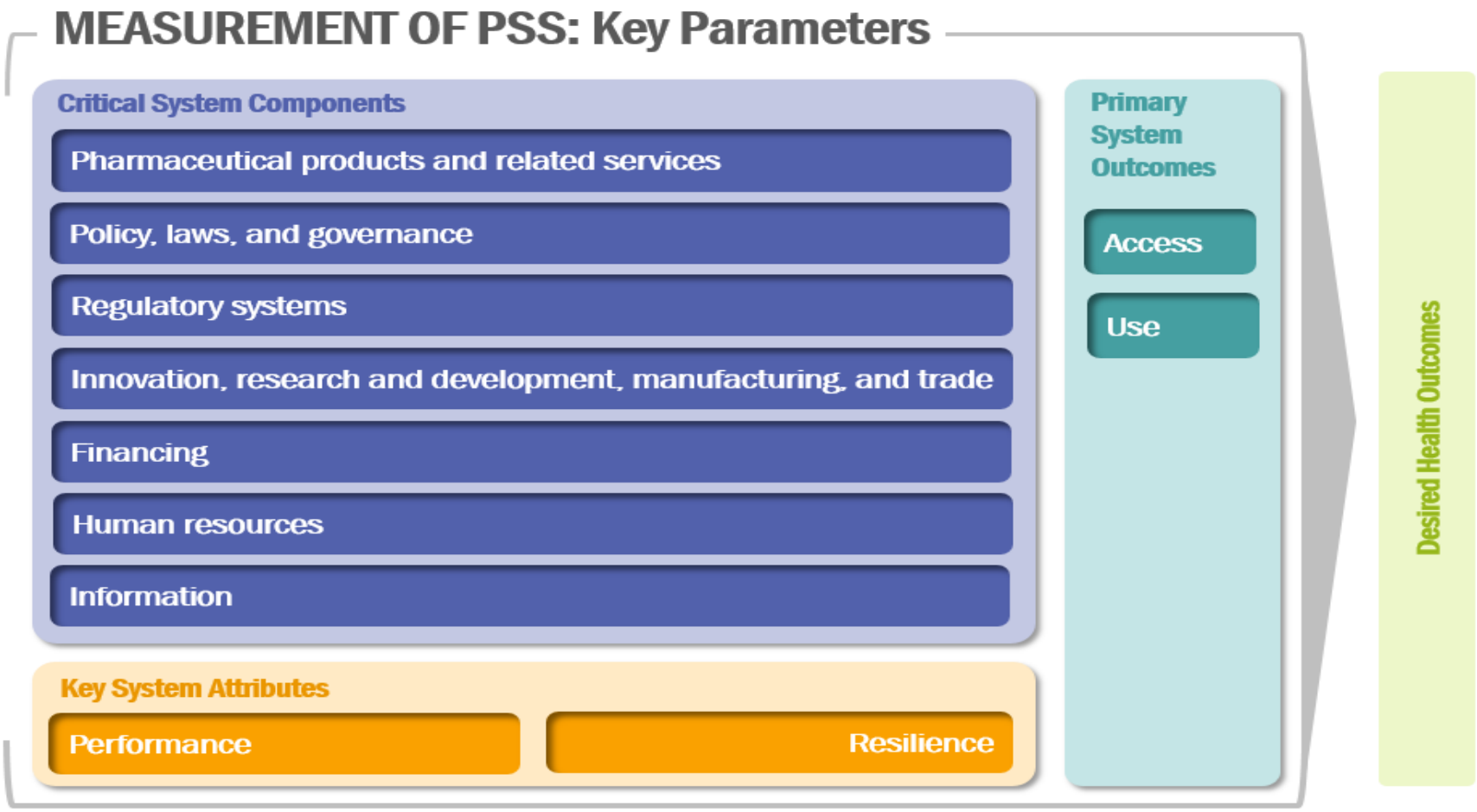


Figure 1. PSS measurement framework: Critical components, key attributes, and primary outcomes[5]

[5] Please refer to annex B for the framework and accompanying definitions of components, elements, and system attributes and outcomes.

METHODOLOGY

Development of Definitions and System Components and Elements for Measurement

As a first step toward the development of a tool for measuring progress in pharmaceutical systems strengthening, SIAPS needed to identify clear conceptualizations of the parameters that the tool was intended to measure. SIAPS conducted an extensive literature review, searching for existing definitions of a *pharmaceutical system* and *pharmaceutical systems strengthening*.

Ensuring equitable access to essential medicines, vaccines, and technologies and their appropriate use is a core function of a health system. The components involved in this function may be conceptualized as a pharmaceutical system—that is, a subset of the health system. Various terms have been used, sometimes interchangeably, to refer to these system components. These include pharmaceutical system, pharmaceutical management system, pharmaceutical supply system, pharmaceutical sector, and medical products building block.

Our literature review revealed three existing definitions of a pharmaceutical system that were developed for a specific purpose and therefore quite limited in scope and no existing definitions of pharmaceutical systems strengthening.

Based on reviews of the existing related definitions, frameworks, and literature on the subject, SIAPS proposed definitions of both a *pharmaceutical system* and *pharmaceutical systems strengthening* for discussion at a consultative meeting held in September 2014 (annex A). Following the consultative meeting, the definitions were updated to reflect input from meeting participants. The definitions included in annex A were changed slightly to include the concept of system resilience, following additional research. The final proposed definitions are as follows:

- A *pharmaceutical system* consists of all structures, people, resources, processes, and their interactions within the broader health system that aim to ensure equitable and timely access to safe, effective, quality pharmaceutical products and related services that promote their appropriate and cost-effective use to improve health outcomes.[i]

- *Pharmaceutical systems strengthening* is the process of identifying and implementing strategies and actions that achieve coordinated and sustainable improvements in the critical components of a pharmaceutical system to make it more resilient and to enhance its performance for achieving better health outcomes.[i]

Meeting participants also reviewed pharmaceutical system components and proposed elements of each component to guide indicator selection and measurement (annex A). Following the meeting, the SIAPS team conducted additional discussions with Boston University School of Public Health and SIAPS subject matter experts to finalize the definitions of the components and elements for measurement. The elements in particular warranted further scrutiny after the consultative meeting. Due to interactions between the components and the inclusion of system attributes and outcomes in our framework for measurement, some elements could fit under more

than one component. The SIAPS team also merged other elements to develop a pragmatic and feasible tool. Annex B describes the components and elements in more detail as well as the rationale for their inclusion in the measurement framework.

Health system resilience can be defined as the capacity of health actors, institutions, and populations to prepare for and effectively respond to crises; maintain core functions when a crisis hits and to be informed by lessons learned during the crisis and reorganize if conditions require it. Health systems are resilient if they protect human life and produce good health outcomes for all during a crisis and in its aftermath.[ii,iii]

Indicator Selection Process

Once the components and elements for measurement had been established and defined, the next step involved selecting indicators to measure these parameters. The team aimed to choose validated indicators from existing indicator-based assessment tools wherever possible to enable countries, researchers, and other future users to extract data from publicly available datasets, which would minimize the data collection efforts required to populate the tool. Indicators from the assessment tools identified in the literature review and from tools used internally by Management Sciences for Health (MSH) (annex C) were collated in a database. The list of indicators was organized according to the elements within each component—we aimed to select one structural, one process, and one outcome indicator to measure each element, enabling us to measure and score the elements individually and combine the element findings to appraise the component overall.

We based our indicator selection process on the criteria set forth by Boston University School of Public Health (annex D) and input from SIAPS subject matter experts as to the relevance of each indicator to the element as defined and whether the indicator measured an essential aspect of that element. Other criteria were also considered, including feasibility of data collection and whether the indicator was previously validated in other existing indicator-based assessments. Where the subject matter experts and the proposed indicators from Boston University based on the selection criteria disagreed, we included both selections in the draft of the tool for piloting. Indicator selection was an iterative process—it was quite challenging to select just three indicators per element, considering that some elements were fairly broad in scope as defined. In many instances, sets of indicators were selected for the pilot to assess feasibility, with the intention of narrowing the number of indicators subsequent to the pilot activities. Following the preliminary indicator selection process, 182 indicators were selected for inclusion in the pilot.

This exercise highlighted several areas where established measures are lacking, including the component of *Innovation, Research and Development, Manufacturing, and Trade*, as well as one element of the *Information* component, namely *Use of Information for Decision Making*. In these areas, the team formulated some new indicators for inclusion in the pilot, and in other cases, it altered or expanded existing indicators to align them more consistently with element definitions.

Development of Performance Indicator Reference Sheets

In many instances, we needed to develop or elaborate on performance indicator reference sheets (PIRS) for existing indicators to ensure definitional clarity and provide guidance and other

supporting information required for data collection in the pilot. PIRS are used to define indicators for measurement, state the intended purpose of collecting the indicator, demonstrate how to calculate or compute the indicator, identify likely data sources for the indicator, state assessment questions used to capture the indicator, and identify anticipated issues with data collection. We developed PIRS for each of the 182 indicators selected for piloting, and broke each indicator down into assessment questions to be asked verbatim to key informants to collect the data necessary to complete the indicator.

Pilot Activities

The pilot consisted of two separate, concurrent activities—primary data collection in two countries and desktop reviews to identify existing data sets containing the required indicator data for each country. The objectives of the pilot were to:

- Test indicators and PIRS for feasibility of collection, data availability, and clarity
- Assess the clarity and refine the instructions for data collection to ensure data consistency across collection sites and data collectors
- Determine level of effort and resources required to collect data
- Finalize the proposed data collection source for each indicator—which entity or key informant has the highest likelihood of providing the requested information
- Identify redundant indicators and indicators with consistently poor data as candidates for removal from the tool
- Determine which (if any) indicators could be removed from the interview portion of the tool and completed through desktop review alone.

In-country Pilots: Namibia and Bangladesh

Bangladesh and Namibia were selected as the in-country pilot sites due to their status as USAID Ending Preventable Maternal and Child Death countries. In addition, SIAPS had large field offices in both countries, and the tool could be used in English, given the language competencies of SIAPS staff and most key informants in these settings. Data collection teams from both countries were trained virtually by the SIAPS PSS Insight Team using WebEx. Trainings consisted of four one- to two-hour sessions that included a background and introduction to the PSS Insight framework and definitions; objectives and parameters for the pilot; data collection procedures, including solicitation of interviews, interview etiquette and guidelines, sampling methodologies, and obtaining informed consent; and instructions on how to use the Excel-based tool developed for the pilot.

Prior to the pilot activities, various approvals were required from both USAID missions and Ministries of Health. These approvals took several weeks, and future implementation of the assessment tool should account for this in the timeline. Since the tool is quite broad in scope, individual approvals from a variety of agencies and actors may be required. Individual country requirements regarding ethical approval processes should also be considered, given that patient interviews and prescription and dispensing record reviews are included in the tool.

Each pilot took about six weeks to complete, including visits to all central-level institutions included in the tool, any subnational storage facilities located within the capital or within one day of travel, and 10 health facilities located within the capital city. The in-country pilot sites, including health facilities and peripheral storage sites, were restricted to the capital to expedite data collection and conserve resources. Since the pilot was not intended to serve as a baseline but rather a test of the tool, we determined that the site sample did not need to be representative of the country as a whole.

Following the completion of primary data collection and interviews, each data collector submitted a brief summary report highlighting any challenges they encountered in using the tool and collecting data and suggesting changes to be made when finalizing the tool.

Desktop Review

While the in-country pilots were ongoing, SIAPS staff performed a desktop review for the two pilot countries to assess the availability of country-specific data for each indicator included in the pilot tool. These reviews were guided by the PIRS for each indicator, which includes the indicator source and any contributing information sources used in indicator development. Key word lists were developed based on the wording of the indicator itself, accompanying assessment questions, and underlying sources for the indicator. The desktop review team used these lists to formulate online search terms to determine first, whether the original assessment tool had been applied in the country of interest (Bangladesh or Namibia); second, when the source assessment tool was last applied in the setting; and third, whether the data were publicly available. If the data were available, the information was entered into the pilot tool for comparison to responses collected through key informant interviews and primary data collection during the in-country pilot. If an indicator was not directly extracted from an existing tool or source, the desktop reviewers performed keyword searches using Google and select sites such as the World Health Organization (WHO) website to ascertain whether the information required to complete the indicator was publicly available. If so, the information was also entered in the pilot tool, along with URLs to the data sources and the search strategy used to locate the data.

Data Compilation and Analysis

Once both the desktop review and in-country pilots were completed, the data for each indicator and assessment question were compiled in a single Excel workbook. Conditional formatting was used to color code missing data and, if data were available from multiple sources, the responses that were equivalent and those that diverged. This information was used to determine the best source for each data point so that assessment questions and indicators could be targeted to the most appropriate respondent. During the initial design phase of the pilot, if the SIAPS team in the US was unsure which entity or key informant was the most appropriate source for a particular indicator or assessment question, we identified multiple possibilities and collected the data from each source for comparison. Following the pilot, we were able to compare replies and on the basis of the two pilot countries, we determined the recommended place or person to assign each indicator and assessment question.

The desktop review activity highlighted the lack of publicly available data for even well-established indicators. In many cases, the underlying tools from which the indicators were sourced were designed to diagnose an issue within a given component or element to inform the intervention design. In these instances, data were collected using the tool and then repeated following implementation of a given intervention. The application of the tools in these cases was highly inconsistent—in many cases, the data were not publicly available, and when the data sets were accessible, the assessment was usually several years old. The instruments were also not used routinely, and therefore the existing data sets could not be used for monitoring over time as is required for PSS Insight. In other instances, data on basic census-based information were available; however, these data were used in combination with other data for a given reference year, such as the country's population and public expenditure on pharmaceuticals to determine public expenditure on pharmaceuticals per capita. In many cases, the population data were available online, but the date of the population data did not match the available data for expenditure, so the indicator data needed to be collected from key informant interviews despite the partial availability of data from desktop review searching.

Scoring and Weighting

Once the best source of data was determined, those responses were moved to a separate column for data analysis and scoring. General scoring rules were developed by SIAPS and reviewed by Boston University School of Public Health to check the underlying assumptions and determine whether the proposed method for scoring each indicator was reasonable. In some cases, indicators were designated as "descriptive"—the indicator data would not be assigned a score or used to compute element or component scores. Indicators with partial or missing data were left as incomplete and not scored. For indicators that were scored, scores were between 0 and 1. The majority of scored indicators fall into the following types:

Table 1. Methods Used to Score Indicators

Type	Description	Scoring	Example		Example Scoring
			Assessment Question(s)	***Response***	
Type 1	Binary Yes/No indicators	Earn 1 point for a "Yes" response, 0 points for a "No" response	Is there a national medicines policy?	Yes	1
Type 2	Composite Yes/No indicators	The indicator consists of several Yes/No assessment questions. 1 point is earned for each "Yes" response, which is divided by the total number of Yes/No assessment questions for the indicator.	Is there a national medicines policy? Has the policy been formally adopted?	Yes No	1 0 $\frac{(1+0)}{2} = 0.5$
Type 3	Percentages, ratios, and proportions	These are converted to decimals	Proportion of health facilities surveyed that posted prices for medicines	100/250	$\frac{100}{250} = 0.4$

Type	Description	Scoring	Example		Example Scoring
			Assessment Question(s)	***Response***	
Type 4	Dates	When dates are used to compute scores, an indicator-appropriate threshold or range is set. If the date is within this range, 1 point is earned. If the date is outside the range, 0 points are earned.	What is the date of the latest version of the national medicines policy?	2015	In this example, we set a five-year threshold for reviewing or revising the document. If the assessment year is 2018, the indicator would be scored as follows: $2018 - 2015 = 3$ $3 \leq 5$, so 1 point is earned

When computing element scores, each indicator score is treated equally. If there are 5 points available for scoring in a single element, the element score is computed as $\frac{Points\ Earned}{5}$. When computing component scores, we decided to weight each indicator, rather than each element score, equally. This implicitly weights some elements more heavily than others, since indicators are not distributed equally across elements and some elements contained more descriptive indicators than others. This method of scoring treats each indicator equally, rather than weighting the indicators to treat the elements equally (table 2). As mentioned previously, some elements were rather broad and encompassed more than one phenomenon for measurement. In these cases, we included additional indicators. For example, the distribution element of the products and services component encompasses both pharmaceutical product storage and transport. Rather than diminish the contributions of these indicators to the component score by weighting the element equally to a more narrowly tailored element with fewer indicators, we determined that each indicator should count equally.

Table 2. Example Element Score Calculation

Element	Points Earned	Points Available	Score
A	3	5	$\frac{3}{5} = 0.6$
B	2.36	7	$\frac{2.36}{7} = 0.337$
C	2	2	$\frac{2}{2} = 1.0$
D	3	4	$\frac{3}{4} = 0.75$
Component Score	10.36	18	$\frac{10.36}{18} = 0.5755$

Indicator Finalization

Following the pilot, the SIAPS team re-evaluated the 182 piloted indicators to attempt to reduce the number of indicators included in the web-based version of the tool. We revisited the initial selection criteria and prioritized indicator lists from Boston University School of Public Health and considered this information alongside data on indicator completeness from the pilot, feedback from pilot data collectors, and notes from consultations with SIAPS subject matter experts. Using these criteria, we selected 117 indicators for inclusion in the web-based tool and updated some of the PIRS to improve their clarity based on feedback from pilot data collectors.

WEB-BASED PSS INSIGHT

SIAPS partnered with SoftWorks in Bangladesh to convert the Excel version of the tool to a web-based platform. The online version of PSS Insight maintains the selected indicators, PIRS, and scoring rules from the Excel-based tool and adds several additional functions informed by the data collection experiences of the pilot users, including a robust survey builder to define and assign operator roles, customize agency and personnel names and titles, select individual components for inclusion in each survey instance, and detail site sampling and selection processes for survey inclusion. First, since PSS Insight is intended as a globally generalizable tool but must operate within each specific country context, we developed a survey builder feature prior to data collection (figure 2). This enables users to select individual components for each instance of a survey—for example, if a country or project only had the resources to complete three of the seven components of PSS Insight in a given year, they could make this selection, and in a subsequent year they might complete the remaining four components. These two data sets may be grouped together for analysis so that the data may be viewed together despite the different years of collection. In addition, countries may designate different technical partners or organizations to complete different survey components. In these cases, different teams can select their respective components, and the results may be viewed separately or together.

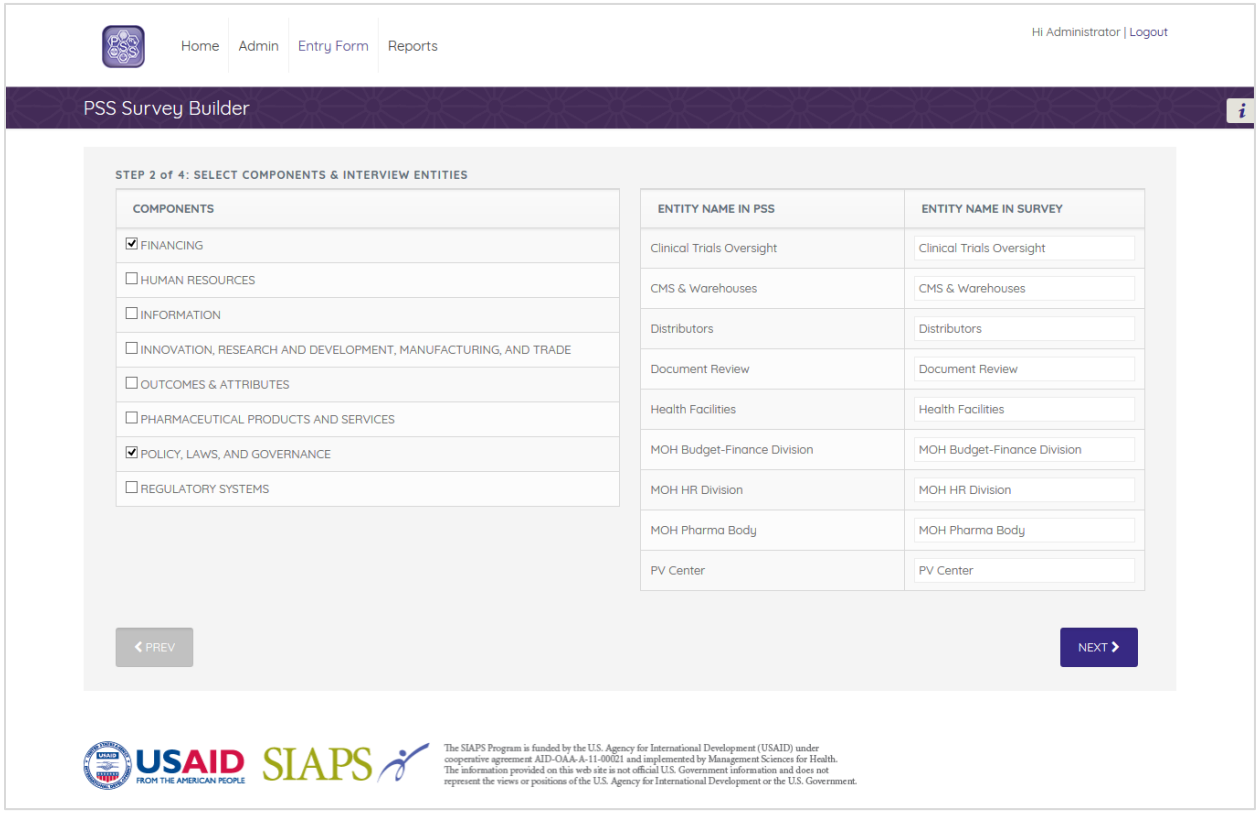


Figure 2. PSS Insight Survey Builder

During the component selection step, the corresponding interview entity names for data collection appear on the right hand side of the screen. The tool enables survey administrators to rename these entities for their surveys so that data collectors know where to collect the required information. This is another customization feature that allows countries to tailor the tool to better suit their specific contexts, but it maintains the original names within the tool for generalizability across countries.

Following this step, survey administrators select individual warehouses and service delivery points according to a proposed site selection methodology (annex E). Survey administrators select the criteria that best describe the facility included, such as the funding source (public, private, other) and the level within the system (primary care, hospital, etc.).

Once the survey builder is completed and the responses are confirmed, the individual survey questionnaires are generated based on the selections from the survey builder. Each questionnaire may be completed online (figure 3) or exported to Excel for offline data entry. If data entry is completed online, users may use a laptop or tablet to complete the data entry questionnaires. The data entry screen is streamlined so that users answer one assessment question at a time and progress from one set of component indicators to the next. The indicator definition appears on the right hand side of the screen, and if the "Read More" link is clicked, the entire PIRS will appear in the window. This prevents users from having to toggle between screens to refer to the PIRS for clarity during interviews. Progress through each questionnaire may be saved and resumed, and each user's progress is displayed for team leaders and survey administrators in a dashboard. This allows managers to keep better track of progress and identify data gaps where additional support may be needed to complete the survey efficiently.

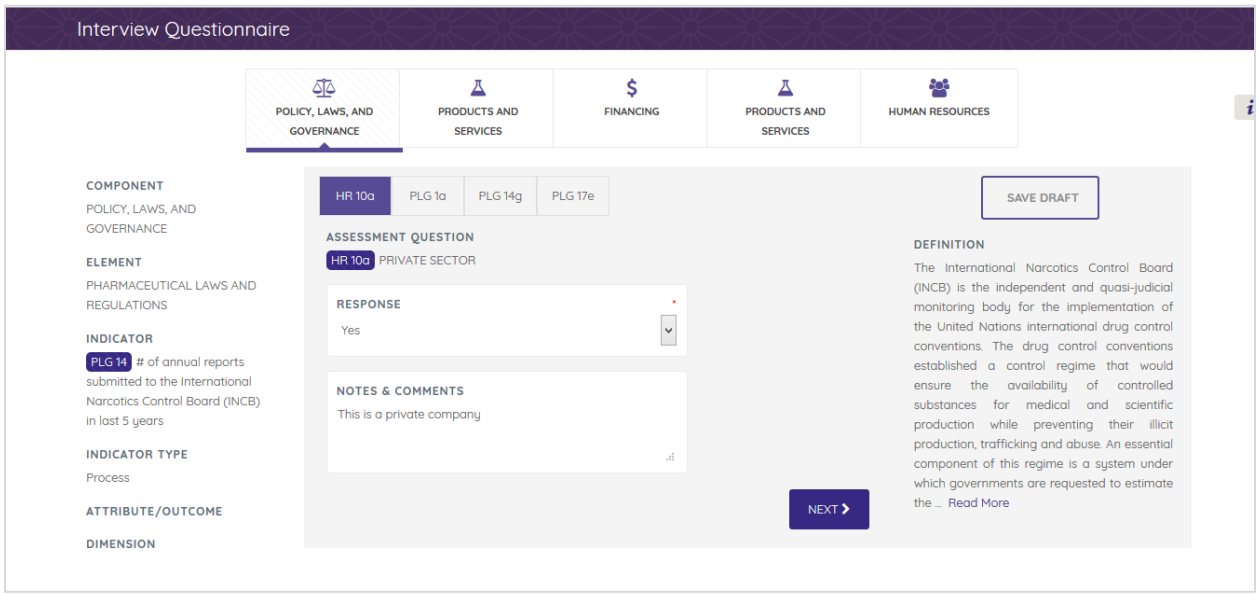


Figure 3. PSS Insight Questionnaire Screen

If a reliable data connection is not available, each questionnaire may be exported to Excel for offline data entry. The PIRS are also exported to a separate workbook tab so that users may refer to this information as interviews are ongoing. Completed questionnaires are then uploaded into the tool for data compilation and analysis. The administrator and team leader dashboards will also keep track of which questionnaires have been uploaded by which users, with the time and date, to help them keep track of offline data entry and ensure that completed questionnaires are uploaded as required.

Once data collection is complete, there is a series of review and approval processes to check the data, and there are several points at which specific questionnaires and indicators may be flagged for correction, clarification, or follow up and remanded to submitting users for verification (annex E). After final review, the survey is published and included in the online data bank within the PSS Insight platform at pssinsight.org.

The data repository includes component scores (figure 4), element scores (figure 5), indicator scores (figure 6), and responses to individual assessment questions (figure 7). No personally or facility identifiable information is displayed in any of the results pages or reports. The reports and data visualizations are publicly available to any registered user of the site, and data may be exported as .csv files for further analysis. Where possible, data included in reports are disaggregated according to facility characteristics (e.g., urban/rural, public/private/other). As surveys are published on the site, users may select custom report settings to view comparative data across selected countries or within a particular country over time.

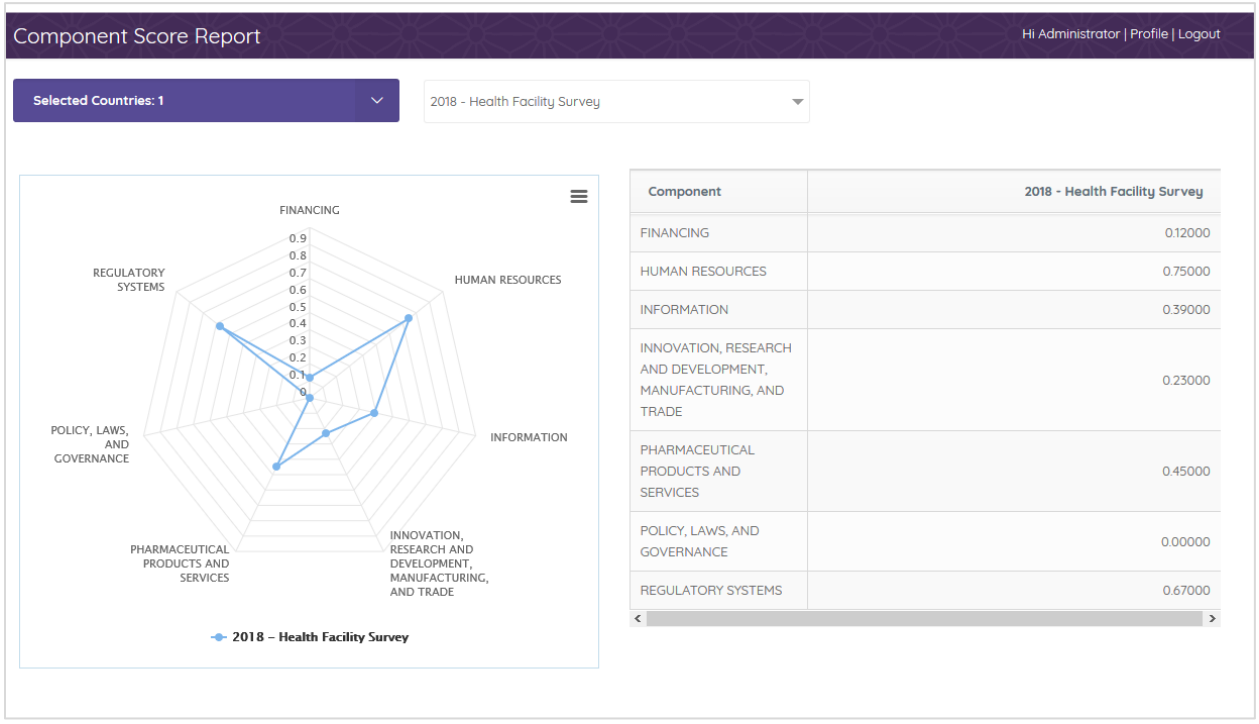


Figure 4. PSS Insight Component Score Report

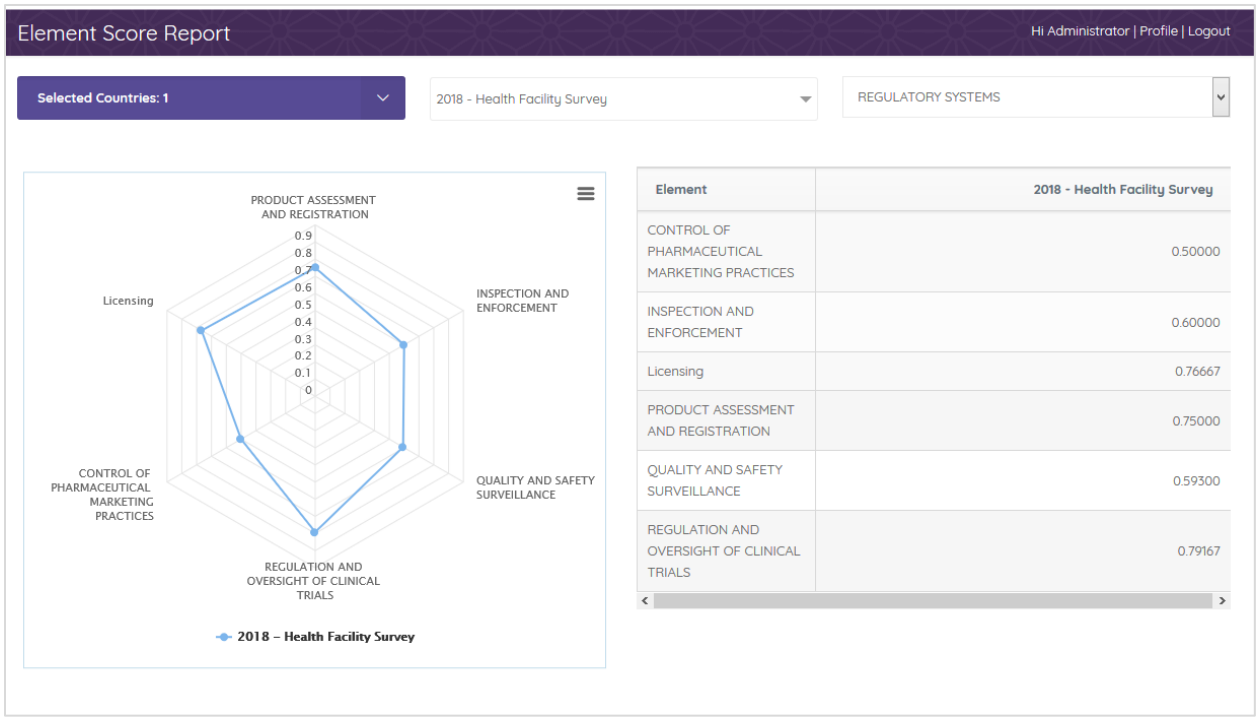
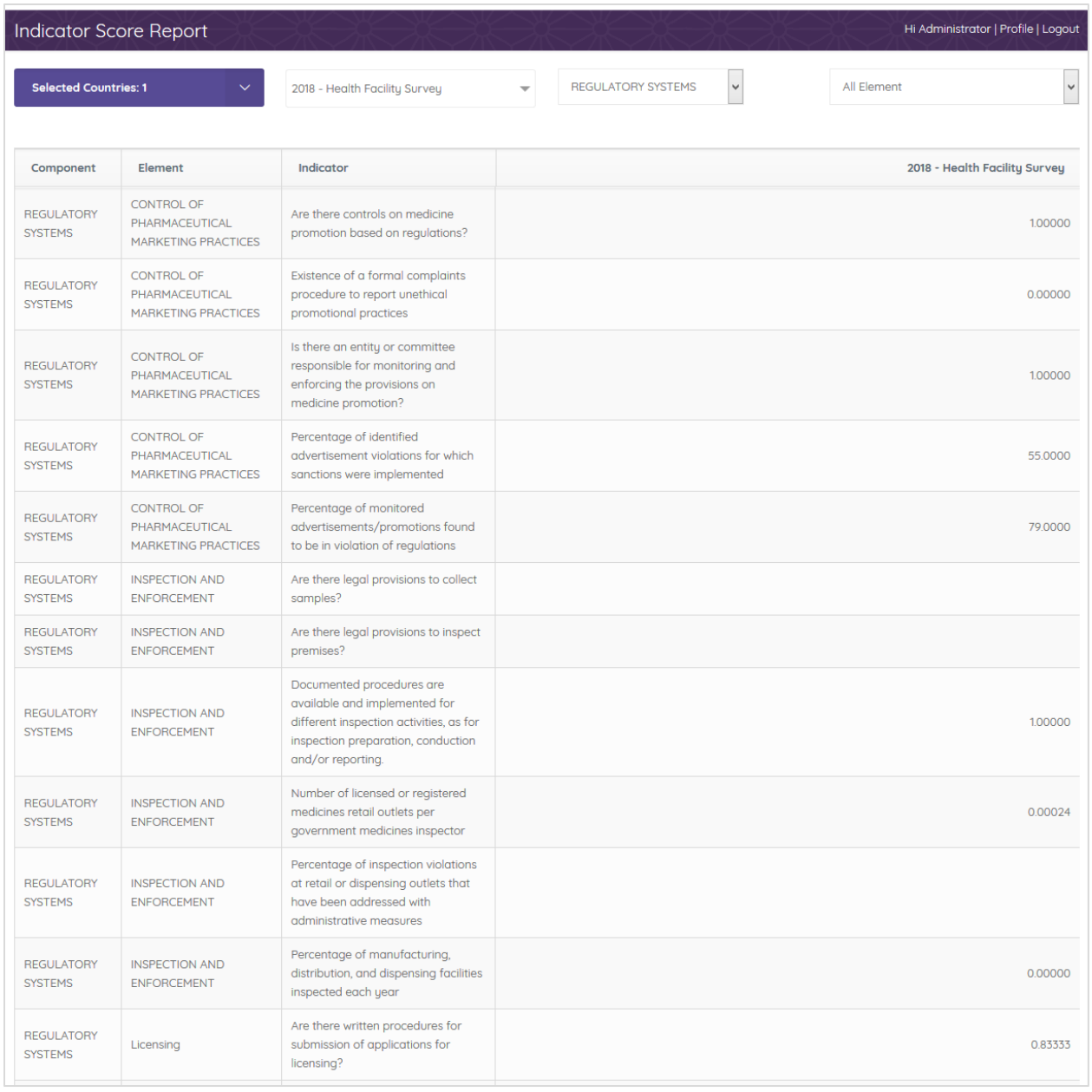


Figure 5. PSS Insight Element Score Report



Indicator Score Report

Hi Administrator | Profile | Logout

Selected Countries: 1 | 2018 - Health Facility Survey | REGULATORY SYSTEMS | All Element

Component	Element	Indicator	2018 - Health Facility Survey
REGULATORY SYSTEMS	CONTROL OF PHARMACEUTICAL MARKETING PRACTICES	Are there controls on medicine promotion based on regulations?	1.00000
REGULATORY SYSTEMS	CONTROL OF PHARMACEUTICAL MARKETING PRACTICES	Existence of a formal complaints procedure to report unethical promotional practices	0.00000
REGULATORY SYSTEMS	CONTROL OF PHARMACEUTICAL MARKETING PRACTICES	Is there an entity or committee responsible for monitoring and enforcing the provisions on medicine promotion?	1.00000
REGULATORY SYSTEMS	CONTROL OF PHARMACEUTICAL MARKETING PRACTICES	Percentage of identified advertisement violations for which sanctions were implemented	55.0000
REGULATORY SYSTEMS	CONTROL OF PHARMACEUTICAL MARKETING PRACTICES	Percentage of monitored advertisements/promotions found to be in violation of regulations	79.0000
REGULATORY SYSTEMS	INSPECTION AND ENFORCEMENT	Are there legal provisions to collect samples?	
REGULATORY SYSTEMS	INSPECTION AND ENFORCEMENT	Are there legal provisions to inspect premises?	
REGULATORY SYSTEMS	INSPECTION AND ENFORCEMENT	Documented procedures are available and implemented for different inspection activities, as for inspection preparation, conduction and/or reporting.	1.00000
REGULATORY SYSTEMS	INSPECTION AND ENFORCEMENT	Number of licensed or registered medicines retail outlets per government medicines inspector	0.00024
REGULATORY SYSTEMS	INSPECTION AND ENFORCEMENT	Percentage of inspection violations at retail or dispensing outlets that have been addressed with administrative measures	
REGULATORY SYSTEMS	INSPECTION AND ENFORCEMENT	Percentage of manufacturing, distribution, and dispensing facilities inspected each year	0.00000
REGULATORY SYSTEMS	Licensing	Are there written procedures for submission of applications for licensing?	0.83333

Figure 6. PSS Insight Indicator Report

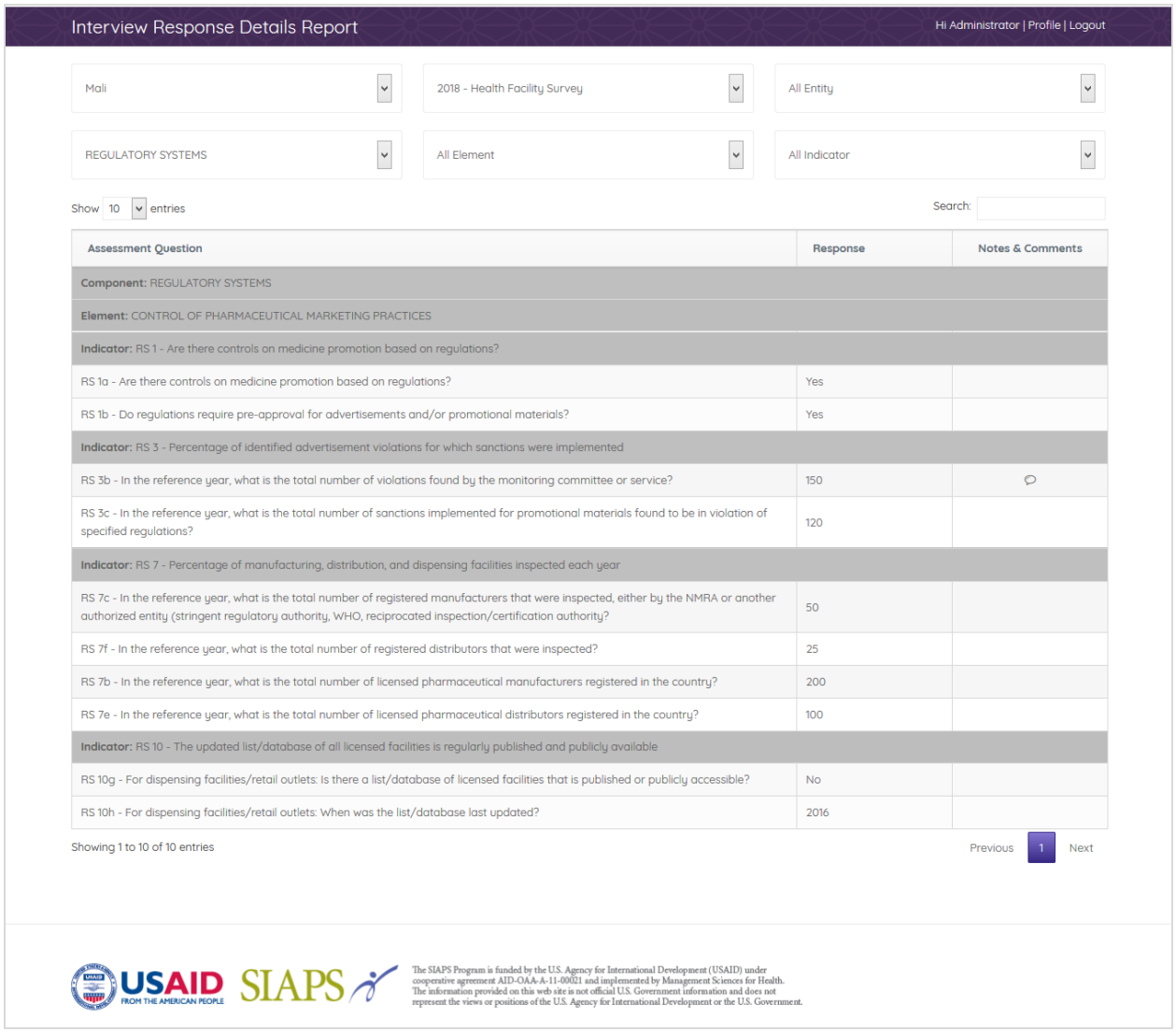


Figure 7. PSS Insight Interview Response Report

CONCLUSION

PSS Insight is a powerful, easy-to-use tool for measuring progress in pharmaceutical systems strengthening across countries and over time. It was designed as a globally minded tool to allow countries, donors, technical assistance partners, decision makers, and other stakeholders to get a high-level picture of the impact of pharmaceutical systems strengthening efforts; characterize systems in a specific context; and follow trends across countries, regions, projects, and time. Further work in additional countries is needed to provide baseline survey data to populate the tool, as is additional stakeholder consultation to further validate the indicators and discuss the proposed methodologies for scoring and weighting within the tool.

Once country data are included in the data repository, the tool will allow stakeholders to identify priority areas for additional scrutiny, investment, and strengthening and demonstrate the impacts of these efforts through repeated measurements. The inclusion of all survey data in an open data repository will hopefully encourage further research and discussion of trends, challenges, and lessons learned in pharmaceutical systems strengthening and promote sharing of experiences and outcomes across countries, donors, and projects.

ANNEX A. CONSULTATIVE MEETING REPORT

The meeting report for the consultative meeting to develop definitions of a *pharmaceutical system* and *pharmaceutical systems strengthening* is included in the following pages. This report also includes the process for the selection of critical components for measurement and identification of subelements of these components.

DEFINING AND MEASURING PHARMACEUTICAL SYSTEMS STRENGTHENING

Report of the SIAPS Partners' Consultative Meeting

September 11-12, 2014

USAID FROM THE AMERICAN PEOPLE

SIAPS Systems for Improved Access to Pharmaceuticals and Services

Defining and Measuring Pharmaceutical Systems Strengthening: Report of the SIAPS Partners' Consultative Meeting

September 11-12, 2014

Defining and Measuring Pharmaceutical Systems Strengthening: Partners' Meeting Report

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This report should be read in conjunction with the associated background discussion paper as revised after the meeting (page 18).

Contributors and Reviewers

Tamara Hafner, SIAPS consultant and Helena Walkowiak, SIAPS Principal Technical Advisor prepared this meeting report and the background discussion paper.

The background discussion paper reflects the contributions of David Lee, CPM/MSH Director, Technical Strategy and Quality. Veronika Wirtz and Richard Laing, both from the Department of Global Health at Boston University School of Public Health, contributed to the section on composite indicators. This section was revised after the meeting to reflect their contribution.

Richard Laing and the following SIAPS and MSH staff reviewed the draft of the background discussion paper: Francis (Kofi) Aboagye-Nyame, Michael Cohen, Ruth Musila, Sue Putter, and Maura Soucy.

About SIAPS

The goal of the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is to assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. Toward this end, the SIAPS result areas include improving governance, building capacity for pharmaceutical management and services, addressing information needed for decision-making in the pharmaceutical sector, strengthening financing strategies and mechanisms to improve access to medicines, and increasing quality pharmaceutical services.

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Key Words

pharmaceutical systems strengthening, measurement framework

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CONTENTS

Acronyms

AOR	Agreement Officer's Representative [USAID]
CPM	Center for Pharmaceutical Management [MSH]
HSAA	Health System Assessment Approach
DFID	Department for International Development
HDI	Human Development Index
HTA	Health Technology Assessment
IHP+	The International Health Partnership
JSI	John Snow International
MSH	Management Sciences for Health
OECD	Organisation for Economic Co-operation and Development
PAHO	Pan American Health Organization
RPM Plus	Rational Pharmaceutical Management Plus Program
SIAPS	Systems for Improved Access to Pharmaceuticals and Services Program
SPS	Strengthening Pharmaceutical Systems Program
USAID	US Agency for International Development
WHO	World Health Organization

Executive Summary

The Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program convened a consultative meeting of its partners to identify definitions of a pharmaceutical system and pharmaceutical systems strengthening and components to be included in a measurement framework for systems strengthening. The meeting held on September 11-12, 2014, brought together SIAPS core and resource partners, experts from the US Agency for International Development (USAID), the Pan American Health Organization (PAHO) (representing the World Health Organization), and Boston University School of Public Health. The discussions were guided by a background discussion paper prepared by SIAPS staff (page 18) and presentations given at the beginning of each session.

More than 30 participants, who represented 13 different organizations working to improve access and use of pharmaceuticals in low- and middle-income countries, agreed on the following working definitions of a pharmaceutical system and pharmaceutical systems strengthening:

- A *pharmaceutical system* consists of all structures, people, resources, processes, and their interactions within the broader health system that aim to ensure equitable and timely access to safe, effective, quality pharmaceutical products and related services that promote their appropriate and cost-effective use to improve health outcomes.

- *Pharmaceutical systems strengthening* is the process of identifying and implementing strategies and actions that achieve coordinated and sustainable improvements in the critical components of a pharmaceutical system to enhance responsive and resilient system performance for achieving better health outcomes. The critical components of a pharmaceutical system are its core functions, structures, the supporting health system resources, and an enabling policy, legal, and governance framework.

Participants also identified the pharmaceutical system components to be included as part of a measurement framework for systems strengthening: policy, law and governance; regulatory systems; pharmaceutical products and services; human resources; financing; information; innovation, research and development, manufacturing, and trade. In addition, for each of these system components, participants proposed critical elements to guide SIAPS in the selection of indicators for a measurement framework. Recommendations were also made to inform the use of composite indicators as an approach for measuring and ranking the performance of national pharmaceutical systems.

Key next steps include developing the measurement framework for pharmaceutical systems strengthening. In addition, indicators and tools to measure progress made in strengthening systems must be identified and piloted. The framework and indicators will help guide health system planners and donors that are considering investing scarce resources in ways that will have lasting results.

Background

In 2012, the US Agency for International Development (USAID) awarded the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program[1] to promote and utilize a systems strengthening approach to improve access to pharmaceutical products and services consistent with the US Government's Global Health Initiative objectives of improved and sustainable health impact. Although the impact of investments in strengthening health systems must be effectively captured and communicated, there is no standardized approach for measuring progress toward stronger, more sustainable pharmaceutical systems. Furthermore, there is no widely accepted definition of what constitutes a pharmaceutical system, or its strengthening. In the absence of clear definitions and generally accepted reliable measures, countries and donors lack information to direct interventions and investments to address weaknesses and ascertain that these investments are resulting in stronger, more resilient pharmaceutical systems. To address this need, SIAPS is working with partners to develop a measurement framework with clearly linked metrics to enable stakeholders to objectively measure the performance of pharmaceutical systems and changes thereof, and use this information for intervention design and evaluation to enhance the delivery of pharmaceutical services.

A literature review was undertaken as a first step to gain conceptual clarity on what a pharmaceutical system is and what strengthening the system entails. The resulting report (page 18) was the background discussion paper and basis for discussions at the SIAPS Partner Consultative Meeting held at the Management Sciences for Health (MSH) offices in Arlington, Virginia, on September 11-12, 2014. The participants (page 14) brought a wealth of expertise in an array of pharmaceutical management technical areas to the meeting.

[1] The USAID-funded SIAPS Program is implemented by MSH with core partners Accreditation Council for Pharmacy Education, Harvard University, Logistics Management Institute, and University of Washington and specialized resource partners African Medical and Research Foundation, Ecumenical Pharmaceutical Network, Results for Development, IMPERIAL Health Sciences, VillageReach, and William Davidson Institute

Meeting Objectives

The objectives of the meeting were to:

1. Agree on working definitions of what constitutes a *pharmaceutical system* and *pharmaceutical systems strengthening*.
2. Based on these definitions, identify the key elements that must be operationalized and turned into indicators and discuss potential sources of data.
3. Agree on next steps for selecting or developing appropriate indicators for measuring pharmaceutical systems strengthening outcomes.

The meeting was structured around four sessions that centered on addressing the meeting objectives. The first session focused on deriving definitions of a pharmaceutical system and pharmaceutical systems strengthening. In the second and third sessions, meeting participants discussed and identified the system components to be included in the measurement framework and the key elements of each component that should guide the selection of indicators. The final session focused on discussing next steps for identifying appropriate indicators for measuring pharmaceutical systems strengthening outcomes, including approaches and challenges to using composite indicators. The meeting agenda can be found on page 15.

Each session began with a presentation that summarized relevant background information and findings from the literature review, which were summarized in the background discussion paper distributed to participants prior to the meeting. Participants then engaged in small-group deliberations to address the session objectives and presented the results in plenary. A list of the members in each group can be found on page 17. Each session concluded with a plenary discussion to review the results of the group work and, where appropriate, reach agreement on the session outputs and recommendations. Professor Richard Laing of Boston University facilitated the meeting.

Welcome and Introductory Remarks

Douglas Keene, Vice President of the MSH Center for Pharmaceutical Management (CPM)

Dr. Keene welcomed the participants, wished them a successful meeting, and highlighted the importance of the meeting outcomes for CPM's programs.

Tony Boni, USAID Agreement Officer's Representative (AOR) for the SIAPS Program

In his introductory remarks, Mr. Boni noted that the SIAPS Program was designed to test the theory that a systems approach to pharmaceutical systems strengthening would yield sustainable, country-owned, resilient systems by focusing on the intersections between the medical products building block and the other health systems components of governance, financing, human resources, information systems, and service delivery, all of which have their own interactions. The hypothesis was that pharmaceutical systems strengthening interventions need to be deliberately designed, planned, implemented, and monitored, with systematic consideration of all health systems components. This approach would be more likely to engender sustainable systems improvements.

He stressed that an expected key result of the SIAPS Program was the development and validation of a framework and metrics for pharmaceutical systems strengthening. USAID intended that SIAPS should be able to demonstrate that USAID contributions are making a difference and contributing to the development of stronger systems that can help countries achieve expected health outcomes. USAID and other donors need information to guide them on what to target and invest in as well as metrics to assess whether these investments are resulting in stronger, more resilient pharmaceutical systems. The challenge is to justify investments in pharmaceutical system strengthening and show value for money, as reflected by improved access to and appropriate use of medicines.

> This meeting was an important step in thinking through technical issues as we seek to develop robust measures that can gauge the impact of interventions in promoting sustainability and stronger, more resilient pharmaceutical systems.

Mr. Boni also highlighted the need to distinguish between *support to the health system* and *health system strengthening*. Returning to the metrics issue, he noted that there is often a lack of recognition that performance of the health system is not necessarily indicative of the sustainability and strength of the system. It is essential to determine the factors that strengthen pharmaceutical systems and clearly identify confounding factors such as unsustainable donor support that temporarily improves system performance, but does not actually strengthen systems in a sustainable manner. The bottom line is that metrics to determine when a system has been strengthened are lacking.

He concluded his remarks by saying that this meeting was an important step in thinking through technical issues as we seek to develop robust measures that can gauge the impact of interventions in promoting sustainability and stronger, more resilient pharmaceutical systems.

Francis (Kofi) Aboagye-Nyame, SIAPS Program Director

Mr. Aboagye-Nyame welcomed the meeting participants and introduced Professor Richard Laing, the meeting facilitator. He reminded participants of the SIAPS Program objective—to promote and use a systems strengthening approach consistent with the Global Health Initiative that will result in positive and sustainable health impact—and provided an overview of the pharmaceutical systems strengthening framework that SIAPS uses to guide its work. As noted by Mr. Boni, a key deliverable for the SIAPS Program is the development of a framework with clearly linked indicators to enable stakeholders to objectively measure progress toward stronger, more sustainable systems.

A key deliverable for the SIAPS Program is the development of a framework with clearly linked indicators to enable stakeholders to objectively measure progress toward stronger, more sustainable systems.

The work is now underway to develop this framework and related metrics, which will also help differentiate between interventions that strengthen a system and those that support it. This information will enable health planners and donors to more effectively design and select interventions and direct scarce resources to address critical weaknesses. The metrics will also provide a means for SIAPS to validate that the program's systems strengthening approach is resulting in stronger pharmaceutical systems. SIAPS has convened this meeting of its partners and other experts with knowledge and experience in an array of pharmaceutical management technical areas in low- and middle-income countries as a first step in developing a measurement framework and testable indicators. He concluded by presenting the meeting objectives and thanking the participants for their inputs.

Summary of Presentations and Discussions

Defining a Pharmaceutical System and Pharmaceutical Systems Strengthening

The objective of this session was to reach agreement on working definitions of pharmaceutical system and pharmaceutical systems strengthening.

The session began with a presentation by Tamara Hafner, SIAPS Consultant, reviewing the key findings of the literature review as summarized in the background discussion paper (page 18). She highlighted the three explicit definitions of a pharmaceutical system identified which provide a useful starting point. Two definitions related to pharmaceutical management and eight frameworks that were also identified provided further insight into understanding the goals and scopes of a pharmaceutical system. Based on a review of the identified definitions and frameworks, a pharmaceutical system can include structures/organizations, individuals/people, resources, and functions. The system is often defined in terms of its functions, subsystems, or decision points along the medicine chain. With respect to system goals, a consistent theme is improved access and use. It may be access to medicines, pharmaceuticals, medical products, vaccines, and technologies; these terms were not clearly defined and often used interchangeably.

No explicit definitions of pharmaceutical systems strengthening were found, however, three definitions of health systems strengthening exist which provide some guidance and draw attention to two major themes: improving performance (efficiency and quality) and improving resilience or capacity to address future health challenges and sustain improvements.

SIAPS used these various definitions and frameworks to develop definitions of a pharmaceutical system and pharmaceutical systems strengthening, which were presented as a starting point for group discussions. The proposed definitions were:

- A *pharmaceutical system* consists of all organizations, individuals, resources, and actions and their interactions that aim to ensure equitable and timely access to safe, effective, quality pharmaceutical products and related services that promote their appropriate and cost-effective use.

- *Pharmaceutical systems strengthening* is the process of identifying and implementing strategies and actions that achieve sustainable changes in one or more critical components of a pharmaceutical system to improve system performance and capacity, to address future health and system challenges, and to contribute to better health outcomes through equitable improvements in access, quality, coverage, and use of pharmaceutical products and related services. (Note that the critical components of a pharmaceutical system are its core functions, structures, and the supporting health system resources and an enabling policy, legal, and governance framework.)

The five groups were asked to use these proposed definitions as the basis for their discussions and propose working definitions. None of the five groups proposed entirely new definitions, however, all the groups suggested some modifications.

The groups made the following points on the proposed definition of a pharmaceutical system:

- There was general agreement with the goals of the system as described.
- The definition needs to link the pharmaceutical system in some way to health outcomes and situate it in the context of the broader health system. Although strengthening pharmaceutical systems contributes to improving health outcomes, it is difficult to directly attribute improvements in health outcomes to improvements in system performance, particularly given the many determinants of (ill) health. In the plenary discussion, the participants agreed that appending "towards improving health outcomes" or some variation thereof to the proposed definition would address this issue.
- Several groups suggested that stakeholders in the system may include households or entire communities, and not just individuals. The participants agreed to replace the term *individuals* with *people* to account for communities as stakeholders.
- With regard to the question of "access to what?" – all groups discussed whether *pharmaceutical products* is a sufficiently inclusive term and the use of *health technologies* as an alternate. Noting that *health technologies* is a very broad term that goes beyond medicines and other pharmaceutical products, the participants decided that *pharmaceutical product* was more appropriate as it helped to delineate a clear boundary for the scope of a pharmaceutical system.

The group work feedback regarding the proposed definition of pharmaceutical systems strengthening focused on two main themes:

- The definition should convey a sense of coordination, because without coordination, the various processes and actions are unlikely to lead to a strengthened system.
- The proposed definition does not adequately address the goal of improving system resilience and responsiveness. The participants agreed in the plenary discussion that this goal should be stated explicitly in the definition.

Lastly, the participants agreed that to avoid overly lengthy definitions, a glossary defining terms such as access, pharmaceutical products, resources, and processes should be developed to accompany the definitions.

These and other minor suggestions yielded the following two agreed-upon definitions:

- A *pharmaceutical system* consists of all structures, people, resources, processes, and their interactions within the broader health system that aim to ensure equitable and timely access to safe, effective, quality pharmaceutical products and related services that promote their appropriate and cost-effective use to improve health outcomes.

- *Pharmaceutical systems strengthening* is the process of identifying and implementing strategies and actions that achieve coordinated and sustainable improvements in the critical components of a pharmaceutical system to enhance responsive and resilient system performance for achieving better health outcomes. The critical components of a pharmaceutical system are its core functions, structures, the supporting health system resources, and an enabling policy, legal, and governance framework.

Key Components of the Pharmaceutical System

The objective of this session was to identify the key components of a pharmaceutical system to inform the development of a framework for measurement of pharmaceutical systems strengthening.

Helena Walkowiak, Principal Technical Advisor, CPM, opened this session with a presentation of the pharmaceutical system components compiled from a review of the 8 frameworks and 44 assessment tools discussed in the background discussion paper (page 18). Although none of the frameworks explicitly depict a pharmaceutical system, they provide a useful starting point for identifying the key components of a pharmaceutical system. The compilation of these framework elements, presented in table 2 of the background discussion paper, includes the following:

- Functions (subsystems; "medicine chain"): selection; procurement; distribution; use; research, and development; clinical trials; regulation; manufacturing; and packaging

- "Building blocks" (policy and legal framework, management support systems, resources/inputs): service delivery; [leadership and] governance; policies, law, and regulation (supported by good governance); medical products, vaccines, health technologies; human resources; information; financing [pricing; price setting/negotiation]; infrastructure; organization

- Environment: market forces, innovation, transparency, donors' agenda, and funding

Ms. Walkowiak explained that, due to the scarcity of explicit definitions and frameworks for a pharmaceutical system, the literature review had also sought to identify tools and indicator sets that have focused on assessing a pharmaceutical system or measuring its performance. Many such tools exist and much of the thinking on and knowledge of pharmaceutical systems and their assessment have been incorporated into the development and refinement of these tools over time.

Of the 53 assessment tools identified in the literature review, 44 were reviewed and the categories of indicators and survey questions compiled to further inform the process on identifying key pharmaceutical system components (summarized in table 3 of the background discussion paper).

The meeting participants discussed the system components identified from the frameworks and assessment tools in their assigned groups and proposed key components of a pharmaceutical system for inclusion in a measurement framework (table 1). Participants agreed that the challenge lay in distilling the most critical components to avoid a list so exhaustive that the resulting measurement framework becomes impractical. In the plenary discussion, the participants focused on the commonalities across the various lists from the group discussions. As an illustration, for leadership and governance, groups 1 and 3 identified these as one component, group 2 listed them as two separate components, and group 5 identified a legal framework with governance and transparency as part of that component. The participants agreed to have policy, laws and governance as a system component to capture these themes.

These and other plenary deliberations yielded the following list of components for the measurement framework:

1. Policy, laws and governance
2. Regulatory systems
3. Pharmaceutical services
4. Human resources
5. Financing
6. Information
7. Innovation, research and development, manufacturing, trade

Group 4 also identified several cross-cutting themes which the meeting participants agreed could further inform this work. They include sustainability, equity, financial protection and health, resilience, efficiency, country ownership, and evidence-based decision making.

Key Elements for Selecting Indicators

The objective of this session was to identify important elements within each of the agreed upon system components that SIAPS can use as the basis for selecting indicators.

Each group was assigned one or two of the system components (page 17) and worked to identify the most important elements within each of the assigned components for which associated indicators should be later selected to track pharmaceutical systems strengthening. The group discussions yielded the elements presented in table 2.

Table 1. Key Pharmaceutical System Components Proposed by the Five Groups

Group 1	Group 2	Group 3	Group 4	Group 5
Service delivery • Use **Leadership and governance** (policy, law, governance) • Regulation • Pharmacovigilance **Pharmaceuticals and diagnostics** • Selection • Procurement • Distribution • Manufacturing **Information** • Information technology • Research and development • Operational research **Financing** • Pricing **Human resources**	**Financing** **Payment** **Governance** **Leadership** **Information systems** **Human resources** **Management(?)** **Organization** **Regulation** • Pricing • Registration • Licensing and inspection • Research and development • Marketing • Pharmacovigilance • Safety • Quality control **Policies and legislation** **Pharmaceutical service delivery** • Distribution • Procurement • Selection • Use	**Policies, legislation and regulation** (includes quality assurance) **Manufacturing, industry, trade, research and development** **Financing** **Governance and leadership** **Organization and management** (includes information systems and human resources) **Service delivery** • Selection • Procurement • Distribution • Use • Patient safety	**Inputs** • Manufacturing • Procurement • Research and development • Selection • Human Resources • Financing **Processes** • Distribution • Human resource education • Information management • Service delivery **Outcomes** • Access • Use • Quality • Safety **Cross-cutting** • Affordability • Evidence-based decision making • Sustainability • Equity • Financial protection and health • Resilience • Efficiency • Country ownership	**Legal framework** • International intellectual property rights policies • Policy and laws • Pharmaceutical sector structure • Governance/transparency **Pharmaceutical services** • Selection • Procurement • Distribution • Use **Human resources** • Pre-service and continuing training • Numbers and distribution **Regulatory systems** • Products (registration) • People • Facilities • Quality assurance **Management support** • Information systems • Pricing information • Forecasting • Budgeting • Quantification **Financing** • Supply and demand • Resource mobilizations • Costing/purchasing • Financial protection • Expenditure analysis **Innovation, research and development, manufacturing, and trade** **Access and use listed as outcomes**

Table 2. Suggested Elements to Inform the Selection of Pharmaceutical Systems Strengthening Indicators

System Component	Elements

Policy and legal framework	• Policies and laws
	  ○ Availability, safety, quality, manufacturing, trade, and promotion of pharmaceutical products
	  ○ Standards of practice and accreditation of facilities
	  ○ Drug information
	  ○ Pricing and insurance coverage
	• Governance
	  ○ Structures and mechanisms to ensure accountability and transparency
	  ○ Engagement and participation of civil society
	• High-level strategic planning

Regulatory systems	• Quality control • Licensing and accreditation (people, places, and education) • Medicines registration • Inspection and enforcement • Pharmacovigilance • Regulation of clinical trials • Advertising, promotion, and marketing

Pharmaceutical services	• Pharmaceutical supply
	  ○ Product selection
	  ○ Procurement
	  ○ Inventory management and distribution
	  ○ Quality assurance (including quality control)
	  ○ Repackaging
	• Safe, appropriate, cost-effective prescribing and use
	• Dispensing and supply to individuals
	• Health promotion and disease prevention

Human resources	• Human resources policy
	• Human resources planning/management
	  ○ Workforce analysis
	  ○ Workforce strategy
	  ○ "Rational use of human resources"- equitable allocation
	  ○ Recruitment/job descriptions/performance appraisals
	• Human resources development
	  ○ Pre-service
	  ○ Career path/retention
	  ○ Training/mentoring/supervision
	• Professionalization

Financing	• Resource mobilization and allocation • Costing and pricing • Financial protection mechanisms for medicines and services • Expenditure tracking
Information	• Data standards/standardization • Country-appropriate information systems • Data transparency/access/feedback (and accountability) • Data analysis and use (data for decision making) • Coordination and accountability • Evaluation system (operational research)

System Component	Elements

Innovation, research and development, manufacturing, and trade	• Manufacturing capacity
	  ○ Rated on a spectrum from low to high, with low meaning packaging capability alone and high meaning development of novel active pharmaceutical ingredients
	• Research, development, and innovation
	  ○ Clinical trials
	  ○ Ethical oversight
	  ○ Research priority setting (based on health need)
	  ○ Technology transfer
	• Trade
	  ○ Interaction with global and bilateral trade agreements
	  ○ TRIPS/TRIPS Plus
	• Import/export duties and restrictions

Discussion on Composite Indicators

USAID is interested in approaches for ranking the performance of national pharmaceutical systems. Given the multi-dimensional nature of the pharmaceutical sector, composite indicators may be a suitable measure of overall performance of a pharmaceutical system or other aspects such as its maturity. The objective of this session was to obtain participants' inputs on the merits and disadvantages of composite indicators to help inform the selection and/or development of appropriate indicators to measure the strengthening of a pharmaceutical system.

To frame the discussion, Professor Veronika J. Wirtz of Boston University presented a review of the advantages and disadvantages associated with composite indicators (included in the background discussion paper as table 4). She also reviewed the development and structure of the Access to Medicine Index[2] to illustrate the potential usefulness of such indicators and the process and resources needed to produce robust composite indicators.

Meeting participants were then asked to review the advantages and disadvantages presented in the slides and background discussion paper. They were asked to discuss whether SIAPS should consider developing composite indicators for pharmaceutical systems strengthening and under what conditions. There was general agreement that composite indicators could provide tremendous value by allowing for comparisons across countries and over time in the dimensions being measured. Further, if the composite indicators are developed in such a way to allow for comparison in the various technical component areas (as with the Access to Medicine Index), then these indicators could potentially be useful for ranking countries and identifying where investments are needed. However, the meeting participants, both in the working groups and the broader plenary discussion, acknowledged that composite indicators presented substantial challenges, both in terms of the resources needed and some practical methodological issues.

[2] The Access to Medicine Index ranks the efforts of pharmaceutical companies to improve access to medicine in low- and middle-income countries. The Index is produced by the Access to Medicine Foundation and the reports are available at www.accesstomedicineindex.org.

The major concerns included:

- Understanding the causal pathway of the phenomenon being measured in order to derive appropriate weights and develop a valid composite indicator. Some meeting participants wondered if there is a clear enough understanding of the causal pathways that affect any given change or output in the pharmaceutical system.

- The feasibility of gathering quality and comparable data that are sensitive to change. There was a discussion about who would fund these efforts in a sustainable manner and an acknowledgment that SIAPS' clients and stakeholders would need to be willing to pay for this endeavor.

- Incentives for countries to participate in data collection efforts, especially if the results are used to rank their performance in some dimension. These indicators would clearly be useful to donors, but it is unclear what the utility would be for the countries. With the Access to Medicines Index, there is a clear benefit for pharmaceutical companies to participate (even if they are ranked low on the index)—their willingness to participate provides reputational gains. Some participants noted that the process of discussing results with the countries involved could itself be part of systems strengthening. Further, if the composite indicator(s) is aligned with the interests of the countries, they would have an incentive to participate.

The discussions were concluded with an acknowledgement of some of the potential advantages of using composite indicators but given the challenges, the need for ongoing discussion and assessment of their utility for SIAPS. Participants' recommendations will be used to inform decisions on the use of composite indicators as SIAPS moves forward with developing a measurement framework for pharmaceutical system strengthening and identifying associated indicators.

Close of the Meeting

The meeting was closed with brief remarks by Mr. Kofi Aboagye-Nyame who noted that the meeting objectives had been met and thanked the participants and organizers, particularly acknowledging the efforts of Dr. Richard Laing as the meeting facilitator. He outlined the next steps for developing the measurement framework and metrics and expressed the hope that the meeting participants would continue to provide inputs in the development process. Mr. Boni also thanked the meeting participants for their contributions on behalf of USAID.

Next Steps

SIAPS will continue to work with its partners and other experts to develop the framework for measurement of pharmaceutical systems strengthening, identify associated metrics, and check the feasibility of obtaining data to routinely generate them.

The key next steps for SIAPS include:

- Disseminating the meeting report and developing the background discussion paper and meeting outcomes into a paper for peer-reviewed publication.
- Developing a framework for measurement based on agreements reached on the definitions of a pharmaceutical system and pharmaceutical systems strengthening, and the components of a pharmaceutical system. The resulting framework will be shared with the partners for comment.
- Using the elements proposed in this meeting to identify associated indicators and implementing a process to get input from SIAPS partners on the selection of appropriate indicators for piloting.

A follow up meeting is anticipated for the end of 2015 or early in 2016.

Meeting Participants

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SIAPS Partner Consultative Meeting Agenda

Thursday, September 11, 2014

Time	Duration	Topic	Presenter/Facilitator
9:00-9:30	30 min	Registration and coffee/tea	
9:30-9:35	5 min	Welcoming remarks and introduction of meeting facilitator	Kofi Aboagye-Nyame (SIAPS Program Director) Richard Laing (Facilitator)
9:35-9:50	15 min	Introduction of participants	All Richard Laing (Facilitator)
9:50-9:55	5 min	Logistics	Kate Onyejekwe (Results Senior Manager, SIAPS)
9:55-10:05	10 min	Welcoming remarks	Douglas Keene (Vice President of CPM)
10:05-10:15	10 min	Welcoming remarks/introduction	Tony Boni (USAID AOR)
10:15-10:30	15 min	Introduction, meeting objectives, and overview of agenda	Kofi Aboagye-Nyame (SIAPS Program Director)
10:30-11:00	30 min	Pharmaceutical systems and pharmaceutical systems strengthening: definitions and frameworks: Overview of the literature	Tamara Hafner (SIAPS Consultant) David Lee (Director, Technical Strategy and Quality, CPM) Richard Laing (Facilitator)
11:00-11:30	30 min	**Coffee/tea**	
11:30-1:00	1 hr 30 min	Group work: Defining pharmaceutical system and pharmaceutical systems strengthening	Group members Richard Laing (Facilitator)
1:00-2:00	1 hr	**Lunch**	
2:00-2:30	30 min	Toward a framework for measuring pharmaceutical systems strengthening: Existing frameworks and approaches	Helena Walkowiak (Principal Technical Advisor, SIAPS)
2:30-3:30	1 hr	Group work: Identifying key components of a pharmaceutical system and a framework for measurement of systems strengthening	Group members Richard Laing (Facilitator)
3:30- 3:45	15 min	**Coffee/tea**	
3:45-4:15	30min	Group work: Identifying key components of a pharmaceutical system and a framework for measurement of systems strengthening (continued)	Group members Richard Laing (Facilitator)
4:15-4:30	15 min	Summarizing discussions for the day and comments/feedback from participants	David Lee (Director, Technical Strategy and Quality, CPM)
4:30-5:30		Opportunity for individual or group partner-SIAPS meetings	

Friday, September 12, 2014

Time	Duration	Topic	Presenter/Facilitator
8:30-8:45	15 min	**Coffee/tea**	
8:45-9:00	15 min	Review of day 1	David Lee (Director, Technical Strategy and Quality, CPM)
9:00-9:15	15 min	Introduction: Identifying key elements to operationalize and turn into indicators	Helena Walkowiak (Principal Technical Advisor, SIAPS)
9:15-10:45	1 hr 30 min	Group work: Identifying key elements to operationalize and turn into indicators	Richard Laing (Facilitator)
10:45-11:15	30 min	**Coffee/tea**	
11:15-11:45	30 min	Discussion on country-level composite index: Approaches and challenges	Veronika Wirtz (Facilitator) Richard Laing (Facilitator)
11:45-12:45	1 hr	Plenary discussion: Recommendations on the use of composite indices and methodological approaches for development and validation	All Veronika Wirtz (Facilitator) Helena Walkowiak (Principal Technical Advisor, SIAPS)
12:45-1:45	1 hr	**Lunch**	
1:45-2:30	45 min	Summary of discussions and deliberations	David Lee (Director, Technical Strategy and Quality, CPM) Richard Laing (Facilitator)
2:30-2:40	10 min	Closing remarks and next steps	Kofi Aboagye-Nyame (SIAPS Program Director)
2:40-2:45	5 min	Closing remarks	Tony Boni (USAID AOR)
2:45-5:30		Opportunity for individual or group partner-SIAPS meetings	

Work Group Members

Group 1	Group 2	Group 3	Group 4	Group 5
Edgar Barillas	Diana Bowser	Kofi Aboagye-Nyame	Emily Bancroft	Gege Buki
Kwesi Eghan	Chuck Daniels	Tony Boni	Tobey Busch (Rapporteur)	Tamara Hafner
Andy Stergachis	Dumebi Mordi (Rapporteur)	Peter Hobby	Michael Cohen	Brittany Johnson
Abeba Taddese	Mirfin Mpundu	Michael Johnson	Clinton DeSouza	Richard Laing
Reshma Trasi	Kate Onyejekwe	Mohan Joshi	Lisa Ludeman	David Lee
Eme Unanaowo (day 2 only)	Patricia Paredes	Niranjan Konduri (Rapporteur)	David Mabirizi	Analia Porras
Helena Walkowiak	Sameh Saleeb	Catherine Vialle-Valentin	Kidwell Matshotyana	Maura Soucy (Rapporteur)
Kiley Workman (Rapporteur)		Linda Zackin	Veronika Wirtz	Michele Teitelbaum

Identification of Elements for Each Component: Group Assignments

Component	Group
Policy and legal framework	Group 2
Regulatory systems	Group 1
Pharmaceutical services	Group 3
Human resources	Group 4
Financing	Group 1
Information	Group 4
Innovation, research and development, manufacturing, and trade	Group 5

BACKGROUND DISCUSSION PAPER

DEFINING AND MEASURING PHARMACEUTICAL SYSTEMS STRENGTHENING

Tamara Hafner
Helena Walkowiak

September 3, 2014[3]

USAID FROM THE AMERICAN PEOPLE

SIAPS Systems for Improved Access to Pharmaceuticals and Services

[3] The background discussion paper was completed on September 3, 2014. However, the section on composite indicators was revised after the SIAPS Partner Consultative Meeting (September 11-12, 2014) to reflect contributions from Veronika Wirtz and Richard Laing, both from the Department of Global Health at Boston University School of Public Health.

Background Discussion Paper

Introduction

Various frameworks, indicators, and assessment tools are available to assess and monitor the performance of pharmaceutical systems. These indicators and tools tend to measure inputs, processes, outputs, and outcomes centered around key functions, namely, selection, procurement, distribution, and use of pharmaceuticals. A general theme among these various frameworks and tools is that the goal of a pharmaceutical system is to ensure timely and equitable access to and appropriate use of pharmaceuticals and/or other health technologies. However, there is no widely accepted definition of what constitutes a pharmaceutical system, nor is there a standardized approach for measuring progress toward stronger, more sustainable systems. The US Agency for International Development (USAID) and partners are calling for the development of a framework and indicators that can monitor and measure the strengthening, or weakening, of a pharmaceutical system and track whether investments in systems strengthening interventions are yielding the expected results. As such, the USAID-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program[4] aims to develop a framework with clearly linked measures to enable stakeholders to measure performance of pharmaceutical systems and changes thereof, and use this information for intervention design and evaluation to enhance the delivery of pharmaceutical services.

This paper is intended to serve as a starting point for discussions at the SIAPS Partners Meeting (September 11-12, 2014) to address the following objectives:

- Agree on working definitions of what constitutes a "pharmaceutical system" and "pharmaceutical systems strengthening"
- Based on these definitions, identify the key elements that must be operationalized and turned into indicators and discuss potential sources of data
- Agree on next steps for selecting or developing appropriate indicators for measuring pharmaceutical systems strengthening outcomes

The paper provides an overview of the literature on existing definitions and frameworks regarding pharmaceutical systems and pharmaceutical systems strengthening. It highlights some of the major issues to be considered in developing a working definition of what a pharmaceutical system is, what strengthening it entails, and for deriving a framework and metrics for measurement.

[4] The USAID-funded SIAPS Program is implemented by Management Sciences for Health (MSH) with core partners Accreditation Council for Pharmacy Education, Harvard University, Logistics Management Institute, and University of Washington and specialized resource partners African Medical and Research Foundation, Ecumenical Pharmaceutical Network, Results for Development, IMPERIAL Health Sciences, VillageReach, and William Davidson Institute.

Methodology

Sources from the grey and academic literature and a list of search terms (Appendix 1) developed through consultation among SIAPS program staff were used for the literature search. The primary inclusion criteria were reports or studies that focused on a definition of pharmaceutical system, pharmaceutical management system, pharmaceutical systems strengthening, or health systems strengthening; a description of a framework aligned with one of these definitions; an identification of one or more components of a pharmaceutical (management) system; description of a measure of performance for such a system; description of an intervention to improve, support, or strengthen such a system; and a review or discussion of the conceptual or theoretical basis for such a system or one of its components. Assessment tools were included in the review if they were in the public domain, assess or evaluate a pharmaceutical system or an important component thereof, or were judged to add meaningfully to the conceptualization of pharmaceutical systems or pharmaceutical systems strengthening. In addition, logistics assessment tools developed for low- and middle-income country public health systems were included. Assessment tools that were simple modifications of other tools, e.g., for use in a particular country, were excluded. Various iterations of the search were done and relevant references from retrieved documents were also tracked. One limitation of the search strategy is that it was limited to academic and grey literature sources available online. It is therefore possible that we have missed internal conceptual or background papers that were not widely distributed and are the basis for the development of some of the assessment tools considered herein.

Systems Thinking in Health

Given the relationship between a pharmaceutical system and the broader health system and the interconnectedness between its components, a discussion of pharmaceutical systems strengthening must build on existing approaches aimed at understanding and strengthening health systems. There has been an emerging interest in systems thinking to understand how actors, institutions, and resources interact and operate within a health system to influence better health outcomes (de Savigny and Adam 2009; Gilson 2012). This follows a period of renewed attention on health systems, which began with the publication of the World Health Report in 2000 with health system performance as the theme. In the report, the World Health Organization (WHO) advanced a definition for health systems as "all activities whose primary purpose is to promote, restore or maintain health" (WHO 2000, p. 5) and proposed a performance measurement framework. The fundamental goals of the health system include improving the health of the population, responding to people's expectations, and providing financial protection against the costs of ill-health. To achieve these goals, health systems must perform four basic functions: service provision, resource creation, stewardship, and mobilization and allocation of finances. This report helped to usher in a renewed focus on health systems and their strengthening and has led to a robust debate and a multiplicity of health systems and health systems strengthening frameworks (de Savigny and Adam 2009; Shakarishvili et al. 2010; van Olmen et al. 2012; WHO 2007).

WHO subsequently developed its "building blocks" framework to create a common understanding about what a health system is and what constitutes health systems strengthening. It expands the World Health Report (WHO 2000) definition of a health system to include "all organizations, people, and actions whose primary intent is to promote, restore or maintain health" (WHO 2007, p. 2). The framework identifies six essential building blocks—service delivery; health workforce; information; medical products, vaccines, and technologies; financing; leadership/governance—built around the key functions of a health system. It defines health systems strengthening as "improving these six health system building blocks and managing their interactions in ways that achieve more equitable and sustained improvements across health services and health outcomes" (WHO 2007; p. 4). It is the multiple relationships and interactions between the building blocks, more so than the blocks themselves, that define the system.

Several scholars have since applied a systems thinking approach to guide the debate on health systems and their strengthening (de Savigny and Adam 2009; van Olmen et al. 2012). Systems thinking is advocated as an approach to understand how health interventions exert their system-wide effects and to guide the design and evaluation of sustainable system-strengthening interventions (de Savigny and Adam 2009). Although the interactions between health interventions and health systems are not well understood, systems thinking brings into clear focus two basic ideas: all health interventions tend to have a system-level effect and health system processes are non-linear. Systems are dynamic; they react to the same input in different ways and generate their own behaviors. The complexity of these reactions and interactions can render the system "policy resistant [in that] seemingly obvious solutions may fail or worsen the situation" (de Savigny and Adam 2009, p. 42). Although the academic and grey literature on pharmaceutical system and pharmaceutical systems strengthening is sparse, the complexity of these reactions has long been appreciated. This is reflected in existing frameworks, such as the

pharmaceutical systems framework developed by the Center for Pharmaceutical Management (CPM)/Management Sciences for Health (MSH) which depicts the interrelationship and interdependence of the key pharmaceutical management functions. The abundant scholarship on health systems and health systems strengthening along with existing pharmaceutical systems frameworks serve as a logical guide in working toward an understanding and agreement on what a pharmaceutical system is, its strengthening, and how to measure its performance.

Existing Definitions

Pharmaceutical System

Given the number of assessment tools for measuring various aspects of pharmaceutical system performance, we surprisingly found only three explicit definitions of pharmaceutical system. Roberts and Reich (2011) use the terms system and sector interchangeably and define the pharmaceutical system as involving eight complex subsystems: research and development, clinical trials, registration, manufacturing and packaging, procurement and importing, supply chain, dispensing, and sales/use. This definition is similar to that in the WHO transparency assessment instrument (2009). WHO, however, makes a distinction between pharmaceutical system and pharmaceutical sector defining the former as "the relationship/interactions between the various actors of the pharmaceutical sector and the way decisions are made in particular in the government" (WHO 2009; p. 1). Pharmaceutical sector is used to refer to the various actors (the government, private-for-profit organizations, private not-for-profit organizations, etc.) engaged in the "medicine chain." The medicine chain includes research and development of new medicines; conducting clinical trials; filing patents; manufacture; registration; selection of essential medicines, medicines procurement and distribution; inspection of manufacturers and distributors; prescribing; dispensing; pharmacovigilance; and the control of medicine promotion (WHO 2009). So WHO views the pharmaceutical system as the interactions and decision-making processes among the various pharmaceutical sector actors that determine the roles and functions that they undertake to achieve the goal of medicines access and appropriate use. Kohler et al. (2014), in their paper on the need for good governance in pharmaceutical systems, also define the pharmaceutical system in terms of actors and their actions. A pharmaceutical system encompasses "the actions of public and private stakeholders as they move drugs through the supply chain from purchasing to providing to patients" (p. 3).

These definitions are a helpful starting point for conceptualizing a pharmaceutical system; however, they were generated for a specific purpose. The WHO and Kohler definitions relate to governance and transparency issues in the medicine chain. The Roberts and Reich definition is in the context of implementing pharmaceutical sector reforms and depicts the sector as a linear progression of functions. It focuses almost exclusively on policy interventions for governments to influence these functions.

Related definitions were also considered to gain further insight into understanding the goals and scopes of pharmaceutical systems. In the literature reviewed, references were commonly made to pharmaceutical management or pharmaceutical supply system. The USAID-funded Rational Pharmaceutical Management Plus (RPM Plus) Program (2005) and Miralles (2010) use the term pharmaceutical supply system, which is defined by the procedures and methods used to accomplish the four key pharmaceutical management functions—selection, procurement, distribution, and use. The Health Systems 20/20 assessment approach (HSAA) defines the management of medical products, vaccines, and technologies as "the whole set of activities aimed at ensuring the timely availability and appropriate use of safe, effective, quality medicines and related products and services in any health care setting" (Health Systems 20/20 2012, p. 242).[5] There are earlier versions of this definition in various RPM Plus training materials and

[5] Health Systems 20/20 Program (2006-2012) was funded by the USAID and led by Abt Associates.

Islam's (2007) edited HSAA manual, which was developed in collaboration with RPM Plus and the Quality Assurance Program.[6]

Pharmaceutical Systems Strengthening

With respect to pharmaceutical systems strengthening, no explicit definitions were found. The review included a search for definitions of systems strengthening with respect to the other five health system building blocks but no explicit statements were found. However, several definitions of health systems strengthening exist and provide some guidance. Islam (2007) defines health systems strengthening "as any array of initiatives and strategies that improves one or more of the functions of the health system and that leads to better health through improvements in access, coverage, quality, or efficiency" (p. 1-1). As mentioned previously, WHO (2007) defines health systems strengthening as "improving [the] six health system building blocks and managing their interactions in ways that achieve more equitable and sustained improvements across health services and health outcomes" (p. 3). The WHO Health Systems Strengthening Glossary (WHO 2014a) also defines health systems strengthening as "the process of identifying and implementing the changes in policy and practice in a country's health system, so that the country can respond better to its health and health system challenges." The latter two definitions draw attention to both performance and the capacity of the system to respond to future health and health system challenges.

[6] The Rational Pharmaceutical Management (RPM) Program, along with the RPM Plus Program and the Strengthening Pharmaceutical Systems (SPS) Program are predecessors to the SIAPS Program, which were all funded by USAID and implemented by MSH and partners (and for RPM, in collaboration with the United States Pharmacopeia). The Quality Assurance Program was implemented by the University Research Corporation.

Existing Frameworks

Eight frameworks relevant to pharmaceutical systems were identified in the review: the pharmaceutical management system framework (RPM Plus 2005); CPM/MSH's pharmaceutical management framework (MSH 1997); John Snow International (JSI) logistics cycle (USAID | DELIVER 2009); the WHO's 'building blocks' (WHO 2007); the International Health Partnership and related initiatives (IHP+) monitoring and evaluation of health systems strengthening framework (WHO et al. 2009; WHO 2010); the access to medicines from a health system perspective framework (Bigdeli et al. 2013); the "control knobs" framework (Roberts and Reich 2011); and the SIAPS pharmaceutical systems strengthening framework (SIAPS 2013). These are a mix of conceptual and operational frameworks. Table 1 provides a summary of the key frameworks.

Table 1. Overview of Frameworks Relevant to Pharmaceutical Systems

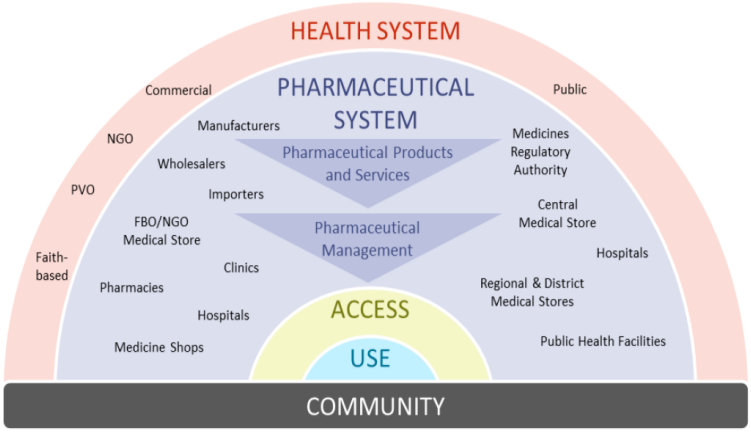
Framework	Source	Focus	Key Elements of the Framework	Goal	Overarching principles and qualifiers
Pharmaceutical management system framework	RPM Plus 2005; Miralles 2010	Relationship between health system and pharmaceutical sub-system	• Health system and its pharmaceutical sub-system • Institutions and stakeholders in the public and private sectors • Four interrelated core (pharmaceutical management) functions: selection, procurement, distribution, and use • Human, financial, and informational resources • Overarching policies and legislation	• Access (accessibility, availability, acceptability, affordability) • Appropriate use • Access to/use of pharmaceutical products and services	• Timely • Equitable • Safe, effective, quality medicines and services
Pharmaceutical management framework	MSH 1997; MSH 2012	Functions and elements of pharmaceutical management	• Four interrelated key functions: selection, procurement, distribution, and use • Management support systems: organization; financing; information management; and human resource management • Policy, law, and regulations supported by good governance	• Access (accessibility, availability, acceptability, affordability) • Rational use • Access to/use of pharmaceutical products	• Quality of products and services; specifically, product safety, quality, and cost-effectiveness
Medical products building block, WHO health systems framework	WHO 2007; WHO 2010	Core functions (building blocks) of a health system	• One of six interdependent building blocks: medical products, vaccines, and health technologies; service delivery; health workforce; information; financing; leadership and governance • Five requirements (to achieve goal) ○ National policies, standards, guidelines, and regulations ○ Market information; price setting/negotiation ○ Reliable manufacturing practices and quality assessment ○ Effective procurement, supply, storage, distribution systems ○ Support for rational use	• Access • Scientifically sound and cost-effective use • Access to/use of essential medical products, vaccines and technologies	• Equity • Products of assured quality, safety, efficacy, and cost-effectiveness

Framework	Source	Focus	Key Elements of the Framework	Goal	Overarching principles and qualifiers
Control knobs framework	Roberts and Reich 2011	Means for effecting adjustments in the pharmaceutical system	• Five "control knobs" (adjustable independent variables): financing, payments decisions, organization of activities, regulation, and persuasion methods • Eight subsystems of pharmaceutical system: research and development; clinical trials; registration; manufacturing and packaging; procurement and importing; supply chain; dispensing; and sales/use	• Intermediate performance goals: efficiency, quality, and access (physical availability and effective availability) • Ultimate performance goals: health status, financial protection, and citizen satisfaction	• Reliable access • Safe, effective, affordable medicines
Conceptual framework of access to medicines from a health systems perspective	Bigdeli et al. 2013	Health systems perspective to address demand- and supply-side barriers to access to medicines	• Context: international, national, sub-national, local • Demand-side: individuals, households, and communities • Six building blocks and their multiple and dynamic relationships: service delivery; health sector resources—medicines, financing, information, human resources, [infrastructure]; governance (health and non-health sectors) • National and international contextual determinants: market forces, innovation, transparency, donors' agenda, and funding	• Access to medicines (accessibility, availability, acceptability, affordability, quality) • Better health outcomes	• Equity • Human rights • Quality
Pharmaceutical systems strengthening framework	SIAPS 2013	Approach to strengthening pharmaceutical systems	• Six overlapping building blocks with medical products building block at center depicts dynamic relationships between the pharmaceutical system and health system input (human resources, information, financing), governance, and service delivery elements • Stakeholders: government, providers, and community • Analysis of local context, existing system; priority health concerns; selection and implementation of evidence-based strategies; monitoring and evaluating performance against expected outcomes	• Access (accessibility, availability, acceptability, affordability) • Appropriate use • Access to/use of pharmaceutical products and services • Improved coverage and access of evidence-based interventions • [Contribute to] sustainable health outcomes	• Equity • Timely • Safe, effective and quality pharmaceuticals • Evidence-based

Background Discussion Paper

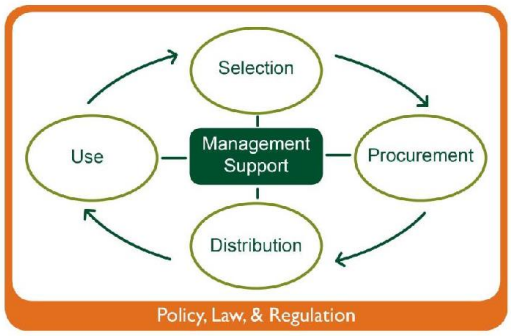
CPM/MSH Pharmaceutical Management System and Pharmaceutical Management Frameworks

The pharmaceutical management system framework (RPM Plus 2005; Miralles 2010) conceptualizes the pharmaceutical system as a subsystem of the health system (Figure 1). The pharmaceutical system includes all the institutions and stakeholders in both the public and private sectors that are involved in the procedures and methods used to accomplish the four key interdependent pharmaceutical management functions—selection, procurement, distribution, and use. Pharmaceutical management aims to ensure the timely and equitable access to and appropriate use of safe, effective, quality medicine and related products and services (Miralles 2010). The four management functions are spelled out in the CPM/MSH pharmaceutical management framework (MSH 1997; figure 2). The functions are supported by a core of management support systems: organization, financing and sustainability, information management, and human resources management. The core and support functions are enabled (and constrained) by policies, laws, and regulations and supported by good governance principles and practices that establish and sustain the public commitment to essential medicine supply (MSH 2012).



Source: Miralles 2010; RPM Plus 2005

Figure 1. Pharmaceutical management system framework

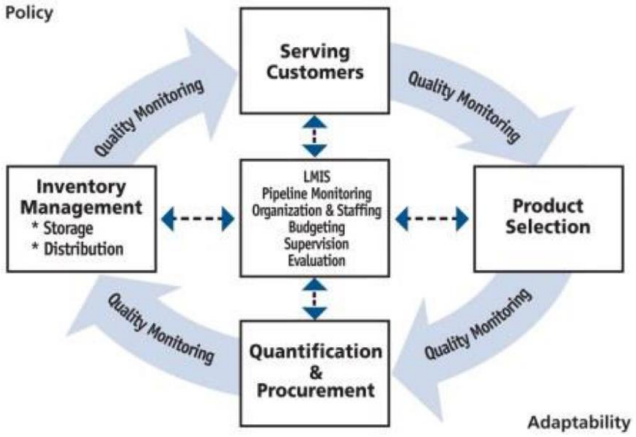


Source: SPS 2011

Figure 2. Pharmaceutical management framework

JSI Logistics Cycle

The JSI logistics cycle shares similarities with the pharmaceutical management system framework, but focuses only on aspects of the functions that relate to logistics (Figure 3). It describes logistics management as a cycle that includes serving customers, product selection, quantification, procurement, and inventory management with a set of core management support functions (USAID | DELIVER 2009; 2011).



Source: USAID | DELIVER PROJECT, Task Order 1. 2011

Figure 3. The logistics cycle

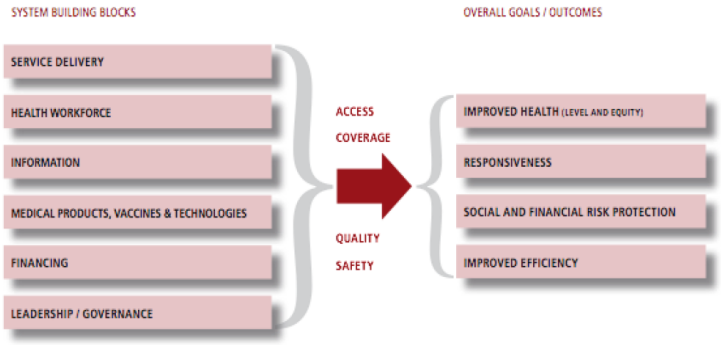
Background Discussion Paper

WHO Health Systems Building Blocks and IHP+ Monitoring and Evaluation of Health Systems Strengthening Frameworks

The WHO health systems building blocks framework (WHO 2007) does not refer to a pharmaceutical system, but rather to the provision of medical products as a core function of the health system (Figure 4). "A well-functioning health system ensures equitable access to essential medical products, vaccines and technologies of assured quality, safety, efficacy and cost-effectiveness, and their scientifically sound and cost-effective use" (WHO 2007, p. 3). WHO does not define the building block but identifies five requirements for achieving access and use, which are:

- national policies, standards, guidelines and regulations, that support policy;
- information on prices, international trade agreements, and capacity to set and negotiate prices;
- reliable manufacturing practices and quality assessment of priority products;
- procurement, supply, storage, and distribution systems that minimize leakage and other waste;
- support for rational use of essential medicines, commodities, and equipment through guidelines and strategies to assure adherence, reduce resistance, maximize patient safety, and training.

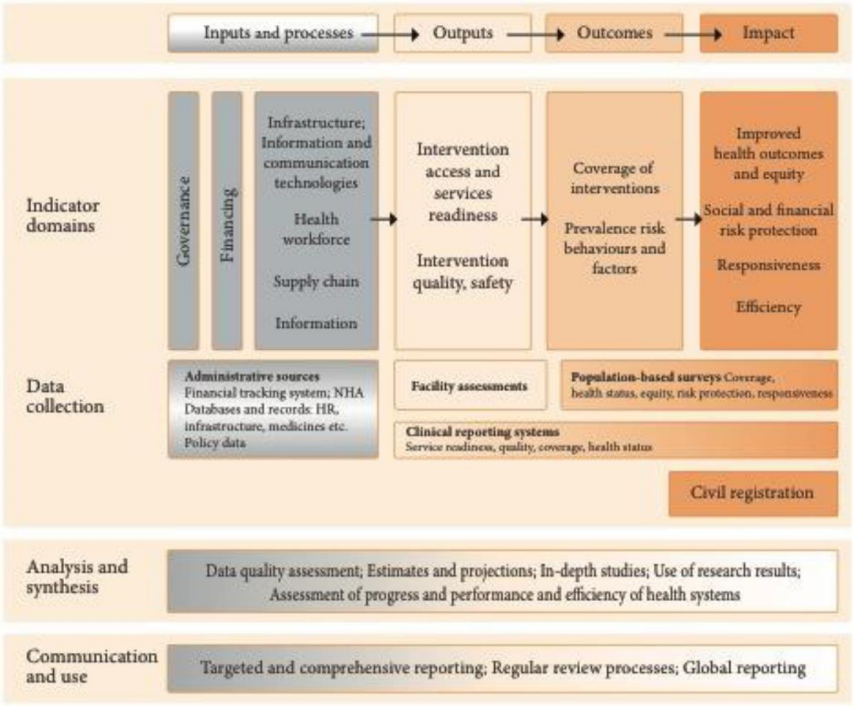
By implication, the pharmaceutical system is a subunit of the health system that aims to achieve access and rational use. The framework developed by IHP+ for monitoring and evaluating health systems strengthening (WHO et al. 2009; WHO 2010) is based on the building blocks framework (Figure 5).



Source: WHO 2007

Figure 4. WHO health system framework

Background Discussion Paper



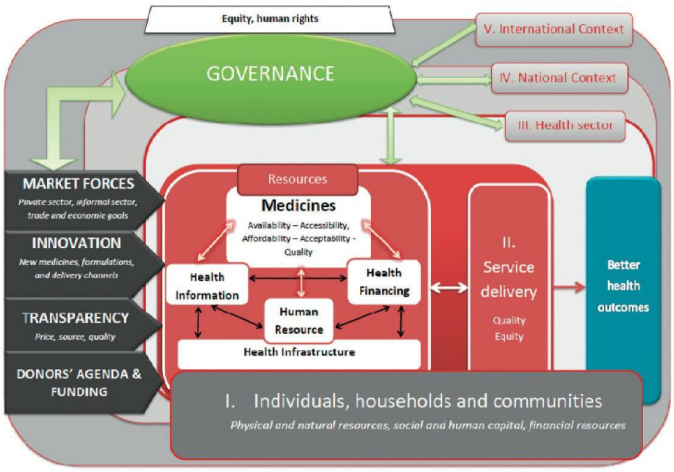
Source: WHO 2010

Figure 5. IHP+ monitoring and evaluation of health systems strengthening framework

Access to Medicines from a Health System Perspective Framework

Bigdeli et al. (2013) adapted the building blocks framework to develop a systems approach to access to medicines (Figure 6). The authors do not attempt to define a pharmaceutical system but rather to highlight the interactions between the health systems' building blocks and medicines. They identify the demand- and supply-side barriers to access and their interactions with the building blocks throughout the various levels of the health system.

Background Discussion Paper



Source: Bigdeli et al. 2013

Figure 6. Conceptual framework of access to medicines from a health systems perspective

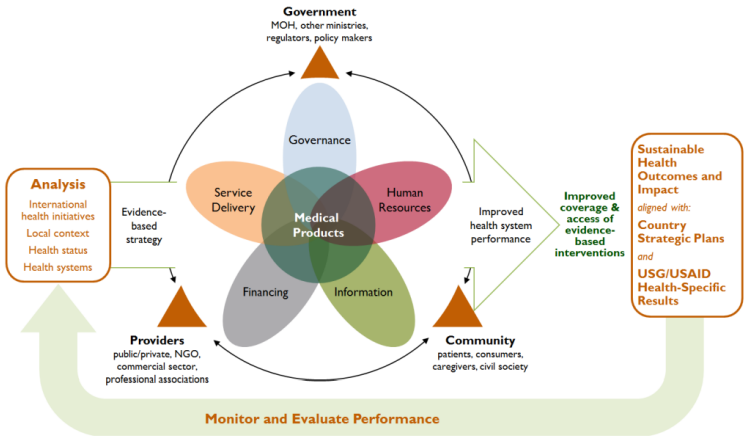
Control Knobs Framework

The Roberts and Reich (2011) control knobs framework focuses on the role of government in influencing pharmaceutical sector performance. It identifies five control knobs—financing, payment decisions, organization of activities, regulation, and persuasion efforts—as structural components of the pharmaceutical system, which can be adjusted to improve system performance. It divides the system goals into intermediate and ultimate performance goals. The intermediate performance goals—efficiency, quality, and access—are characteristics of the functioning of the system. They are intermediate between policy causes and performance effects and can be treated as a means to the ultimate performance goals, which are health status, financial protection, and citizen satisfaction. The control knobs are the adjustable, independent variables that influence the ultimate goals of the system. It should be noted that this framework was originally developed as the flagship framework for health system/sector reform (Roberts et al. 2008) and was later applied to reforming pharmaceutical systems. The authors do not make the relationship between the pharmaceutical and health systems explicitly clear. They imply that the health system is an external factor that can influence the pharmaceutical system. They also acknowledge an overlap of the various components and functions of the pharmaceutical system with those of the general health system (Roberts and Reich 2011).

SIAPS Pharmaceutical Systems Strengthening Framework

SIAPS pharmaceutical systems strengthening framework is the only one found in the review (Figure 7). The framework illustrates the proposed SIAPS approach to pharmaceutical systems strengthening, which includes analyzing and selecting appropriate interventions on the basis of

evidence, implementing, and monitoring and evaluating them against expected outcomes (SIAPS 2013). It builds on the WHO health systems framework and identifies the pharmaceutical system components, placing the medical products function at the center of the set of interacting building blocks. Also depicted are the key stakeholders categorized as government, providers, and community and the expected outcomes, as the pharmaceutical system contribution to health outcomes.



Source: SIAPS 2013

Figure 7. SIAPS pharmaceutical systems strengthening framework

What is the Goal of a Pharmaceutical System?

A consistent theme across the various definitions and frameworks is that the goal of the pharmaceutical system is to ensure access and manage use, with each of these terms being associated with some qualifier. The term access is most commonly understood in the reviewed literature as availability, affordability, (geographical) accessibility, and (cultural) acceptability of quality products and services (CPM 2003). Access may be described as timely and/or equitable. Use, explained as prescribing, dispensing or sale, and consumption by the patient, is sometimes qualified as rational, appropriate, cost-effective, timely, and/or equitable.[7] Then there is the question of access to what? It may be access to medicines, pharmaceuticals, vaccines, pharmaceutical products, medical products, health technologies, and/or commodities, with associated qualifiers including essential, quality, safe, or effective (Health Systems 20/20 2012; WHO 2007; 2010). The various terms used for the products are not interchangeable. Pharmaceutical products, medical products, and health technologies are broad terms. For example, the health technologies assessment glossary defines health technologies as interventions that "may be used to promote health, to prevent, diagnose or treat acute or chronic

[7] Although national medicine policies were not included in our review, it is worth noting that use has also been described as quality (Australia's *Quality Use of Medicines*) and optimal (New Zealand Pharmaceutical Management Agency) in such policies.

disease, or for rehabilitation. [They] include pharmaceuticals, devices, procedures, and organizational systems used in health care" (HTA Glossary 2014, July 1).

Beyond access and use, there are other intermediate and ultimate system goals. According to Roberts and Reich (2011), the intermediate system performance goals—efficiency, quality, and access—are the means to improving health status, financial protection, and citizen satisfaction in the target population. This conceptualization is similar to the health system goals identified by WHO (2007) in the building blocks framework. In this case, ensuring access to and coverage for quality and safe services is the intermediate goal and the means for achieving the ultimate goals—improved health, system responsiveness, social and financial risk protection, and improved efficiency. Interestingly, the goals are comparable between the two frameworks, even though the Roberts and Reich framework refers to the pharmaceutical sector whereas the WHO building blocks framework focuses on the broader health system.

Key Stakeholders and Their Roles in the Pharmaceutical System

The health and pharmaceutical systems framework and the SIAPS pharmaceutical systems strengthening framework depict a pharmaceutical system as including all the institutions and stakeholders in the private and public sectors that are engaged in or influence pharmaceutical management functions. The Bigdeli et al. (2013) framework serves as a useful lens for examining the various stakeholders and their roles in the system. The framework assigns five levels to the health system. At the first level are individuals, households, and communities. Individual preferences, household economics, and social and cultural factors in the community influence health-seeking behavior and trigger demand in the system. The authors place the population at the center of the health system and argue that individuals and the community are more than mere passive end-users. They can help achieve better access to medicines and health services by supporting other patients and addressing some of the social and cultural barriers to access through collective networks and actions. Individuals and communities also act as stewards of the system by demanding quality service and better accountability and expressing their (dis)satisfaction with products and services (Roberts and Reich 2011; WHO 2007).

Levels 2 through 5 address the supply side of the system. Health service delivery, the second level, includes wholesalers, manufacturers, and various service providers such as hospitals, pharmacies, clinics, and medicine shops, whether public or private, formal or informal (Bigdeli et al. 2013). These actors perform their pharmaceutical management activities within the context of the policy and regulatory environment of the health sector, the third level of the health system according to Bigdeli et al. The second and third levels are analogous to the pharmaceutical system depicted in the pharmaceutical management system framework, which shows the various actors carrying out the pharmaceutical management functions to ensure access and use (Figure 1). Levels 4 and 5 refer to the national and international contexts, respectively. Cross-cutting policies and other national priorities at the national level impact the health system and hence the pharmaceutical system (Bigdeli et al. 2013; Roberts and Reich 2011). At the international level, the agenda of donor agencies and global health initiatives, and trade issues can also have supply-side effects (Bigdeli et al. 2013; Marchal et al. 2009; Roberts and Reich 2011).

Table 2 presents a compilation of the dimensions and components identified in the various frameworks reviewed above.

Table 2. Summary of Framework Elements. (The most commonly mentioned elements are in bold.)

Dimensions	Framework elements
Goals	• **Improved access (accessibility, availability, acceptability, affordability**, quality) • **Better use (appropriate, rational)** • **Health outcomes**; health status • Coverage • Efficiency • Financial protection • Satisfaction
Access to and use of what?	• **Medicines** • **Pharmaceuticals** • **Medical products** • **Vaccines** • **Health technologies** • Pharmaceutical services
Qualities of access and use	• **Quality** • Essential • **Safe/safety** • **Effective** • **Cost-effectiveness**
Overarching principles	• **Equity** • **Timeliness** • Human rights
Stakeholders	• **Structures/institutions/organizations** • **Individuals/**people • **Government** • **Providers** • **Communities** and households • **Public sector** • **Private sector** • International, national, sub-national, and local
Functions (subsystems):	• **Selection** • **Procurement** (procurement and importing) • **Distribution (supply chain)** • **Use** (dispensing; sales) • Research and development • Clinical trials • **Regulation** (including **registration** and licensing of individuals and facilities) • Manufacturing and packaging

"Building blocks" (policy and legal framework; management support systems; resources/ inputs)	• **Service delivery**
	• (Leadership and) **governance**
	• **Policies, law, and regulation (supported by good governance)**
	• Resources (management support systems/inputs)
	  ○ **Medical products, vaccines, health technologies**
	  ○ **Human resources**
	  ○ **Information**
	  ○ **Financing** (pricing; price setting/negotiation)
	  ○ Infrastructure
	  ○ Organization

Environment	• Market forces • Innovation • Transparency • Donor's agenda and funding

Background Discussion Paper

Issues to Consider in Defining Pharmaceutical Systems and Pharmaceutical Systems Strengthening

Pharmaceutical System

On account of the preceding discussion we can begin to think about what a pharmaceutical system is and what pharmaceutical systems strengthening entails. There is agreement that the goal of a pharmaceutical system is to ensure access to and rational use of pharmaceuticals. A fundamental question is what constitutes a pharmaceutical product. How do we distinguish pharmaceuticals from other medical products or health technologies? And what qualifiers, if any, should we use for access and use?

Then there is the question of what a pharmaceutical system is and how to operationalize the definition. A logical approach is to treat the pharmaceutical system as a subsystem of the broader health system. What then are the components of a pharmaceutical system? We can think of the pharmaceutical system in terms of structures/organizations (e.g., manufacturers, regulatory agencies, procurement agencies); individuals/people; resources (human, financial, information); functions/actions; or some combination thereof. How do these components contribute to the overall performance of the pharmaceutical system, the broader health system, and, ultimately to health outcomes?

Based on the reviewed definitions and frameworks presented earlier, we propose as a point of departure for further deliberation that a pharmaceutical system be defined as follows:

> A *pharmaceutical system* consists of all organizations, individuals, resources, and actions and their interactions that aim to ensure equitable and timely access to safe, effective, quality pharmaceutical products and related services that promote their appropriate and cost-effective use.

Pharmaceutical Systems Strengthening

With regard to pharmaceutical systems strengthening, we can agree that it is about improving performance (efficiency and quality), but is that all? Systems are not static, and they need the capacity to adapt to changes in their environment. Do we also need to think of systems strengthening in terms of system maturity, sustainability, and/or resilience? There have been concerns about the resilience of health systems, particularly in light of changing disease patterns, natural disasters, and the recent global financial crisis (DFID 2014; European Commission 2014; Hou et al. 2013; Thomas et al. 2013; WHO 2014b). We can think of resilience as "the capacity of a system to absorb disturbance and reorganize while undergoing change so as to still retain essentially the same function, structure, identity, and feedbacks" (Walker et al. 2004, p. 2). So should pharmaceutical systems strengthening seek to build resilience or capacity to address challenges and sustain improvements? If so, what characterizes system resilience? How do we capture this resilience both in our definition of pharmaceutical systems strengthening and some operational measure? And what is the target or endpoint for pharmaceutical systems strengthening? In other words, what does a strengthened and resilient system look like?

Pharmaceutical systems strengthening also needs to be distinguished from other pharmaceutical system interventions. In the literature, there is concern that health systems strengthening interventions continue to be designed around individual building blocks with little regard for the relationships and interactions with and among the other building blocks (Chee et al. 2013, Marchal et al. 2009; van Olmen et al. 2012). Chee et al. (2013) distinguish system support—addressing the constraints currently found—from systems strengthening, which targets the performance drivers and changes the system so that it can address future constraints. They propose four criteria for assessing whether an intervention is health systems strengthening:

- Has cross-cutting benefits beyond a single disease
- Addresses policy and organizational constraints or strengthens relationships between the building blocks
- Produces permanent systemic impact beyond the term of the project
- Tailored to country-specific constraints and opportunities, with clearly defined roles for country institutions

These criteria can provide some scope for our discussions regarding the distinction between pharmaceutical systems strengthening and other system interventions.

We propose the following definition as a starting point for our discussions on what constitutes pharmaceutical systems strengthening:

> *Pharmaceutical systems strengthening* is the process of identifying and implementing strategies and actions that achieve sustainable changes in one or more critical components[8] of a pharmaceutical system to improve system performance and capacity, to address future health and system challenges, and to contribute to better health outcomes through equitable improvements in access, quality, coverage, and use of pharmaceutical products and related services.

[8] The critical components of a pharmaceutical system are its core functions, structures, and the supporting health system resources and enabling policy, legal, and governance framework.

Background Discussion Paper

Framework for Measuring Pharmaceutical Systems Strengthening

Components of a Pharmaceutical System

As we have seen from reviewing definitions and frameworks, the system is often described in terms of its functions (Miralles 2010; WHO 2010; USAID 2011), subsystems, (Roberts and Reich 2011), or decision points along the medicine chain (Kohler 2014; WHO 2009). An extensive body of work focused on these components and their measurement already exists. This is evident in the myriad of assessment tools and indicator sets developed by key actors such as MSH, JSI, WHO, and Harvard Medical School with support from various funders including USAID (Appendix 2). Much of the thinking on and knowledge of pharmaceutical systems and assessment of their performance has been incorporated into the development and refinement of these tools and indicators over time. A detailed review of the system components measured in these tools can help identify a preliminary list of key components of a pharmaceutical system and associated indicators.

Appendix 2 lists 53 assessment tools and indicator sets that were reviewed. The majority of tools focus on some aspect of service delivery or supply chain management; 22 were developed by MSH, many under projects that were funded by USAID and have their conceptual basis in the pharmaceutical management framework. Among the non-MSH assessment tools, a few were aligned with a specific framework. The WHO "Monitoring the Building Blocks" and Health Systems 20/20 assessment tools are both aligned with the WHO health systems building block frameworks. The JSI tools are based on the logistics cycle framework.

Several of the assessment tools are used to measure performance for comparison over time and across countries. The WHO's Country Pharmaceutical Situation assessment tool, for example, monitors key aspects of a country's pharmaceutical situation and the efforts to improve the medicines situation at the global level. It has three levels of indicators. Level I measures key structures and processes and has six categories: national medicine policy, regulatory system, medicines supply system, medicines financing, production and trade, and rational use. Level II indicators measure outcomes at the health facility and pharmacy levels. Level III indicators are for in-depth assessments of specific components of the pharmaceutical sector, such as pricing or regulatory capacity. The Health System 20/20 (2012) health system assessment tool uses equity, efficiency, access, quality, and sustainability as five performance criteria for getting a holistic view of the health system. Sustainability, which refers to financial or institutional sustainability, is defined as the capacity of the system to continue its activities into the future (Health Systems 20/20 2012). Another approach uses the "capability maturity model" to monitor systems strengthening interventions in HIV/AIDS supply chain systems (Supply Chain Management System 2012). The tool defines capability maturity as a "continuum representing successively evolved 'current states' of supply chain's processes, infrastructure, technology and human resources. [Health] supply chains encompass four levels of capability maturity: ad hoc, organized, integrated and extended" (p. 5). Capability is benchmarked against five maturity levels: no/minimal, marginal, qualified, advanced practices, or best practices.

Among the tools reviewed, more than 160 unique categories of indicators and survey questions were identified.[9] Many of these categories were similar, but the labels were slightly different. Many also closely align with the subsystems and pharmaceutical management functions identified in the review of the frameworks. In an attempt to identify the primary measurement categories and reduce duplication, the assessment tools were divided into three groups (Figure 8):

- Group A includes comprehensive system tools that focus on access, use, pharmaceutical management/policy, and/or supply chain
- Group B includes tools for specific diseases or health programs and are mostly adaptations of those in group A
- Group C includes tools that are for specific system components, such as governance, human resources, or logistics

Group B tools were omitted from subsequent analyses in this paper to reduce duplication. The categories of indicators and survey questions from tools in groups A and C were then reorganized into broader categories to summarize the pharmaceutical system components measured by these various tools (Table 3).[10] The dimensions and components identified in the review of the frameworks and assessment tools (Tables 2 and 3) can serve as a preliminary list of the key components of the pharmaceutical system and can help identify associated indicators.

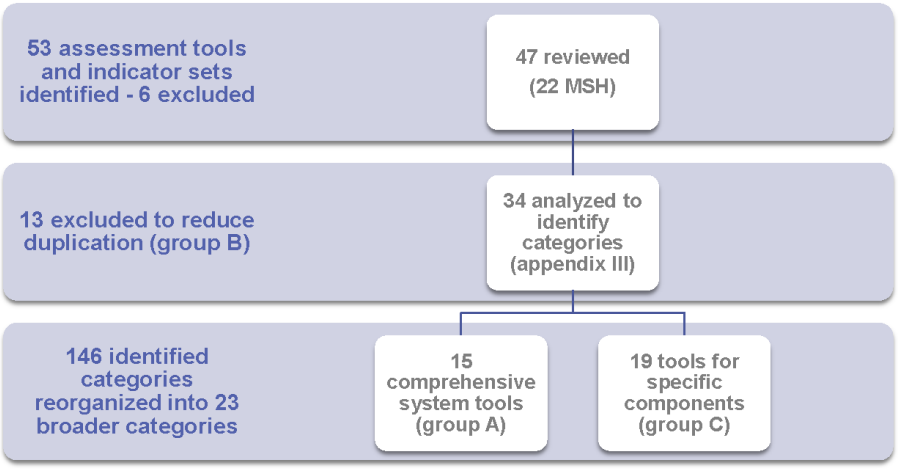


Figure 8. Organization of assessment tools and indicator sets for analysis

[9] Not all assessment tools included indicators; some were survey instruments (questionnaires). In such cases and when available, we included in our analysis the category labels used to group the survey questions.

[10] Appendix 3 provides a detailed list showing the original categories of measures that comprise the reassigned broader categories.

Table 3. Summary of Reassigned Categories of Indicators and Survey Questions (Listed Alphabetically) from Group A and Group B Tools. (The original categories included in these reassigned categories are listed in Appendix 3.)

Reassigned Category		No. of Tools
Access		15
Access and use		2
Financing		8
Governance		4
Health/pharmaceutical services/laboratory services		6
Human resources		7
Information systems		3
Manufacturing, industry, and trade		5
Miscellaneous indicator categories		13
Organization and management support		2
Policies, legislation, and regulation		20
Quality/quality assurance/pharmacovigilance		15
Service Delivery	Distribution	6
	Procurement	8
	Procurement and distribution	2
	Selection	3
	Selection and procurement	2
	Selection and use	1
	Selection and registration	1
	Services and logistics	1
	Supply chain/supply chain management/logistics	7
	Transport	1
Use		21

Note: For assessment tools with indicators, our analysis also included a count of the number of indicators in each category. These counts were excluded from the table because the possible duplication of indicators or redundancies across the various tools could bias the interpretation of the relative importance of a particular component.

Thoughts on Composite Indicators[11]

One of the issues for deliberation concerns the potential use of composite scores/measures.[12] USAID has been enquiring about approaches for ranking the performance of national pharmaceutical systems, which would likely require the use of a composite measure. Given the multi-dimensional nature of the pharmaceutical system, a single indicator cannot adequately capture the entire system or even a component. Further, it is difficult to make an overall

[11] Veronika Wirtz and Richard Laing contributed to the writing of this section.

[12] According to OECD's *Handbook on Constructing Composite Indicators*, a composite indicator is formed when individual indicators are compiled into a single index on the basis of an underlying model of the multi-dimensional concept that is being measured (OECD 2008).

judgment about the performance of the pharmaceutical system when looking at a large number of individual indicators. Creating a single or several composite indicators that incorporate a series of single measures is therefore worth considering.

Composite indicators are commonly used in fields such as economics (e.g., Gini Index) and international development (e.g., Human Development Index).[13] Composite indicators have also been used to rank health systems (WHO 2000) or provide a level of performance (e.g., performance rating of the National Health Service Trusts in England). A few of the assessment tools discussed earlier include composite scores/indices to provide summary measures or monitor improvements in specific areas of the system over time. For example, the WHO Monitoring the Building Blocks of Health Systems Assessment Instrument (2010) includes composite indices for leadership/governance, service delivery, and information systems building blocks. The composite index on governance is a simple additive index comprising 10 indicators and provides a summary measure of governance quality. More recently the Access to Medicine Index has used composite indicators to compare the efforts of major pharmaceutical companies to improve access to medicines in low- and middle-income countries.[14]

Several critical questions should be addressed when considering the suitability of compiling indicators into a country-level composite index, possibly as a marker for the current (maturity) level of the pharmaceutical system or for ranking countries in terms of their pharmaceutical performance. First, when and how are the use of such composite indicators appropriate and do they add value? It is therefore important to identify the intended audience (e.g., international donors, national governments, healthcare providers, citizens, patients) and the pharmaceutical system components or the dimensions of system performance the indicators are intended to measure. Donors may be particularly interested in the disease areas they invest in (e.g., reproductive health, HIV, malaria) rather than more general system aspects, such as market authorization speed and promotion of medicines.

Second, what systematic criteria are needed to determine the inclusion of individual indicators within composite indicators? Constructing composite indicators requires trade-offs between different measures of performance, which can be difficult and controversial. If not carefully designed, composite indicators may be misleading and result in wrong policy and planning decisions. Because composite indicators would aim for a comprehensive assessment of the pharmaceutical system, they should include all important aspects of performance, even those indicators that are difficult to measure. The choice of indicators should be driven not only by the feasibility of data collection but also by theoretical importance. The types of performance indicators, that is, whether the measures should relate to input, process, output and/or outcome at the various levels of the system, are another issue. Measuring outcomes is desirable as it is

[13] The Gini index measures the extent to which the distribution of income or consumption expenditure among individuals or households within an economy deviates from a perfectly equal distribution. More information is available at http://data.worldbank.org/indicator/SI.POV.GINI.
The Human Development Index (HDI) is a summary measure of human development in three key dimensions: a long and healthy life, being knowledgeable and having a decent standard of living. More information is available at http://hdr.undp.org/en/content/human-development-index-hdi.

[14] The Access to Medicine Index ranks the efforts of pharmaceutical companies to improve access to medicine in low- and middle-income countries. The Index is produced by the Access to Medicine Foundation and the reports are available at www.accesstomedicineindex.org.

relevant to know about the impact on goals, such as improving health or financial protection. However, directly attributing health improvements to pharmaceutical system performance is problematic given the multiple determinants of (ill) health.

The third critical question is, would composite indicators actually help identify where to target resources or would they obscure performance/resource gaps? The aggregation of individual measures into composite indicators may disguise serious failings in specific parts of a system. Aggregation typically involves transformation of individual indicators and the application of weights. Some kind of data transformation is usually necessary to make the individual indicators comparable and to account for outliers. Weights may be applied for various reasons, but they typically reflect the relative importance assigned to the individual indicators or the opportunity cost of achieving good performance on each individual indicator (Goddard and Jacobs 2009). In some cases, good performance on one indicator could offset low performance on another indicator, depending on the weights assigned. It is therefore important that aggregation is done in a systematic fashion to ensure that the resulting composite indicators are transparent, easily understood, and have the intended incentive effects (Goddard and Jacobs 2009). The Access to Medicines Index, for example, provides details of the methodology used to weight and aggregate the individual indicators.

Last, how can validity and robustness be ensured? The validity and robustness of any composite indicator is dependent on good data quality, comparability across countries and systems, and a consensus on the appropriate interpretation of the composite indicator. However, there is an inherent trade-off between developing a robust composite indicator that captures the complex and comprehensive dimensions of pharmaceutical system performance for a wide range of countries and the practical issues of gathering good data on such dimensions (Goddard and Jacobs 2009). Table 4 summarizes some of the advantages and disadvantages of composite indicators. It is important to reflect on these issues to determine whether composite indicators are suitable for the program objectives.

Table 4. Summary of the strengths and weaknesses of composite indicators (adapted from Smith 2002, OECD 2008).

Strengths
• System performance is placed at the center of the policy arena. • A rounded assessment of system performance is more easily attained with composite indicators than a collection of diverse indicators. • Composite indicators allow judgments to be made on system efficiency. • A single, simple measure captures policy attention more easily and facilitates communication with the public about performance issues, thus enhancing public accountability. • Composite indicators allow for comparison and identification of which systems represent the beacons of best performance or the priority for improvement efforts.
Weaknesses
• The aggregation of individual measures of performance into composite indicators may disguise serious failings in some parts of some systems. • As measures of performance become more aggregated, it becomes increasingly difficult to distinguish the causes of poor performance and what remedial action to take. • Individual elements of a composite indicator are often contentious. • A composite that seeks to be comprehensive in its coverage may rely on very feeble or opaque data in some dimensions of performance. • Methodology for calculating weights is seriously inadequate. • The choice of weights may be ad hoc and arbitrary with a lack of consideration for whose preferences the weights reflect and how robust these are. • Variations in performance as measured by the composite indicators may be due to random variation (uncertainty) associated with the underlying indicators and not real differences in performance.

Conclusion

Pharmaceutical systems strengthening is complex, involving numerous elements that influence the performance of a pharmaceutical system. The starting point for identifying metrics for its measurement is better conceptual clarity on what a pharmaceutical system is, including its key components and performance objectives, and clearly delineating what its strengthening entails. This paper reviews a wide range of earlier work in defining and conceptualizing pharmaceutical systems and its strengthening, as well as relevant insights from the health systems literature to highlight common themes and insights. It also draws on the significant body of work and experience in assessing and monitoring health systems, noting the different purposes and applications of the various tools and metrics, to identify common elements that are considered to constitute or influence a pharmaceutical system. Agreeing on common indicators, whether individual or composite, is a key step towards having a common understanding of pharmaceutical systems.

We look forward to further discussions on these topics at the upcoming meeting.

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Contributors and Reviewers

Tamara Hafner, SIAPS consultant and Helena Walkowiak, SIAPS Principal Technical Advisor prepared this background paper. The paper reflects the contributions of David Lee, CPM/MSH Director, Technical Strategy and Quality. Veronika Wirtz and Richard Laing, both from the Department of Global Health at Boston University School of Public Health, contributed to the section on composite indicators. The section on composite indicators was revised after the meeting to reflect their contribution. That is the only section of the background discussion paper that was revised after the meeting.

Richard Laing and the following SIAPS and MSH staff reviewed the draft: Francis (Kofi) Aboagye-Nyame, Michael Cohen, Ruth Musila, Sue Putter, and Maura Soucy.

Appendix 1. Literature Review Protocol

The literature search was conducted to identify reports and published articles related to pharmaceutical systems and pharmaceutical systems strengthening. Specifically, we sought to develop a systematic collection of literature that included an implied or explicit definition of pharmaceutical systems, pharmaceutical systems strengthening, or described frameworks and metrics for measuring the performance of these systems.

We used institutional knowledge in consultations with senior experts at MSH to create an initial list of search terms, key actors and agencies involved in pharmaceutical systems. The search terms listed in Table 1.1 were searched by themselves and in various combinations with each other or the names of the organizations listed to maximize the saturation of our search. We conducted a search for reports from the grey literature using the search terms, Google and websites of organizations such as the World Health Organization (WHO), US Agency for International Development (USAID), the World Bank (Table 1.1). For published articles, we used Google Scholar, PubMed, and EBSCO. In cases where publications were organized by subject on the websites of organizations, the publication lists under the appropriate subjects were reviewed for relevance. The search was an iterative process in which the results and bibliographies of relevant articles in the first iteration were used to guide subsequent searches. We deemed the search had reach saturation when subsequent searches failed to provide any noticeably new publications or other organizations to add to our list of interest.

The primary inclusion criteria were reports or studies that focused on: a definition of pharmaceutical system, pharmaceutical management system; pharmaceutical systems strengthening or health systems strengthening; a description of a framework aligned with one of these definitions; an identification of one or more components of a pharmaceutical (management) system; description of an indicator or metric for measuring the performance of such a system; description of an intervention to improve, support or strengthen such a system; a review or discussion of the conceptual or theoretical basis for such a system or one of its components. We excluded national assessment reports and articles focused on pharmaceutical innovation and industry performance; governance, transparency or corruption in the pharmaceutical sector; and pharmacology-related topics. We also excluded materials produced by Management Sciences for Health (MSH) because an extensive in-house archive of relevant documents already existed. The search was restricted to English language sources but there was no restriction on the date of publication.

The title and/or abstract of the publications resulting from each search were quickly screened for relevance. In instances where a search returned a hundred or more results, we took two actions. First, we sorted the list by relevance and quickly screened the first few pages of results or stopped when it was obvious from the titles that the results were no longer relevant. Second, we refined the search by including additional keywords to narrow the scope of the results. The abstracts of the materials selected from the searches were then read more carefully and sorted into three virtual bins: assessment tools; pharmaceutical systems and strengthening; health systems strengthening.

Background Discussion Paper

Table 1.1. Search terms, databases and other websites used for the literature search.

Databases and Websites	Search terms
'Grey' Literature Boston University Center for Global Health and Development DFID Research for Development Database Google International Impact Evaluation Initiative Harvard DPM USAID Health Systems 20/20 DELIVER Project Development Experience Clearinghouse International Network for the Rational Use of Drugs International Pharmaceutical Federation MEASURE Evaluation WHO Essential Medicines and Health Products Information Portal Medicines Publications and Documentation System Institutional Repository for Information Sharing Alliance for Health Policy and Systems Research The World Bank Published Articles EBSCO Google Scholar PubMed	access to medicines access to pharmaceuticals assessment drug supply system framework health systems health systems strengthening indicators measurement medicines metrics monitoring performance pharmaceutical management pharmaceutical systems pharmaceutical systems strengthening strengthening

Full List of References Identified

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Appendix 2. Assessment Tools

Table 2.1. Non-MSH tools

	Assessment Tool Reference	Code	Group for Analysis
1	Aronovich, Dana, Marie Tien, Ethan Collins, Adriano Sommerlatte, and Linda Allain. (2010). *Measuring supply chain performance: Guide to key performance indicators for public health managers*. Arlington, Va.: USAID | DELIVER PROJECT, Task Order 1. http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/MeasSCPerf.pdf	DELIV-2012	A
2	USAID | DELIVER PROJECT, Task Order 1. 2008. *Logistics indicators assessment tool (LIAT). Arlington, Va.: USAID | DELIVER PROJECT, Task Order 1*. http://deliver.jsi.com/dhome/whatwedo/monitoreval/meavailability/meliatlsatresources USAID | DELIVER. 2006. *Monitoring and evaluation indicators for assessing logistics systems performance*. Arlington, Va.: DELIVER, for the U.S. Agency for International Development. http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/ME_Indi.pdf	LIAT-2008	C
3	USAID | DELIVER PROJECT, Task Order 4. 2012. *Procurement performance indicators guide—Using procurement performance indicators to strengthen the procurement process for public health commodities*. Arlington, Va.: USAID | DELIVER PROJECT, Task Order 4. http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/ProcIndiGuid.pdf	JSIPROC-2012	C
4	FHI 360. (2012). *Health system rapid diagnostic tool. Framework, operational guide, and metrics to measure the strength of priority health system functions*. Durham NC: FHI 360. http://www.fhi360.org/resource/health-system-rapid-diagnostic-tool	FHI360-2012	A
5	Health Systems 20/20. (2012). *The health system assessment approach: A how-to manual*. Version 2.0. Module 6. www.healthsystemassessment.org	HS20-2012	A
6	Brudon, P., Rainhorn, J. D., Reich, M. R. (1999). *Indicators for monitoring national drug policies: a practical manual*. Geneva: World Health Organization. *http://apps.who.int/medicinedocs/pdf/whozip14e/whozip14e.pdf*	WHONDP-1999	A
7	WHO. (2007). *Operational package for monitoring and assessing country pharmaceutical situations. Guide for coordinators and data collectors*. Geneva: World Health Organization. http://apps.who.int/medicinedocs/index/assoc/s14877e/s14877e.pdf	WHOPS-2007	A
8	WHO. (1993). *How to investigate drug use in health facilities: selected drug use indicators*. EDM Research Series No. 007. Geneva: World Health Organization. http://apps.who.int/medicinedocs/en/d/Js2289e/	WHODU-1993	A
9	WH0. (2009). *Medicines use in primary care in developing and transitional countries. FactBook summarizing results from studies reported between 1990 and 2006*. Geneva: World Health Organization. http://www.who.int/medicines/publications/who_emp_2009.3/en/	WHOUSE-2009	A
10	Ratanawijitrasin, S. & Wondemagegnehu, E. (2002). *Effective drug regulation. A multicountry study. Geneva: World Health Organization*. http://apps.who.int/medicinedocs/pdf/s2300e/s2300e.pdf	WHODR-2002	C
11	WHO. (2007). *WHO data collection tool for the review of drug regulatory*	WHODR-	C

	Assessment Tool Reference	Code	Group for Analysis
	systems. Practical guidance for conducting a review. Geneva: World Health Organization. http://www.who.int/medicines/areas/quality_safety/regulation_legislation/assessment/en/	2007	
12	WHO and HAI. (2008). *Measuring medicine prices, availability, affordability and price components*, 2nd ed. Geneva: World Health Organization and Health Action International. http://www.haiweb.org/medicineprices/manual/documents.html	WHOHAI-2008	A
13	WHO. (2009). *Measuring transparency in the public pharmaceutical sector. Assessment instrument*. Geneva: World Health Organization. http://www.who.int/medicines/areas/policy/goodgovernance/AssessmentInstrumentMeastranspENG.PDF	WHOTR-2009	C
14	WHO. (2009). *Monitoring and evaluation of health systems strengthening. An operational framework*. Geneva: World Health Organization. http://www.who.int/healthinfo/HSS_MandE_framework_Nov_2009.pdf	WHOHSS-2009	C
15	WHO. (2010). *Monitoring the building blocks of health systems: a handbook of indicators and their measurement strategies*. Geneva: World Health Organization. http://www.who.int/healthinfo/systems/monitoring/en/	WHOHSS-2010	A
16	WHO. (2011). *Harmonized monitoring and evaluation indicators for procurement and supply management systems: early-warning indicators to prevent stock-outs and overstocking of antiretroviral, antituberculosis and antimalaria medicines*. Geneva: World Health Organization. http://www.who.int/hiv/pub/amds/monitoring_evaluation/en/	WHOHTM-2011	B
17	WHO. (2011). *Pharmaceutical human resources assessment tools*. Geneva: World Health Organization. http://apps.who.int/medicinedocs/en/d/Js18717en/	WHOHR-2011	B
18	Supply Chain Management System. 2012. *National supply chain key performance indicators: User's guide & data dictionary*. Submitted to the US Agency for International Development by the Supply Chain Management System (SCMS).	SCMS-2012	B
19	Seiter, A. (2010). *A practical approach to pharmaceutical policy. Appendix A*. Washington DC: World Bank Publications. https://openknowledge.worldbank.org/bitstream/handle/10986/2468/552030PUB0Phar10Box349442B01PUBLIC1.pdf?sequence=4	SEITER	A
20	USAID | DELIVER PROJECT, Task Order 1. 2010. *Assessment tool for laboratory services and supply chains* (ATLAS). Arlington, Va.: USAID | DELIVER PROJECT, Task Order 1.	ATLAS-NI	C
21	Global Fund, *Pharmaceutical sector country profile questionnaire*. http://www.who.int/medicines/areas/coordination/Empty_English_Questionnaire.pdf	GFPSP-NI	A
22	Global Fund, *The pharmaceutical and health product management (PHPM) assessment tool*.	GFPHPM-NI	A
23	JSI, *Transport assessment tool*. http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/TransAssesTool.pdf	JSIT-NI	C
24	USAID | DELIVER PROJECT, Task Order 1. 2009. *logistics system assessment tool (LSAT)*. Arlington, Va.: USAID | DELIVER PROJECT, Task Order 1.	LSAT-NI	C

	Assessment Tool Reference	Code	Group for Analysis
	http://deliver.jsi.com/dhome/whatwedo/monitoreval/meavailability/meliatlsatresources		
25	USAID | DELIVER PROJECT, Task Order 4. 2013. *Human resource capacity development in public health supply chain management: Assessment guide and tool.* Arlington,VA.:USAID|DELIVER PROJECT,Task Order 4. *http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/HumaResoCapaDeve_AsseGuid.pdf*	DELIVHR-NI	C
26	USP. (2007). *Rapid assessment of medicines quality assurance and medicines quality control.* http://www.usp.org/sites/default/files/usp_pdf/EN/dqi/rapidAssessmentTool.pdf	USPQ-NI	C
27	Global Fund.(2011). The Global Fund monitoring and evaluation toolkit. http://www.theglobalfund.org/en/me/documents/toolkit/	N/A	N/A
28	AIDSRelief. *ART commodity management and supply chain assessment tool.*	N/A	N/A
29	MEASURED SPA Medicines Availability. http://www.dhsprogram.com/pubs/pdf/SPAQ5/Service_Readiness_Indicators_042012.pdf	N/A	N/A
30	WHO. (2001). *Guidelines for the formulation, implementation, monitoring and evaluation of national drug policies*. Harare: WHO Regional Office of Africa. http://www.who.int/medicines/technical_briefing/tbs/guidelines-formulation.pdf *(A questionnaire based on Brudon et al. 2009, which is included in the inventory)*	N/A	N/A
31	WHO. (2013). *Service Availability and Readiness Assessment (SARA). An annual monitoring system for service delivery*. Version 2.1. Geneva: World Health Organization. http://www.who.int/healthinfo/systems/sara_introduction/en/	N/A	N/A

Note: Tools 27-31 were excluded from any analysis because they did not add any meaningful insight regarding components of the pharmaceutical system.

Table 2.2 MSH Tools

	Assessment Tool Reference	Code	Group for Analysis
1	MSH, Center for Pharmaceutical Management, University Research Corporation, PAHO, USAID. *Rapid Pharmaceutical Management Assessment: an Indicator-Based Approach*. Rational Pharmaceutical Management Project, Drug Management Program. (July 1995).	1.1	A
2	MSH, Center for Pharmaceutical Management. *Inventory Management Assessment Tool*. Excel Workbook. (1997).	1.2	N/A
3	MSH, Center for Pharmaceutical Management. *Access to Essential Medicines: Tanzania, 2001*. Prepared for the Strategies for Enhancing Access to Medicines Program. Arlington, VA: Management Sciences for Health. (2003).	1.3	A
4	MSH, Center for Pharmaceutical Management. *Uganda Inspection, Monitoring, and Supervision Model*. Prepared for the East African Drug Seller Initiative Project. Management Sciences for Health and the Bill & Melinda Gates Foundation. (Date not available).	1.4	C
5	MSH, Center for Pharmaceutical Management. *Medicines Building Block Tracking and Monitoring Framework (draft version 5.0, never completed)*. Prepared for the Strengthening Pharmaceutical Systems project. (2009).	1.5	A
6	MSH, Center for Pharmaceutical Management. *Guidance for incorporating SIAPS-Global Indicators into Portfolio PMPs*. Prepared for the Systems for Improved Access to Pharmaceuticals and Services Project. MSH/USAID (February 2013).	1.6	C
7	Keene, D; Ickx, P; McFadyen, J. *Drug Management for Childhood Illness Manual*. Published for the U.S. Agency for International Development by the Rational Pharmaceutical Management Project. Arlington, VA: Management Science for Health. (September 2000).	2.1	B
8	Briggs, CJ; Frye, J; Senauer, K. *District Pharmaceutical Management for Childhood Illness: An Assessment and Monitoring Tool*. Submitted to the U.S. Agency for International Development by the Rational Pharmaceutical Management Plus Program. Arlington, VA: Management Sciences for Health. (March 2008).	2.2	B
9	Nachbar, N; Briggs, J; Aupont, O; Shafritz, L; Bongiovanni, A; Acharya, K; Zimicki, S; Holschneider, S; Ross-Degnan, D. *Community Drug Management for Childhood Illness: Assessment Manual*. Submitted to the U.S. Agency for International Development by the Rational Pharmaceutical Management Plus Program. Arlington, VA: Management Sciences for Health. (December 2003).	2.3	B
10	MSH, Center for Pharmaceutical Management. *Pharmaceutical Management for Malaria Manual*. Prepared by Malcolm Clark 2002 and revised by Rima Shretta 2003. Submitted to the U.S. Agency for International Development by the Rational Pharmaceutical Management Plus Program. Arlington, VA: Management Sciences for Health. (Revised ed. 2004).	3.1	B
11	MSH, Center for Pharmaceutical Management. *Malaria Community Pharmaceutical Management Survey Instruments, Laos*. Submitted to the U.S. Agency for International Development under the Rational Pharmaceutical Management Plus Program by Management Sciences for Health. (September 2005).	3.2	B
12	MSH, Center for Pharmaceutical Management. *Monitoring and Evaluation of Pharmaceutical Management Aspects of ACT Policy Implementation: An Indicator–Based Tool*. Submitted to the U.S. Agency for International Development by the Strengthening Pharmaceutical Systems Program.	3.3	B

	Assessment Tool Reference	Code	Group for Analysis
	Arlington, VA: Management Sciences for Health. (2009).		
13	Barrientos, R; Busch, T; Goredema, W; and Tjipura, D. *End Use Verification Survey for Monitoring Availability and Use of Malaria and other Key Health Commodities in Angola; August-September 2011*. Submitted to the U.S. Agency for International Development by the Strengthening Pharmaceutical Systems (SPS) Program. Arlington, VA: Management Sciences for Health. (August-September 2011)	3.4	B
14	MSH, Center for Pharmaceutical Management. *President's Malaria Initiative Situation Assessment Tool*. (2009).	3.5	B
15	Rational Pharmaceutical Management (RPM) Plus Program. 2005. *Pharmaceutical Management for Tuberculosis Assessment Manual*. Edited by A. Zagorskiy, C. Owunna, and T. Moore. Submitted to the U.S. Agency for International Development by the RPM Plus Program. Arlington, VA: Management Sciences for Health.	4.1	B
16	Walkowiak, H. *HIV/AIDS Pharmaceutical Management Capacity Building in Karnataka, India. Baseline Assessment: April and August 2010*. Submitted to the U.S. Agency for International Development by the Strengthening Pharmaceutical Systems (SPS) Program. Arlington, VA: Management Sciences for Health. (2010).	5.1	B
17	Strengthening Pharmaceutical Systems (SPS) Program. *How to Investigate Antimicrobial Use in Hospitals: Selected Indicators*. Published for the U.S. Agency for International Development by the Strengthening Pharmaceutical Systems Program. Arlington, VA: Management Sciences for Health. (February 2012).	6.1	C
18	MSH, Center for Pharmaceutical Management. *Antimicrobial Resistance Module for Population-Based Surveys*. Submitted to the U.S. Agency for International Development by the RPM Plus Program. Arlington, VA: Management Sciences for Health. (2008).	6.2	C
19	MSH. *Building Local Coalitions for Containing Drug Resistance: A Guide*. Submitted to the U.S. Agency for International Development by the Strengthening Pharmaceutical Systems (SPS) Program. Arlington, VA: Management Sciences for Health. (September 2011).	6.3	C
20	MSH, Center for Pharmaceutical Management. *Regulatory Systems Assessment Tool*. Excel file. Internal tool. (2012.)	7.1	C
21	Strengthening Pharmaceutical Systems (SPS) Program. *Indicator-Based Pharmacovigilance Assessment Tool: Manual for Conducting Assessments in Developing Countries*. Submitted to the U.S. Agency for International Development by the SPS Program. Arlington, VA: Management Sciences for Health. (December 2009).	7.2	C
22	Internal document: Annex A in T. Wuliji et al. *Strengthening Pharmaceutical Human Resources in Afghanistan: Assessment and Strategic Framework Development*. Submitted to the US Agency for International Development by the Strengthening Pharmaceutical Systems (SPS) Program. Arlington, VA: Management Sciences for Health (March 2013).	8.1	C

Appendix 3. Reassigned Indicator Categories

Table 3.1 Reassigned categories of indicators and survey questions

(listed alphabetically) from 'Group A' assessment tools.

Reassigned Categories		Original Categories		
Label	No.of Tools	Label	No. of Tools	Tool Reference
Access	12	Acceptability/ Satisfaction	1	1.3
		Access (Level II)	1	WHOPS-2007
		Access to Essential Medicines	1	WHOHSS-2010
		Affordability	2	WHOHAI-2008, 1.3
		Affordability of essential drugs	1	WHONDP-1999
		Availability	1	WHOHAI-2008
		Availability and Access to Quality Products	1	HS20-2012
		Availability of essential drugs	1	WHONDP-1999
		Availability of Medicines and Information	1	1.3
		Geographic Accessibility	1	1.3
		Household Access	1	GFPSP-NI
Access and use	2	Access and Use	1	1.5
		Patient Access and Drug Utilization	1	1.1
Distribution	6	Distribution/Transport	1	DELIV-2012
		Inventory Management/LMIS/Customer Response	1	DELIV-2012
		Inventory Storage and Distribution	1	FHI360-2012
		Storage and Distribution	1	HS20-2012
		Storage, Inventory Management, and Transportation	1	1.5
		Warehousing/Storage	1	DELIV-2012
Financing	7	Drug allocation in the health budget/public sector financing policy	1	WHONDP-1999
		Financing of Medical Products, Vaccines and Technologies	1	HS20-2012
		Health Systems Financing	1	WHOHSS-2010
		Medicines Financing	1	GFPSP-NI
		Medicines Financing (Level I)	1	WHOPS-2007
		Ministry of Health Budget and Finance	1	1.1
		Public and Private Drug Expenditure	1	SEITER
Governance	2	Governance	1	1.5
		Leadership & Governance	1	WHOHSS-2010
Health/	4	Health Service Delivery	1	WHOHSS-2010

Reassigned Categories		Original Categories		
Label	No.of Tools	Label	No. of Tools	Tool Reference
pharmaceutical services		Health Services	1	GFPSP-NI
		Physical infrastructure for service delivery	1	FHI360-2012
		Serving Customers	1	FHI360-2012
Human Resources	2	Health Workforce	1	WHOHSS-2010
		Other (level II)	1	WHOPS-2007
Miscellaneous indicator category	4	Additional Indicators	1	WHOUSE-2009
		Facility indicators	1	WHOUSE-2009
		Standard Indicators	1	HS20-2012
		Health and Demographic Data	1	GFPSP-NI
Information Systems	2	Health Information Systems	1	WHOHSS-2010
		The Logistics Management Information System	1	FHI360-2012
Manufacturing, industry and trade	5	Industry and Trade	1	SEITER
		Medicines and Trade Production	1	GFPSP-NI
		Pharmaceutical Market	1	SEITER
		Private Sector Pharmaceutical Activity	1	1.1
		Production and Trade (Level I)	1	WHOPS-2007
Organization & management support	1	Management Support	1	1.5
Policies, legislation, regulation	11	Drug Pricing	1	SEITER
		Legislation and regulation	1	WHONDP-1999
		Medicine Price	1	WHOHAI-2008
		Medicines Regulation	1	GFPSP-NI
		National Medicines (Drug) Policy (Level I)	1	WHOPS-2007
		Pharmaceutical Policy, Laws and Regulations	1	HS20-2012
		Policy and Regulation	1	SEITER
		Policy Issues	1	GFPSP-NI
		Policy, Legislation and Regulation	1	1.1
		Pricing Policy	1	WHONDP-1999
		Regulatory System (Level I)	1	WHOPS-2007
Procurement	7	Forecasting and procurement	1	FHI360-2012
		Ministry of Health Pharmaceutical Procurement	1	1.1
		Procurement	1	HS20-2012
		Public sector procurement procedures	1	WHONDP-1999
		Purchasing, Reimbursement and Procurement	1	SEITER

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Reassigned Categories		Original Categories		
Label	No.of Tools	Label	No. of Tools	Tool Reference
		Quantification and Procurement	1	1.5
		Supplier/Sourcing	1	DELIV-2012
Procurement and distribution	2	Pharmaceutical Procurement and Distribution	1	GFPSP-NI
		Procurement & Supply Management	1	GFPHPM-NI
Quality/Quality Assurance/PV	6	Product Quality Assurance	1	1.1
		Quality (Level II)	1	WHOPS-2007
		Quality and Safety Monitoring	1	FHI360-2012
		Quality Assurance and Medication Safety	1	1.5
		Quality of drugs	1	WHONDP-1999
		Quality of Products and Services	1	1.3
Selection	3	Formulary/Essential Drugs List and Drug Information	1	1.1
		Product Selection	1	FHI360-2012
		Selection of Pharmaceuticals	1	HS20-2012
Selection and procurement	1	Product Selection, Forecasting, and Procurement	1	DELIV-2012
Selection and registration	1	Essential drug selection and drug registration	1	WHONDP-1999
Selection and use	1	Selection and Rational Use	1	GFPSP-NI
Services and logistics	1	Service Delivery and logistics	1	SEITER
Supply chain/supply management/ logistics	4	Medicines and supplies required for essential services	1	FHI360-2012
		Medicines Supply Systems (Level I)	1	WHOPS-2007
		Ministry of Health Pharmaceutical Logistics	1	1.1
		Public sector distribution and logistics	1	WHONDP-1999
Use	13	Appropriate Use	1	HS20-2012
		ARI treatment indicators	1	WHOUSE-2009
		Complementary medicines use indicators	1	WHOUSE-2009
		Diarrhoea treatment indicators	1	WHOUSE-2009
		Information and continuing education on drug use	1	WHONDP-1999
		Malaria treatment indicator	1	WHOUSE-2009
		Patient care indicators	1	WHOUSE-2009
		Prescribing indicators	1	WHOUSE-2009
		Rational use of drugs	2	WHONDP-1999, SEITER

Reassigned Categories		Original Categories		
Label	No.of Tools	Label	No. of Tools	Tool Reference
		Rational Use of Medicines (Level I)	1	WHOPS-2007
		Rational Use of Medicines (level II)	1	WHOPS-2007
		Use	1	WHODU-1993

Table 3.2. Reassigned categories of indicators and survey questions

(listed alphabetically) from 'Group C' assessment tools

Reassigned Categories		Original Categories		
Label	No. of Tools	Label	No. of Tools	Tool Reference
Access	3	Acceptability/Satisfaction	1	1.4
		Affordability	1	1.4
		Availability	1	1.4
Financing	1	Financing strategies and mechanisms	1	1.6
Governance	2	Pharmaceutical sector governance	1	1.6
		Transparency	1	WHOTR-2009
Health/pharmaceutical services	1	Pharmaceutical Services	1	1.6
Human resources	5	Human Resources	1	DELIVHR-NI
		Human Resources Planning	1	8.1
		Human Resources Policies	1	8.1
		Practice Distribution of Pharmaceutical Human Resources	1	8.1
		Total Pharmaceutical Human Resources	1	8.1
Information systems	1	Information for decision-making	1	1.6
Laboratory services and supply chain	1	Laboratory Services and Supply Chain	1	ATLAS-NI
Miscellaneous indicator category	7	General Information	1	8.1
		Hospital Indicators	1	6.1
		Impact	1	WHOHSS-2009
		Inputs and processes	1	WHOHSS-2009
		Outcomes	1	WHOHSS-2009
		Outputs	1	WHOHSS-2009
		Supplemental Indicator	1	6.1
Organization & management support	1	Management Support	1	6.3

Background Discussion Paper

Reassigned Categories		Original Categories		
Label	No. of Tools	Label	No. of Tools	Tool Reference
Policies, legislation and regulation	9	Drug regulation overview	1	WHODR-2002
		Enforcement	1	7.1
		Inspection	1	7.1
		Medicine Policy	1	6.3
		Policy, Law, and Regulation	1	7.2
		Registration	1	7.1
		Regulatory Environment	1	6.3
		Regulatory functions	2	WHODR-2002, WHODR-2007
Procurement	1	Procurement	1	JSIPROC-2012
Quality/quality assurance/PV	9	Pharmacovigilance	1	7.1
		Quality Assurance & Control	1	USPQ-NI
		Quality of Products	1	1.4
		Quality of Services	1	1.4
		Quality Surveillance	1	7.1
		Risk Assessment and Evaluation	1	7.2
		Risk Management and Communication	1	7.2
		Signal Generation and Data Management	1	7.2
		Systems, Structures, and Stakeholder Coordination	1	7.2
Selection & procurement	1	Selection and Procurement	1	6.3
Supply chain/supply management/logistics	3	Logistics	1	LSAT-NI
		Logistics System	1	LIAT 2008
		Pharmaceutical Supply Management and Services	1	1.6
Transport	1	Transport	1	JSIT-NI
Use	8	AMR Containment and Advocacy	1	6.3
		Correct Antimicrobial Medicine Knowledge and Behavior	1	6.2
		Correct Antimicrobial Resistance Knowledge	1	6.2
		Correct Use of Medicines	1	6.2
		Education and Training on Use	1	6.3
		Medicines Information	1	7.1
		Patient Care Indicators	1	6.1
		Prescribing Indicators	1	6.1

ANNEX B. PHARMACEUTICAL SYSTEMS STRENGTHENING: DEFINITIONS AND MEASUREMENT FRAMEWORK

The following pages include the definitions for a *pharmaceutical system* and *pharmaceutical systems strengthening* as well as the definitions of the critical components for measurement, their elements, key system attributes, and primary system outcomes.

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PHARMACEUTICAL SYSTEMS STRENGTHENING: DEFINITIONS AND MEASUREMENT FRAMEWORK

DEFINITIONS

Efforts to measure progress in strengthening pharmaceutical systems (PSS) have been hampered by the lack of clear definitions and widely accepted reliable measures. In 2016, the SIAPS program proposed the following definitions, which emerged from a comprehensive literature search and an expert consultation based on an analysis of existing definitions and frameworks.[1]

A *pharmaceutical system* consists of all structures, people, resources, processes, and their interactions within the broader health system that aim to ensure equitable and timely access to safe, effective, quality pharmaceutical products and related services that promote their appropriate and cost-effective use to improve health outcomes.

Pharmaceutical systems strengthening is the process of identifying and implementing strategies and actions that achieve coordinated and sustainable improvements in the critical components of a pharmaceutical system to make it more responsive and resilient and to enhance its performance for achieving better health outcomes.

MEASUREMENT FRAMEWORK FOR PHARMACEUTICAL SYSTEMS STRENGTHENING

The above definitions underscore that a pharmaceutical system should be regarded as a subsystem of a health system and that the outcomes of a pharmaceutical system—and the goals of pharmaceutical systems strengthening (PSS)—contribute to achieving better health outcomes and other health system goals. The pharmaceutical system definition provides the foundation for measuring the system's performance. The PSS definition identifies resilience as a key characteristic of a well-functioning pharmaceutical system and underlines the need to measure it as a system attribute along with dimensions of system performance, including responsiveness. These definitions form the basis for the PSS measurement framework presented in Figure 1 which SIAPS is using to guide the development of a tool for measuring progress in systems strengthening.

Critical System Components

Underperformance within a critical component can disrupt the overall performance of the pharmaceutical system. Identifying areas of underperformance and neglect in a system is therefore a prerequisite for strengthening. *Seven system components* were identified in the expert consultation as essential for measuring progress in PSS. Table 1 presents the reasoning for selecting the components shown in Figure 1.

[1] Hafner, Tamara, Helena Walkowiak, David Lee, and Francis Aboagye-Nyame. "Defining pharmaceutical systems strengthening: concepts to enable measurement." *Health Policy and Planning*, 2016. doi:10.1093/heapol/czw153

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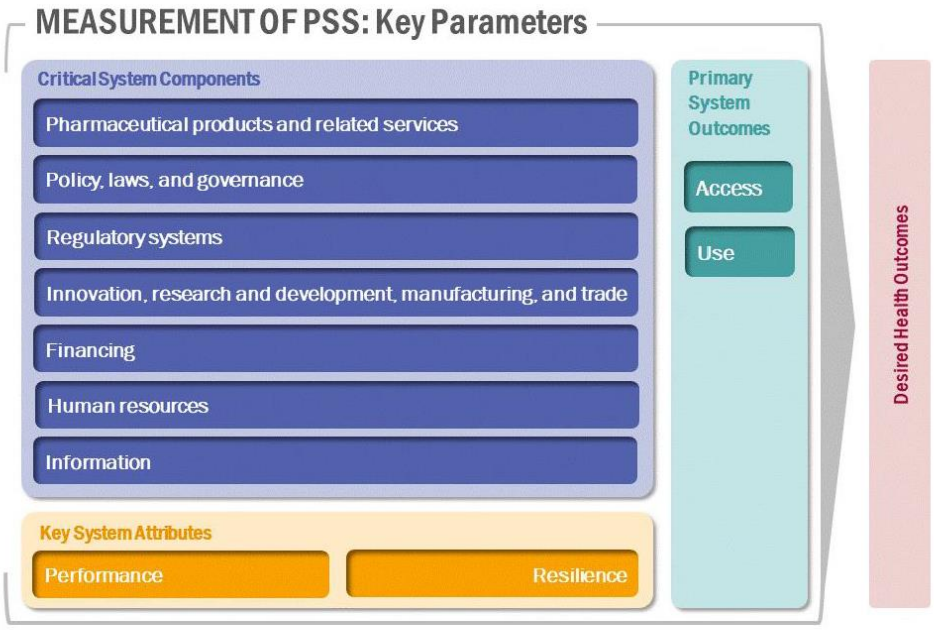

Figure 1: PSS Measurement Framework: Critical Components, Key Attributes, and Primary Outcomes

These seven components are not intended as an exhaustive list of what constitutes a pharmaceutical system. Rather, they are meant to guide the measurement of PSS and provide a high-level picture of the functioning of the pharmaceutical system as a complete entity. The connections of the pharmaceutical system with the broader health system are reflected in components such as *Policy, Laws and Governance; Financing; Human Resources;* and *Information*. However, a seven-component system cannot and is not intended to capture the full complexity of these and other interrelationships.

The seven critical system components are not intended to be an exhaustive list of what constitutes a pharmaceutical system. Rather, they are meant to guide the measurement of PSS and provide a high-level picture of the functioning of the pharmaceutical system as a complete entity.

For each of the critical components, the most important *elements* that reflect performance and are associated with resilience and sustainability were identified. The key elements associated with each component are listed and described in Table 1. These elements provide the foundation for the selection of three types of indicators—structural, process, and outcome. *Structural indicators* provide information on the system's capacity to achieve the objectives of each component. *Process indicators* assess the degree to which activities necessary to attain the

objectives are carried out. *Outcome indicators* measure the results achieved for each component. The selection of indicators was guided by the following criteria: validity, availability, reliability, policy-relevance, repeatability, and attributability.

Outcome indicators that demonstrate underperformance can point to areas for more in-depth assessment to identify structural and process-related weaknesses and failures that threaten system sustainability. Monitoring the system and identifying underperformance using a comprehensive set of indicators allows for the selection of strategies that address the specific areas where a pharmaceutical system can be strengthened. Full interpretation of these indicators will have to consider the various relationships and interactions that exist among the system components. In addition to providing a snapshot of the system, regular monitoring over time can demonstrate change and track the effects of interventions across system components that are interconnected.

Primary System Outcomes

PSS measurement tools also need to include indicators that track the extent to which a pharmaceutical system is achieving its purpose in ensuring access to pharmaceutical products and related services, and positively influencing use. Equitable and timely access to, and appropriate and cost-effective use of, safe, effective and quality pharmaceutical products ultimately contribute to the achievement of desired health outcomes and other health system goals.

All seven components contribute in varying degrees to *access and use*, the primary system outcomes. Access refers to *affordability, acceptability (or satisfaction), geographical accessibility,* and *availability*.[2] Access indicators also need to account for *equity* to measure the extent to which the system deals fairly with different population subgroups defined socially, economically, demographically or geographically within countries. Use refers to *prescribing*, *dispensing (or sale or supply to the user)* and *consumption (or end-use)*.

The key dimensions associated with each primary system outcome are described in Table 2, which also lists the associated indicators selected for piloting. Poor system function will be reflected in these measures and should lead to further probing of relationships and interactions among system components to identify possible causes.

Key System Attributes

Performance and *resilience* are two system attributes that are important for measuring pharmaceutical systems strengthening. Three dimensions of performance were selected for inclusion in the PSS measurement framework; the *efficiency* with which the system allocates

[2] Management Sciences for Health. 2012. *MDS-3: Managing Access to Medicines and Health Technologies*. Arlington, VA: Management Sciences for Health.

products and services among the population and at what cost; the *quality and safety* of pharmaceutical products and related services; and the *responsiveness* of the pharmaceutical system to the health needs of the population. Metrics associated with these three dimensions of performance can be useful in identifying underperformance in pharmaceutical systems and the effects—intended or not—of interventions in these systems.

While a pharmaceutical system may function adequately now, it will need to adapt to future challenges which brings in concepts related to sustainability and resilience. Resilience is the capacity of the system to prepare for and effectively respond to crises thereby maintaining core functions, adapting to changing circumstances as needed and, transforming when social and economic conditions make the existing system no longer viable.[3]

The key dimensions associated with these attributes are described in Table 3 which also lists the associated indicators selected for piloting.

Contribution to Health System Outcomes

Pharmaceutical systems do not operate in a vacuum; they are embedded in health systems. Pharmaceutical system outcomes aim to contribute to the wider health system goals. Here we explain how the primary system outcomes and key attributes identified in the PSS measurement framework relate to the achievement of desired health outcomes and other health system goals.

Existing health system and health system strengthening frameworks, including the World Health Organization (WHO) health systems 'building blocks' framework[4] and framework used by US Agency for International Development (USAID) to guide its work in health systems strengthening[5] commonly identify health improvement, equity, efficiency, responsiveness, financial protection, access, coverage, quality and safety as health system goals but sometimes differ in their treatment of these goals as intermediate or ultimate system goals.

The PSS measurement framework identifies equitable access to and use of safe, effective, quality and safe pharmaceutical products and related services as primary system outcomes (Table 2). The affordability dimension of access to pharmaceutical products includes the monitoring of costs at both the user and system level and so accounts for the financial protection goals of the health system. The PSS framework also identifies efficiency, quality and safety, and responsiveness as dimensions of system performance, which together with resilience are the two primary system attributes (Table 3).

[3] Adapted from Kruk ME, Myers M, Varpilah ST et al. 2015. What is a resilient health system? Lessons from Ebola. *The Lancet* 385(9980): 1910-1912

[4] World Health Organization. Everybody's business: strengthening health systems to improve outcomes. WHO's framework for action. Geneva: WHO, 2007

[5] USAID's Vision for Health Systems Strengthening (2015-2019) https://www.usaid.gov/sites/default/files/documents/1864/HSS-Vision.pdf

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The multiple determinants of coverage extend beyond the boundaries of the pharmaceutical system and so it is not included as an explicit parameter in the PSS measurement framework. Further, although the ultimate goal of a pharmaceutical system is to improve health outcomes, the multiple determinants of health make it impossible to solely attribute positive improvements in health to changes within the pharmaceutical system.

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TABLE 1: MEASURING PSS: CRITICAL SYSTEM COMPONENTS AND ASSOCIATED ELEMENTS

COMPONENT	ELEMENT	
PHARMACEUTICAL PRODUCTS AND SERVICES At the center of the pharmaceutical system and encompasses the functions of selection, procurement, and distribution of pharmaceutical products. It also includes systems for monitoring and promoting appropriate and cost-effective prescribing, dispensing, retail practices, and correct use by end-users. This component affects all dimensions of access and use.	SELECTION	Developing, updating and publishing standard treatment guidelines for priority health problems; selecting products and dosage forms for essential pharmaceutical product lists, formularies, and insurance reimbursement lists; and deciding which products will be available at each level of the health system.
	PROCUREMENT	Systems for deciding which products to procure, quantifying pharmaceutical product needs, choosing procurement methods, managing procurements (including local purchasing) and donations, assuring pharmaceutical quality, tracking prices, and monitoring supplier performance.
	DISTRIBUTION	Systems for importing, managing, storing inventory; monitoring consumption, stock, quality and security, and delivering products to their point of use.
	USE	Systems for monitoring and promoting appropriate and cost-effective prescribing, dispensing, and retail practices within culturally acceptable, integrated service delivery that supports appropriate (including initial and long-term) use by the end user.
POLICY, LAWS, AND GOVERNANCE The hub of coordination for the entire system, providing the framework, structures, and systems for organizing, financing, and regulating the system; and coordinating the activities of the various institutions and stakeholders to achieve the system objectives. It takes account of systems for facilitating participation, transparency, and accountability, and the promotion of ethical practices. This component affects all dimensions of access and use.	PHARMACEUTICAL POLICIES	Accessing, analyzing, and using data to formulate a national medicines policy and other pharmaceutical policies and strategies, and developing and implementing evidence-based strategic plans to support the achievement of identified priorities and goals.
	PHARMACEUTICAL LAWS AND REGULATIONS	Formulating, implementing and enforcing comprehensive legislation to regulate activities (including controlled substance scheduling, importation, storage, prescribing, dispensing and reporting) and pharmaceutical workforce management.
	COORDINATION AND LEADERSHIP	Systems for providing direction; engaging, coordinating and aligning expectations, interests and activities among state and non-state institutions and stakeholders; and maximizing the use of resources.
	ETHICS, TRANSPARENCY AND ACCOUNTABILITY	Stipulation of key principles to guide ethics and the integrity of professional behavior; ethical practices; maintenance of professional competence; and compliance with regulations and accepted standards. Formal processes to consult with and inform key stakeholders, including civil society about major decisions and actions in the pharmaceutical system; and to hold entities and decision makers accountable for their decisions and actions.

Component	Element	
Regulatory Systems Focuses on ensuring the safety, efficacy, and quality of pharmaceutical products and related services. This component affects both access and use.	Product Assessment and Registration	Systems for evaluating the safety, efficacy, and quality of pharmaceutical products and appropriateness of product information; and issuing, varying or revoking marketing authorizations.
	Licensing of Establishments and Personnel	Systems for authorizing pharmaceutical establishments and personnel to manufacture, import, export, store, distribute, assess product quality, and sell, supply or dispense pharmaceutical products in accordance with approved and published norms, standards, guidelines, and regulations.
	Inspection and Enforcement	Systems for verifying and taking appropriate action to ensure that pharmaceutical establishments and personnel perform pharmaceutical operations in accordance with approved norms, standards, guidelines, and regulations. This applies to manufacturing, import control, supply chain management, and dispensing.
	Quality and Safety Surveillance	Systems for monitoring and taking action to ensure that pharmaceutical products in the distribution system meet specified quality standards; and detecting, evaluating, and preventing adverse reactions, medication errors, product-related quality problems and others.
	Regulation and Oversight of Clinical Trials	Systems for authorizing clinical trials and verifying that they are conducted in accordance with approved norms, standards, guidelines and regulations.
	Control of Pharmaceutical Marketing Practices	Systems for reviewing and monitoring the marketing practices including advertising of pharmaceutical products (both prescription and non-prescription) to prevent the dissemination of inaccurate and misleading information; and taking action in case of violations.
Innovation, Research and Development, Manufacturing, and Trade The entry point for pharmaceutical products into the system. Includes research and development of products; domestic manufacturing capacity; and intellectual property protections in national legislation and international trade agreements that shape innovation and trade, and affect access to pharmaceutical products. This component primarily affects access.	Innovation, Research and Development	Priority setting, investment, and building country capacity in research and development and technological innovation to develop pharmaceutical products based on unmet/inadequately addressed public health needs.
	Manufacturing Capacity	Human resources, financing, physical infrastructure, and mechanisms to facilitate technology transfer and domestic production of pharmaceutical products of assured quality in compliance with good manufacturing practice (GMP) standards.
	Intellectual Property and Trade	Incorporating measures consistent with TRIPS into national legislation and using these provisions to promote innovation and safeguard access to affordable essential pharmaceutical products; regulating duties, tariffs for importation of pharmaceutical active ingredients, products and packaging, and non-tariff import controls.

COMPONENT	ELEMENT	
FINANCING The management of resources to ensure the adequate and sustainable financing of the pharmaceutical product purchase, related services, and other costs associated with system functioning. Includes financial risk protection strategies and monitoring and controlling costs and prices to reduce financial barriers to accessing pharmaceutical products and related services. This component affects access and use, but especially the availability, accessibility, and affordability dimensions.	RESOURCE COORDINATION, ALLOCATION, DISTRIBUTION AND PAYMENT	Coordinating country and donor inputs, allocating resources, and distributing adequate and sustainable funding for the purchase, contracting, and payment for pharmaceutical products, human resources, services, infrastructure and other costs associated with system functioning.
	FINANCIAL RISK PROTECTION STRATEGIES	Establishment and management of systems for pooling resources and providing financial risk protection that include coverage for pharmaceutical products and related services.
	REVENUE AND EXPENDITURE TRACKING AND MANAGEMENT	Systems for tracking and oversight of pharmaceutical revenue and expenditures; analyzing and using information to address inequities in access, control expenditures, and reduce inefficiencies and wastage.
	COSTING AND PRICING	Systems for analyzing, monitoring and controlling costs and prices for pharmaceutical products and services.
HUMAN RESOURCES Ensures the availability of adequate numbers of appropriately trained staff for managing the supply and delivery of pharmaceutical products and related services. This component contributes to all dimensions of access and use.	HUMAN RESOURCES POLICY AND STRATEGY	Human resources policy, strategy, and guidelines for scopes of practice, work standards, and workforce planning for recruiting, developing, and deploying the pharmacy workforce to provide the necessary coverage and capacity.
	HUMAN RESOURCES MANAGEMENT	Systems for registration/counting, recruiting, hiring, deploying, evaluating, supporting, and retaining the pharmacy workforce through the integrated use of data, policy, and practice.
	HUMAN RESOURCES DEVELOPMENT	Development and maintenance of a skilled pharmaceutical workforce of multiple levels including basic, post-basic and continuous education; systems for authorizing and monitoring educational facilities and training programs to ensure that education is provided in accordance with approved norms, standards, guidelines, and regulations.
INFORMATION The generation and dissemination of timely and reliable information, which is the foundation for decision making, policy development and implementation, governance and regulation, and planning and allocation of financial, infrastructure, and human resources in the pharmaceutical system. This component affects both access and use.	INFORMATION POLICY AND DATA STANDARDIZATION	Policy, legislation, regulation, and guidelines for secure information collection, transmission, management and storage; coordinating stakeholder roles and inputs; data confidentiality and security; selection of core indicators; and use of standards for data.
	DATA COLLECTION, PROCESSING, AND DISSEMINATION	Systems, technologies, and infrastructure for the collection, verification, and processing of data and dissemination of timely, accurate, and relevant information.
	USE OF INFORMATION FOR DECISION MAKING	Routine and extraordinary use of information for policy and decision making, governance, regulation, monitoring system performance, and resource planning and allocation to support system functioning and promote transparency.

TABLE 2: MEASURING PSS: PRIMARY SYSTEM OUTCOMES

PRIMARY OUTCOME	DIMENSION	INDICATOR(S) FOR PILOTING
ACCESS	AFFORDABILITY The relationship between the prices of the products and services and the user's ability to pay for them.[6] Accounts for the financial risk protection goals of the health system.	# of days worked by lowest paid government employee to pay for treatment of specified tracer conditions (incl. Malaria & ARI (amoxicillin))
		Median drug price ratio for tracer drugs
	EQUITY IN AFFORDABILITY The extent to which a system deals fairly with all concerned[7]	Out of pocket expenditure for health on medicines disaggregated into different subgroups (e.g. geographic location, age group, gender, race and ethnicity, socioeconomic status)
	ACCEPTABILITY (OR SATISFACTION) The relationship between the user's attitudes and expectations about the products and services and the actual characteristics of the products and services.[6]	Satisfaction with the results of the last visit to a public health facility
	GEOGRAPHICAL ACCESSIBILITY The relationship between the location of the product or service and the location of the eventual user of the product or service[6]	Percentage of households more than 20 kilometers away from a health facility and/or pharmacy
		Population per facility that dispenses or sells pharmaceutical products, disaggregated by public and private
	EQUITY IN GEOGRAPHICAL ACCESSIBILITY The extent to which a system deals fairly with all concerned[7]	Percentage of households more than 20 kilometers away from a health facility and/or pharmacy disaggregated into urban and rural populations
		Population per facility that dispenses or sells pharmaceutical products, disaggregated by public and private and into urban and rural populations

[6] Management Sciences for Health. 2012. *MDS-3: Managing Access to Medicines and Health Technologies*. Arlington, VA: Management Sciences for Health

[7] Kelley,E., & Hurst, J. (2006). Health care quality indicators project. Conceptual framework paper. OECD Health Working Papers, No. 23, OECD Publishing. http://dx.doi.org/10.1787/440134737301

Primary Outcome	Dimension	Indicator(s) for Piloting
Access (continued)	Availability The relationship between the type and quantity of product or service needed, and the type and quantity of product or service provided[8]	Mean (average) % availability across a basket of medicines
	Equity In Availability The extent to which a system deals fairly with all concerned[9]	Mean (average) % availability across a basket of medicines disaggregated into different subgroups (e.g. geographical locations, pediatric vs. adult preparations, across disease/treatment groups)
Use	Prescribing Selecting and advising the use of a pharmaceutical product, whether prescription or non-prescription, for the prevention, treatment or management of a medical condition based on safety, efficacy, suitability, and cost. Includes the provision of information and counseling to support appropriate decision making and use by the consumer or end-user.	Optimal level of drug prescribing indicators: % Prescriptions including antibiotic; % Polypharmacy prescription (polypharmacy defined as 5 or more medicines); % Prescriptions including injection; % Drugs prescribed by generic name.
	Dispensing / Sale or Supply The preparation and sale or supply of a pharmaceutical product, whether or not by prescription. Includes the provision of information and counseling to support appropriate decision making and use by the consumer or end-user.	Percentage of patients surveyed that know correct information about their medications
	Consumption / End-Use Intake or application of a pharmaceutical product by the consumer or administration by the caregiver or end use. Includes adherence which is the extent to which a person takes or uses the product as prescribed by a health care provider.	Percentage of patients with 100% on time pill pickup during a defined period for HIV, TB, or other chronic diseases

[8] Management Sciences for Health. 2012. *MDS-3: Managing Access to Medicines and Health Technologies*. Arlington, VA: Management Sciences for Health
[9] Kelley,E., & Hurst, J. (2006). Health care quality indicators project. Conceptual framework paper. OECD Health Working Papers, No. 23, OECD Publishing. http://dx.doi.org/10.1787/440134737301

TABLE 3: MEASURING PSS: KEY SYSTEM ATTRIBUTES

SYSTEM ATTRIBUTE	DIMENSION		INDICATOR(S) FOR PILOTING
PERFORMANCE	EFFICIENCY The capacity to produce the maximum output for a given input.[10] Allocative efficiency refers to using the optimal mix of resources to maximize benefits to society. Technical efficiency refers to using the least amount of resources to produce a given mix of goods and services.		Percentage of median international price paid for a set of tracer drugs that was part of the last regular MOH procurement Product losses by value due to expired drugs, damage, and theft per value received (percentage and number)
	QUALITY AND SAFETY An essential component of access cutting across all the dimensions, but which specifically applies to products in terms of their safety, efficacy, and cost-effectiveness[11]	PHARMACEUTICAL PRODUCTS	Number of drugs/batches that failed quality control testing, out of the total number of drugs/batches surveyed (tested)
		PHARMACEUTICAL / RELATED SERVICES	Percentage of encounters at (a) MOH health facilities and (b) private facilities at which health care staff members explained the dose and frequency of the prescribed medicines to the patient or caregiver **OR** Percentage of prescriptions reviewed that were adequately labeled Percentage of patients surveyed that know correct information about their medications
	RESPONSIVENESS Non clinical aspects related to the way individuals are treated and the environment in which they are treated.[12] Domains of responsiveness include: respect for autonomy, choice of care provider, respect for confidentiality, communication, respect for dignity, access to prompt attention, quality of basic amenities, and access to family and community support.		Existence of mechanisms, such as surveys for obtaining opportune client input on appropriate, timely and effective access to pharmaceutical products and related services

[10] WHO Terminology Information System [online glossary] http://www.who.int/health-systems-performance/docs/glossary.htm
[11] Management Sciences for Health. 2012. *MDS-3: Managing Access to Medicines and Health Technologies*. Arlington, VA: Management Sciences for Health
[12] Valentine NB, de Silva A, Kawabata K, Darby C, Murray CJL, Evans DB. (2003.) Health system responsiveness: concepts, domains and measurement. In Murray CJL, Evans DB (Eds). Health systems performance assessment: debates, methods and empiricism. Geneva: World Health Organization. http://www.who.int/responsiveness/papers/MCSS_Analytical_Guidelines.pdf

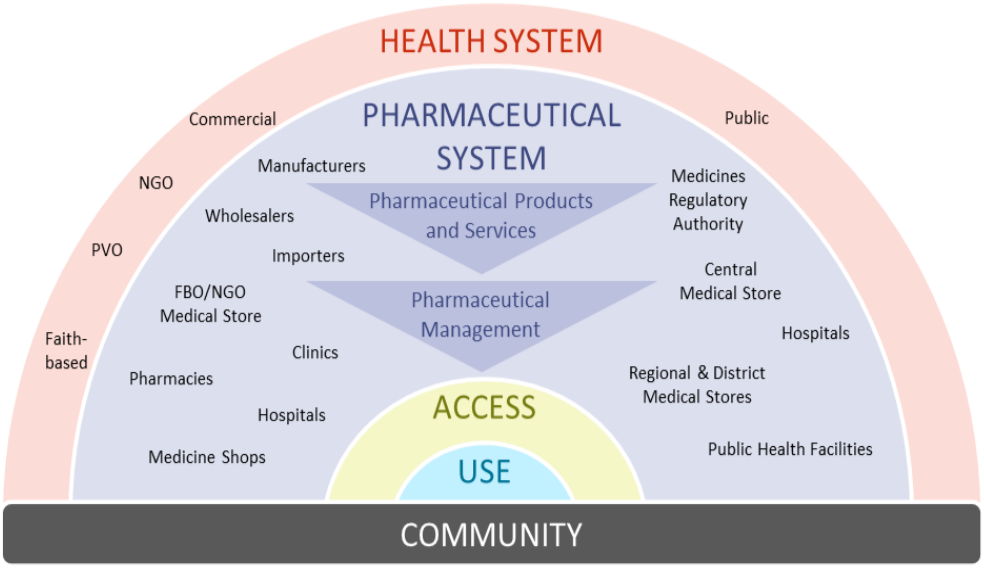
System Attribute	Dimension	Indicator(s) for Piloting
Resilience	Aware Resilient health systems are aware of the potential health threats and risks to the population and knowledge of the current human, physical, and information assets that highlight areas of strength and vulnerability. This requires effective health information systems and epidemiological surveillance networks.[13]	Annual data produced on the availability of tracer medicines and commodities in public and private facilities
		Is procurement based on a reliable quantification of needs
	Diverse Has the capacity to address a broad range of health challenges rather than a select few.[13]	Mean (average) % availability across a basket of medicines
		Total expenditure on pharmaceuticals (per capita at average exchange rate) in US$
	Self-regulating Can contain and isolate health threats while delivering core health services and avoiding cascading disruptions throughout the system.[13]	Average time lag between identification of safety signal of a serious ADR or significant medicine safety issue and communication to health care workers and the public
	Integrated Brings together diverse stakeholders and ideas to formulate solutions and initiate actions, with clear channels for communication and coordination.[13]	Existence of an intersectoral committee for pharmaceutical sector policy and planning
	Adaptive Has the ability to transform in ways that improve function in times of crises, and adapt to epidemiological and demographic changes in normal times.[13]	Emergency Pharmaceutical Preparedness Plan in place

[13] Kruk, M.E., Myers, M., Varpilah, S. T., & Dahn, B. T. (2015) What is a resilient health system? Lessons from Ebola. *The Lancet,* 385(9980), 1910-1912.

ANNEX C. LIST OF FRAMEWORKS AND REVIEWED TOOLS

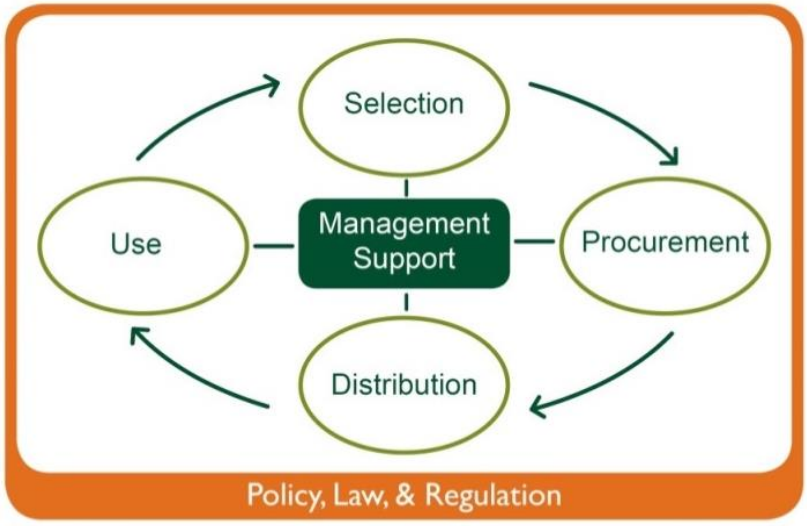
This text is excerpted from supplementary Appendices A and B from Hafner T, Walkowiak H, Lee D, Aboagye-Nyame F; *Defining pharmaceutical systems strengthening: concepts to enable measurement*, Health Policy and Planning, Volume 32, Issue 4, 1 May 2017, Pages 572–584.

Supplementary Appendix A. Reviewed Frameworks



Source: Miralles 2010; RPM Plus Program 2005

Figure A1. Pharmaceutical management system framework



Source: MSH 2011

Figure A2. Pharmaceutical management framework

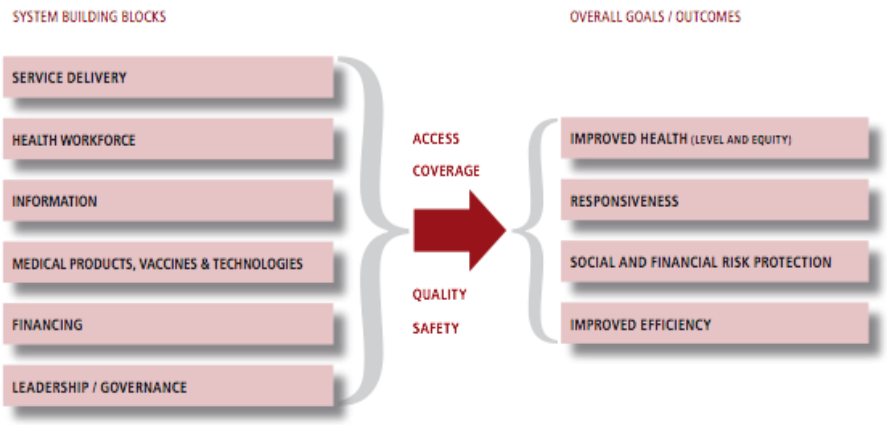


Figure A3. WHO health system framework[6]

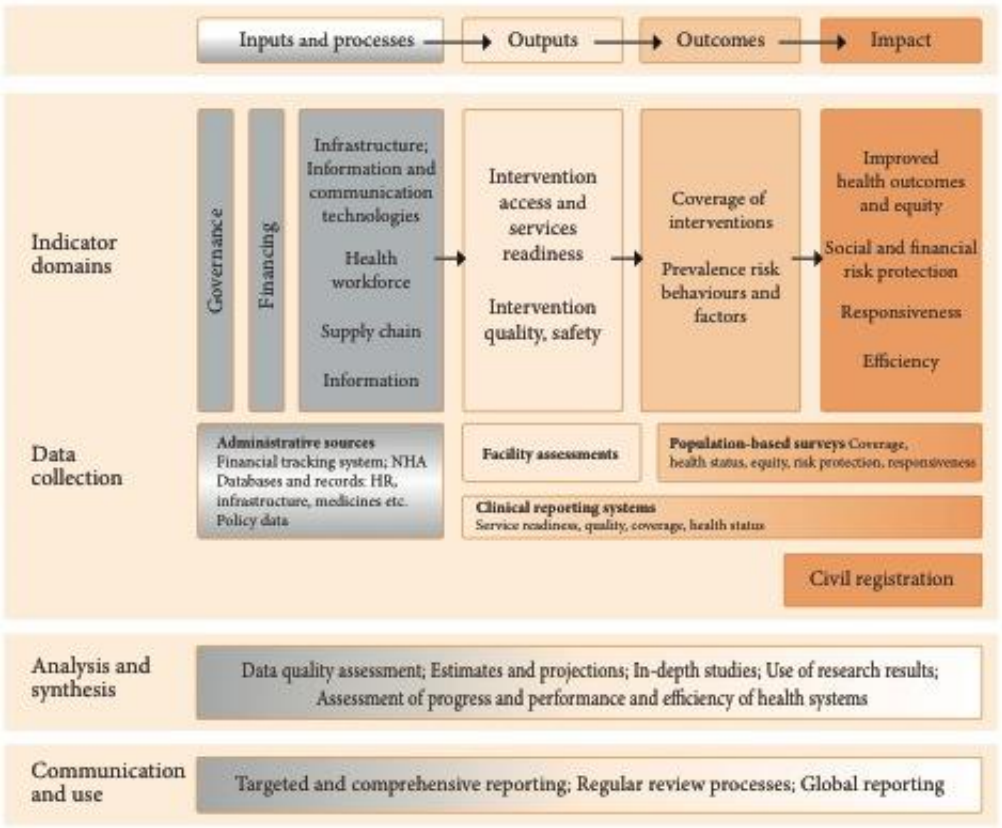
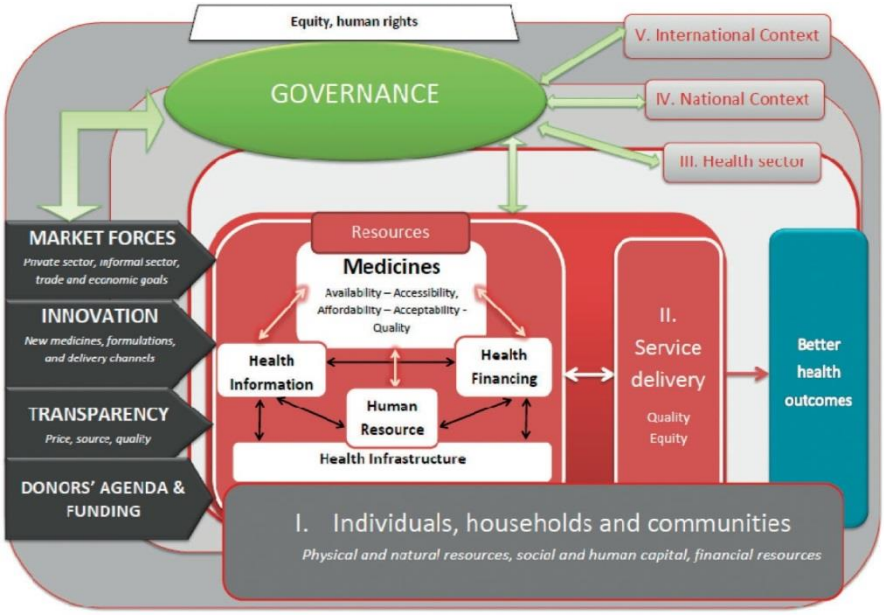


Figure A4. IHP+ monitoring and evaluation of health systems strengthening framework[7]

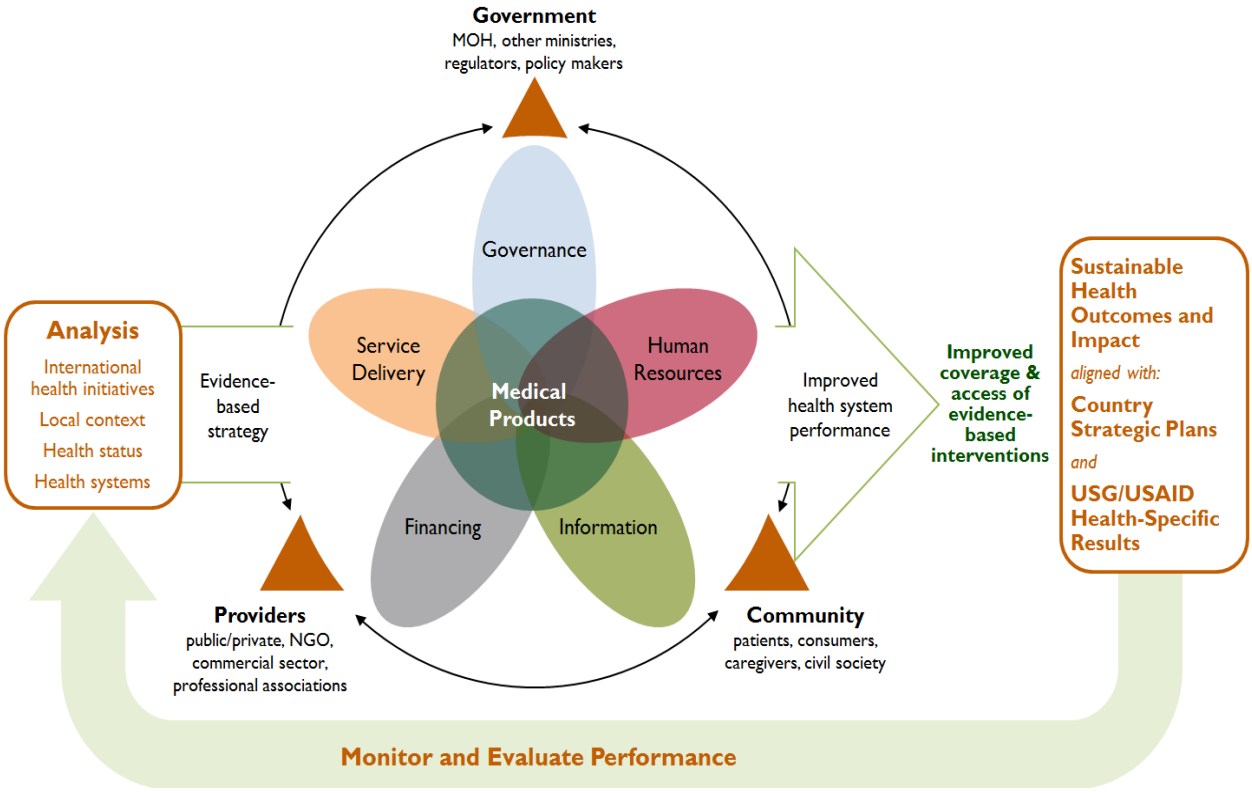
[6] Reprinted from Everybody's Business—Strengthening Health Systems to Improve Health Outcomes: WHO's Framework for Action, WHO, Page 3. Available at: http://www.who.int/healthsystems/strategy/everybodys_business.pdf

[7] Reprinted from Monitoring the Building Blocks of Health Systems: A Handbook of Indicators and Their Measurement Strategies, WHO, Page viii, 2010. Available at: http://www.who.int/healthinfo/systems/WHO_MBHSS_2010_full_web.pdf



Source: Bigdeli et al. 2013

Figure A5. Conceptual framework of access to medicines from a health systems perspective



Source: SIAPS 2013

Figure A6. SIAPS PSS framework

Supplementary Appendix B. Review and Analysis of Assessment Tools

The categories/classification of indicators in the assessment tools served as a resource for identifying the key components of the pharmaceutical system (table 4); 53 assessment tools were screened, of which 47 were reviewed (table B1). In cases where the assessment tool was a survey instrument (questionnaire), we included the category labels used to group the survey questions. Among the tools reviewed, more than 100 unique categories of indicators and survey questions were identified. Many of these categories were similar, but the labels were slightly different. Many also closely align with the subsystems and pharmaceutical management functions identified in the review of the frameworks. In an attempt to identify the primary measurement categories and reduce duplication, the assessment tools were divided into three groups (figure B1):

- Group A includes comprehensive system tools that focus on access, use, pharmaceutical management/policy, and/or supply chain
- Group B includes tools for specific diseases or health programs that are mostly adaptations of those in group A
- Group C includes tools that are for specific system components, such as governance, human resources, or logistics

Group B tools were omitted from subsequent analyses in the paper to reduce duplication. The categories of indicators and survey questions from tools in groups A and C were then reorganized into broader categories to summarize the pharmaceutical system components measured by these various tools (tables B2 and B3). The counts in tables B2 and B3 were combined to summarize the pharmaceutical components and functions measured by the assessment tools (table 4).

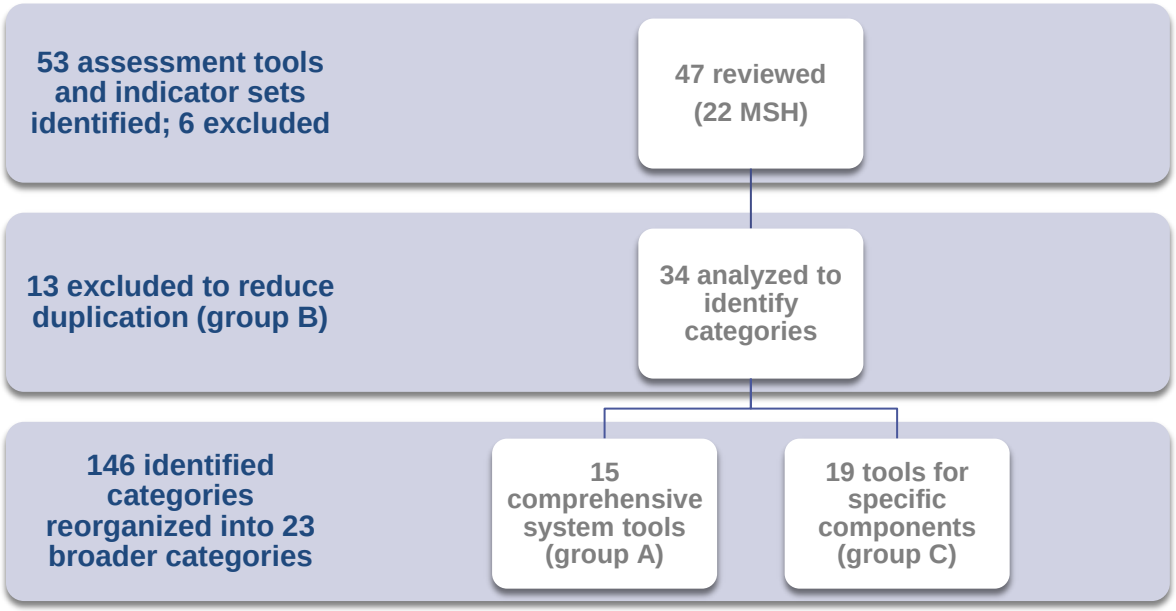


Figure B1. Organization of assessment tools and indicator sets for analysis

The following tools resulted from our search but were completely excluded from the review. They were mainly survey instruments (questionnaires) without any meaningful categories to add any insight regarding possible components of the pharmaceutical system.

1. AIDSRelief. ART commodity management and supply chain assessment tool.
2. Global Fund. (2011). The Global Fund monitoring and evaluation toolkit. https://reliefweb.int/sites/reliefweb.int/files/resources/ME_MonitoringEvaluation_Toolkit_en.pdf
3. MEASURED SPA Medicines Availability. http://www.dhsprogram.com/pubs/pdf/SPAQ5/Service_Readiness_Indicators_042012.pdf
4. MSH, Center for Pharmaceutical Management. (1997). Inventory Management Assessment Tool. Excel Workbook.
5. WHO. (2001). Guidelines for the formulation, implementation, monitoring and evaluation of national drug policies. Harare: WHO Regional Office of Africa. http://www.who.int/medicines/technical_briefing/tbs/guidelines-formulation.pdf (A questionnaire based on Brudon et al. 2009 that is included as a reviewed assessment tool)
6. WHO. (2013). Service Availability and Readiness Assessment (SARA). An annual monitoring system for service delivery. Version 2.1. Geneva: World Health Organization. http://www.who.int/healthinfo/systems/sara_introduction/en/

Table B1. Assessment Tools Reviewed[8]

Analysis Group	Assessment Tool Reference	Reference Code
A	Aronovich D, Tien M, Collins E, Sommerlatte A, Allain L. (2010). Measuring supply chain performance: Guide to key performance indicators for public health managers. Arlington, Va.: USAID | DELIVER PROJECT, Task Order 1. https://www.jsi.com/JSIInternet/Inc/Common/_download_pub.cfm?id=11153&lid=3	DELIV-2012
A	Brudon P, Rainhorn JD, Reich MR. (1999). Indicators for monitoring national drug policies: a practical manual. Geneva: World Health Organization. http://apps.who.int/medicinedocs/pdf/whozip14e/whozip14e.pdf	WHONDP-1999
A	FHI 360. (2012). Health system rapid diagnostic tool. Framework, operational guide, and metrics to measure the strength of priority health system functions. Durham NC: FHI 360. http://www.fhi360.org/resource/health-system-rapid-diagnostic-tool	FHI360-2012
A	WHO and Global Fund, Pharmaceutical sector country profile questionnaire. http://www.who.int/medicines/areas/coordination/Empty_English_Questionnaire.pdf	GFPSP-NI
A	Global Fund, The pharmaceutical and health product management (PHPM) assessment tool.	GFPHPM-NI
A	Health Systems 20/20. (2012). The health system assessment approach: A how-to manual. Version 2.0. Module 6. www.healthsystemassessment.org	HS20-2012
A	MSH, Center for Pharmaceutical Management, University Research Corporation, PAHO, USAID. (1995). Rapid Pharmaceutical Management Assessment: an Indicator-Based Approach. Rational Pharmaceutical Management Project, Drug Management Program.	1.1
A	MSH, Center for Pharmaceutical Management. (2003). Access to Essential Medicines: Tanzania, 2001. Prepared for the Strategies for Enhancing Access to Medicines Program. Arlington, VA: Management Sciences for Health.	1.3
A	MSH, Center for Pharmaceutical Management. (2009). Medicines Building Block Tracking and Monitoring Framework (draft version 5.0, never completed). Prepared for the Strengthening Pharmaceutical Systems project.	1.5
A	Seiter A. (2010). A practical approach to pharmaceutical policy. Appendix A. Washington DC: World Bank Publications. https://openknowledge.worldbank.org/bitstream/handle/10986/2468/552030PUB0Phar10Box349442B01PUBLIC1.pdf?sequence=4	SEITER
A	WHO. (2009). Medicines use in primary care in developing and transitional countries. FactBook summarizing results from studies reported between 1990 and 2006. Geneva: World Health Organization. http://www.who.int/medicines/publications/who_emp_2009.3/en/	WHOUSE-2009
A	WHO and HAI. (2008). Measuring medicine prices, availability, affordability and price components, 2nd ed. Geneva: World Health Organization and Health Action International. http://www.haiweb.org/medicineprices/manual/documents.html	WHOHAI-2008
A	WHO. (1993). How to investigate drug use in health facilities: selected drug use indicators. EDM Research Series No. 007. Geneva: World Health Organization. http://apps.who.int/medicinedocs/en/d/Js2289e/	WHODU-1993
A	WHO. (2007). Operational package for monitoring and assessing country pharmaceutical situations. Guide for coordinators and data collectors. Geneva: World Health Organization. http://apps.who.int/medicinedocs/index/assoc/s14877e/s14877e.pdf	WHOPS-2007
A	WHO. (2010). Monitoring the building blocks of health systems: a handbook of indicators and their measurement strategies. Geneva: World Health Organization. http://www.who.int/healthinfo/systems/monitoring/en/	WHOHSS-2010
B	Barrientos R, Busch T, Goredema W, Tjipura D. (2011). End Use Verification Survey for Monitoring Availability and Use of Malaria and other Key Health Commodities in Angola; August–September 2011. Submitted to the US Agency for International Development by the Strengthening Pharmaceutical Systems (SPS) Program. Arlington, VA: Management Sciences for Health.	3.4

[8] Following the submission of this article for publication, the SIAPS team reviewed an early version of the indicators from the WHO Global Benchmarking Tool (draft received 6 December 2016) for inclusion in the Regulatory Systems component.

Analysis Group	Assessment Tool Reference	Reference Code
B	Briggs CJ, Frye J, Senauer K. (2008). District Pharmaceutical Management for Childhood Illness: An Assessment and Monitoring Tool. Submitted to the US Agency for International Development by the Rational Pharmaceutical Management Plus Program. Arlington, VA: Management Sciences for Health.	2.2
B	Keene D, Ickx P, McFadyen J. (2000). Drug Management for Childhood Illness Manual. Submitted to the US Agency for International Development by the Rational Pharmaceutical Management Project. Arlington, VA: Management Science for Health.	2.1
B	MSH, Center for Pharmaceutical Management. (2005). Community Pharmaceutical Management Survey Instruments, Laos. Submitted to the US Agency for International Development under the Rational Pharmaceutical Management Plus Program by Management Sciences for Health.	3.2
B	MSH, Center for Pharmaceutical Management. (2009). Monitoring and Evaluation of Pharmaceutical Management Aspects of ACT Policy Implementation: An Indicator–Based Tool. Submitted to the US Agency for International Development by the Strengthening Pharmaceutical Systems Program. Arlington, VA: Management Sciences for Health.	3.3
B	MSH, Center for Pharmaceutical Management. (2004). Pharmaceutical Management for Malaria Manual. (Revised ed. 2004, Prepared by Malcolm Clark 2002 and revised by Rima Shretta 2003). Submitted to the US Agency for International Development by the Rational Pharmaceutical Management Plus Program. Arlington, VA: Management Sciences for Health.	3.1
B	MSH, Center for Pharmaceutical Management. (2009). President's Malaria Initiative Situation Assessment Tool.	3.5
B	Nachbar N, Briggs J, Aupont O, Shafritz L, Bongiovanni A, Acharya K, Zimicki S, Holschneider S, Ross-Degnan D. (2003). Community Drug Management for Childhood Illness: Assessment Manual. Submitted to the US Agency for International Development by the Rational Pharmaceutical Management Plus Program. Arlington, VA: Management Sciences for Health.	2.3
B	Rational Pharmaceutical Management (RPM) Plus Program. (2005). Pharmaceutical Management for Tuberculosis Assessment Manual. Edited by Zagorskiy A, Owunna C, Moore T. Submitted to the US Agency for International Development by the RPM Plus Program. Arlington, VA: Management Sciences for Health.	4.1
B	Supply Chain Management System. (2012). National supply chain key performance indicators: User's guide & data dictionary. Submitted to the US Agency for International Development by the Supply Chain Management System (SCMS).	SCMS-2012
B	Walkowiak H. (2010). HIV/AIDS Pharmaceutical Management Capacity Building in Karnataka, India. Baseline Assessment: April and August 2010. Submitted to the US Agency for International Development by the Strengthening Pharmaceutical Systems (SPS) Program. Arlington, VA: Management Sciences for Health.	5.1
B	WHO. (2011). Harmonized monitoring and evaluation indicators for procurement and supply management systems: early-warning indicators to prevent stock-outs and overstocking of antiretroviral, antituberculosis and antimalaria medicines. Geneva: World Health Organization. http://www.who.int/hiv/pub/amds/monitoring_evaluation/en/	WHOHTM-2011
B	WHO. (2011). Pharmaceutical human resources assessment tools. Geneva: World Health Organization. http://apps.who.int/medicinedocs/en/d/Js18717en/	WHOHR-2011
C	Annex A in Wuliji T, et al. (2013). Strengthening Pharmaceutical Human Resources in Afghanistan: Assessment and Strategic Framework Development. Submitted to the US Agency for International Development by the Strengthening Pharmaceutical Systems (SPS) Program. Arlington, VA: Management Sciences for Health.	8.1
C	JSI, Transport assessment tool. http://iaphl.org/wp-content/uploads/2016/05/Transport-Assessment-Tool.pdf	JSIT-NI
C	MSH, Center for Pharmaceutical Management. (2008). Antimicrobial Resistance Module for Population-Based Surveys. Submitted to the US Agency for International Development by the RPM Plus Program. Arlington, VA: Management Sciences for Health.	6.2
C	MSH, Center for Pharmaceutical Management. (2013). Guidance for incorporating SIAPS-Global Indicators into Portfolio PMPs. Prepared for the Systems for Improved Access to Pharmaceuticals and Services Project. MSH/USAID.	1.6
C	MSH, Center for Pharmaceutical Management. (2012). Regulatory Systems Assessment Tool. Excel file. Internal tool.	7.1
C	MSH, Center for Pharmaceutical Management. (Undated). Uganda Inspection, Monitoring, and Supervision Model. Prepared for the East African Drug Seller Initiative Project. Management Sciences for Health and the Bill & Melinda Gates Foundation.	1.4

Analysis Group	Assessment Tool Reference	Reference Code
C	MSH. (2011). Building Local Coalitions for Containing Drug Resistance: A Guide. Submitted to the US Agency for International Development by the Strengthening Pharmaceutical Systems (SPS) Program. Arlington, VA: Management Sciences for Health.	6.3
C	Ratanawijitrasin S, Wondemagegnehu E. (2002). Effective drug regulation. A multicountry study. Geneva: World Health Organization. http://apps.who.int/medicinedocs/pdf/s2300e/s2300e.pdf	WHODR-2002
C	Strengthening Pharmaceutical Systems (SPS) Program. (2012). How to Investigate Antimicrobial Use in Hospitals: Selected Indicators. Submitted to the US Agency for International Development by the Strengthening Pharmaceutical Systems Program. Arlington, VA: Management Sciences for Health.	6.1
C	Strengthening Pharmaceutical Systems (SPS) Program. (2009). Indicator-Based Pharmacovigilance Assessment Tool: Manual for Conducting Assessments in Developing Countries. Submitted to the US Agency for International Development by the SPS Program. Arlington, VA: Management Sciences for Health.	7.2
C	USAID | DELIVER PROJECT, Task Order 1. (2008). Logistics indicators assessment tool (LIAT). Arlington, Va.: USAID | DELIVER PROJECT, Task Order 1. https://www.k4health.org/toolkits/fp-logistics/logistics-indicators-assessment-tool-liat	LIAT-2008
C	USAID | DELIVER PROJECT, Task Order 1. (2009). Logistics system assessment tool (LSAT). Arlington, Va.: USAID | DELIVER PROJECT, Task Order 1. https://www.jsi.com/JSIInternet/Inc/Common/_download_pub.cfm?id=14130&lid=3	LSAT-NI
C	USAID | DELIVER PROJECT, Task Order 1. (2010). Assessment tool for laboratory services and supply chains (ATLAS). Arlington, Va.: USAID | DELIVER PROJECT, Task Order 1.	ATLAS-NI
C	USAID | DELIVER. (2006). Monitoring and evaluation indicators for assessing logistics systems performance. Arlington, Va.: DELIVER, for the US Agency for International Development. http://1i4rh11vccjs3zhs5v8cwkn2.wpengine.netdna-cdn.com/wp-content/uploads/2016/05/M_E_indicators_hdbk.pdf USAID | DELIVER PROJECT, Task Order 4. (2012). Procurement performance indicators guide—Using procurement performance indicators to strengthen the procurement process for public health commodities. Arlington, Va.: USAID | DELIVER PROJECT, Task Order 4. http://apps.who.int/medicinedocs/en/d/Js20157en/	JSIPROC-2012
C	USAID | DELIVER PROJECT, Task Order 4. (2013). Human resource capacity development in public health supply chain management: Assessment guide and tool. Arlington, Va.: USAID|DELIVER PROJECT, Task Order 4. https://www.k4health.org/toolkits/fp-logistics/human-resource-capacity-development-public-health-supply-chain-management	DELIVHR-NI
C	USP. (2007). Rapid assessment of medicines quality assurance and medicines quality control.	USPQ-NI
C	WHO. (2007). WHO data collection tool for the review of drug regulatory systems. Practical guidance for conducting a review. Geneva: World Health Organization. http://www.who.int/medicines/areas/quality_safety/regulation_legislation/assesment/en/	WHODR-2007
C	WHO. (2009). Measuring transparency in the public pharmaceutical sector. Assessment instrument. Geneva: World Health Organization. http://www.who.int/medicines/areas/policy/goodgovernance/AssessmentInstrumentMeastranspENG.PDF	WHOTR-2009
C	WHO. (2009). Monitoring and evaluation of health systems strengthening. An operational framework. Geneva: World Health Organization. http://www.who.int/healthinfo/HSS_MandE_framework_Nov_2009.pdf	WHOHSS-2009

Table B2. Reassigned Categories (Listed Alphabetically) of Indicators and Survey Questions from Group A Assessment Tools

Reassigned Categories	No. of Tools	Original Categories	No. of Tools	Reference Code
Access	12	Acceptability/Satisfaction	1	1.3
		Access (Level II)	1	WHOPS-2007
		Access to Essential Medicines	1	WHOHSS-2010
		Affordability	2	WHOHAI-2008, 1.3
		Affordability of Essential Drugs	1	WHONDP-1999
		Availability	1	WHOHAI-2008
		Availability and Access to Quality Products	1	HS20-2012
		Availability of Essential Drugs	1	WHONDP-1999
		Availability of Medicines and Information	1	1.3
		Geographic Accessibility	1	1.3
		Household Access	1	GFPSP-NI
Access and Use	2	Access and Use	1	1.5
		Patient Access and Drug Utilization	1	1.1
Distribution	6	Distribution/Transport	1	DELIV-2012
		Inventory Management/LMIS/Customer Response	1	DELIV-2012
		Inventory Storage and Distribution	1	FHI360-2012
		Storage and Distribution	1	HS20-2012
		Storage, Inventory Management, and Transportation	1	1.5
		Warehousing/Storage	1	DELIV-2012
Financing	7	Drug Allocation in the Health Budget/Public Sector Financing Policy	1	WHONDP-1999
		Financing of Medical Products, Vaccines, and Technologies	1	HS20-2012
		Health Systems Financing	1	WHOHSS-2010
		Medicines Financing	1	GFPSP-NI
		Medicines Financing (Level I)	1	WHOPS-2007
		Ministry of Health Budget and Finance	1	1.1
		Public and Private Drug Expenditure	1	SEITER
Governance	2	Governance	1	1.5
		Leadership and Governance	1	WHOHSS-2010
Health/Pharmaceutical Services	4	Health Service Delivery	1	WHOHSS-2010
		Health Services	1	GFPSP-NI
		Physical Infrastructure for Service Delivery	1	FHI360-2012
		Serving Customers	1	FHI360-2012
Human Resources	2	Health Workforce	1	WHOHSS-2010
		Other (Level II)	1	WHOPS-2007
Miscellaneous Indicator Category	4	Additional Indicators	1	WHOUSE-2009
		Facility Indicators	1	WHOUSE-2009
		Standard Indicators	1	HS20-2012
		Health and Demographic Data	1	GFPSP-NI
Information Systems	2	Health Information Systems	1	WHOHSS-2010
		Logistics Management Information System	1	FHI360-2012
Manufacturing, Industry, and Trade	5	Industry and Trade	1	SEITER
		Medicines and Trade Production	1	GFPSP-NI
		Pharmaceutical Market	1	SEITER
		Private-sector Pharmaceutical Activity	1	1.1
		Production and Trade (Level I)	1	WHOPS-2007
Organization and Management Support	1	Management Support	1	1.5
Policies, Legislation, Regulation	11	Drug Pricing	1	SEITER
		Legislation and Regulation	1	WHONDP-1999
		Medicine Price	1	WHOHAI-2008

Reassigned Categories	No. of Tools	Original Categories	No. of Tools	Reference Code
		Medicines Regulation	1	GFPSP-NI
		National Medicines (Drug) Policy (Level I)	1	WHOPS-2007
		Pharmaceutical Policy, Laws, and Regulations	1	HS20-2012
		Policy and Regulation	1	SEITER
		Policy Issues	1	GFPSP-NI
		Policy, Legislation, and Regulation	1	1.1
		Pricing Policy	1	WHONDP-1999
		Regulatory System (Level I)	1	WHOPS-2007
Procurement	7	Forecasting and Procurement	1	FHI360-2012
		Ministry of Health Pharmaceutical Procurement	1	1.1
		Procurement	1	HS20-2012
		Public-sector Procurement Procedures	1	WHONDP-1999
		Purchasing, Reimbursement, and Procurement	1	SEITER
		Quantification and Procurement	1	1.5
		Supplier/Sourcing	1	DELIV-2012
Procurement and Distribution	2	Pharmaceutical Procurement and Distribution	1	GFPSP-NI
		Procurement and Supply Management	1	GFPHPM-NI
Quality/Quality Assurance/PV	6	Product Quality Assurance	1	1.1
		Quality (Level II)	1	WHOPS-2007
		Quality and Safety Monitoring	1	FHI360-2012
		Quality Assurance and Medication Safety	1	1.5
		Quality of Drugs	1	WHONDP-1999
		Quality of Products and Services	1	1.3
Selection	3	Formulary/Essential Drugs List and Drug Information	1	1.1
		Product Selection	1	FHI360-2012
		Selection of Pharmaceuticals	1	HS20-2012
Selection and Procurement	1	Product Selection, Forecasting, and Procurement	1	DELIV-2012
Selection and Registration	1	Essential Drug Selection and Drug Registration	1	WHONDP-1999
Selection and Use	1	Selection and Rational Use	1	GFPSP-NI
Services and Logistics	1	Service Delivery and Logistics	1	SEITER
Supply Chain/Supply Management/Logistics	4	Medicines and Supplies Required For Essential Services	1	FHI360-2012
		Medicines Supply Systems (Level I)	1	WHOPS-2007
		Ministry of Health Pharmaceutical Logistics	1	1.1
		Public Sector Distribution and Logistics	1	WHONDP-1999
Use	13	Appropriate Use	1	HS20-2012
		ARI Treatment Indicators	1	WHOUSE-2009
		Complementary Medicines Use Indicators	1	WHOUSE-2009
		Diarrhea Treatment Indicators	1	WHOUSE-2009
		Information and Continuing Education on Drug Use	1	WHONDP-1999
		Malaria Treatment Indicator	1	WHOUSE-2009
		Patient Care Indicators	1	WHOUSE-2009
		Prescribing Indicators	1	WHOUSE-2009
		Rational Use of Drugs	2	WHONDP-1999, SEITER
		Rational Use of Medicines (Level I)	1	WHOPS-2007
		Rational Use of Medicines (Level II)	1	WHOPS-2007
		Use	1	WHODU-1993

Table B3. Reassigned Categories (Listed Alphabetically) of Indicators and Survey Questions from Group C Assessment Tools

Reassigned Categories	No. of Tools	Original Categories	No. of Tools	Reference Code
Access	3	Acceptability/Satisfaction	1	1.4
		Affordability	1	1.4
		Availability	1	1.4
Financing	1	Financing Strategies and Mechanisms	1	1.6
Governance	2	Pharmaceutical Sector Governance	1	1.6
		Transparency	1	WHOTR-2009
Health/Pharmaceutical Services	1	Pharmaceutical Services	1	1.6
Human Resources	5	Human Resources	1	DELIVHR-NI
		Human Resources Planning	1	8.1
		Human Resources Policies	1	8.1
		Practice Distribution of Pharmaceutical Human Resources	1	8.1
		Total Pharmaceutical Human Resources	1	8.1
Information Systems	1	Information for Decision Making	1	1.6
Laboratory Services and Supply Chain	1	Laboratory Services and Supply Chain	1	ATLAS-NI
Miscellaneous Indicator Category	7	General Information	1	8.1
		Hospital Indicators	1	6.1
		Impact	1	WHOHSS-2009
		Inputs and Processes	1	WHOHSS-2009
		Outcomes	1	WHOHSS-2009
		Outputs	1	WHOHSS-2009
		Supplemental Indicator	1	6.1
Organization and Management Support	1	Management Support	1	6.3
Policies, Legislation, and Regulation	9	Drug Regulation Overview	1	WHODR-2002
		Enforcement	1	7.1
		Inspection	1	7.1
		Medicine Policy	1	6.3
		Policy, Law, and Regulation	1	7.2
		Registration	1	7.1
		Regulatory Environment	1	6.3
		Regulatory Functions	2	WHODR-2002, WHODR-2007
Procurement	1	Procurement	1	JSIPROC-2012
Quality/Quality Assurance/PV	9	Pharmacovigilance	1	7.1
		Quality Assurance and Control	1	USPQ-NI
		Quality of Products	1	1.4
		Quality of Services	1	1.4
		Quality Surveillance	1	7.1
		Risk Assessment and Evaluation	1	7.2
		Risk Management and Communication	1	7.2
		Signal Generation and Data Management	1	7.2
		Systems, Structures, and Stakeholder Coordination	1	7.2
Selection & Procurement	1	Selection and Procurement	1	6.3
Supply Chain/Supply Management/Logistics	3	Logistics	1	LSAT-NI
		Logistics System	1	LIAT 2008
		Pharmaceutical Supply Management and Services	1	1.6
Transport	1	Transport	1	JSIT-NI
Use	8	AMR Containment and Advocacy	1	6.3
		Correct Antimicrobial Medicine Knowledge and Behavior	1	6.2
		Correct Antimicrobial Resistance Knowledge	1	6.2

Reassigned Categories	No. of Tools	Original Categories	No. of Tools	Reference Code
		Correct Use of Medicines	1	6.2
		Education and Training on Use	1	6.3
		Medicines Information	1	7.1
		Patient Care Indicators	1	6.1
		Prescribing Indicators	1	6.1

ANNEX D. INDICATOR SELECTION CRITERIA

This paper was produced by Boston University School of Public Health in January 2016 to guide the selection of candidate indicators for inclusion in the pilot.

Selection criteria for indicators measuring health system performance or pharmaceutical system performance

Background

There is no widely agreed standard of criteria to select indicators to measure performance in health or pharmaceutical systems. The Organization for Economic Corporation and Development (OECD) published a series of publications on the development of health system performance measures and quality of care (Marshall et al. 2004). These publications include a list of criteria which the OECD used to guide the selection of their indicators for health systems performance (Marshall et al. 2004).

Similarly, the World Bank (WB) together with the World Health Organization (WHO) has published recently on measuring progress on Universal Health Coverage listing a number of criteria used to defined measurement indicators (Joint WHO / World Bank Group 2013).

In order to take stock of proposed criteria for the selection of performance indicators we conducted a literature of grey and peer-review publication.

Methods

A systematic literature review was outside the scope of this project. Instead we did a target search using three key search engines: PubMed, Web of Science and Google Scholar. Additionally, through the PubMed database, the "similar articles" section and reference section were used as two additional search tools for relevant literature. Searches were limited to English language and publications between 2000 and 2016. Key words used consistently in the search databases were: criteria, indicator selection, performance measures, pharmaceutical systems, and health systems, separate or in combination. A first selection of relevant articles was made through title review. For all relevant titles the abstract was retrieved. If relevant the full publication was retrieved. Data was extracted regarding the criteria used to select indicators related to quality of care or performance of health services or systems. We excluded information that did not specifically mention criteria.
We developed a matrix using the publication by Nolte as the organizing principle since it was the one with the largest number of criteria. We compared and contrasted the criteria mentioned in other publications with the one mentioned by Nolte. The goal was to identify commonalities and differences between the criteria.

Results

In addition to the publications mentioned above by OECD and WB/WHO we found five relevant articles:

(1) a paper summarizing a systematic review of peer-reviewed and grey literature on performance measurement (Adair et al. 2006),

(2) a paper evaluating key conceptual and methodological issues associated with measuring performance of public health organizations (Mays and Halverson 2000) which could not be accessed in full-text, only the abstract,

(3) a paper aimed at developing a performance assessment tool for quality improvement in hospitals (PATH) by the World Health Organization (WHO) regional office for Europe (Veillard et al. 2005) and

(4) a study evaluating nursing care performance whose one objective was to "develop a pool of indicators sensitive to various aspects of nursing care that can be used as a basis for designing a performance measurement system" (Dubois et al. 2013).

(5) a report written by the RAND corporation to examine "international benchmarking of healthcare quality to inform the use of international comparisons for quality improvement in the NHS". (Nolte 2010)

Three articles provided specific lists with a table of criteria for performance measure selection. Adair et al emphasize that this list is comprehensive of health literature papers and represents the appendix below.

The comparative analysis of the different criteria by the five papers is summarized in the table below (Table 1). This analysis shows the criteria set by Nolte et al to be the most comprehensive with a total of 15 attributes. There are three attribute characteristics -validity, availability, and policy-relevance- that are consistent among all five papers. 'Reliable' was mentioned in three other publications. Five of the attributes outlines by Nolte et al had only one or no other paper with similar outlined characteristics (communicable, contextual, interpretable, comparable, adaptable).

Interestingly, several publications apart from Nolte mentioned the need for a set of indicators that represent certain areas. For instance, Adair et al (2006) talk about "the set of measures is balanced across types of relevant domains". Veillard et al (2005) lists "are all dimensions covered?" and "how do indicators relate to each other"?

Table 1: Comparative analysis of selection criteria by the four relevant publications

Nolte, 2010		Marshall et al. 2004 (OECD)	(Joint WHO / World Bank Group 2013	Adair et al. 2006	(Veillard et al. 2005
Criteria	**Explanation**				
Valid	The extent to which a measure accurately represents the concept/phenomenon being evaluated	**Content validity** - does the measure capture meaningful aspects of the quality of care	**Quality** - Do the indicators measure what they intend to measure?	**Evidence based** – There are valid and reliable operational definitions for the measure that have been demonstrated through rigorous research	**Content validity** – Does the measure relate to the subdimension of performance it is supposed to assess?
Communicable	Relevance of measure can be easily explained and understood by target audience	NONE	NONE	**Understandable** – the measure is understandable to a non-technical audience	NONE
Effective	Indicator measures what it aims to measure; free of perverse incentives	**Important Performance Aspect/Susceptibility of being influenced** - Does the health care system have an impact on the indicator independent of confounders like patient risk?	NONE	**Robustness** – Potential adverse effects of the measure can be mitigated, and vulnerability to gaming is minimal	NONE
Reliable	The extent to which a measurement with an indicator is reproducible	NONE	**Availability -** Are the indicators measured reliably?	**Evidence-based –** there are valid and reliable definitions for the measure that have been demonstrated through rigorous research	**Reliability** – Is there demonstrated reliability (reproducibility) of data?
Objective	Data are independent of subjective judgment	**Important Performance Aspect/Susceptibility of being influenced** – Does the health care system have an impact on the indicator independent of confounders like patient risk?	NONE	**Robustness –** Potential adverse effects of the measure can be mitigated, and vulnerability to gaming is minimal	NONE

Nolte, 2010		**Marshall et al. 2004 (OECD)**	**(Joint WHO / World Bank Group 2013**	**Adair et al. 2006**	**(Veillard et al. 2005**
Criteria	**Explanation**				
Available/ feasible	Data are collected for routine (clinical/organisational) reasons and are available quickly and with minimum extra effort or cost	**Data availability (Reporting burden)**	**Availability** - Are the indicators measured…. with existing instruments?	**Feasible** – data collection, reporting and follow-through are cost-effective	**Burden of data collection** – Are data available and easy to access?
Contextual	Measure is context-free, or important context effects should be adjusted for	NONE	NONE	NONE	**Contextual validity** – Is this indicator valid in different contexts?
Attributable	Measure reflects the quality of care delivered by individuals, teams and organisations	**Important Performance Aspect/Impact on Health** – What is the impact on health associate with this problem?	NONE*	**Attributable** – causal links between the measure, service improvements and health outcomes are known	NONE
Interpretable	Measure allows for ready interpretation of core underlying factors	NONE	NONE	NONE	NONE
Comparable	Measure allows for reliable comparison with external benchmarks or to other datasets collected in similar circumstances	NONE	**Availability** - Are the indicators comparably?	NONE	NONE
Remediable/actionable	Measure points to actionable areas for improvement that are likely to impact positively on the measure in question	**Impact on health** – Does the measure address areas in which there is a clear gap between the actual and potential levels of health?	NONE	**Actionable** – The measure addresses a service area that can benefit from improvement **Evidence-based** – There are valid and reliable operational definitions for the measure that have been demonstrated through rigorous research	NONE
Repeatable	Measure is sensitive to improvements over time	NONE	NONE	**Responsive** – The measure is sensitive to change over time	Potential for use (and abuse) and sensitivity to implementation

Nolte, 2010		Marshall et al. 2004 (OECD)	(Joint WHO / World Bank Group 2013	Adair et al. 2006	(Veillard et al. 2005
Criteria	**Explanation**				
Adaptable	Measure is appropriate for use in a variety of contexts and settings	NONE	NONE	NONE	NONE
Acceptable	The extent to which the process of measurement (and reasons for it) is accepted by those affected	**Policy importance** – are consumers concerned with this area?	NONE	NONE	**Face validity** – Is there a consensus among users and experts that this measure is related to the dimension (or subdimension) it is supposed to assess?
Policy-relevant	Indicator reflects important health conditions in terms of burden of disease, cost of care or public interest	**Policy importance** – are policy makers and consumers concerned with this area?	**Relevance** – Do the indicators measure that are priorities or relevant?	**Important –** The measure addresses an important or serious health or health services problem (usually defined as health burden or cost) such that there will be sufficient impact from collection and service improvement initiatives **Relevant and meaningful –** The measure is relevant to most stakeholders, including policy makers, managers, clinicians and the public	**Importance and relevance –** Does the indicator reflect aspects of functioning that matter to users and are relevant in current healthcare context?

Discussion

Although there is a great deal of discussion and agreement on benefits and importance of consistent guidelines to select indicators for performance measures, there is no consensus on a set of criteria that should be followed for performance measurement. There is a gap in literature on such criteria to select indicators to measure health system performance and pharmaceutical systems performance; this is exemplified by the lack of a single MeSH term tagged in the Adair et al paper. The MeSH terms used in the other articles are very general and show a lack of specific terms used for this type of literature. Below is a sample of the MeSH terms used:

Health Services Research/methods
- Humans
- Organizational Objectives
- Public Health Practice/standards
- Quality Assurance, Health Care/methods

United States

Most criteria in the literature are very general in nature, however, the criteria summarized in Adair et al (2006) and Veillard et al (2005) conform with and are complementary to the indicator selection criteria set forth by the Organisation for Economic Co-operation and Development (OECD) and by the World Health Organization (WHO) for monitoring progress towards Universal Health Coverage (UHC) at country and global levels, table 4 and table 5 below.

The other articles touched upon the idea of using criteria that are readily available for selecting indicators but do not directly list the criteria.

Using the criteria characteristics set forth by Nolte et al as a reference due to its comprehensiveness, there is majority consensus that selections of criteria for indicators should be based on the characteristics of those indicators to be (1) valid: the extent to which a measure accurately represents the concept/phenomenon being evaluated, (2) available: data collected are available quickly and with minimum extra effort or cost, (3) reliable: the extent to which a measurement with an indicator is reproducible and (4) policy-relevant: indicator reflects important health conditions in terms of burden of disease, cost of care or public interest. Additionally, the criteria 'reliable' also seems relevant and was mentioned by three out of the four other publications.

The remaining six attributes have two agreements and could potentially be added to the list of criteria based on a one by one case depending on its relevance. Of these six, two attributes (1) repeatable: measure is sensitive to improvements over time and (2) attributable: measure reflects the specified cause, seem to be most important for the purposes of selecting indicators for pharmaceutical system performance and thus should be included.

Also, there seems to be a certain overlap between the attributes set by Nolte et al as demonstrated with subtle differences between the criteria (i.e. policy-relevant vs. acceptable). These differences seem to be grayer and are defined by the author's contextual topic of selecting criteria for indicators for healthcare quality. These differences are not necessarily relevant in the context of pharmaceutical performance and thus could be merged.

We recognize that some of the criteria are necessary conditions (valid, reliable and repeatable). If these criteria do not apply to the indicator there is no point in collecting them. However, other criteria are relative (e.g. attributable) which means that they are important but not always possible to achieve. Hence, we will aim for indicators that valid, reliable and repeatable. Preferable these indicators are available, attributable and policy-relevant.

Conclusion

Given the lack of a wide consensus of criteria to select indicators to measure performance related to health systems or pharmaceutical systems we suggest using the criteria which have the most commonality and consensus among the literature in this report and relevant to indicators measuring pharmaceutical system performance to measure health system performance.

These are indicators that are:

- valid,
- reliable,
- repeatable,
- attributable,
- available, and
- policy-relevant.

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Appendix:

Table 1. Criteria for Performance Measures Selection (Adair et al. 2006)

Criterion	Description
Evidence-based	There are valid and reliable operational definitions for the measure that have been demonstrated through rigorous research
Strategic	The measure directs attention towards the ultimate change desired
Important	The measure addresses an important or serious health or health services problem (usually defined as health burden or cost) such that there will be sufficient impact from collection and service improvement initiatives
Attributable	Causal links between the measure, service improvements and health outcomes are known
Actionable	The measure addresses a service area that can benefit from improvement
Feasible	Data collection, reporting and follow-through are cost-effective (potential benefits outweigh costs) and there is reasonable technical capacity for collection and analysis, including risk adjustment of compared measures
Relevant and meaningful	The measure is relevant to most stakeholders, including policy makers, managers, clinicians and the public
Understandable	The measure is understandable to a non-technical audience (often just a communication issue)
Balanced	The set of measures is balanced across types of treatments, treatment settings, major health problems, age groups, special populations and levels of the healthcare system. The set is balanced across short- and long-term measures, and balance and appropriateness are considered across process-and outcome-type measures
Responsive	The measure is sensitive to change over time
Robustness	Potential adverse effects of the measure can be mitigated, and vulnerability to gaming is minimal
Non-ambiguous	The measure is clear in terms of which direction for service change is desirable

Table 2. Criteria for Indicator Selection (Veillard et al. 2005)

Level	Criteria	Issue Addressed by Criteria
Set of Indicators	Face validity	Is the indicator set acceptable as such by its potential users?
	Content validity	Are all the dimensions covered properly?
	Construct validity	How do indicators relate to each other?

Level	Criteria	Issue Addressed by Criteria
Indicators	Importance and relevance	Does the indicator reflect aspects of functioning that matter to users and are relevant in current healthcare context?
	Potential for use (and abuse) and sensitivity to implementation	Are hospitals able to act upon this indicator if it reveals a problem?
Measurement tools	Reliability	Is there demonstrated reliability (reproducibility) of data?
	Face validity	Is there a consensus among users and experts that this measure is related to the dimension (or subdimension) it is supposed to assess?
	Content validity	Does the measure relate to the subdimension of performance it is supposed to assess?
	Contextual validity	Is this indicator valid in different contexts?
	Construct validity	Is this indicator related to other indicators measuring the same subdimension of hospital performance?
	Burden of data collection	Are data available and easy to access?

Table 3. Quality indicator attributes and descriptions (Nolte 2010)

Attribute	Description
Valid	The extent to which a measure accurately represents the concept/phenomenon being evaluated
Communicable	Relevance of measure can be easily explained and understood by target audience
Effective	Indicator measures what it aims to measure; free of perverse incentives
Reliable	The extent to which a measurement with an indicator is reproducible
Objective	Data are independent of subjective judgement
Available/feasible	Data are collected for routine (clinical/organisational) reasons and are available quickly and with minimum extra effort or cost
Contextual	Measure is context-free, or important context effects should be adjusted for
Attributable	Measure reflects the quality of care delivered by individuals, teams and organisations
Interpretable	Measure allows for ready interpretation of core underlying factors
Comparable	Measure allows for reliable comparison with external benchmarks or to other datasets collected in similar circumstances
Remediable/actionable	Measure points to actionable areas for improvement that are likely to impact positively on the measure in question
Repeatable	Measure is sensitive to improvements over time
Adaptable	Measure is appropriate for use in a variety of contexts and settings
Acceptable	The extent to which the process of measurement (and reasons for it) is accepted by those affected
Policy-relevant	Indicator reflects important health conditions in terms of burden of disease, cost of care or public interest

Table 4. Indicator Selection Criteria from OECD (Marshall et al. 2004)

Criterion	Description
Important Performance Aspect	1. Impact on health – what is the impact on health associated with this problem? Does the measure address areas in which there is a clear gap between the actual and potential levels of health? 2. Policy importance – are policy makers and consumers concerned with this area? 3. Susceptibility to being influenced – can the healthcare system meaningfully address this aspect or problem? Does the health care system have an impact on the indicator independent of confounders like patient risk? Will changes in the indicator give information about the likely success or failure of the policy change?
Scientific Soundness	1. Face validity – Does the measure make sense logically and clinically? The face validity of each indicator should be based on the basic clinical rationale for the indicator and on past usage of the indicator in national or other quality reporting activities. 2. Content validity – does the measure capture meaningful aspects of the quality of care
Potentially Feasible	1. Data availability – re comparable data to constrict an indicator available on the international level? 2. Reporting burden – does the value of information contained in an indicator outweigh the cost of data collection and reporting?

Table 5. Criteria for Indicator Selection Criteria for UHC (Joint WHO / World Bank Group 2013)

Criterion	Description
Relevance	Do the indicators measure that are priorities or relevant? Is the intervention or policy they measure standard?
Quality	Do the indicators measure what they intend to measure? could complementary indicators be used to capture information on a certain dimension?
Availability	Are the indicators measured regularly, reliably and comparably (i.e. numerators, denominators, equity stratification) with existing instruments (e.g. household surveys or health facility information systems)?

ANNEX E. TOOL USER MANUAL

PSS Insight

Technical Guide

SoftWorks
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21 March 2018

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PSS Insight Technical Guide

PSS Insight Technical Guide

Chapter-1: Introduction

Pharmaceutical products are crucial for improving health outcomes. Efforts to build resilient health systems to address emerging health needs must include strengthening pharmaceutical systems. However, there has been little attempt to conceptualize a pharmaceutical system and define its strengthening in a way that allows for measurement.

To address this, the USAID-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) program began work in 2014 to define a "pharmaceutical system" and "pharmaceutical systems strengthening" to provide the basis for developing a systematized approach for measuring pharmaceutical system strengthening.

This site presents the process for developing these definitions, as well as a framework for measuring pharmaceutical systems strengthening, and an indicator-based monitoring tool, PSS Insight, that is being piloted in select USAID priority countries.

The site will also house the results of the application of the Insight Tool in several countries and analysis over time.

Chapter-2: Technologies

Type	Name	Description
Web Server	Apache	HTTP Server, an open-source web server platform
Programming/Back End	PHP	Server side open source scripting language
Database	MySQL	Relational database management system (RDBMS) , a permanent Storage of data
Client User Interface	JQuery	jQuery is a cross-platform JavaScript library designed to simplify the client-side scripting of HTML.
Content Management System	WordPress 4.4.13	Content Management Framework for roles/permissions/user management and menu management.

PSS Insight Technical Guide

Chapter-3: Electronic Forms

3.1. Electronic forms with database objects

Admin Menu > Year Entry:

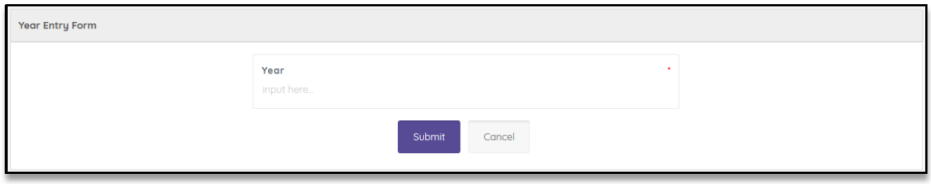


Figure-01

Database object updated: **t_year**

Admin Menu > Master Entity Entry:

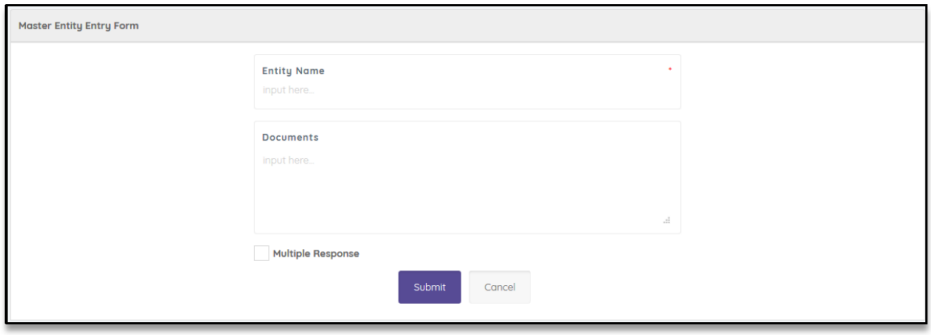


Figure-02

Database object updated: **t_entity_master**

Admin Menu > Value Option Set Entry:

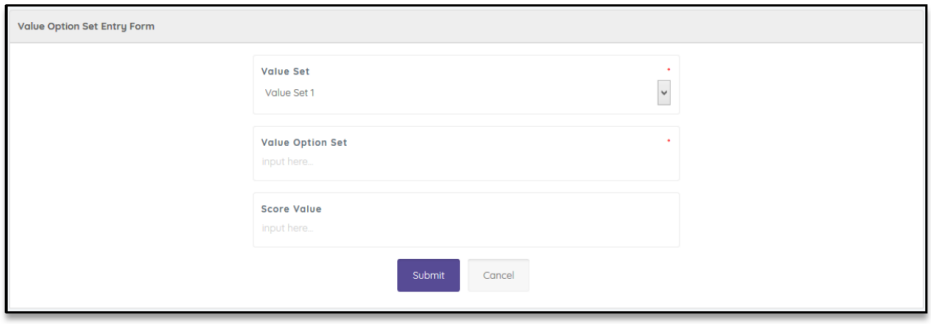


Figure-03

Database object updated: **t_value_option_set**

Admin Menu > Element Entry:

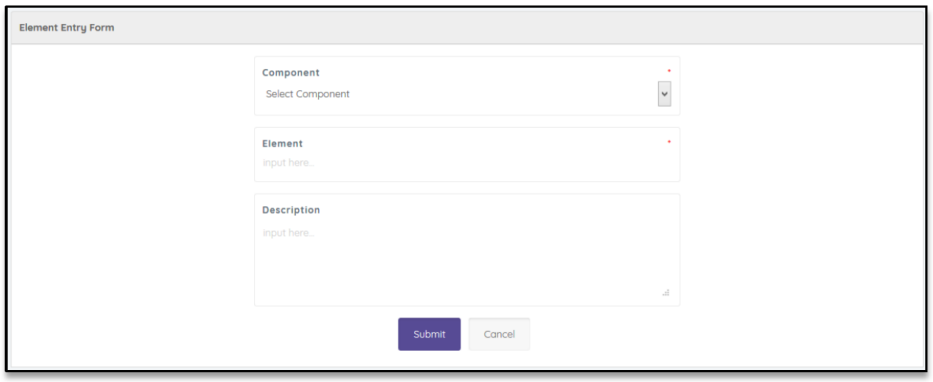


Figure-04

Database object updated: **t_element**

Admin Menu > User Permission Entry:

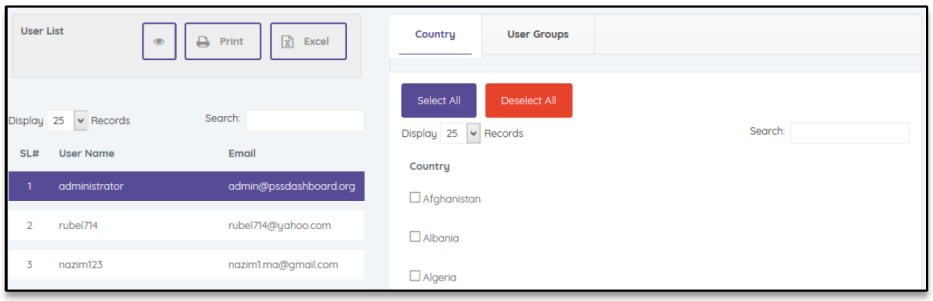


Figure-05

Database object updated: **t_user_country_map**
wp_usermeta
wp_options

Admin Menu > Indicator Dimension Entry:

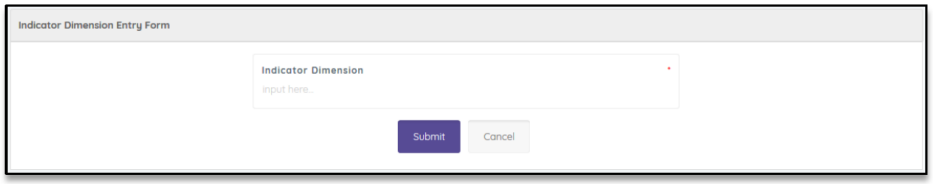


Figure-06

Database object updated: **t_dimension**

Admin Menu > Region Country Map Entry:

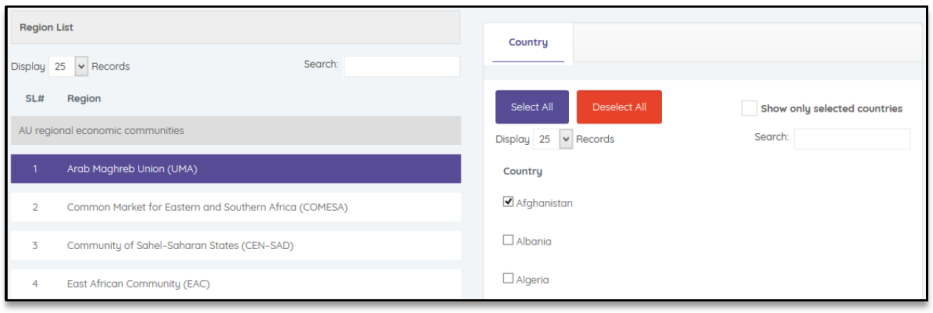


Figure-07

Database object updated: **t_country_region_map**

Admin Menu > Commodity in Tracer Entry:

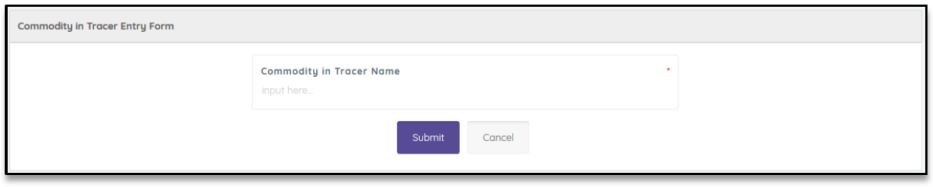


Figure-08

Database object updated: **t_commodity_tracer_list**

Admin Menu > Country Entry:

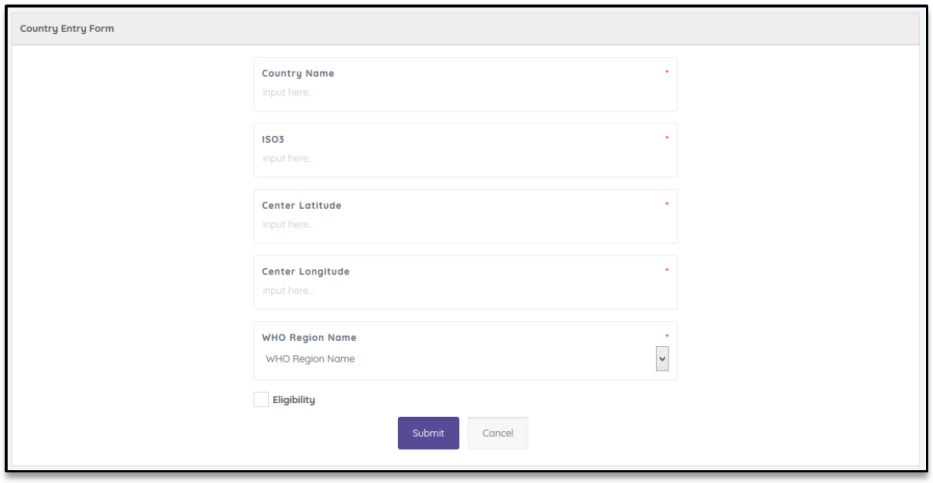


Figure-09

Database object updated: **t_country**

Admin Menu > Indicator Data Type Entry:

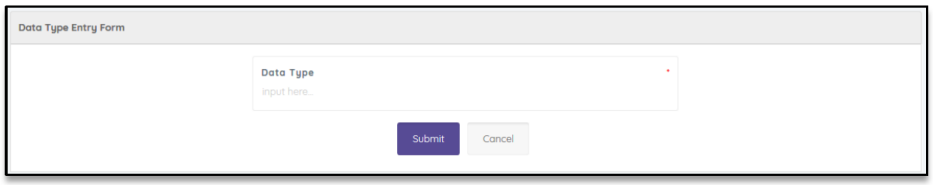


Figure-10

Database object updated: **t_data_type**

Admin Menu > Indicator Category Entry:

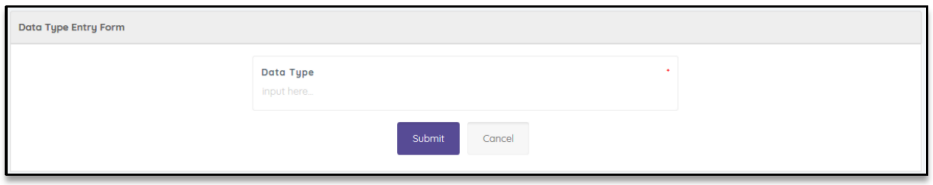


Figure-11

Database object updated: **t_indicator_category**

Admin Menu > Indicator Entry:

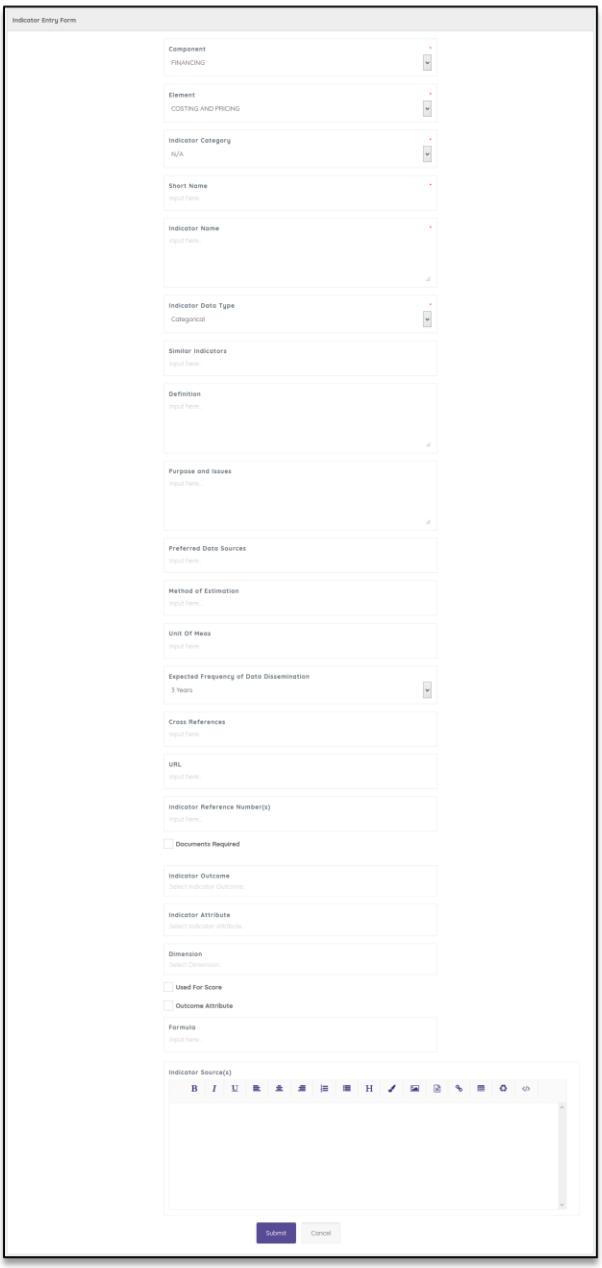


Figure-12

Database object updated: **t_indicator**

Admin Menu > Entity and Question Map Entry:

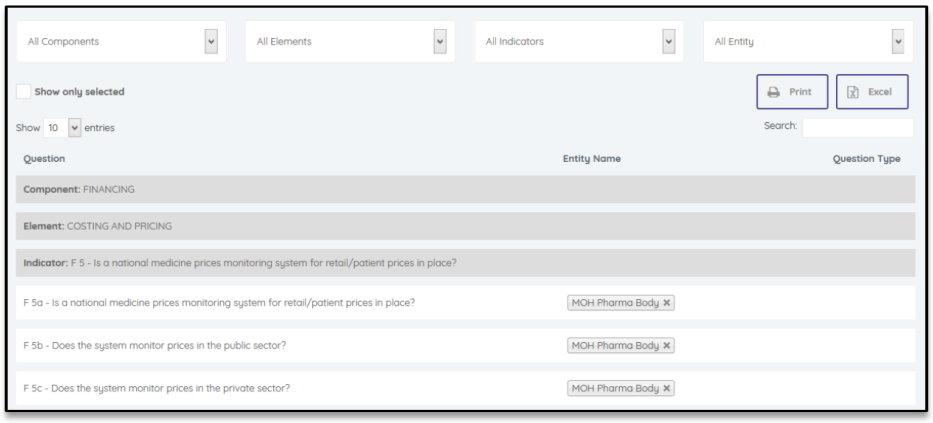


Figure-13

Database object updated: **t_question_entity_map**

Admin Menu > Indicator Frequency Entry:

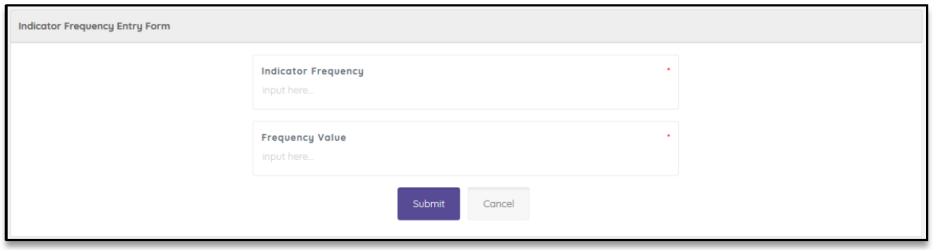


Figure-14

Database object updated: **t_frequency**

Admin Menu > Indicator Attribute Entry:

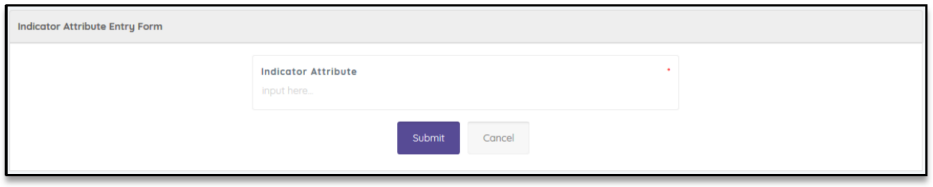


Figure-15

Database object updated: **t_indicator_attribute**

Admin Menu > Designation Entry:

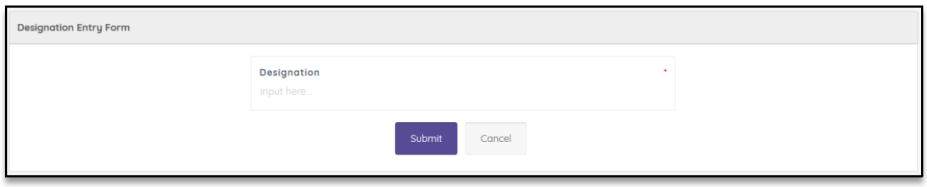


Figure-16

Database object updated: **t_designation**

Admin Menu > WHO Region Entry:

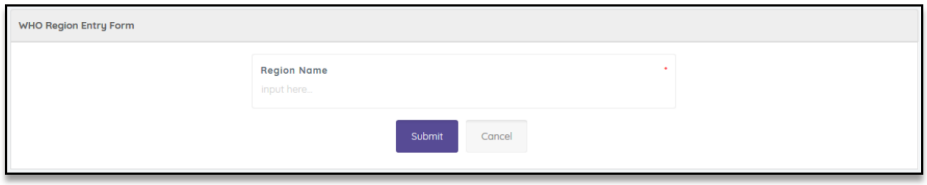


Figure-17

Database object updated: **t_whoregion**

Admin Menu > Value Set Entry:

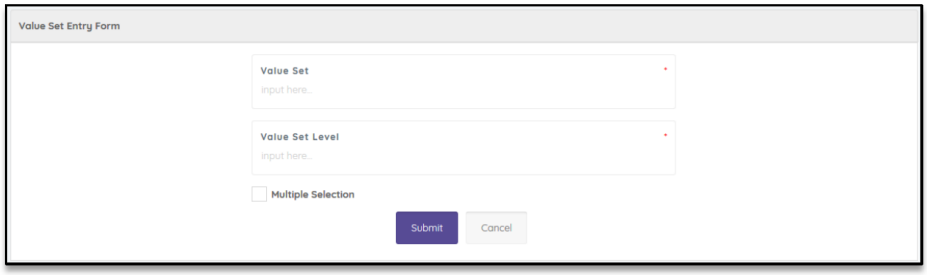


Figure-18

Database object updated: **t_value_set**

Admin Menu > Component Entry:

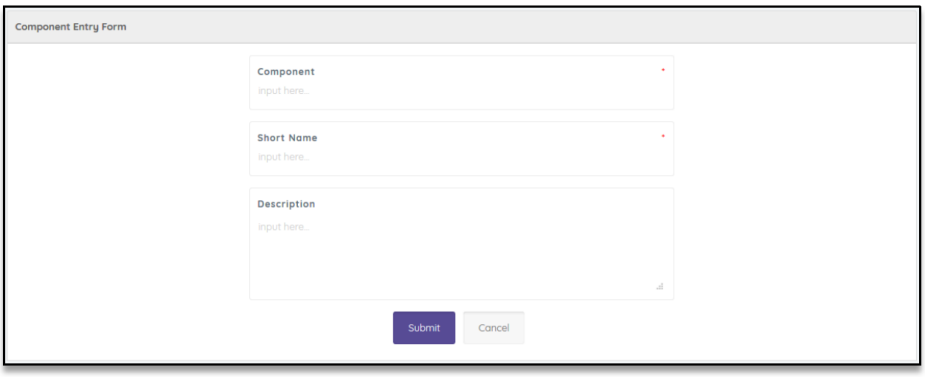


Figure-19

Database object updated: **t_component**

Admin Menu > Assessment Question Entry:

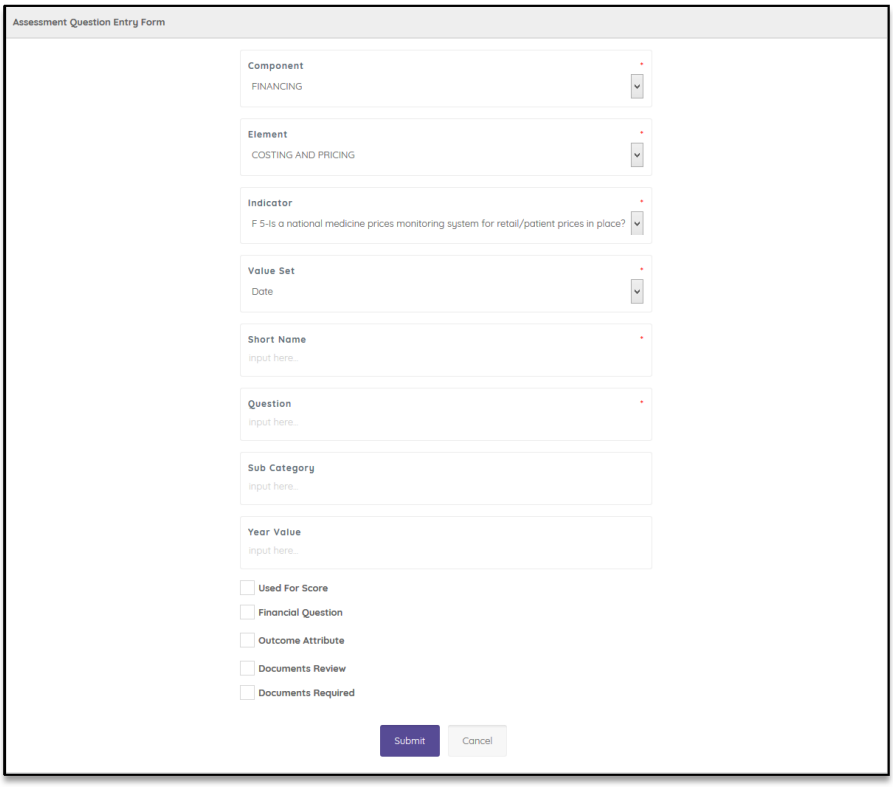


Figure-20

Database object updated: **t_assessment_question**

Admin Menu > Indicator outcome Entry:

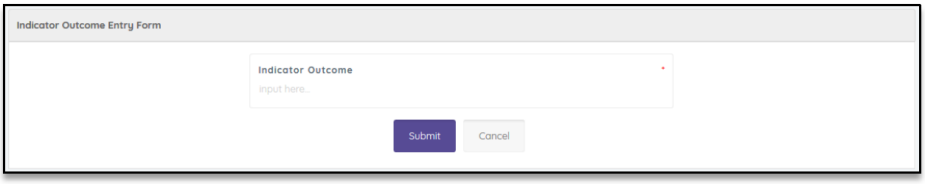


Figure-21

Database object updated: **t_indicator_outcome**

Admin Menu > Region Entry:

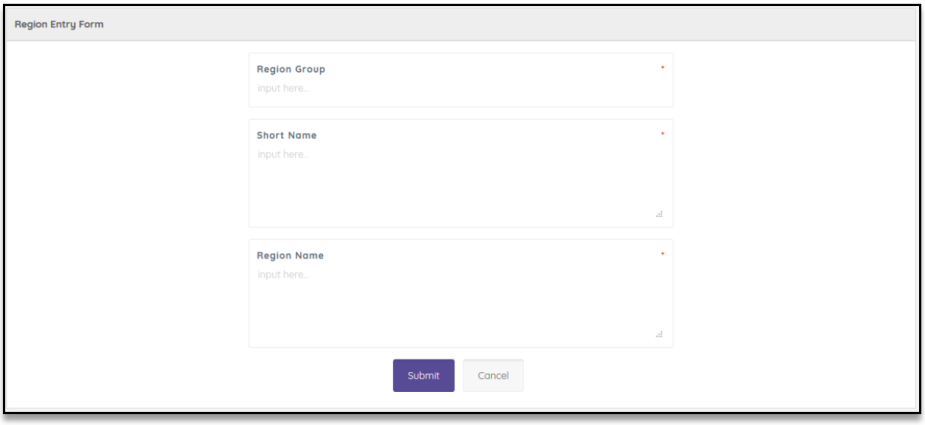


Figure-22

Database object updated: **t_region**

Admin Menu > Customer onboarding Entry:

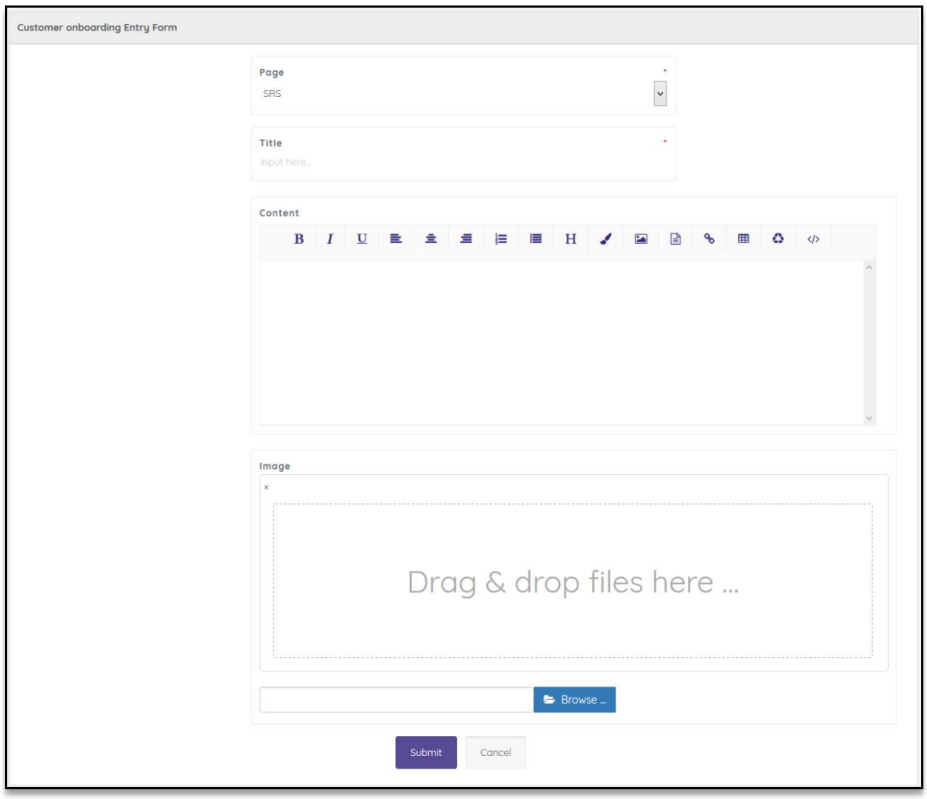
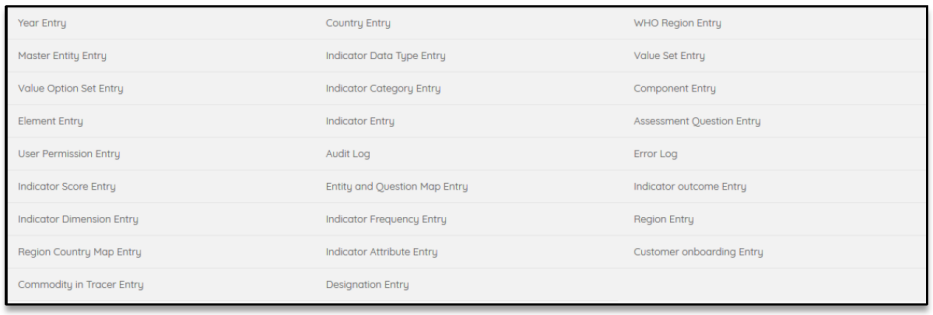


Figure-23

Database object updated: **t_onboarding**

Chapter-4: Data Entry into Basic Forms Admin

The Admin menu will allow user to manage metadata or reference tables. The Admin menu has following sub-menus:



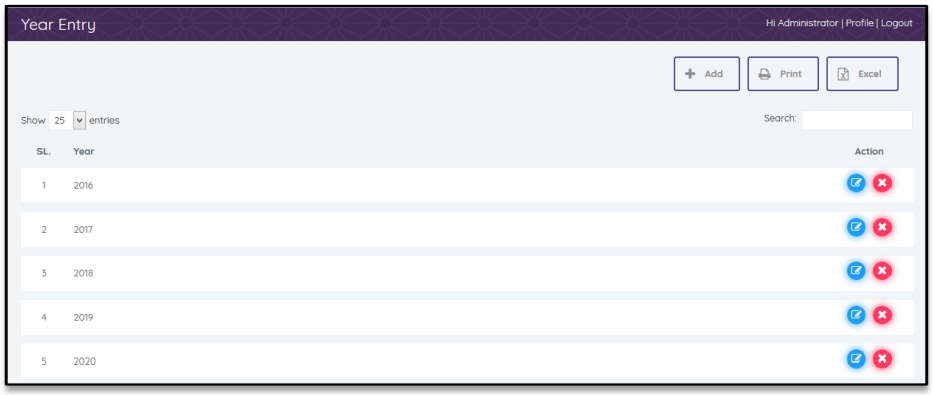
Year Entry	Country Entry	WHO Region Entry
Master Entity Entry	Indicator Data Type Entry	Value Set Entry
Value Option Set Entry	Indicator Category Entry	Component Entry
Element Entry	Indicator Entry	Assessment Question Entry
User Permission Entry	Audit Log	Error Log
Indicator Score Entry	Entity and Question Map Entry	Indicator outcome Entry
Indicator Dimension Entry	Indicator Frequency Entry	Region Entry
Region Country Map Entry	Indicator Attribute Entry	Customer onboarding Entry
Commodity in Tracer Entry	Designation Entry	

4.1. Year Entry

Go to **Admin > Year Entry** from **Admin** menu. This form is used to create, edit and delete Years.

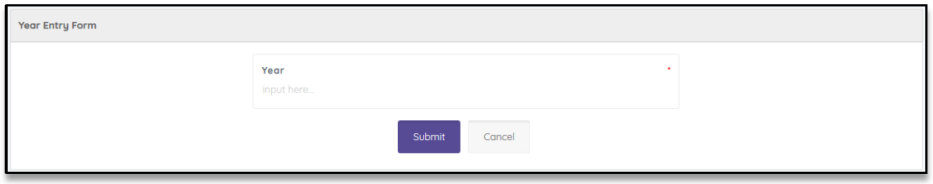
4.1.1. Year List

Select **Admin > Year Entry** to open Year entry page with list of all the Years entered as shown below:



4.1.2. Add New Year

Click **'+ Add'** button at the Top right corner of the above page to add a New Year. The year Entry form is shown below:

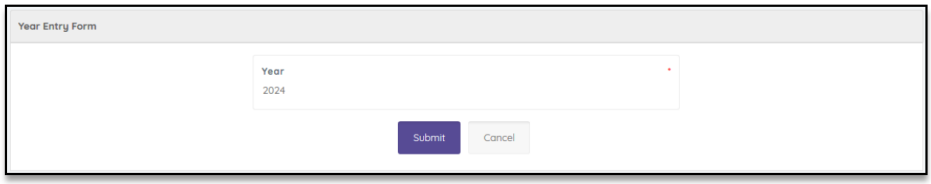


- Year: Enter a maximum 4 digit year name (i.e., '2024'). It is a mandatory field.

After filling the field, click **"Submit"** button to save.

4.1.3. Edit/Delete Year Data

- To edit a Year data 4 digit (i.e., '2024'), User need to click "**Edit**" button from the Action Buttons beside that record and the Pop-up "Do you really want to edit this record?" Message Box will come to confirm the edit and the following form will arrive as follows:



Modify the Year as required and click **"submit"** button to update the record.

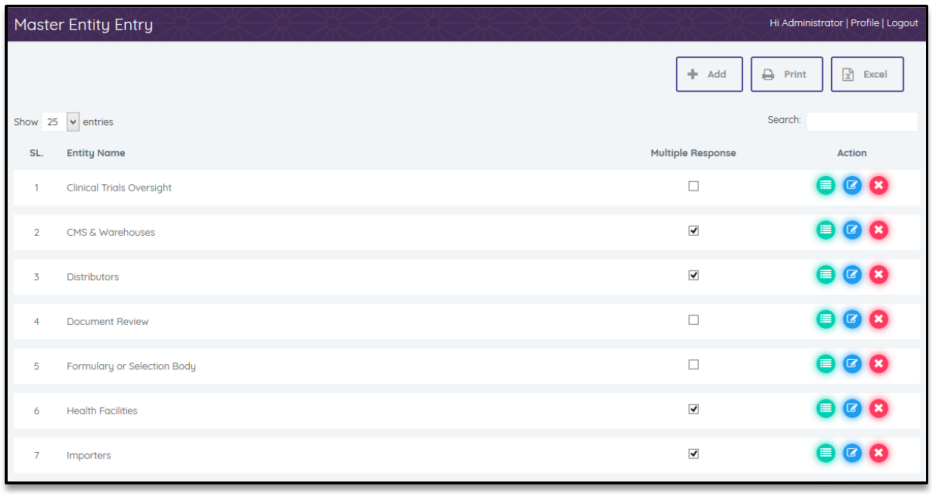
- To delete a Year data (i.e., '2024), User need to click "**Delete**" button from the Action Buttons beside that record and the Pop-up "Do you really want to delete this record?" Message Box will come to confirm the delete. If there is any reference data the data will not be deleted.

4.2. Master Entity Entry

Go to **Admin > Master Entity Entry** from **Admin** menu. This form is used to create, edit and delete Master Entity.

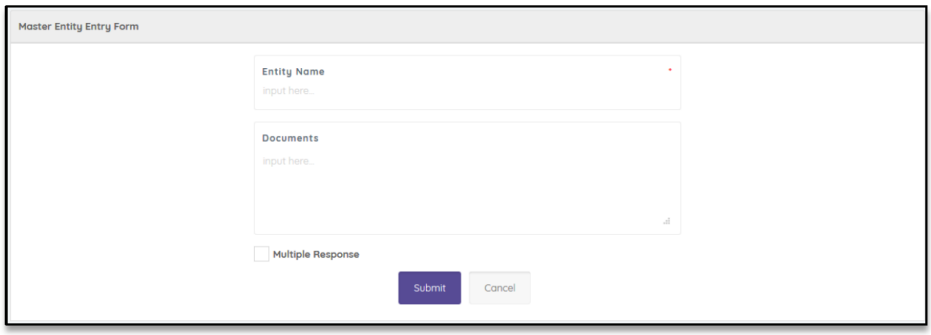
4.2.1. Master Entity List

Select **Admin > Master Entity Entry** to open Master Entity entry page with list of all the Master Entity entered as shown below:



4.2.2. Add New Master Entity

Click **'+ Add'** button at the Top right corner of the above page to add a New Master Entity. The Master Entity Entry form is shown below:



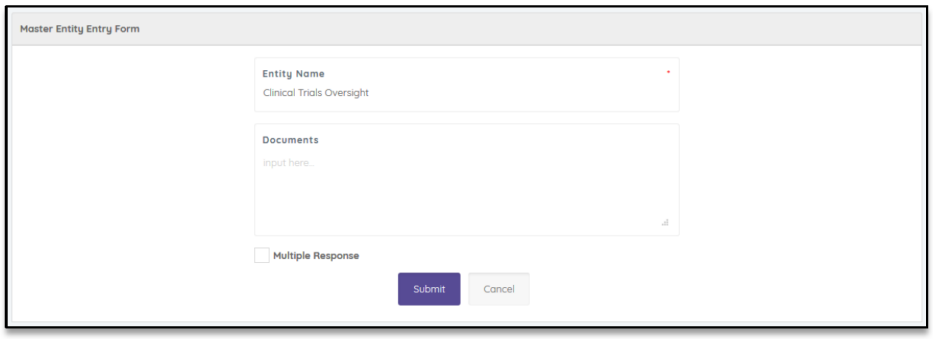
- Entity Name: Enter a maximum 100 characters Entity Name (i.e., 'Clinical Trials Oversight'). It is a mandatory field.
- Documents: Enter a maximum 500 characters Documents. It is not a mandatory field.

- Multiple Response: Check the box for Multiple Response.

After filling the fields, click **"Submit"** button to save.

4.2.3. Edit/Delete Master Entity

- To edit a Master Entity data (i.e., 'Clinical Trials Oversight'), User need to click "**Edit**" button from the Action Buttons beside that record and the Pop-up "Do you really want to edit this record?" Message Box will come to confirm the edit and the following form will arrive as follows:



Modify the Master Entity data as required and click **"Submit"** button to update the record.

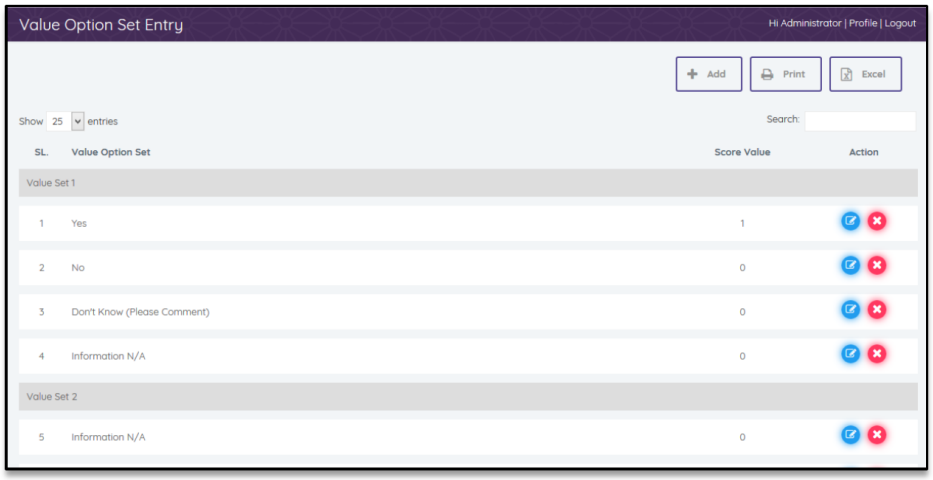
- To delete a Master Entity data (i.e., 'Clinical Trials Oversight'), User need to click "**Delete**" button from the Action Buttons beside that record and the Pop-up "Do you really want to delete this record?" Message Box will come to confirm the delete. If there is any reference data the data will not be deleted.

4.3. Value Option Set Entry

Go to **Admin > Value Option Set Entry** from **Admin** menu. This form is used to create, edit and delete Value Option Set.

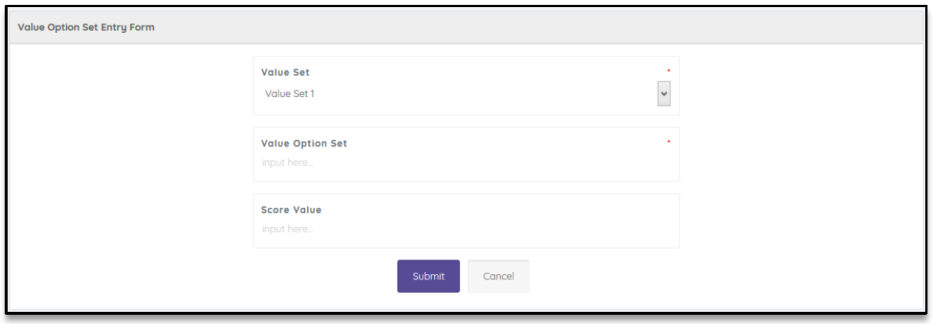
4.3.1. Value Option Set List

Select **Admin > Value Option Set Entry** to open Value Option Set entry page with list of all the Value Option Set entered as shown below:



4.3.2. Add New Value Option Set

Click **'+ Add'** button at the Top right corner of the above page to add a New Value Option Set. The Value Option Set Entry form is shown below:

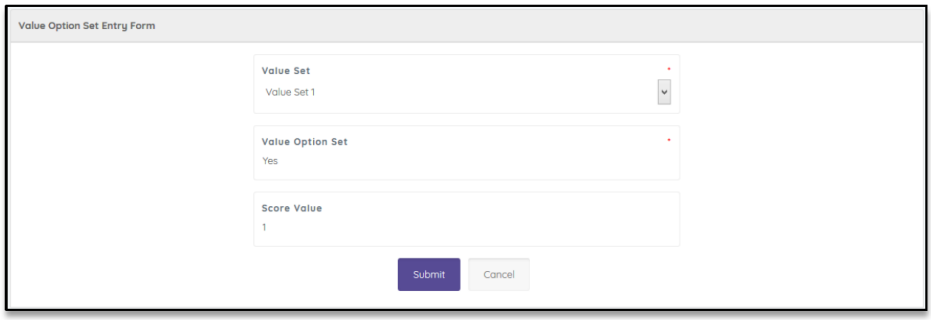


- Value Set: Select Value Set from the list (i.e., 'Value Set 1'). It is a mandatory field.
- Value Option Set: Enter a maximum 100 characters Value Option Set (i.e., 'Yes'). It is a mandatory field.
- Score Value: Enter numeric value into Score Value field (i.e., '1). It is not a mandatory field.

After filling the fields, click **"Submit"** button to save.

4.3.3. Edit/Delete Value Option Set

- To edit a Value Option Set data (i.e., 'Yes'), User need to click "**Edit**" button from the Action Buttons beside that record and the Pop-up "Do you really want to edit this record?" Message Box will come to confirm the edit and the following form will arrive as follows:



Modify the Value Option Set data as required and click **"Submit"** button to update the record.

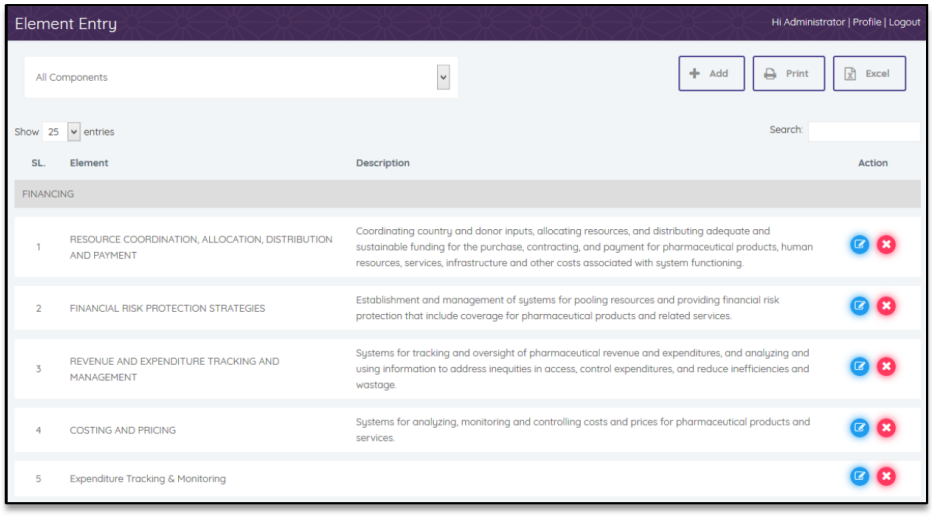
- To delete a Value Option Set data (i.e., 'Yes'), User need to click "**Delete**" button from the Action Buttons beside that record and the Pop-up "Do you really want to delete this record?" Message Box will come to confirm the delete. If there is any reference data the data will not be deleted.

4.4. Element Entry

Go to **Admin > Element Entry** from **Admin** menu. This form is used to create, edit and delete Element.

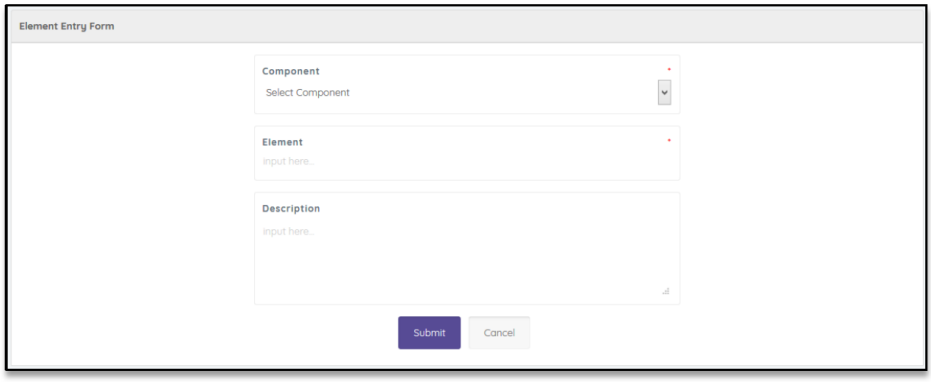
4.4.1. Element List

Select **Admin > Element Entry** to open Element entry page with list of all the Element entered as shown below:



4.4.2. Add New Element

Click **'+ Add'** button at the Top right corner of the above page to add a New Element. The Element Entry form is shown below:

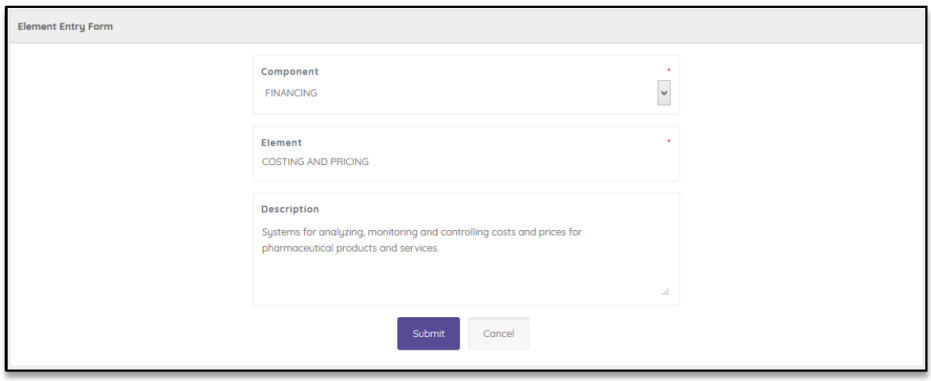


- Component: Select Component from the list (i.e., 'FINANCING). It is a mandatory field.
- Element: Enter a maximum 100 characters Element (i.e., 'COSTING AND PRICING'). It is a mandatory field.
- Description: Enter a maximum 500 characters Element (i.e., 'Systems for analyzing, monitoring and controlling costs and prices for pharmaceutical products and services.'). It is not a mandatory field.

After filling the fields, click **"Submit"** button to save.

4.4.3. Edit/Delete Element

- To edit an Element data (i.e., 'COSTING AND PRICING'), User need to click "**Edit**" button from the Action Buttons beside that record and the Pop-up "Do you really want to edit this record?" Message Box will come to confirm the edit and the following form will arrive as follows:



Modify the Element data as required and click **"Submit"** button to update the record.

- To delete an Element data (i.e., 'COSTING AND PRICING'), User need to click "**Delete**" button from the Action Buttons beside that record and the Pop-up "Do you really want to delete this

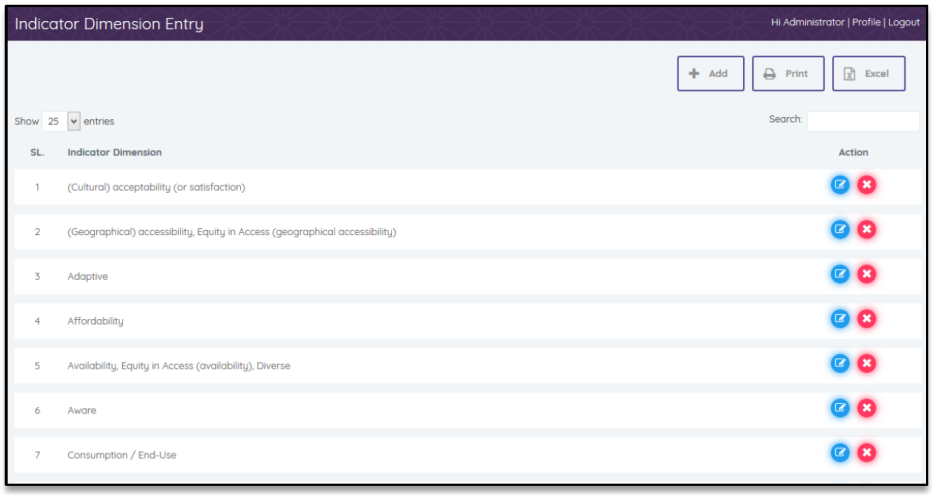
record?" Message Box will come to confirm the delete. If there is any reference data the data will not be deleted.

4.5. Indicator Dimension Entry

Go to **Admin > Indicator Dimension Entry** from **Admin** menu. This form is used to create, edit and delete Indicator Dimension.

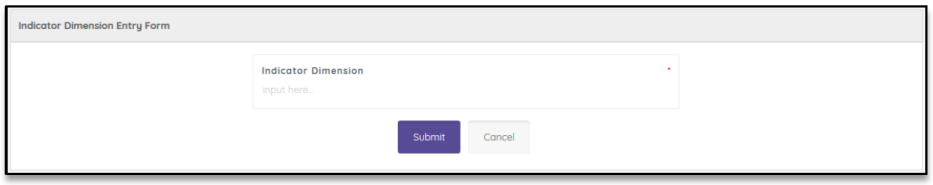
4.5.1. Indicator Dimension List

Select **Admin > Indicator Dimension Entry** to open Indicator Dimension entry page with list of all the Indicator Dimension entered as shown below:



4.5.2. Add New Indicator Dimension

Click **'+ Add'** button at the Top right corner of the above page to add a New Indicator Dimension. The Indicator Dimension Entry form is shown below:

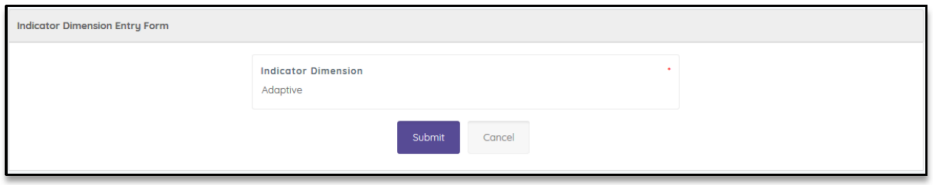


- Indicator Dimension: Enter a maximum 100 characters Indicator Dimension (i.e., 'Adaptive'). It is a mandatory field.

After filling the fields, click **"Submit"** button to save.

4.5.3. Edit/Delete Indicator Dimension

- To edit an Indicator Dimension data (i.e., 'Adaptive'), User need to click "**Edit**" button from the Action Buttons beside that record and the Pop-up "Do you really want to edit this record?" Message Box will come to confirm the edit and the following form will arrive as follows:



Modify the Indicator Dimension data as required and click **"Submit"** button to update the record.

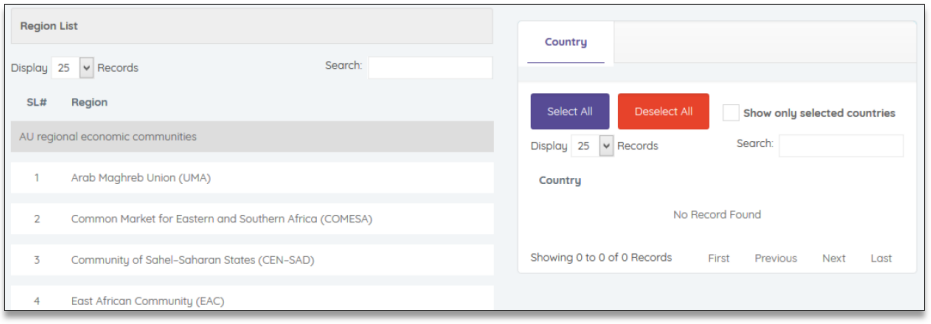
- To delete an Indicator Dimension data (i.e., 'Adaptive'), User need to click "**Delete**" button from the Action Buttons beside that record and the Pop-up "Do you really want to delete this record?" Message Box will come to confirm the delete. If there is any reference data the data will not be deleted.

4.6. Region Country Map Entry

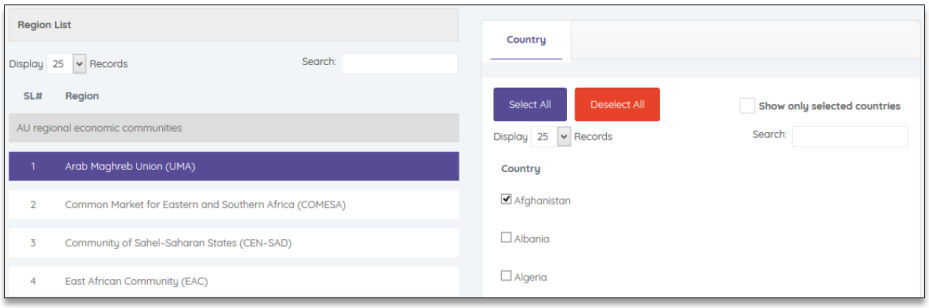
- Go to **Admin > Region Country Map Entry** from **Admin** menu. This form is used to mapping Region with Country.

4.6.1. Region Country Map Entry List

- Select **Admin > Region Country Map Entry** to go into inside.



- Select a Region from the left side panel then the following Country list will be populated -



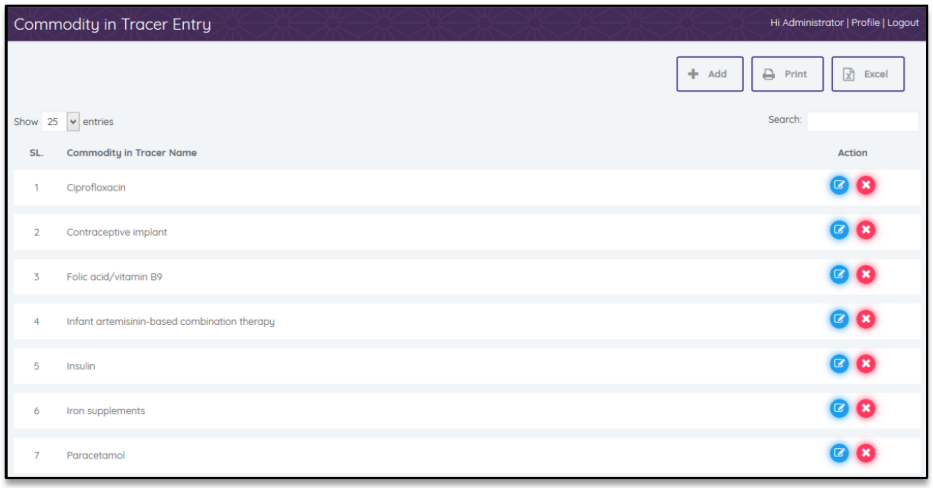
- Check the "Country" from right side country tab which is assign with selected region. To delete the data simply uncheck the box beside country name.

4.7. Commodity in Tracer Entry

Go to **Admin > Commodity in Tracer Entry** from **Admin** menu. This form is used to create, edit and delete Commodity in Tracer.

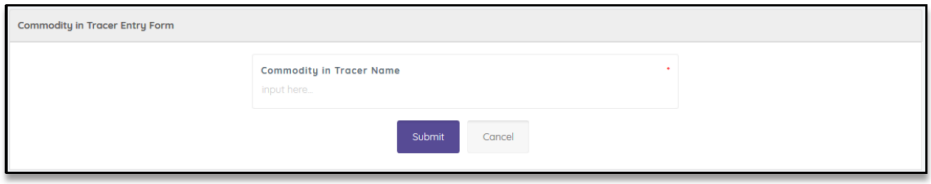
4.7.1. Commodity in Tracer List

Select **Admin > Commodity in Tracer Entry** to open Commodity in Tracer entry page with list of all the Commodity in Tracer entered as shown below:



4.7.2. Add New Commodity in Tracer

Click **'+ Add'** button at the Top right corner of the above page to add a New Commodity in Tracer. The Commodity in Tracer Entry form is shown below:

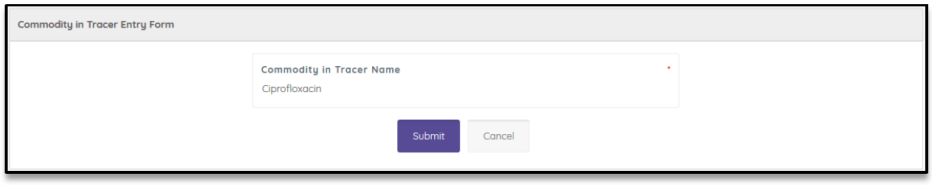


- Commodity in Tracer Name: Enter a maximum 100 characters Commodity in Tracer Name (i.e., 'Ciprofloxacin'). It is a mandatory field.

After filling the fields, click **"Submit"** button to save.

4.7.3. Edit/Delete Commodity in Tracer

- To edit a Commodity in Tracer data (i.e., 'Ciprofloxacin'), User need to click "**Edit**" button from the Action Buttons beside that record and the Pop-up "Do you really want to edit this record?" Message Box will come to confirm the edit and the following form will arrive as follows:



  Modify the Indicator Dimension data as required and click **"Submit"** button to update the record.

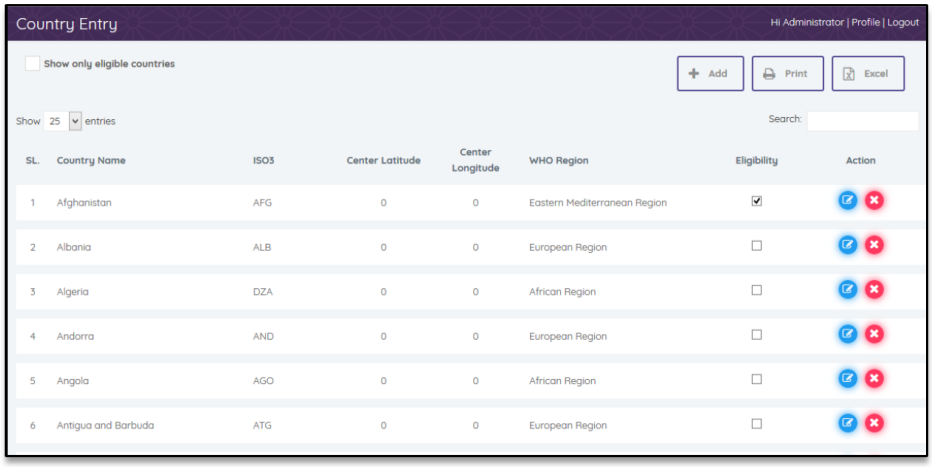
- To delete a Commodity in Tracer data (i.e., 'Ciprofloxacin'), User need to click "**Delete**" button from the Action Buttons beside that record and the Pop-up "Do you really want to delete this record?" Message Box will come to confirm the delete. If there is any reference data the data will not be deleted.

4.8. Country Entry

Go to **Admin > Country Entry** from **Admin** menu. This form is used to create, edit and delete Country.

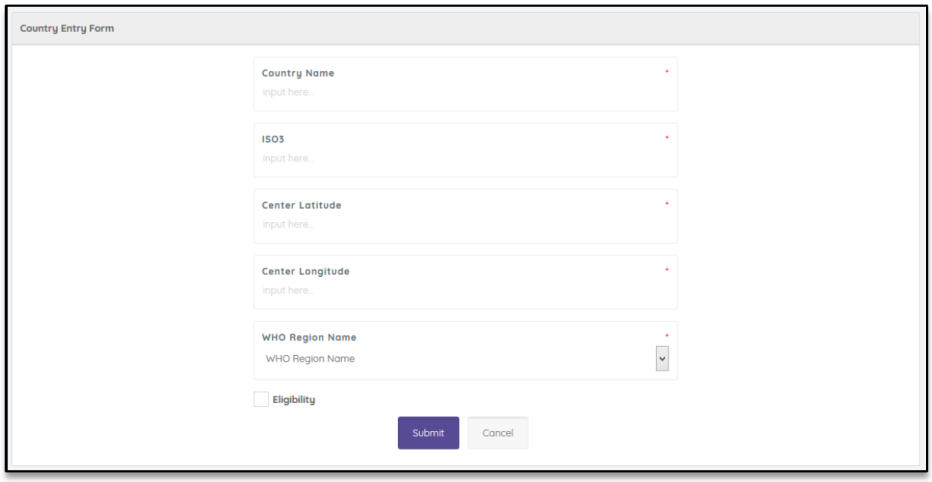
4.8.1. Country List

Select **Admin > Country Entry** to open Country entry page with list of all the Country entered as shown below:



4.8.2. Add New Country

Click **'+ Add'** button at the Top right corner of the above page to add a New Country. The Country Entry form is shown below:



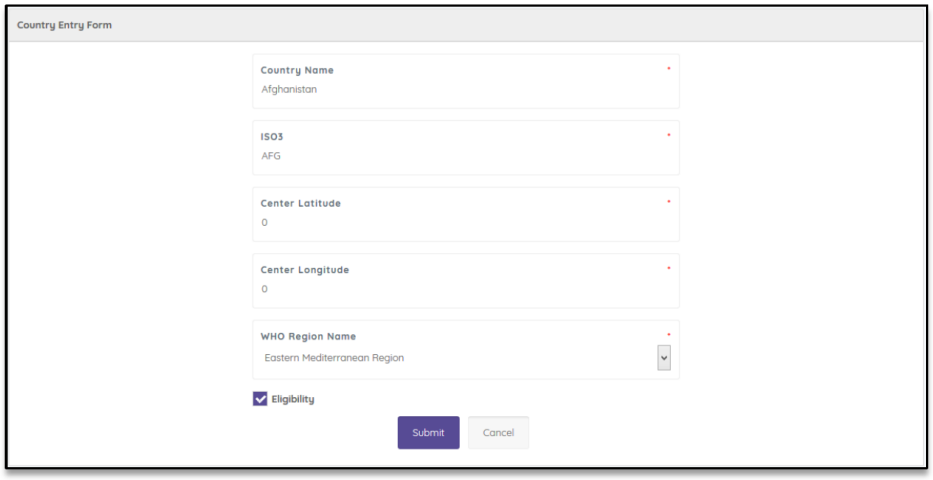
- Country Name: Enter a maximum 100 characters Country Name (i.e., 'Afghanistan'). It is a mandatory field.
- ISO3: Enter ISO3 code (i.e., 'AFG'). It is a mandatory field.

- Centre Latitude: Country's center coordinate (to be used during zoom in and out). It is a mandatory field.
- Centre Longitude: Country's center coordinate (to be used during zoom in and out). It is a mandatory field.
- WHO Region Name: Select WHO Region name from the list (i.e., 'Eastern Mediterranean Region'). It is a mandatory field.
- Eligibility: Check the box if country has eligibility.

After filling the fields, click **"Submit"** button to save.

4.8.3. Edit/Delete Country

- To edit a Country data (i.e., 'Afghanistan'), User need to click "**Edit**" button from the Action Buttons beside that record and the Pop-up "Do you really want to edit this record?" Message Box will come to confirm the edit and the following form will arrive as follows:



Modify the Country data as required and click **"Submit"** button to update the record.

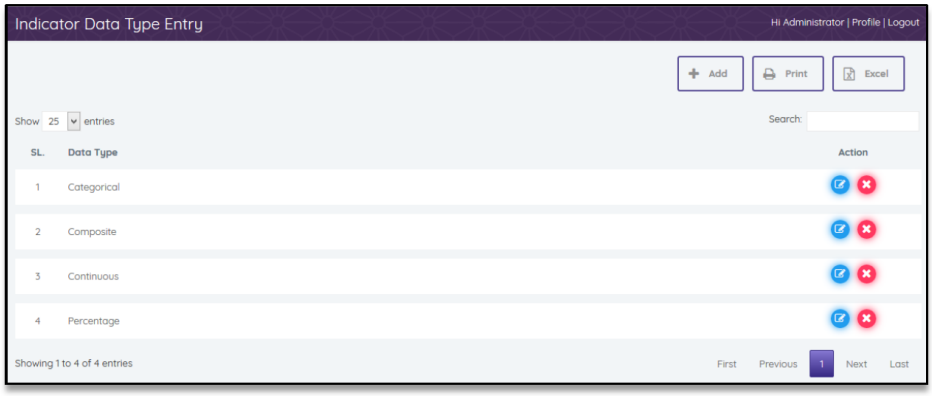
- To delete a Country data (i.e., 'Afghanistan'), User need to click "**Delete**" button from the Action Buttons beside that record and the Pop-up "Do you really want to delete this record?" Message Box will come to confirm the delete. If there is any reference data the data will not be deleted.

4.9. Indicator Data Type Entry

Go to **Admin > Indicator Data Type Entry** from **Admin** menu. This form is used to create, edit and delete Indicator Data Type.

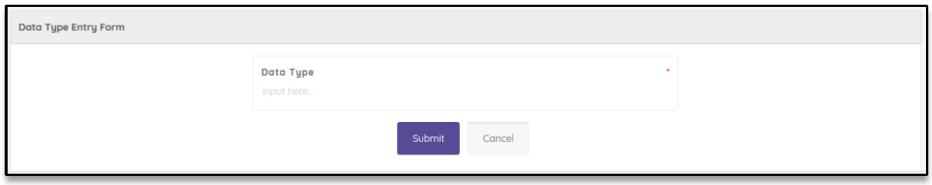
4.9.1. Indicator Data Type List

Select **Admin > Indicator Data Type Entry** to open Indicator Data Type entry page with list of all the Indicator Data Type entered as shown below:



4.9.2. Add New Indicator Data Type

Click **'+ Add'** button at the Top right corner of the above page to add a New Indicator Data Type. The Indicator Data Type Entry form is shown below:

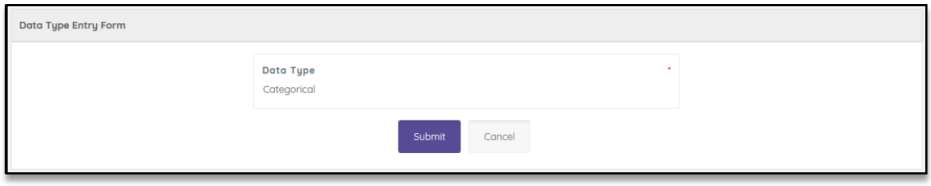


- Data Type: Enter a maximum 100 characters Data Type (i.e., 'Categorical'). It is a mandatory field.

After filling the fields, click **"Submit"** button to save.

4.9.3. Edit/Delete Indicator Data Type

- To edit an Indicator Data Type data (i.e., 'Categorical'), User need to click "**Edit**" button from the Action Buttons beside that record and the Pop-up "Do you really want to edit this record?" Message Box will come to confirm the edit and the following form will arrive as follows:



Modify the Indicator Data Type data as required and click **"Submit"** button to update the record.

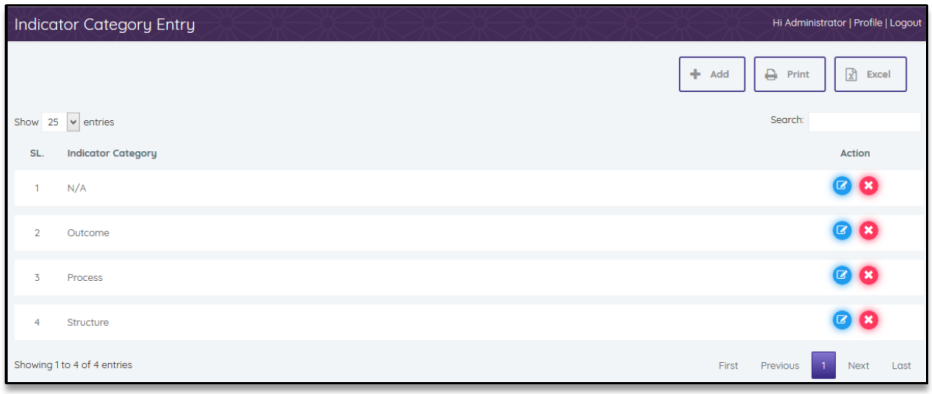
- To delete an Indicator Data Type data (i.e., 'Categorical'), User need to click "**Delete**" button from the Action Buttons beside that record and the Pop-up "Do you really want to delete this record?" Message Box will come to confirm the delete. If there is any reference data the data will not be deleted.

4.10. Indicator Category Entry

Go to **Admin > Indicator Category Entry** from **Admin** menu. This form is used to create, edit and delete Indicator Category.

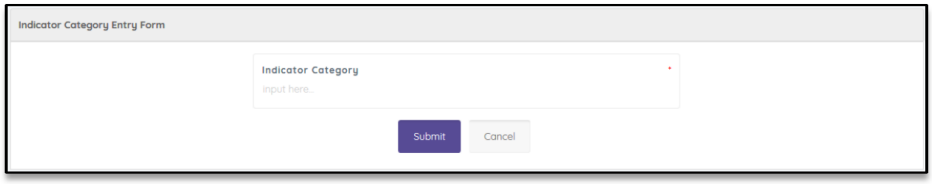
4.10.1. Indicator Category List

Select **Admin > Indicator Category Entry** to open Indicator Category entry page with list of all the Indicator Category entered as shown below:



4.10.2. Add New Indicator Category

Click **'+ Add'** button at the Top right corner of the above page to add a New Indicator Category. The Indicator Category Entry form is shown below:

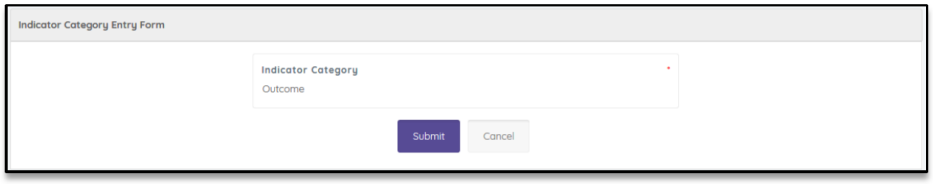


- Indicator Category: Enter a maximum 100 characters Indicator Category (i.e., 'Outcome'). It is a mandatory field.

After filling the fields, click **"Submit"** button to save.

4.10.3. Edit/Delete Indicator Category

- To edit an Indicator Category data (i.e., 'Outcome'), User need to click "**Edit**" button from the Action Buttons beside that record and the Pop-up "Do you really want to edit this record?" Message Box will come to confirm the edit and the following form will arrive as follows:



Modify the Indicator Category data as required and click **"Submit"** button to update the record.

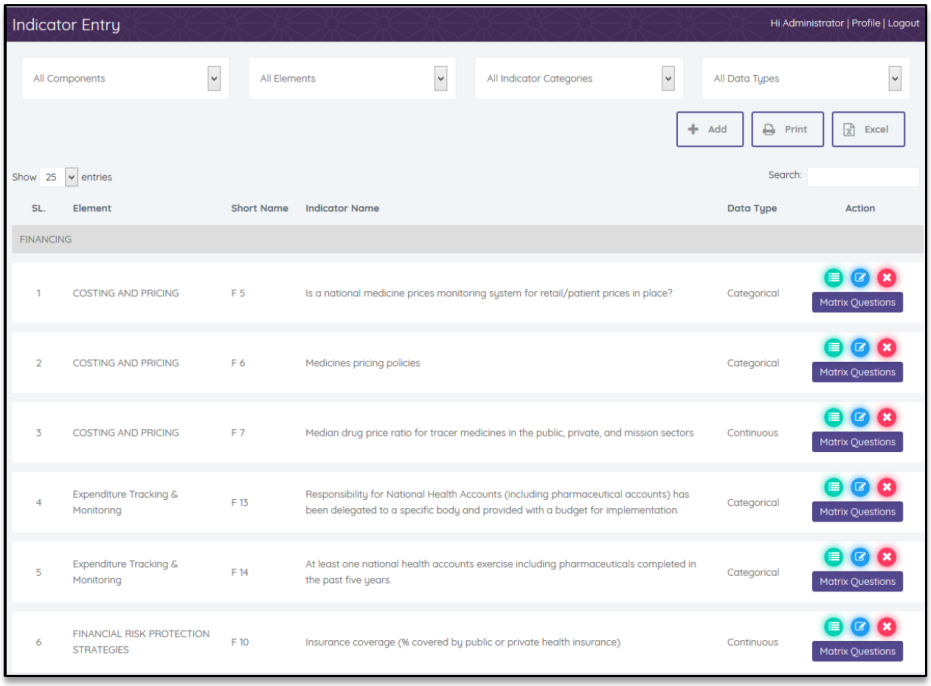
- To delete an Indicator Category data (i.e., 'Outcome'), User need to click "**Delete**" button from the Action Buttons beside that record and the Pop-up "Do you really want to delete this record?" Message Box will come to confirm the delete. If there is any reference data the data will not be deleted.

4.11. Indicator Entry

Go to **Admin > Indicator Entry** from **Admin** menu. This form is used to create, edit and delete Indicator.

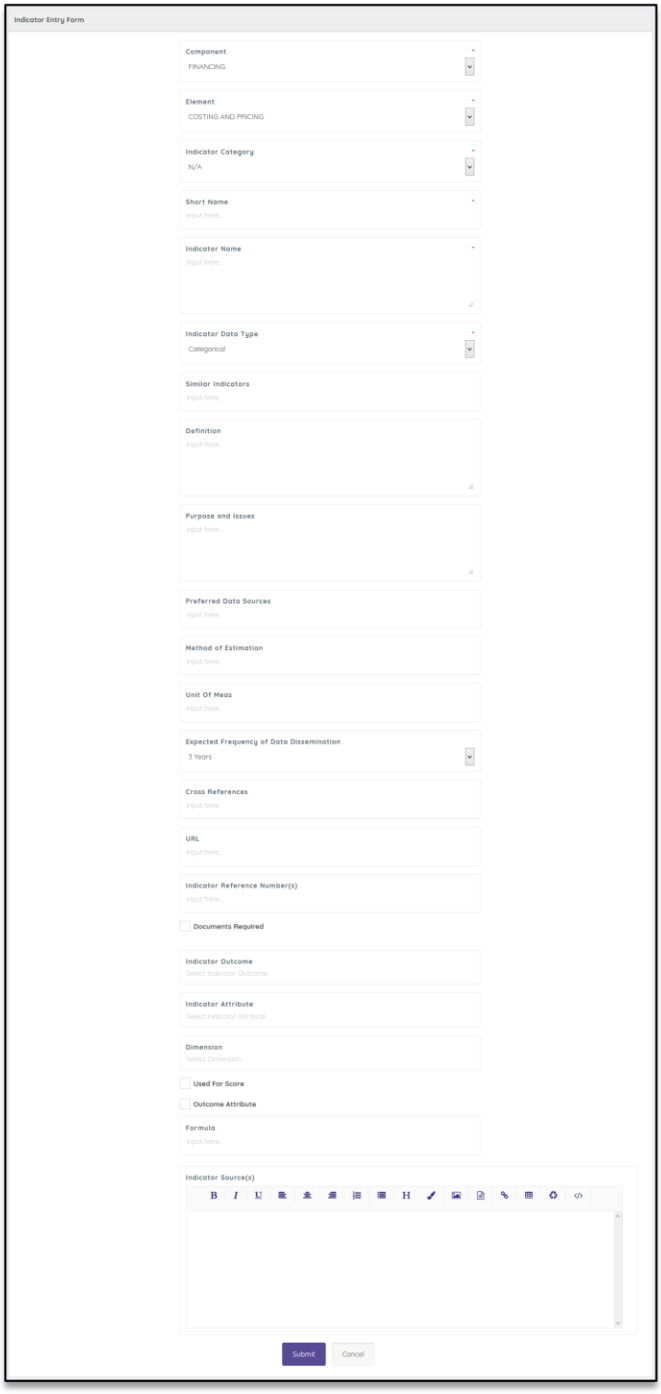
4.11.1. Indicator List

Select **Admin > Indicator Entry** to open Indicator entry page with list of all the Indicator entered as shown below:



4.11.2. Add New Indicator

Click **'+ Add'** button at the Top right corner of the above page to add a New Indicator. The Indicator Entry form is shown below:



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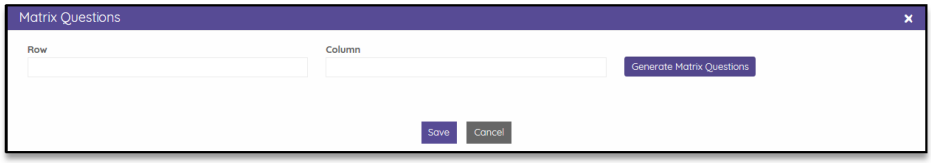
- Component *: Select a component from the list (i.e., 'FINANCING'). It is a mandatory field.
- Element *: Select an element from the list (i.e., 'COSTING AND PRICING'). It is a mandatory field.
- Indicator Category *: Select an Indicator Category (i.e., 'Structure'). It is a mandatory filed.
- Short Name *: Enter a maximum 50 characters Short Name (i.e., 'F 5'). It is a mandatory field.
- Indicator Name *: Enter a maximum 255 characters Indicator Name (i.e., 'is a national medicine prices monitoring system for retail/patient prices in place?'). It is a mandatory field.
- Indicator Data Type *: Select an Indicator Data Type from the list (i.e., 'Categorical'). It is a mandatory field.
- Similar Indicators: Enter a maximum 255 characters Similar Indicators. It is not a mandatory field.
- Definition: Enter Similar Indicators. It is not a mandatory field.
- Purpose and Issues: Enter a maximum 1000 characters Purpose and Issues. It is not a mandatory field.
- Preferred Data Sources: Enter a maximum 1000 characters Preferred Data Sources. It is not a mandatory field.
- Method of Estimation: Enter a maximum 1000 characters Method of Estimation. It is not a mandatory field.
- Unit of Meas: Enter a maximum 50 characters Unit of Meas. It is not a mandatory field.
- Expected Frequency of Data Dissemination: Select an "Expected Frequency of Data Dissemination" from the list. It is not a mandatory field.
- Cross References: Enter a maximum 1000 characters Cross References. It is not a mandatory field.
- URL: Enter URL. It is not a mandatory field.
- Indicator Reference Number(s): Enter Indicator Reference Number(s). It is not a mandatory field.
- Documents Required: Check if Documents Required.
- Documents: If Documents Required Checked then this input field will be shown. Then Enter Documents.
- Indicator Outcome: Select an "Indicator Outcome" from the list. It is not a mandatory field.
- Indicator Attribute: Select an "Indicator Attribute" from the list. It is not a mandatory field.
- Dimension: Select a "Dimension" from the list. It is not a mandatory field.
- Used For Score: Checked if this is used for score.
- Outcome Attribute: Checked if this is Outcome Attribute.
- Formula: Enter a maximum 255 characters Formula. It is not a mandatory field.
- Indicator Source(s): Enter a maximum 1000 characters Indicator Source(s). It is not a mandatory field.

After filling the fields, click **"Submit"** button to save.

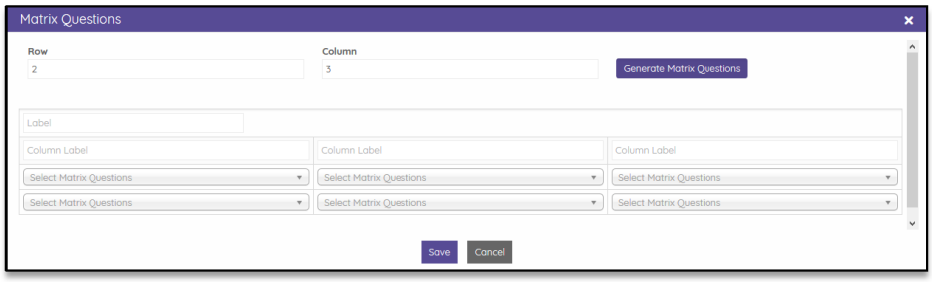
4.11.3. Add Matrix Questions

- Click "**Matrix Questions**" button from the Action Buttons beside that record. The Matrix Questions window will appear:



- Row: Enter number of row.
- Column: Enter number of column.

Then click into **"Generate Matrix Questions"** button. After that appear following fields-

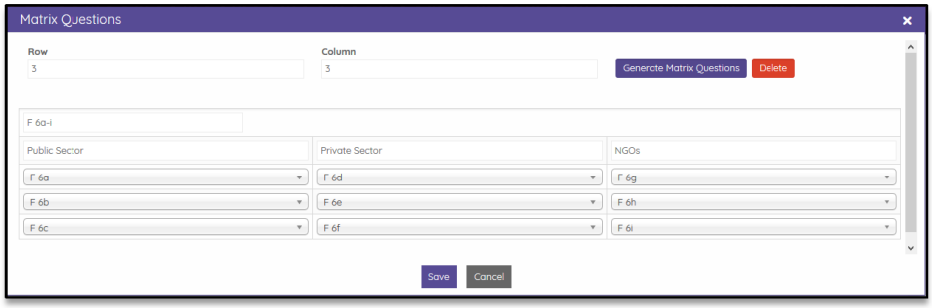


- Label: Enter Matrix questions label.
- Column Label: Enter column label for each column.
- Select Matrix Questions from the list.

After filling the fields, click **"Save"** button.

4.11.4. Edit/Delete Matrix Questions

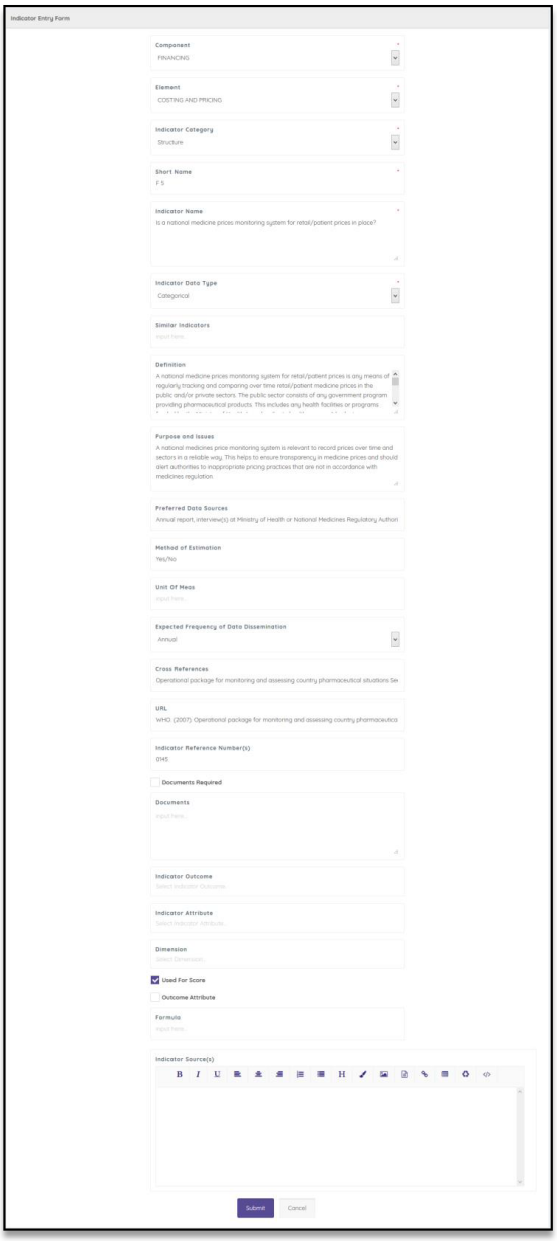
- To edit a Matrix Question data, User need to click "**Matrix Question**" button from the Action Buttons beside that record and the following form will arrive as follows:



Modify the Matrix Question data as required and click **"Save"** button to update the record. To delete a Matrix Question data, User need to click "**Delete**" button from the above Matrix Questions form.

4.11.5. Edit/Delete Indicator

- To edit an Indicator data (i.e., 'is a national medicine prices monitoring system for retail/patient prices in place?'), User need to click "**Edit**" button from the Action Buttons beside that record and the Pop-up "Do you really want to edit this record?" Message Box will come to confirm the edit and the following form will arrive as follows:



Modify the Indicator data as required and click **"Submit"** button to update the record.

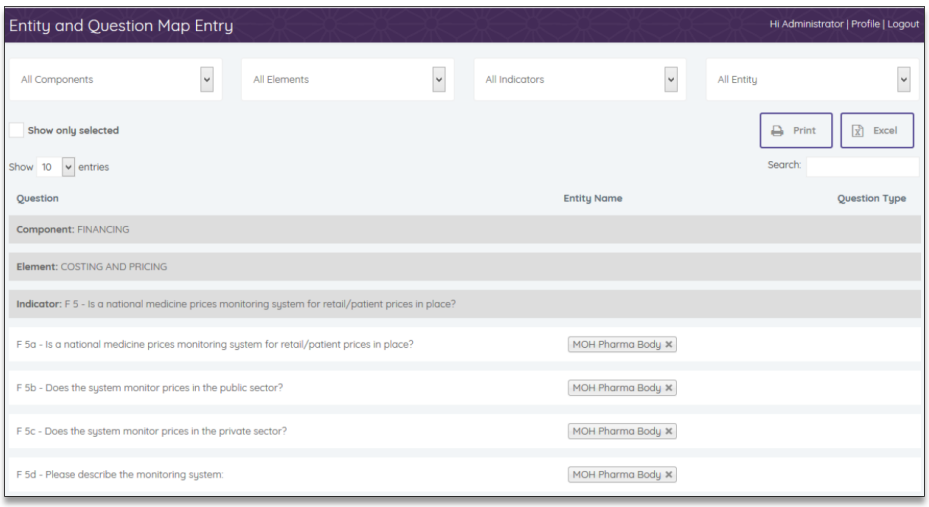
- To delete an Indicator data (i.e., 'is a national medicine prices monitoring system for retail/patient prices in place?'), User need to click "**Delete**" button from the Action Buttons beside that record and the Pop-up "Do you really want to delete this record?" Message Box will come to confirm the delete. If there is any reference data the data will not be deleted.

4.12. Entity and Question Map Entry

Go to **Admin > Entity and Question Map Entry** from **Admin** menu. This form is used to mapping a question to entity.

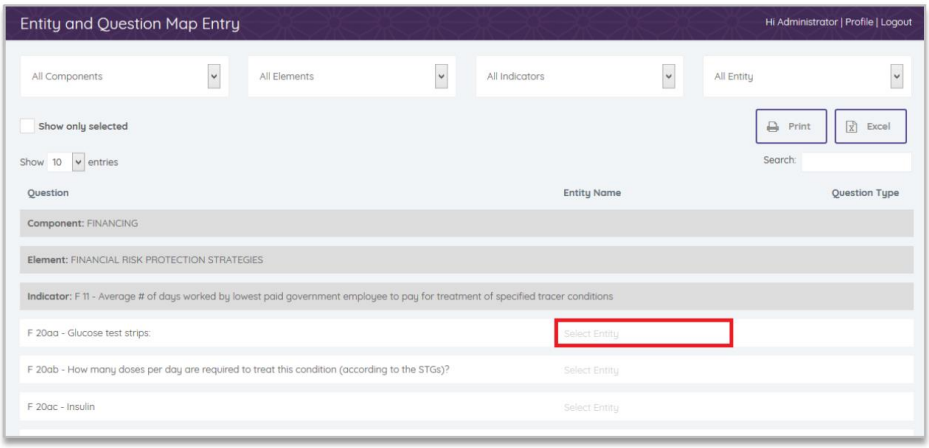
4.12.1. Entity and Question Map List

Select **Admin > Entity and Question Map Entry** to open Admin > Entity and Question Map entry page as shown below:

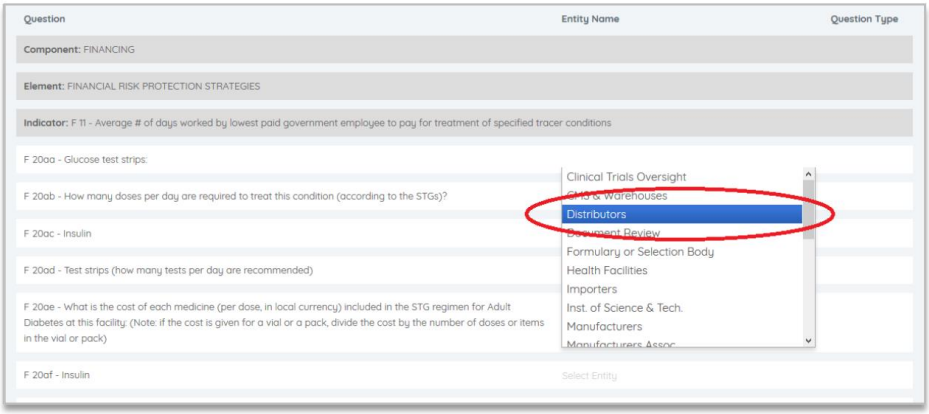


4.12.2. Add New Entity and Question Map

Select a Question from the Left side (i.e., 'F 20aa - Glucose test strips) then click into "Select Entity" filed:

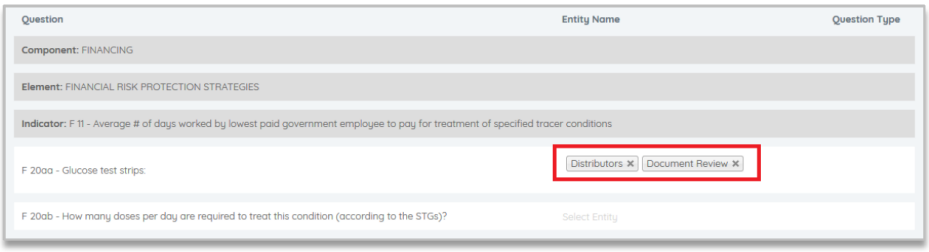


- After click into "Select Entity" filed then following Entity list will be populated-



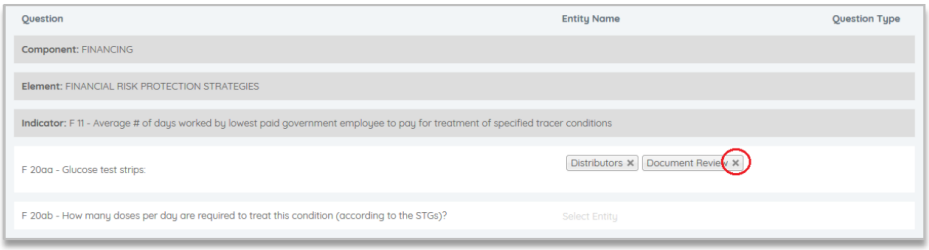
- Now select entity from the list. It will look like the below screen-

- User can select more entity from the list this way-

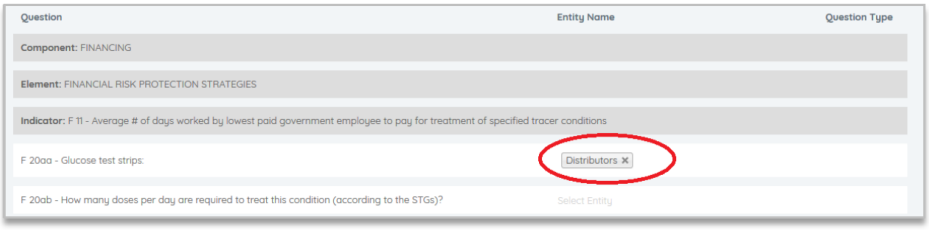


4.12.3. Delete Entity and Question Map Entry

To delete a entity from Entity and Question Map list select question at the Left side (i.e., 'F 20aa - Glucose test strips) then click into (**X**) delete button from entity list. Look like following screen-



- After pressing (**X**) delete button, data will be deleted and entity and It will look like the below screen-

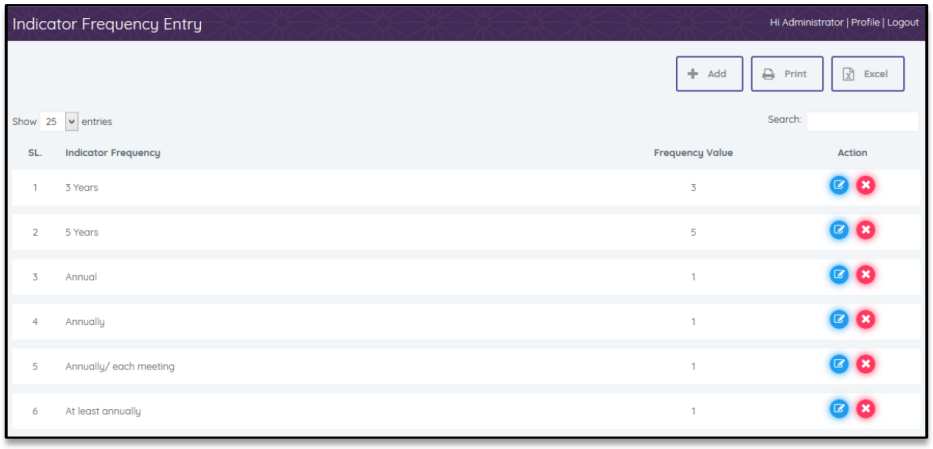


4.13. Indicator Frequency Entry

Go to **Admin > Indicator Frequency Entry** from **Admin** menu. This form is used to create, edit and delete Indicator Frequency.

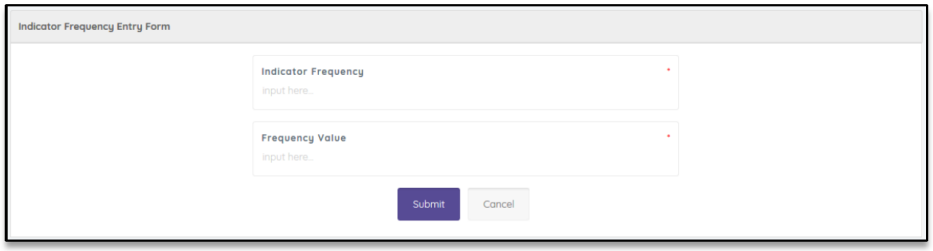
4.13.1. Indicator Frequency List

Select **Admin > Indicator Frequency Entry** to open Indicator Frequency entry page with list of all the Indicator Frequency entered as shown below:



4.13.2. Add New Indicator Frequency

Click **'+ Add'** button at the Top right corner of the above page to add a New Indicator Frequency. The Indicator Frequency Entry form is shown below:

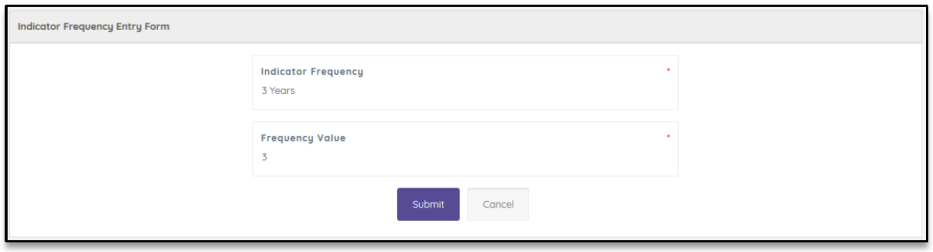


- Indicator Frequency: Enter a maximum 100 characters Indicator Frequency (i.e., '3 Years'). It is a mandatory field.
- Frequency Value: Enter Frequency Value in numeric (i.e., '3). It is a mandatory field.

After filling the fields, click **"Submit"** button to save.

4.13.3. Edit/Delete Indicator Frequency

- To edit an Indicator Frequency data (i.e., '3 Years'), User need to click "**Edit**" button from the Action Buttons beside that record and the Pop-up "Do you really want to edit this record?" Message Box will come to confirm the edit and the following form will arrive as follows:



Modify the Indicator Frequency data as required and click **"Submit"** button to update the record.

- To delete an Indicator Frequency data (i.e., '3 Years'), User need to click "**Delete**" button from the Action Buttons beside that record and the Pop-up "Do you really want to delete this record?" Message Box will come to confirm the delete. If there is any reference data the data will not be deleted.

4.14. Indicator Attribute Entry

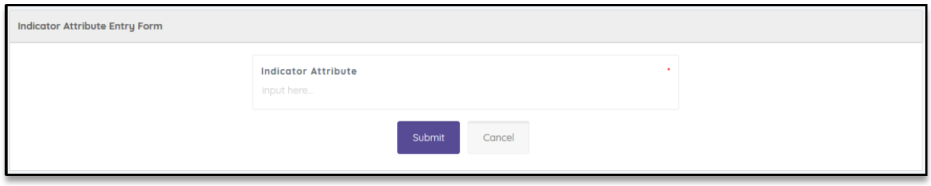
Go to **Admin > Indicator Attribute Entry** from **Admin** menu. This form is used to create, edit and delete Indicator Attribute.

4.14.1. Indicator Attribute List

Select **Admin > Indicator Attribute Entry** to open Indicator Attribute entry page with list of all the Indicator Attribute entered as shown below:

4.14.2. Add New Indicator Attribute

Click **'+ Add'** button at the Top right corner of the above page to add a New Indicator Attribute. The Indicator Attribute Entry form is shown below:

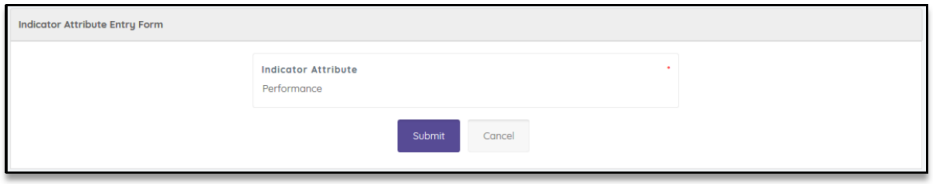


- Indicator Attribute: Enter a maximum 255 characters Indicator Attribute (i.e., 'Performance'). It is a mandatory field.

After filling the fields, click **"Submit"** button to save.

4.14.3. Edit/Delete Indicator Attribute

- To edit an Indicator Attribute data (i.e., 'Performance'), User need to click "**Edit**" button from the Action Buttons beside that record and the Pop-up "Do you really want to edit this record?" Message Box will come to confirm the edit and the following form will arrive as follows:



Modify the Indicator Attribute data as required and click **"Submit"** button to update the record.

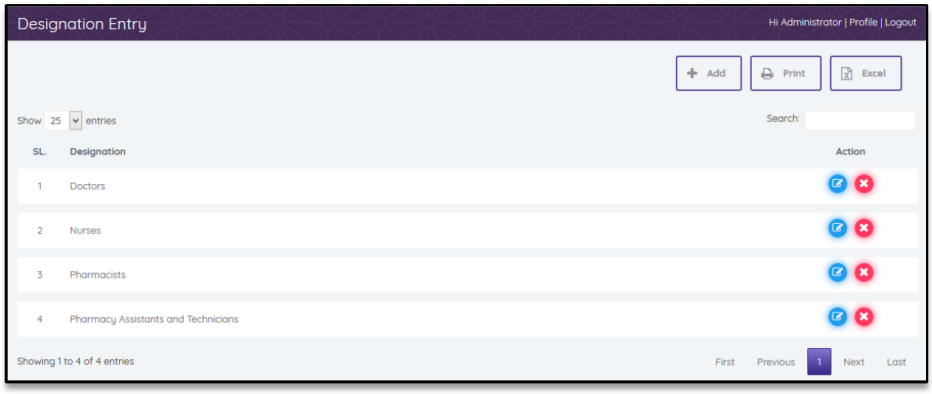
- To delete an Indicator Attribute data (i.e., 'Performance'), User need to click "**Delete**" button from the Action Buttons beside that record and the Pop-up "Do you really want to delete this record?" Message Box will come to confirm the delete. If there is any reference data the data will not be deleted.

4.15. Designation Entry

Go to **Admin > Designation Entry** from **Admin** menu. This form is used to create, edit and delete Designation.

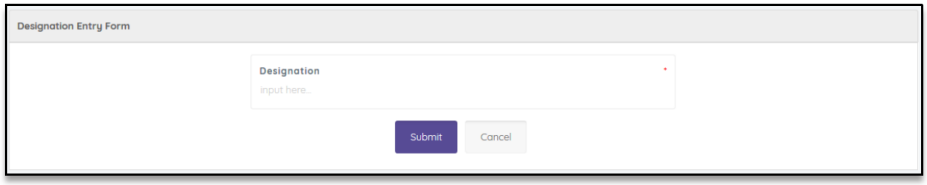
4.15.1. Designation List

Select **Admin > Designation Entry** to open Designation entry page with list of all the Designation entered as shown below:



4.15.2. Add New Designation

Click **'+ Add'** button at the Top right corner of the above page to add a New Designation. The Designation Entry form is shown below:

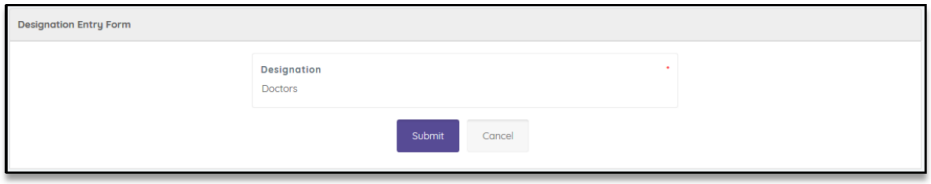


- Designation: Enter a maximum 80 characters Designation (i.e., 'Doctors'). It is a mandatory field.

After filling the fields, click **"Submit"** button to save.

4.15.3. Edit/Delete Designation

- To edit a Designation data (i.e., 'Doctors'), User need to click "**Edit**" button from the Action Buttons beside that record and the Pop-up "Do you really want to edit this record?" Message Box will come to confirm the edit and the following form will arrive as follows:



Modify the Designation data as required and click **"Submit"** button to update the record.

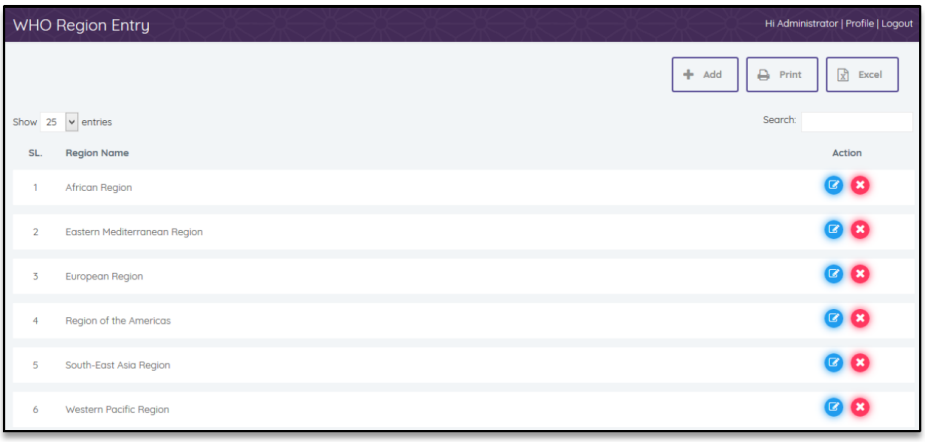
- To delete a Designation data (i.e., 'Doctors'), User need to click "**Delete**" button from the Action Buttons beside that record and the Pop-up "Do you really want to delete this record?" Message Box will come to confirm the delete. If there is any reference data the data will not be deleted.

4.16. WHO Region Entry

Go to **Admin > WHO Region Entry** from **Admin** menu. This form is used to create, edit and delete WHO Region.

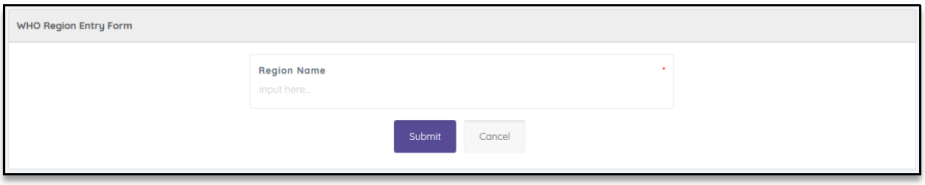
4.16.1. WHO Region List

Select **Admin > WHO Region Entry** to open WHO Region entry page with list of all the WHO Region entered as shown below:



4.16.2. Add New WHO Region

Click **'+ Add'** button at the Top right corner of the above page to add a New WHO Region. The WHO Region Entry form is shown below:

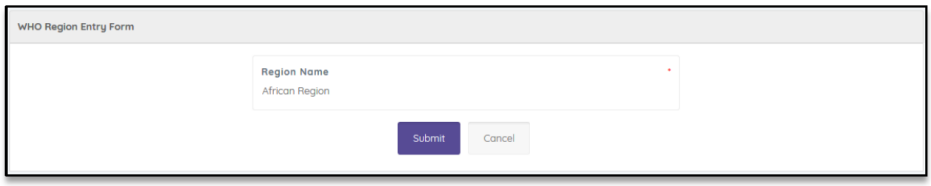


- Region Name: Enter a maximum 30 characters Region Name (i.e., 'African Region'). It is a mandatory field.

After filling the fields, click **"Submit"** button to save.

4.16.3. Edit/Delete WHO Region

- To edit a WHO Region data (i.e., 'African Region'), User need to click "**Edit**" button from the Action Buttons beside that record and the Pop-up "Do you really want to edit this record?" Message Box will come to confirm the edit and the following form will arrive as follows:



Modify the WHO Region data as required and click **"Submit"** button to update the record.

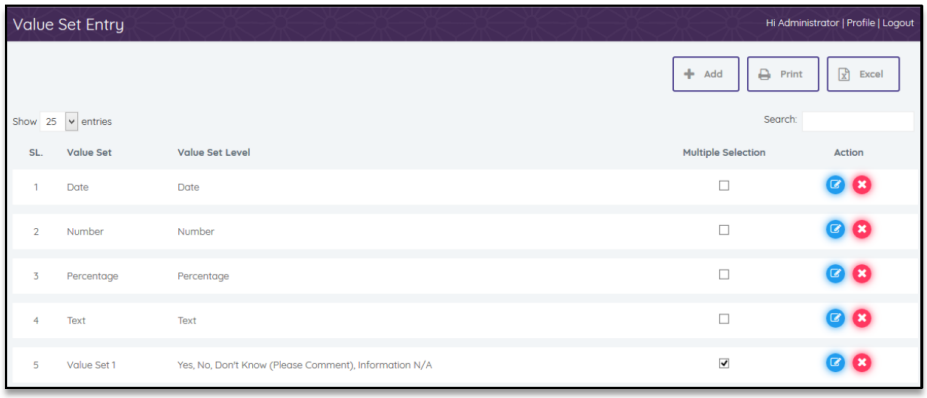
- To delete a WHO Region data (i.e., 'African Region'), User need to click "**Delete**" button from the Action Buttons beside that record and the Pop-up "Do you really want to delete this record?" Message Box will come to confirm the delete. If there is any reference data the data will not be deleted.

4.17. Value Set Entry

Go to **Admin > Value Set Entry** from **Admin** menu. This form is used to create, edit and delete Value Set.

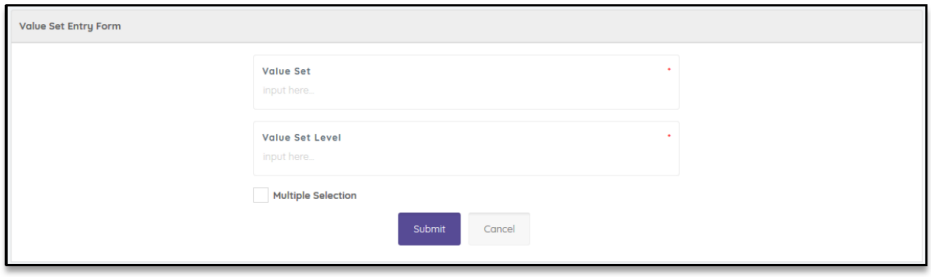
4.17.1. Value Set List

Select **Admin > Value Set Entry** to open Value Set entry page with list of all the Value Set entered as shown below:



4.17.2. Add New Value Set

Click **'+ Add'** button at the Top right corner of the above page to add a New Value Set. The Value Set Entry form is shown below:

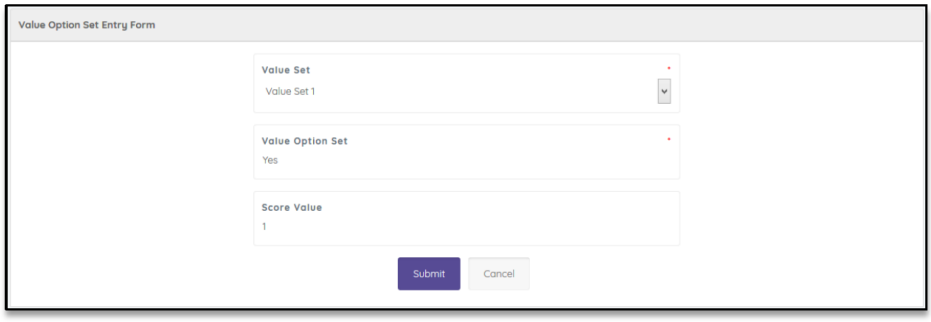


- Value Set: Enter a maximum 50 characters Value Set (i.e., 'Date'). It is a mandatory field.
- Value Set Level: Enter a maximum 255 characters Value Set Level (i.e., 'Date'). It is a mandatory field.
- Multiple Selection: Checked this box if this value set have multiple selection.

After filling the fields, click **"Submit"** button to save.

4.17.3. Edit/Delete Value Set

- To edit a Value Set data (i.e., 'Date'), User need to click "**Edit**" button from the Action Buttons beside that record and the Pop-up "Do you really want to edit this record?" Message Box will come to confirm the edit and the following form will arrive as follows:



Modify the Value Set data as required and click **"Submit"** button to update the record.

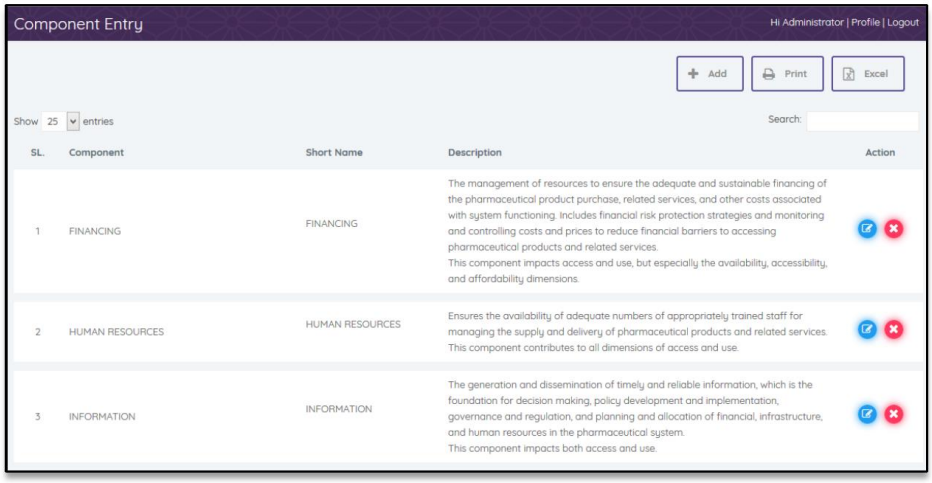
- To delete a Value Set data (i.e., 'Date'), User need to click "**Delete**" button from the Action Buttons beside that record and the Pop-up "Do you really want to delete this record?" Message Box will come to confirm the delete. If there is any reference data the data will not be deleted.

4.18. Component Entry

Go to **Admin > Component Entry** from **Admin** menu. This form is used to create, edit and delete Component.

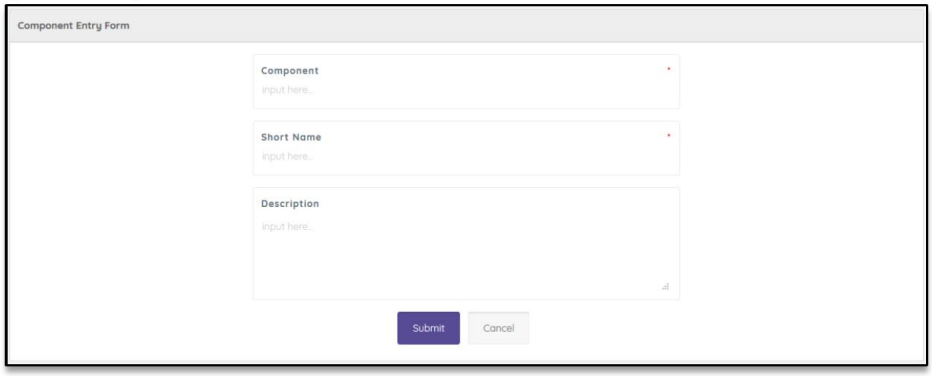
4.18.1. Component List

Select **Admin > Component Entry** to open Component entry page with list of all the Component entered as shown below:



4.18.2. Add New Component

Click **'+ Add'** button at the Top right corner of the above page to add a New Component. The Component Entry form is shown below:

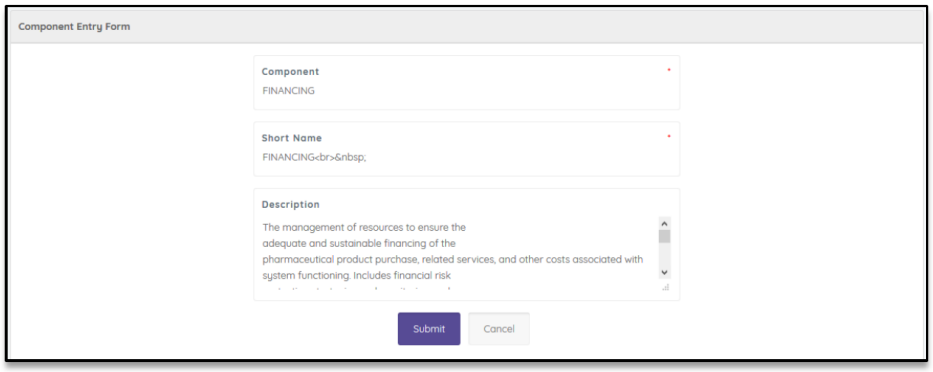


- Component: Enter a maximum 255 characters Component (i.e., 'FINANCING'). It is a mandatory field.
- Short Name: Enter a maximum 100 characters Short Name (i.e., 'FINANCING'). It is a mandatory field.
- Description: Enter a maximum 1000 characters Description. It is a mandatory field. It is not a mandatory filed.

After filling the fields, click **"Submit"** button to save.

4.18.3. Edit/Delete Component

- To edit a Component data (i.e., 'FINANCING''), User need to click "**Edit**" button from the Action Buttons beside that record and the Pop-up "Do you really want to edit this record?" Message Box will come to confirm the edit and the following form will arrive as follows:



Modify the Component data as required and click **"Submit"** button to update the record.

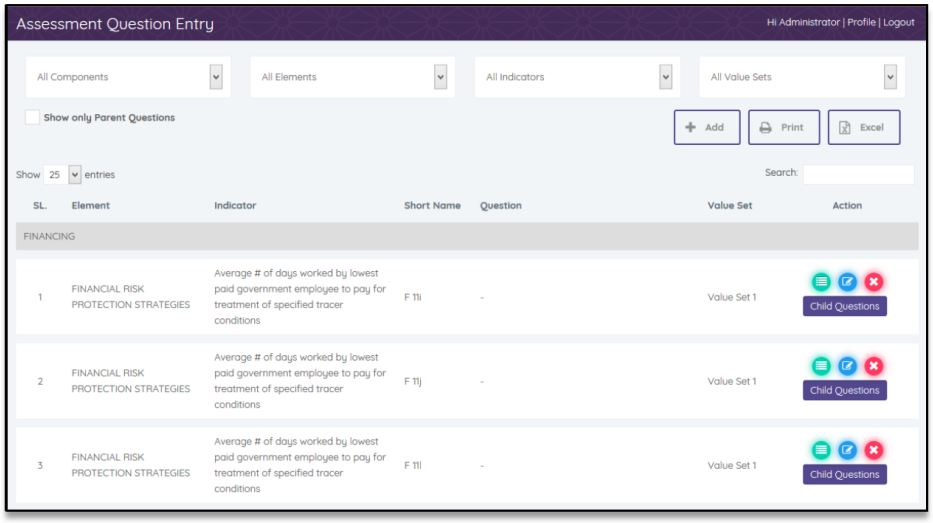
- To delete a Component data (i.e., 'FINANCING''), User need to click "**Delete**" button from the Action Buttons beside that record and the Pop-up "Do you really want to delete this record?" Message Box will come to confirm the delete. If there is any reference data the data will not be deleted.

4.19. Assessment Question Entry

Go to **Admin > Assessment Question Entry** from **Admin** menu. This form is used to create, edit and delete Assessment Question.

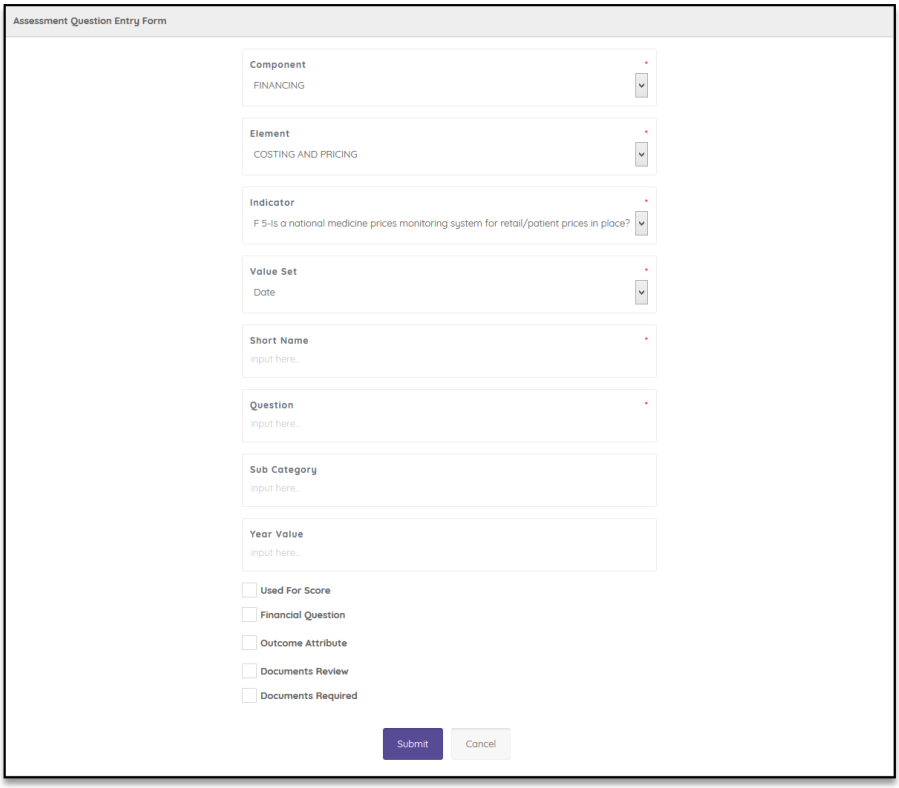
4.19.1. Assessment Question List

Select **Admin > Assessment Question Entry** to open Assessment Question entry page with list of all the Assessment Question entered as shown below:



4.19.2. Add New Assessment Question

Click **'+ Add'** button at the Top right corner of the above page to add a New Assessment Question. The Assessment Question Entry form is shown below:



- Component: Select a component from the list (i.e., 'FINANCING'). It is a mandatory field.
- Element: Select an element from the list (i.e., 'FINANCIAL RISK PROTECTION STRATEGIES'). It is a mandatory field.
- Indicator: Select an Indicator from the list. It is a mandatory field.
- Value Set: Select a value set from the list. It is a mandatory field.
- Short Name: Enter a maximum 50 characters Short Name. It is a mandatory field.
- Question: Enter a maximum 1000 characters Question. It is a mandatory field.
- Sub Category: Enter Sub Category. It is not a mandatory field.
- Year Value: Enter Year Value in numeric. It is not a mandatory field.
- Used For Score: Check the box if used for score.
- Financial Question: Check the box if this is a financial question.
- Outcome Attribute: Check the box if this is outcome attribute.
- Documents Review: Check the box for document review.
- Formula: If Documents Review checked then this input filed will be appear.
- Tracer Question: If Documents Review checked then this check box option will be appear.
- Document Required: Check the box if document required.
- Documents: If Document required filed checked then this filed will be appear. Enter a maximum 1000 characters documents.

After filling the fields, click **"Submit"** button to save.

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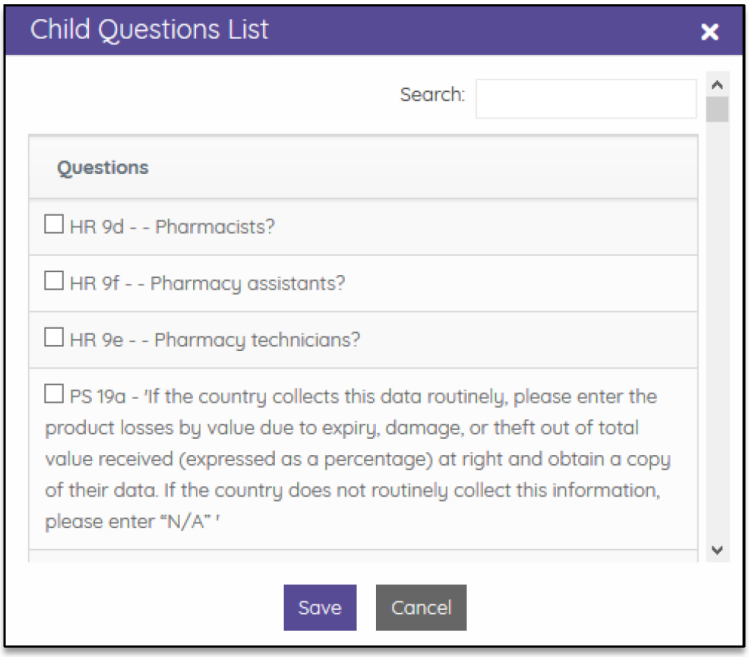
4.19.3. Add Child Questions

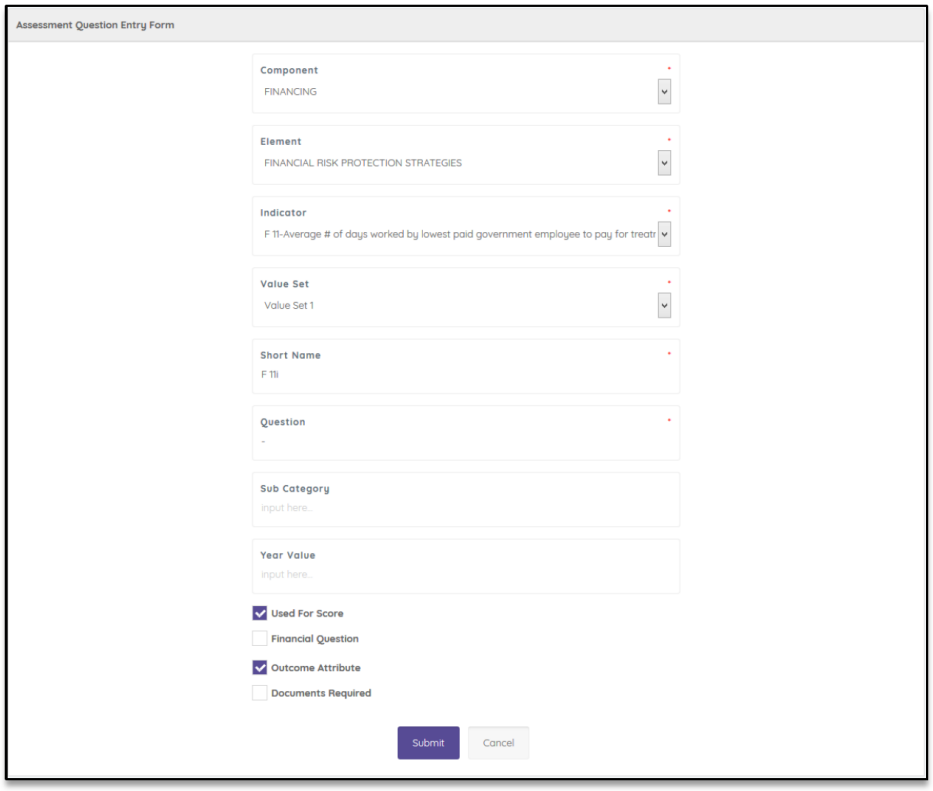
- Click "**Child Questions**" button from the Action Buttons beside that record. The Child Questions List is shown below:



- Check the box beside Question as required and click **"Save"** button to add the record.

4.19.4. Edit/Delete Assessment Question

- To edit an Assessment Question data, User need to click "**Edit**" button from the Action Buttons beside that record and the Pop-up "Do you really want to edit this record?" Message Box will come to confirm the edit and the following form will arrive as follows:



Modify the Assessment Question data as required and click **"Submit"** button to update the record.

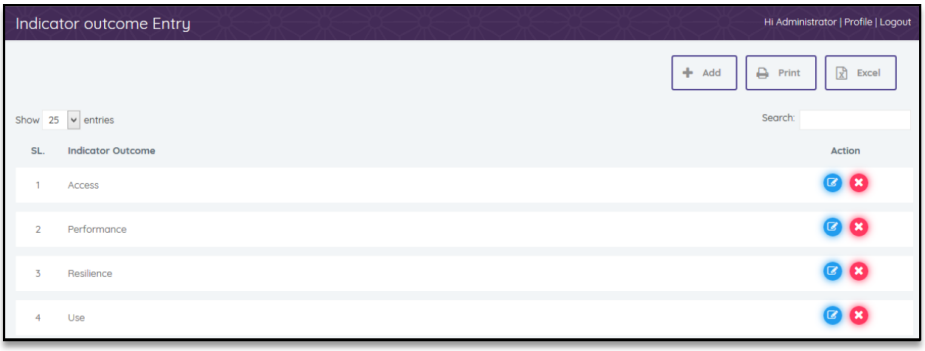
- To delete an Assessment Question data, User need to click "**Delete**" button from the Action Buttons beside that record and the Pop-up "Do you really want to delete this record?" Message Box will come to confirm the delete. If there is any reference data the data will not be deleted.

4.20. Indicator outcome Entry

Go to **Admin > Indicator outcome Entry** from **Admin** menu. This form is used to create, edit and delete Indicator outcome.

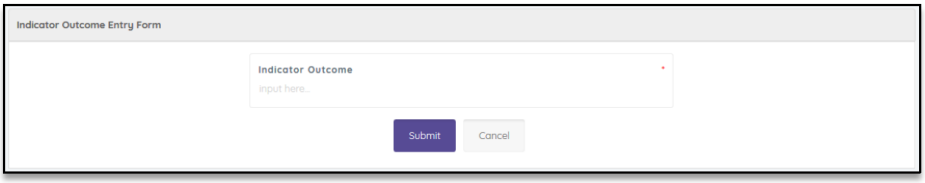
4.20.1. Indicator outcome List

Select **Admin > Indicator outcome Entry** to open Indicator outcome entry page with list of all the Indicator outcome entered as shown below:



4.20.2. Add New Indicator outcome

Click **'+ Add'** button at the Top right corner of the above page to add a New Indicator outcome. The Indicator outcome Entry form is shown below:

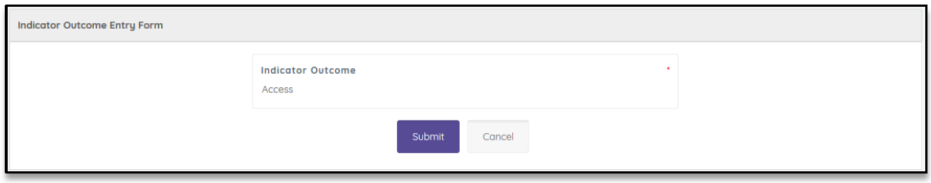


- Indicator outcome: Enter a maximum 100 characters Indicator outcome (i.e., 'Access'). It is a mandatory field.

After filling the fields, click **"Submit"** button to save.

4.20.3. Edit/Delete Indicator outcome

- To edit an Indicator outcome data (i.e., 'Access'), User need to click "**Edit**" button from the Action Buttons beside that record and the Pop-up "Do you really want to edit this record?" Message Box will come to confirm the edit and the following form will arrive as follows:



  Modify the Indicator outcome data as required and click **"Submit"** button to update the record.

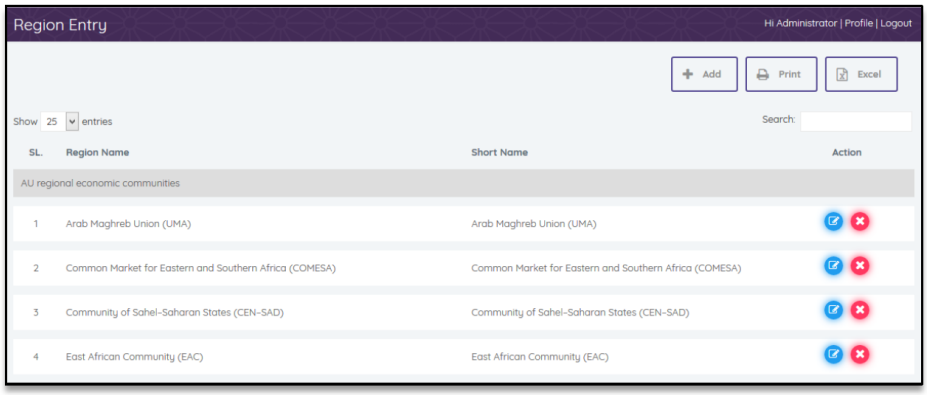
- To delete an Indicator outcome data (i.e., 'Access'), User need to click "**Delete**" button from the Action Buttons beside that record and the Pop-up "Do you really want to delete this record?" Message Box will come to confirm the delete. If there is any reference data the data will not be deleted.

4.21. Region Entry

Go to **Admin > Region Entry** from **Admin** menu. This form is used to create, edit and delete Region.

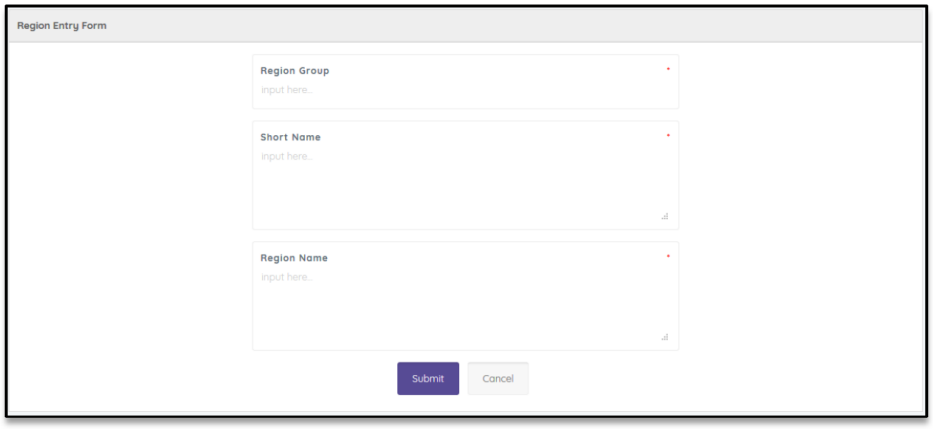
4.21.1. Region List

Select **Admin > Region Entry** to open Region entry page with list of all the Region entered as shown below:



4.21.2. Add New Region

Click **'+ Add'** button at the Top right corner of the above page to add a New Region. The Region Entry form is shown below:

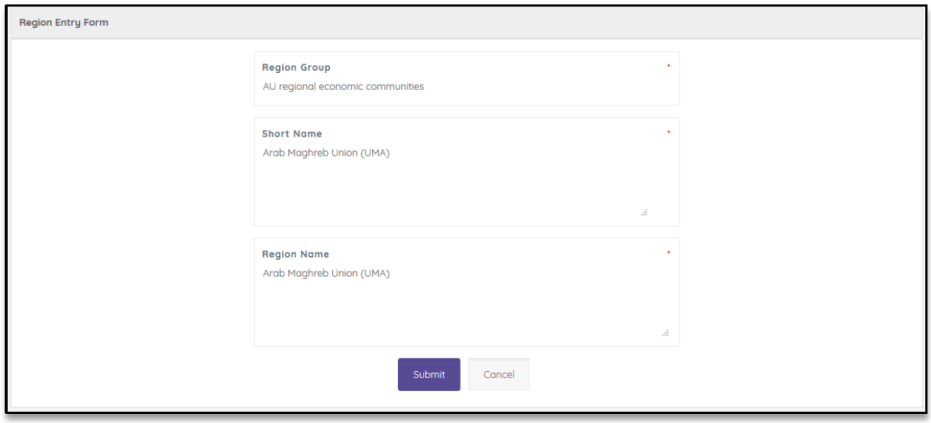


- Region Group: Enter a maximum 255 characters Region Group (i.e., 'AU regional economic communities'). It is a mandatory field.
- Short Name: Enter a maximum 100 characters Short Name (i.e., 'Arab Maghreb Union (UMA)'). It is a mandatory field.
- Region Name: Enter a maximum 255 characters Region Name (i.e., 'Arab Maghreb Union (UMA)'). It is a mandatory field.

After filling the fields, click **"Submit"** button to save.

4.21.3. Edit/Delete Region

- To edit a Region data (i.e., 'Arab Maghreb Union (UMA)'), User need to click "**Edit**" button from the Action Buttons beside that record and the Pop-up "Do you really want to edit this record?" Message Box will come to confirm the edit and the following form will arrive as follows:



Modify the Region data as required and click **"Submit"** button to update the record.

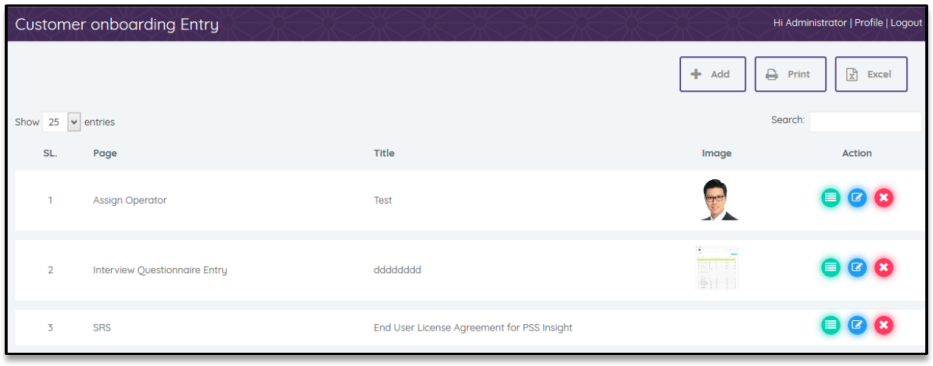
- To delete a Region data (i.e., 'Arab Maghreb Union (UMA)'), User need to click "**Delete**" button from the Action Buttons beside that record and the Pop-up "Do you really want to delete this record?" Message Box will come to confirm the delete. If there is any reference data the data will not be deleted.

4.22. Customer onboarding Entry

Go to **Admin > Customer onboarding Entry** from **Admin** menu. This form is used to create, edit and delete Customer onboarding.

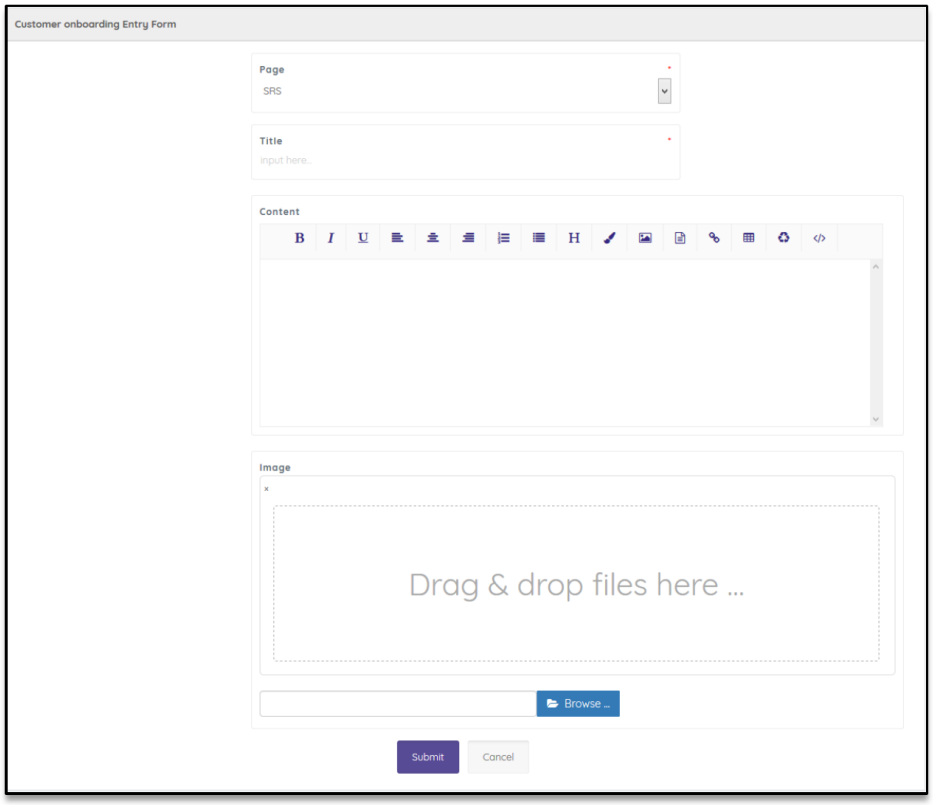
4.22.1. Customer onboarding List

Select **Admin > Customer onboarding Entry** to open Customer onboarding entry page with list of all the Customer onboarding entered as shown below:



4.22.2. Add New Customer onboarding

Click **'+ Add'** button at the Top right corner of the above page to add a New Customer onboarding. The Customer onboarding Entry form is shown below:

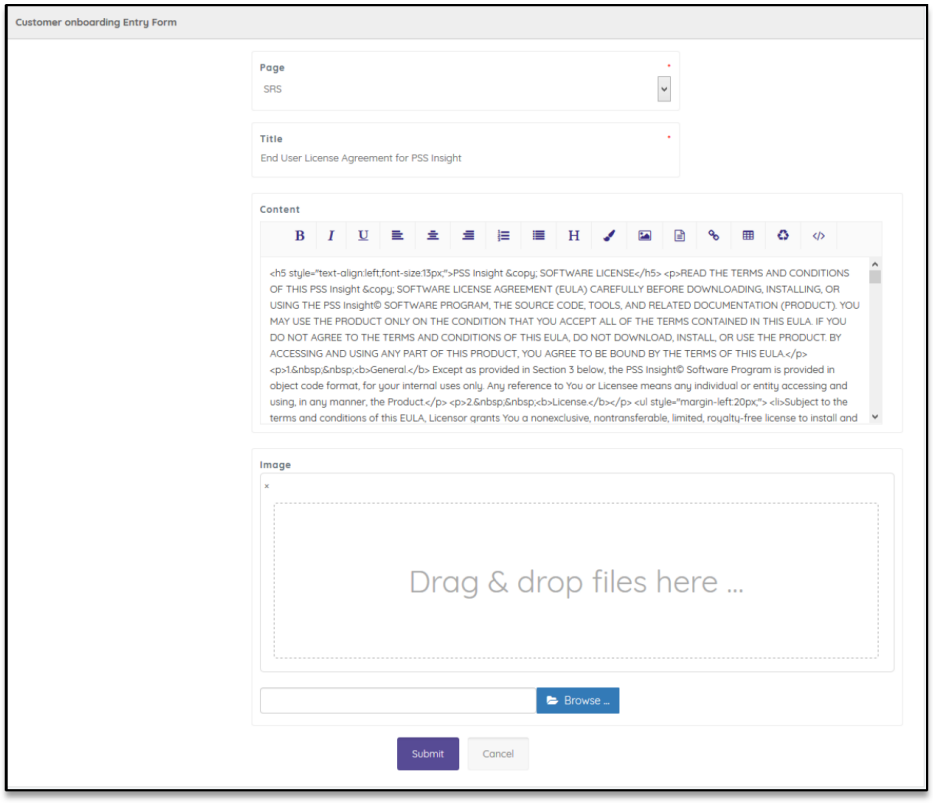


- Page: Select a page from the list. It is a mandatory field.
- Title: Enter a maximum 1000 characters Title. It is a mandatory field.
- Content: Enter Content. It is not a mandatory field.
- Image: Upload an image from local drive. It is not a mandatory field.

After filling the fields, click **"Submit"** button to save.

4.22.3. Edit/Delete Customer onboarding

- To edit a Customer onboarding data, User need to click "**Edit**" button from the Action Buttons beside that record and the Pop-up "Do you really want to edit this record?" Message Box will come to confirm the edit and the following form will arrive as follows:

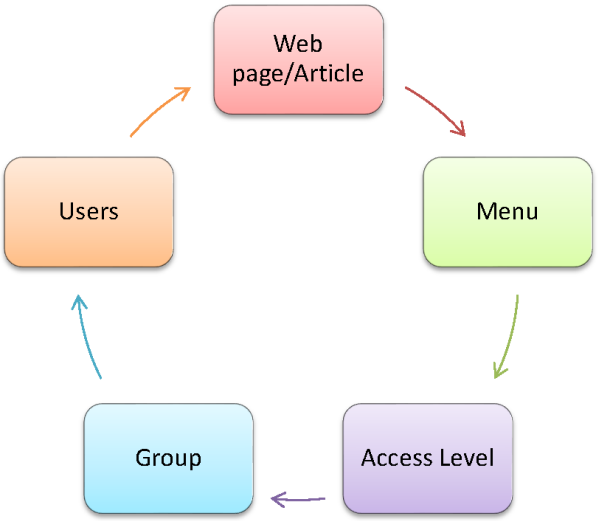


Modify the Customer onboarding data as required and click **"Submit"** button to update the record.

- To delete a Customer onboarding data, User need to click "**Delete**" button from the Action Buttons beside that record and the Pop-up "Do you really want to delete this record?" Message Box will come to confirm the delete. If there is any reference data the data will not be deleted.

Chapter-5: User Management

PSS Insight uses Wordpress content management framework for user access management. In Wordpress the web page access can be represented using following graphic–



Wordpress has a menu system and each menu is linked with a web page – either data entry page or a report page. Roles are defined based on what each role can do. Roles need to be assigned to menus. After users register from front-end, administrator of the web site has to assign a role to the user. This allows users to access certain pages.

Following Roles are defined in the portal –

- **Member** – Users having this role are able to see the Home page and Profile.
- **Country Viewer** – Users having this role are able to see the PSS Insight reports.
- **Global Viewer** – Users having this role are able to see the PSS Insight reports.
- **Data Entry Operator** –These users have access to Interview Questionnaire Entry and Approve. They also have permission to Download & Upload Questionnaire Excel Template.
- **Survey Coordinator** – These users have access to create PSS Survey, Generate Survey Question, Assign Entry Operators, Document Review and PSS Survey Score Calculation. They also have permission to Download & Upload Questionnaire Excel Template.
- **Global Administrator** – Has the option to enter all admin pages and entry forms. They also able to see the PSS Insight reports.
- **Super Admin** – Has the option to enter all admin pages and entry forms. They also able to see the PSS Insight reports.

Web Pages list with permissions

Sl#	Wordpress Menu/Article with Page Link	Member	Country Viewer	Global Viewer	Data Entry Operator	Survey Coordinator	Global Administrator	Super Admin
1	Home http://pssinsight.org/	✓	✓	✓	✓	✓	✓	✓
2	Profile http://pssinsight.org/profile/	✓	✓	✓	✓	✓	✓	✓
3	Contact http://pssinsight.org/contact/	✓	✓	✓	✓	✓	✓	✓
Reports Menu								
4	Interview Response Details Report http://pssinsight.org/interview-response-details-report/		✓	✓			✓	✓
5	Interview Response Details Report For Multiple Sites http://pssinsight.org/interview-response-details-report-for-multiple-sites/		✓	✓			✓	✓
6	Indicator Score Report http://pssinsight.org/indicator-score-report/		✓	✓			✓	✓
7	Element Score Report http://pssinsight.org/element-score-report/		✓	✓			✓	✓
8	Component Score Report http://pssinsight.org/component-score-report/		✓	✓			✓	✓
9	Outcomes and Attributes Report http://pssinsight.org/outcomes-and-attributes-report/		✓	✓			✓	✓
10	PSS Survey Details Dashboard Report http://pssinsight.org/pss-survey-details-dashboard-report/		✓	✓			✓	✓

11	PSS Survey Summary Report http://pssinsight.org/pss-survey-summary-report/		✓	✓			✓	✓
Admin Menu								
12	Year Entry http://pssinsight.org/year/						✓	✓
13	Master Entity Entry http://pssinsight.org/master-entity-entry/						✓	✓
14	Value Option Set Entry http://pssinsight.org/value-option-set-entry/						✓	✓
15	Element Entry http://pssinsight.org/element-entry/						✓	✓
16	User Permission Entry http://pssinsight.org/user-permission-entry/						✓	✓
17	Indicator Dimension Entry http://pssinsight.org/indicator-dimension-entry/						✓	✓
18	Region Country Map Entry http://pssinsight.org/region-country-map-entry/						✓	✓
19	Commodity in Tracer Entry http://pssinsight.org/commodity-in-tracer-entry/						✓	✓
20	Country Entry http://pssinsight.org/country/						✓	✓
21	Indicator Data Type Entry http://pssinsight.org/indicator-data-type-entry/						✓	✓
22	Indicator Category Entry http://pssinsight.org/indicator-category-entry/						✓	✓
23	Indicator Entry http://pssinsight.org/indicator-entry/						✓	✓
24	Audit Log http://pssinsight.org/audit-log/						✓	✓
25	Entity and Question Map Entry http://pssinsight.org/entity-and-question-map-entry/						✓	✓
26	Indicator Frequency Entry						✓	✓

	http://pssinsight.org/indicator-frequency-entry/									
27	Indicator Attribute Entry http://pssinsight.org/indicator-attribute-entry/							✓	✓	✓
28	Designation Entry http://pssinsight.org/designation-entry/							✓	✓	✓
29	WHO Region Entry http://pssinsight.org/who-region-entry/							✓	✓	✓
30	Value Set Entry http://pssinsight.org/value-set-entry/							✓	✓	✓
31	Component Entry http://pssinsight.org/component-entry/							✓	✓	✓
32	Assessment Question Entry http://pssinsight.org/assessment-question-entry/							✓	✓	✓
33	Error Log http://pssinsight.org/error-log/							✓	✓	✓
34	Indicator outcome Entry http://pssinsight.org/indicator-outcome-entry/							✓	✓	✓
35	Region Entry http://pssinsight.org/region-entry/							✓	✓	✓
36	Customer onboarding Entry http://pssinsight.org/customer-onboarding-entry/							✓	✓	✓
Entry Forms Menu										
37	PSS Survey Builder http://pssinsight.org/pss-survey-builder/						✓	✓	✓	✓
38	Generate Survey Question http://pssinsight.org/generate-survey-question/						✓	✓	✓	✓
39	Assign Entry Operators http://pssinsight.org/assign-entry-operators/						✓	✓	✓	✓
40	Interview Questionnaire Entry http://pssinsight.org/interview-questionnaire-entry/					✓		✓	✓	✓
41	Document Review List http://pssinsight.org/document-review-list/						✓	✓	✓	✓

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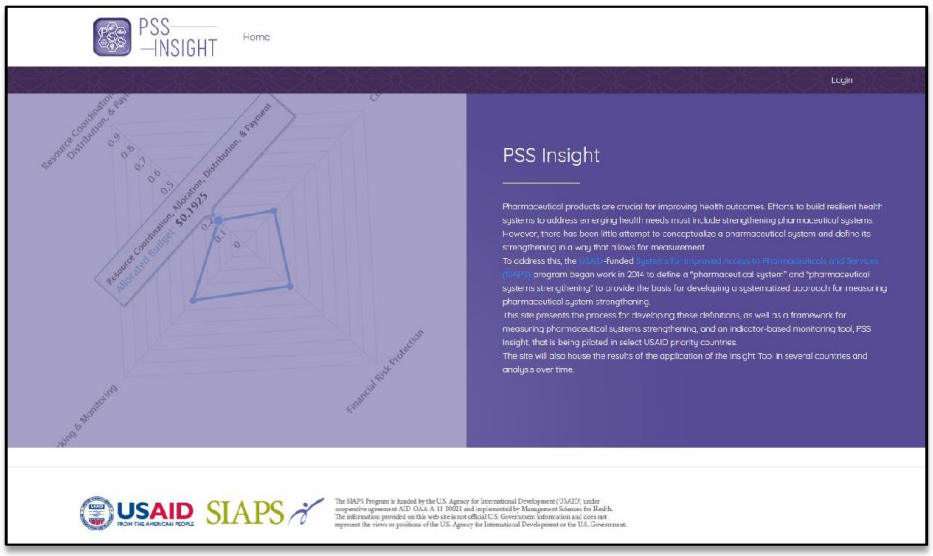
42	Interview Questionnaire Approve http://pssinsight.org/interview-questionnaire-approve/				✓		✓	✓
43	PSS Survey Score Calculation http://pssinsight.org/pss-survey-score-calculation/					✓	✓	✓
44	Download Questionnaire Excel Template http://pssinsight.org/download-questionnaire-excel-template/				✓	✓	✓	✓
45	Upload Questionnaire Excel Template http://pssinsight.org/upload-questionnaire-excel-template/				✓	✓	✓	✓

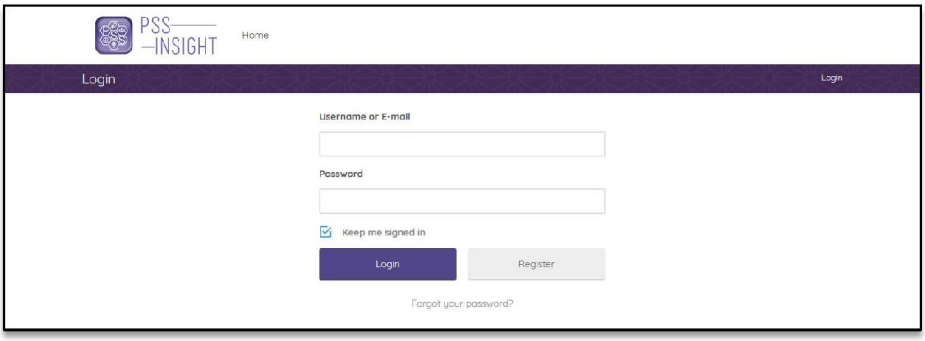
Chapter-6: How to Registration in PSS Insight Pharmaceutical Dashboard?

Users can register directly in PSS Insight web site or Administrator can create a user manually at the back-end.

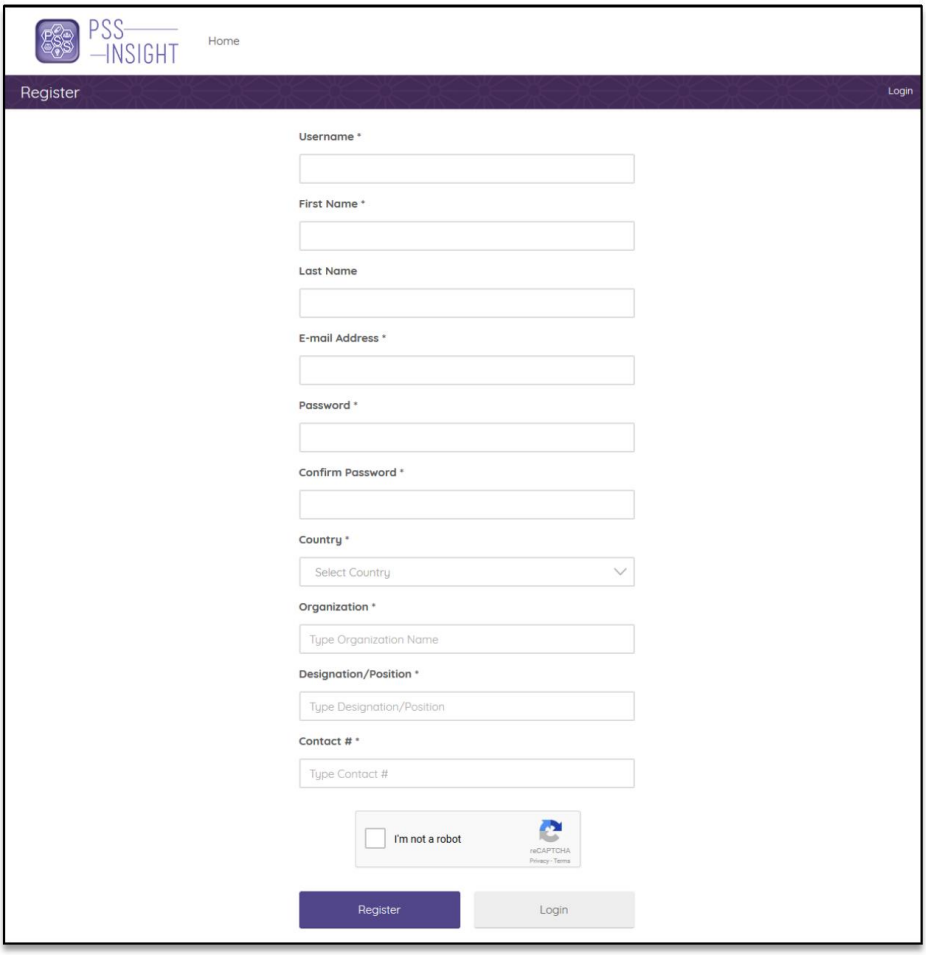
Step-1: Open any internet browser (Google Chrome, Mozilla Firefox) then type: http://pssinsight.org/ which shows the following screen -



Step- 2: Click to the '**Login**' button from this page. Which will bring the following page -



Now click on "**Registration**" button which will bring the following registration page -

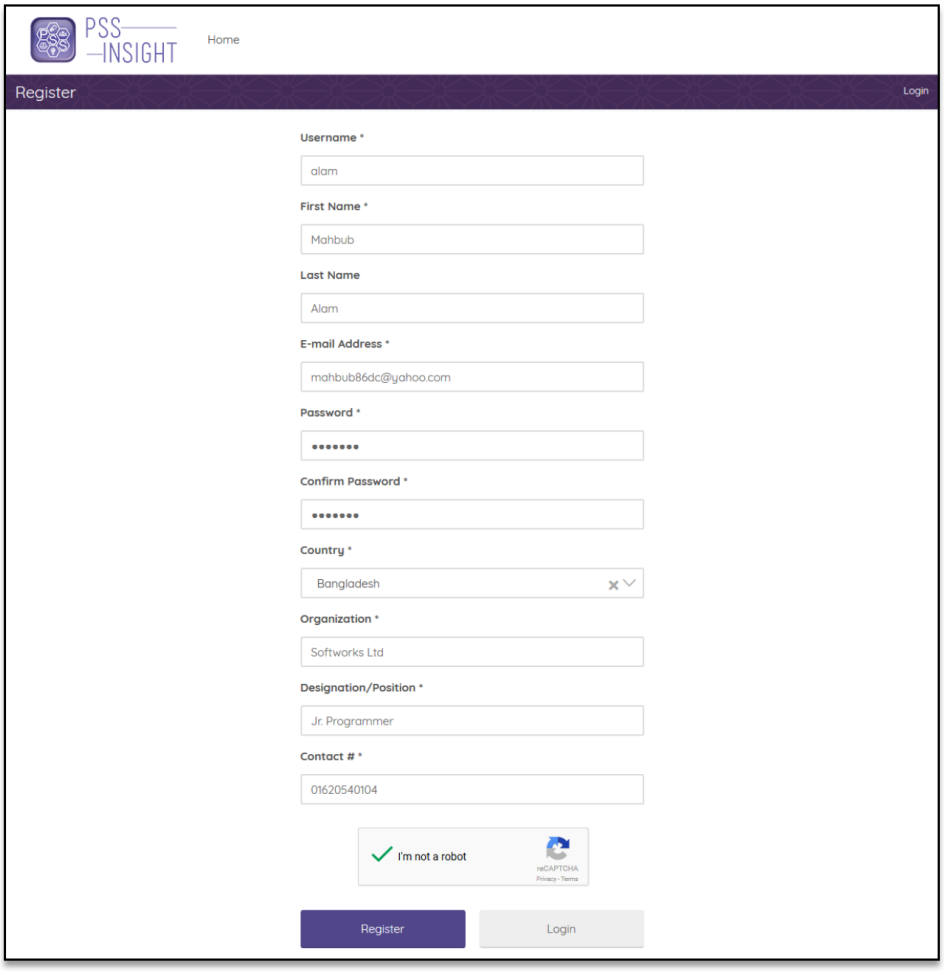


Step-3: Fill in the Necessary Field

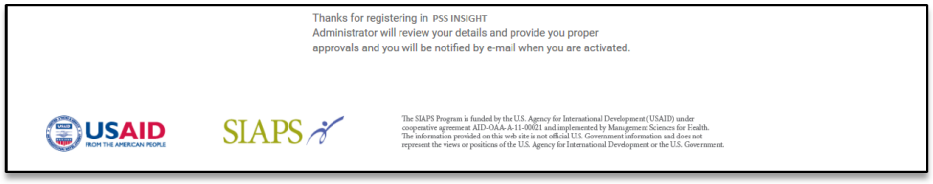
- **Username**
- **First Name**
- **Last Name**
- **E-mail Address**
- **Password**
- **Confirm Password**
- **Country**
- **Organization**
- **Designation/Position**
- **Contact #**

- **Captcha**

User will fill in the form look like following screen –

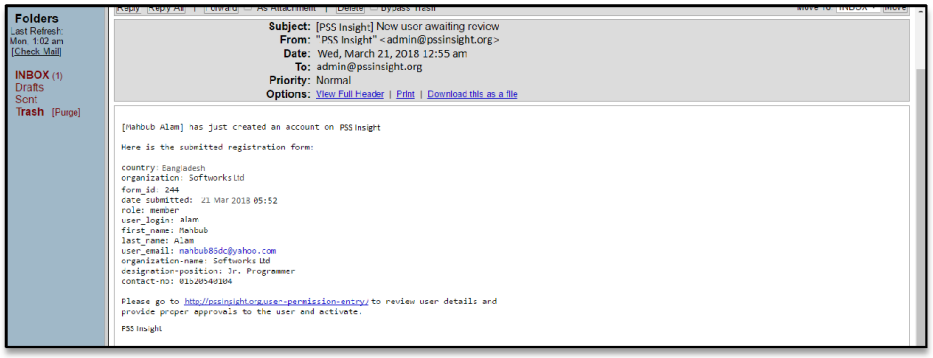


Step-4: Press "**Register**" button from this page bottom side then Show the following screen-

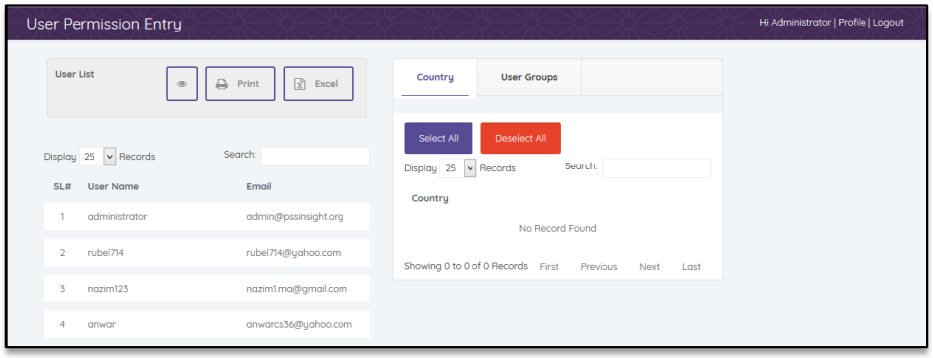


Message shown **"Thanks for registering in PSS Insight. Administrator will review your details and provide you proper approvals and you will be notified by e-mail when you are activated."**

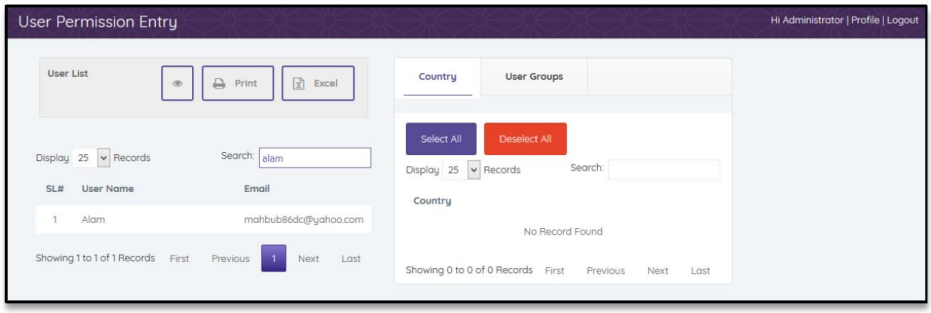
Step -5: Go to Administrator E-mail for approving PSS Insight new users -



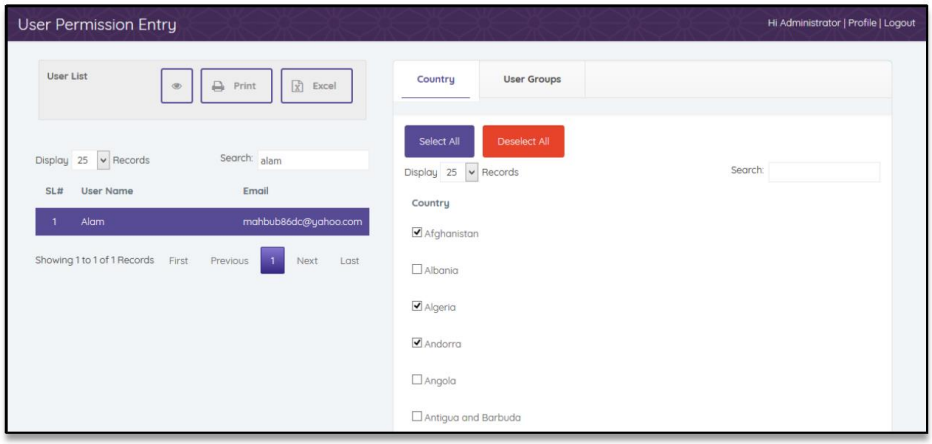
Step -6: Click the link from E-mail body to go "**User Permission Entry**" form. If you are not logged into "http://pssinsight.org/" site then login first. Already logged in user shown the following screen-



Step -7: Search for the newly registered user from the left side user list.

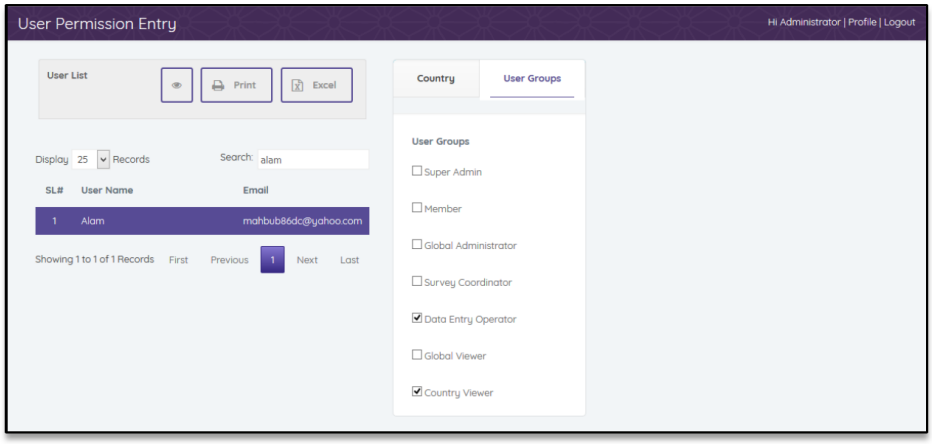


Step- 8: Select the user name in the left side list – and Assign relevant Country. Select Country by check the boxes or Press 'Select All' if you want to assign all Country.

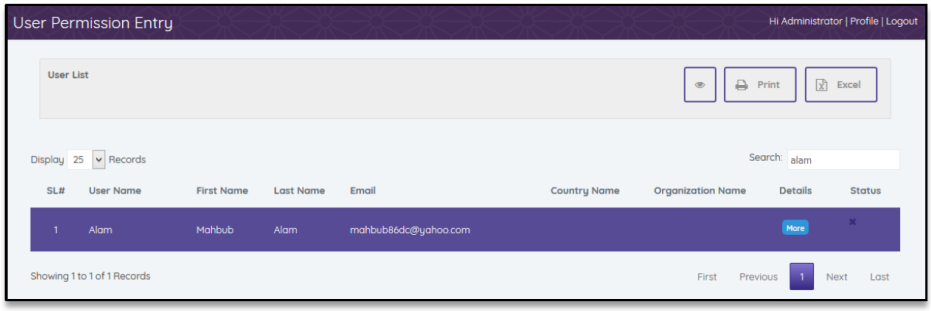


Step- 9: Click into "**User Groups**" tab from the right side. Assign relevant user groups

Select appropriate groups based on requirements –

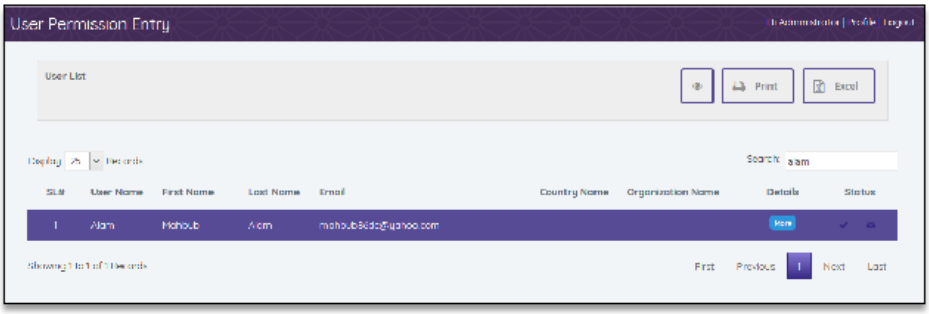


Step -10: Now click into  button to expand user list. User list shown look like following screen-

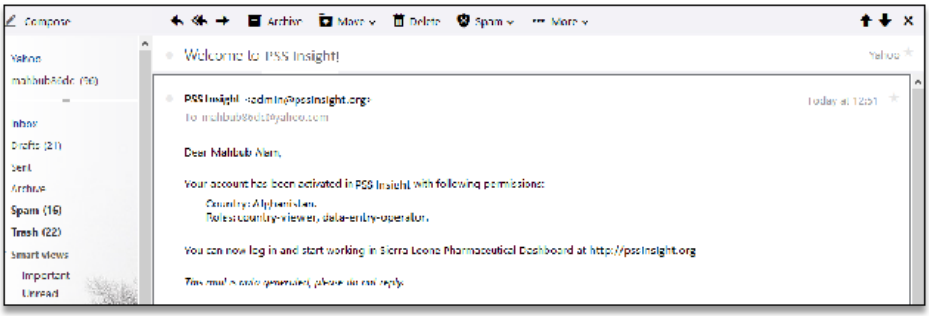


For activate a new user click to the "**Activate**" (**X**) button from right side.

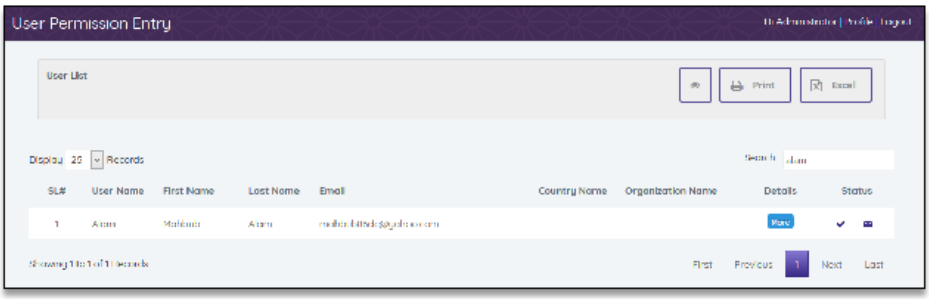
After click into "**Activate**" (X) button, user will activated ✔ successfully look like the following screen-



Step -11: After activated by administrator the newly registered user will receive a confirmation mail-



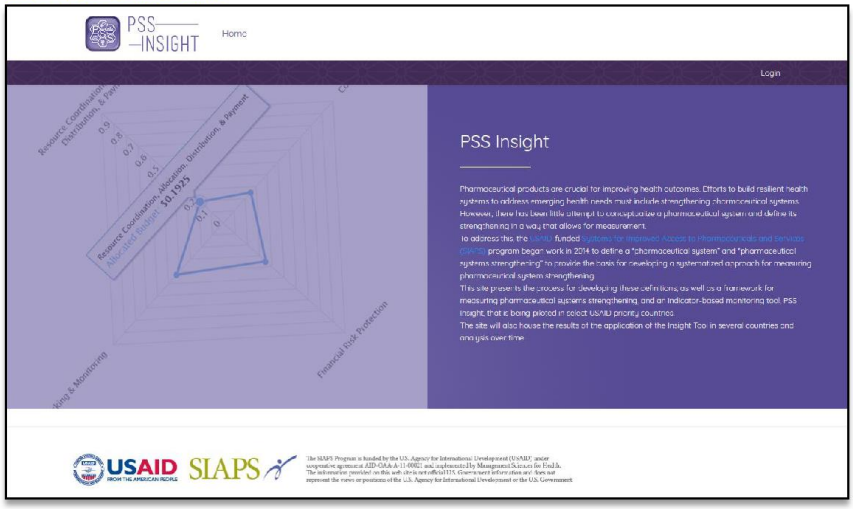
If newly registered user not received a confirmation mail then administrator can resend a mail by click into ✉ "Resend Mail" button.



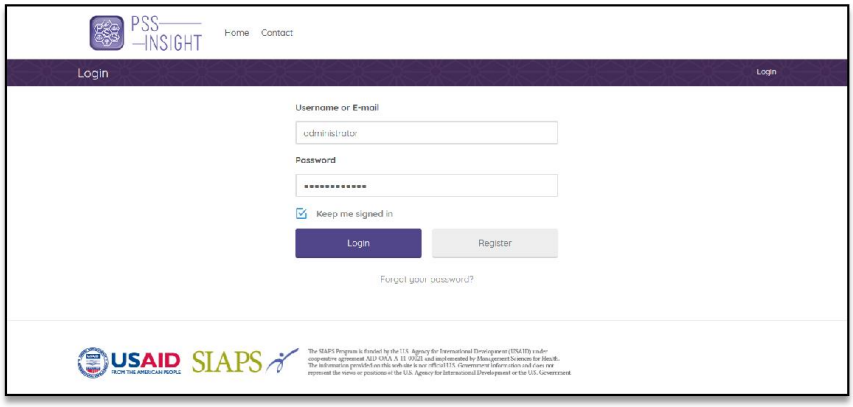
Chapter-7: How to Assign Country/User Groups and Deactivate/Activate an user

7.1 Login to system and go to User Permission Entry Form

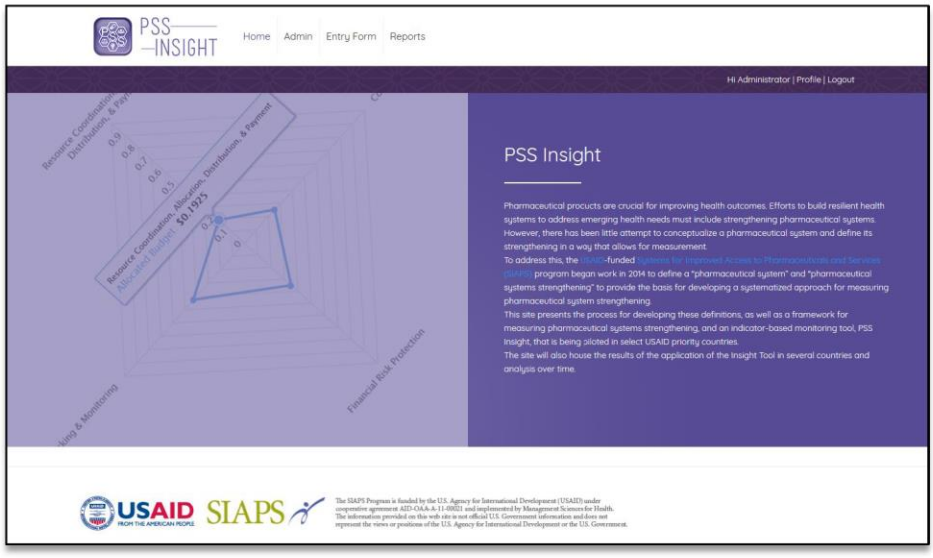
Browse http://pssinsight.org/ site



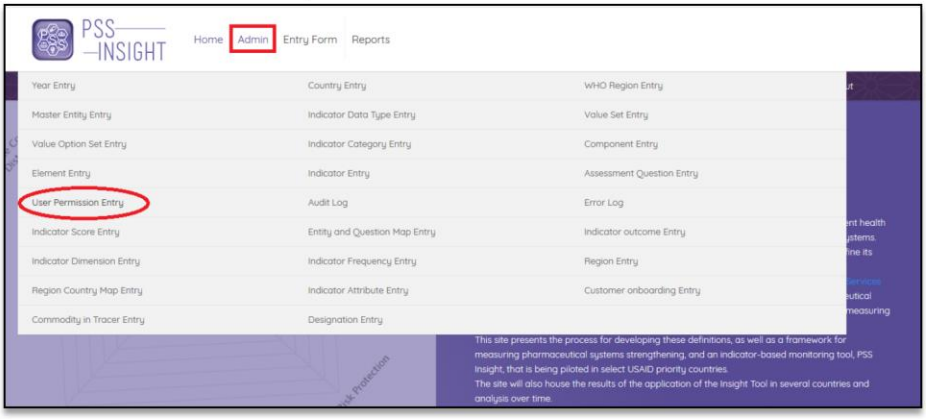
Login as administrator –



After login following screen will show –



Click on the **'User Permission Entry'** sub menu under Admin menu –



Then following screen will come –

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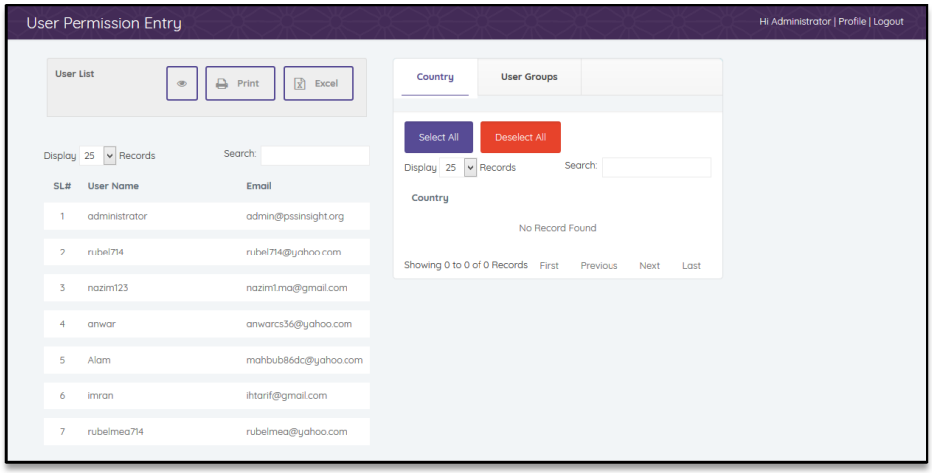
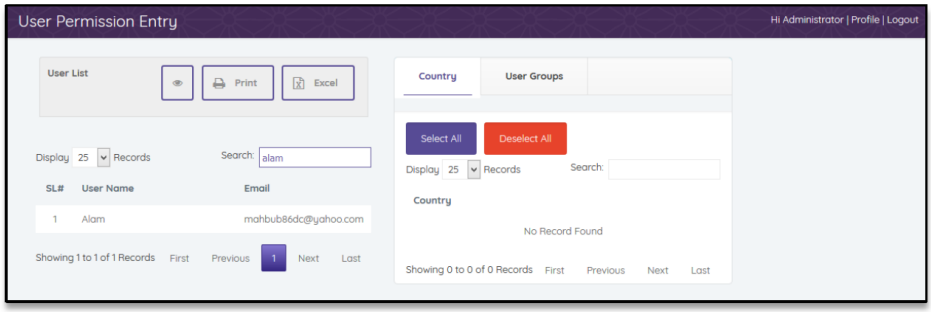
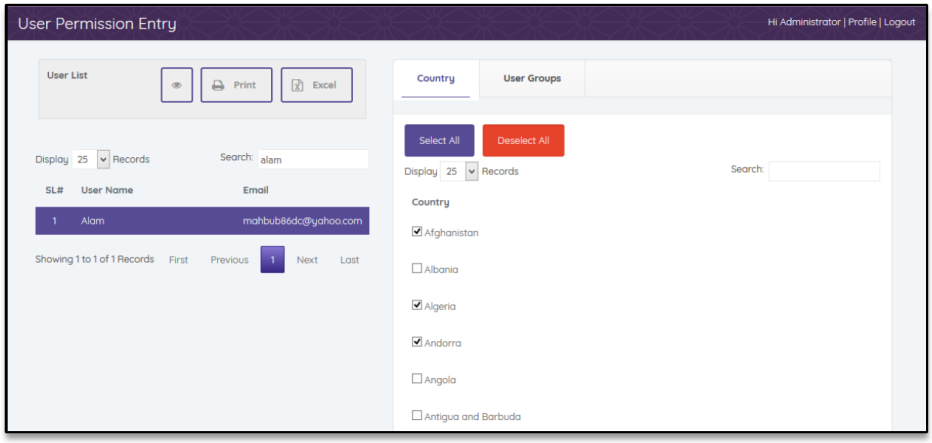


Search for the registered user from user list-



7.2 Assign Country for a user

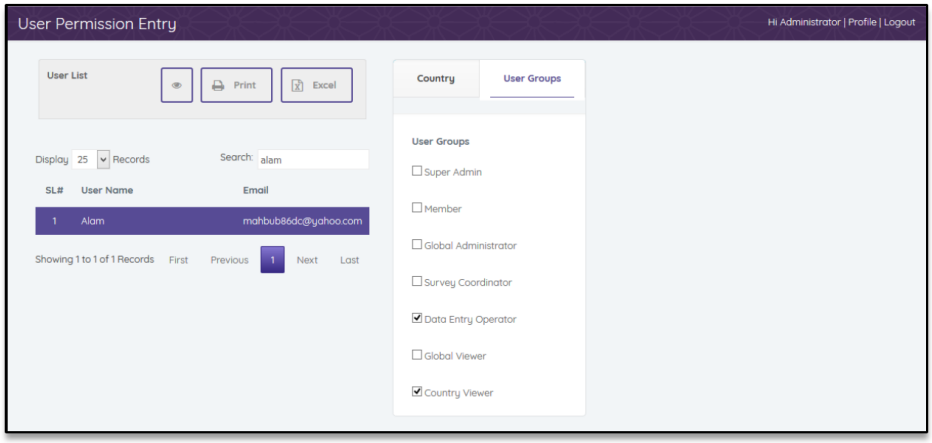
Select the user name in the left side list – and assign relevant Country. Select country by check the boxes or Press 'Select All' of you want to assign all Country from the right side "**Country**" tab.



7.3 Assign User Groups

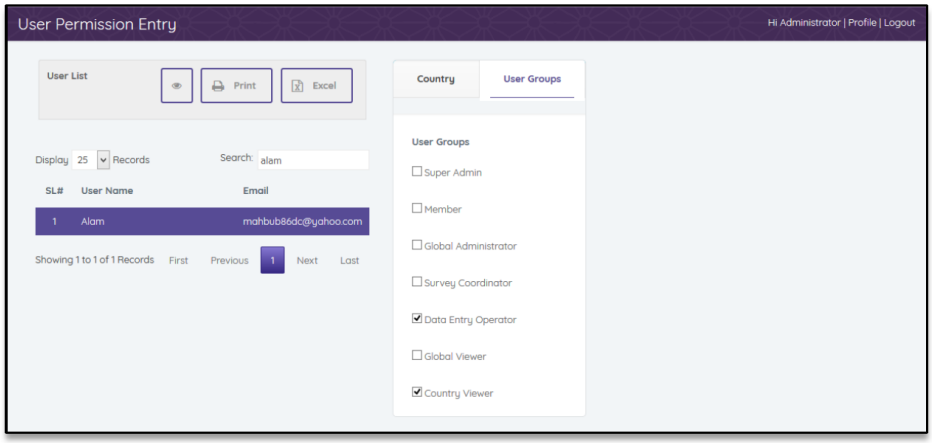
Select appropriate groups based on requirements –

Assign relevant user groups from the right side "**User Groups**" tab.

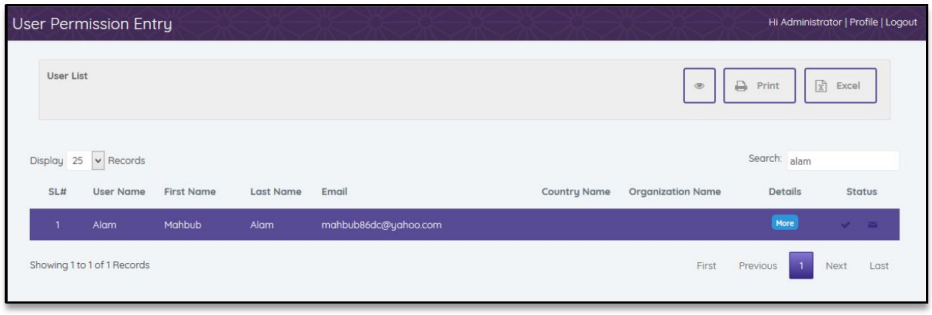


7.4 Deactivate a user

Search and select a user from the right side user list.

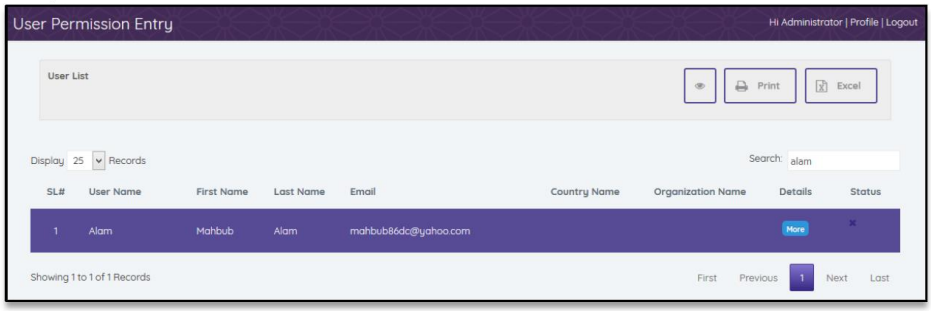


Now click into  button to expand user list. User list shown look like following screen-



Now click into "**Deactivate**" button.

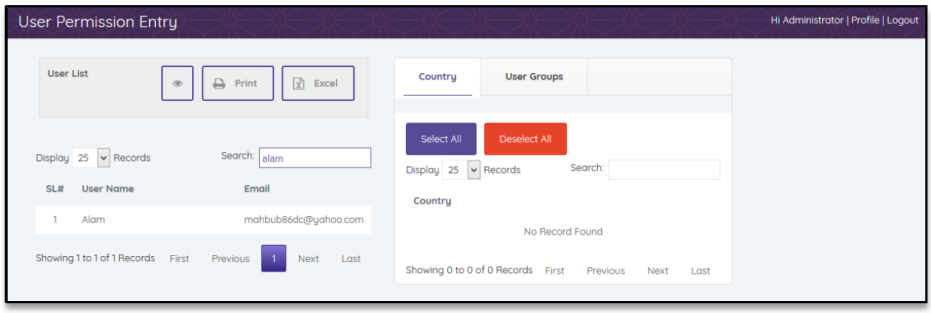
After click into "**Deactivate**" button, user deactivated successfully and button change look like following screen-



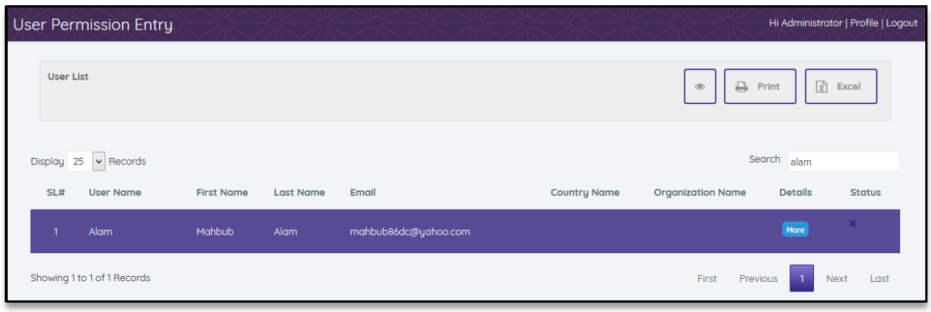
After Deactivated a user by administrator, user will receive a mail-

7.5 Activate a user

Search and select a user from the right side user list.

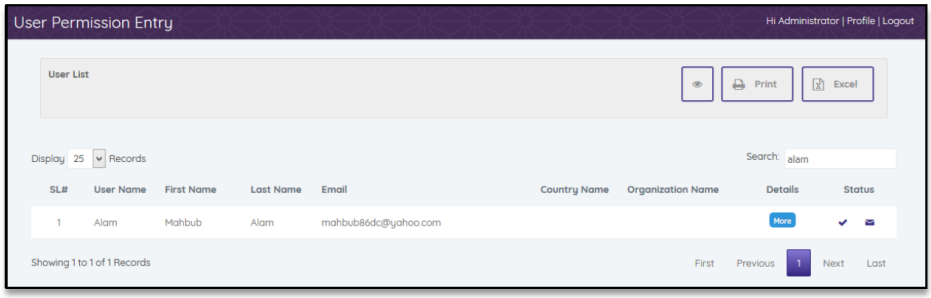


Now click into  button to expand user list. User list shown look like following screen-

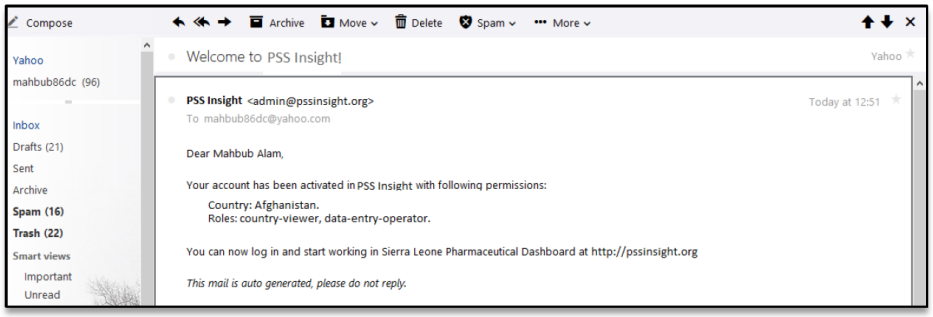


Now click into "**Active this user**" "**X**" button.

After click into "**Active this user**" button user activated successfully and button change look like following screen-



After Activated a user by administrator, user will receive a mail-

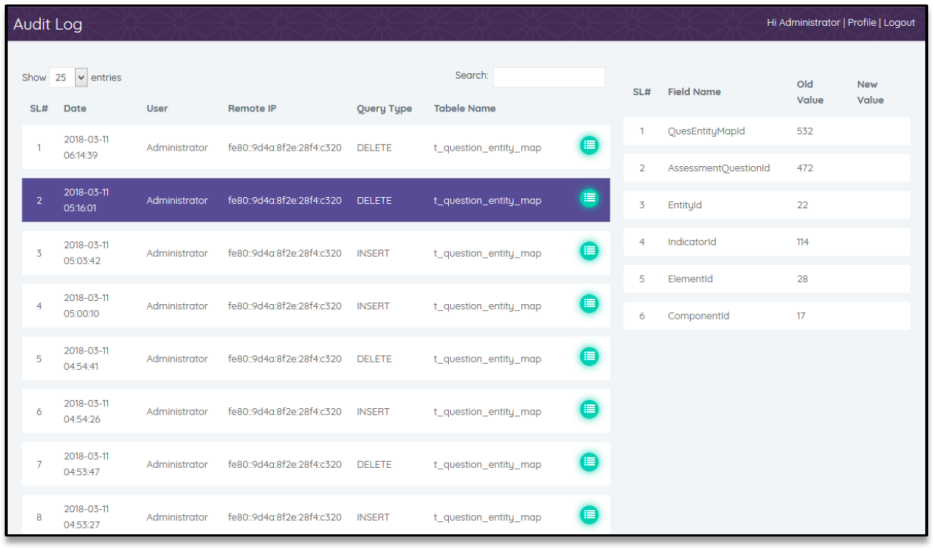


Chapter-8: System Audit

8.1 System Audit Log Tracking

Audit Log keeps track of all the User Actions of Data Entry (i.e., Insert, Update and Delete) in a specific Table of the PSS Insight Database. If a user adds a new record into the system, each field value of this record treated as new value to the system. In this case the old value of that field is empty. If user removes a record then the audit log will record the old value only. Because already existing value i.e., old value can be deleted or removed. Otherwise if user edit a record and save it, the old and new values are saved to the audit log at that time. In other words, all the changes made by a user to the system are logged automatically to avoid the unauthorized changes to the system.

Select Admin > Audit Log menu, which will show the following page -



There are two panels in this page: a left panel and a right panel. The left panel shows the user action of insert, update and delete command. The fields in the left side table -

- SL#: It is the serial number of the records viewing in the page, latest records first.
- Date: It is the date and time of a command executed by the user.
- User: Name of the user who is responsible to execute a command.
- Remote IP: IP address of the user PC in the network.
- Query Type: Command type executing by the user – INSERT/UPDATE/DELETE.
- Table Name: Name of the table on which the user command is being executed.
- SQL Text: Standard query language text that is being executed to the database but this a short notation of the command. When you click on the 'more' button you will be able to see the full text of the command.

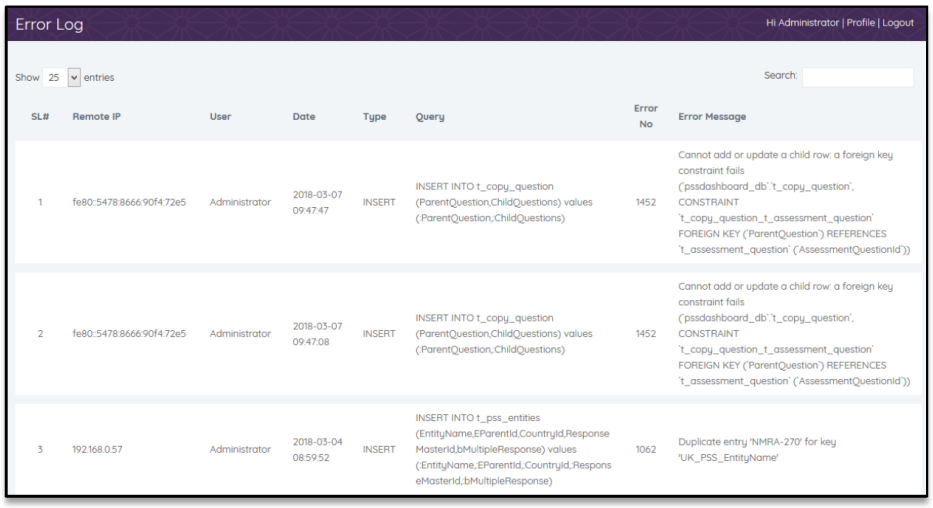
When you select a record from the left side table, the right side table will show the list of values based on command executed. The fields are - field name, old value and new value. If the command

is INSERT, it will show only new values. The old values are empty in this case. If the command is DELETE, it will show only old values new values are empty. It is only the case where both the old and new values are encountered when user edit a record. These are the changes the system will keep track.

8.2 System Error Log Tracking

When a user tries to Add, Edit and Remove a record and if any error occurs during database operations, i.e., a user is trying to add a record that alreay exists in the database, that will raise an error. Again, if a user is trying to delete a record that has a relavent record(s) or reference with other table(s) may raise an error. For clarification to the System Administrator an Error Log is implemented as per previous user experience.

Select Admin > Error Log menu, which will show the following page –



The above image shows the errors which occurred during data entry in PSS Insight. The columns in the table are –

- Remote IP: IP address of the computer where the error initiated
- User: PSS Insight User ID
- Date: It is the date and time of a command executed by the user.
- Type: Command type executing by the user – INSERT/UPDATE/DELETE.
- Query: The SQL command which is the source of error
- Error No: MySQL Error number if available
- Error Message: Error message that explains more about the error.

This error messages can be used by the Administrators to find out what exact errors that happens in PSS Insight and try to solve those.

Chapter-9: How to change "PSS Insight" Home Page Content?

Open any internet browser (Google Chrome, Mozilla Firefox) then type http://pssinsight.org/wp-admin/, which shows the following screen –

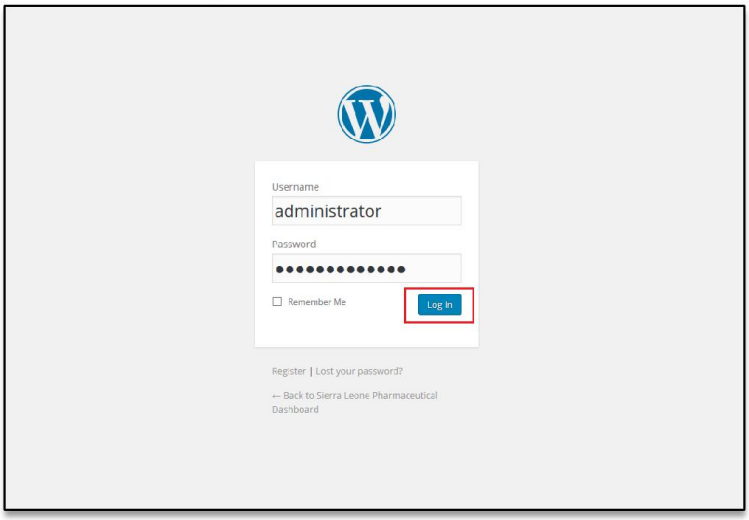


Figure: H-1

Type Username and Password and then click "**Log In**" button. After clicking "**Log In**" button user will see the following page-

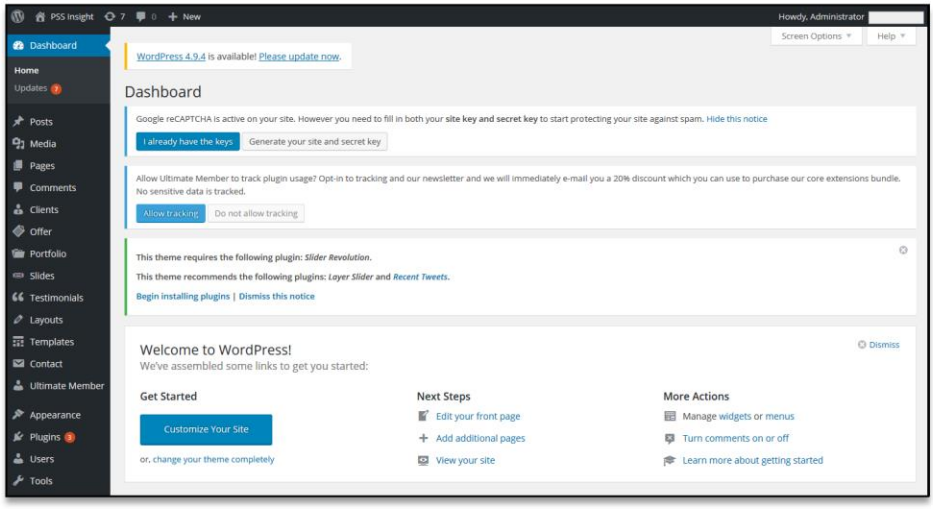


Figure: H-2

Now, Click **All Pages** submenu of **Pages** menu from left side menu bar.

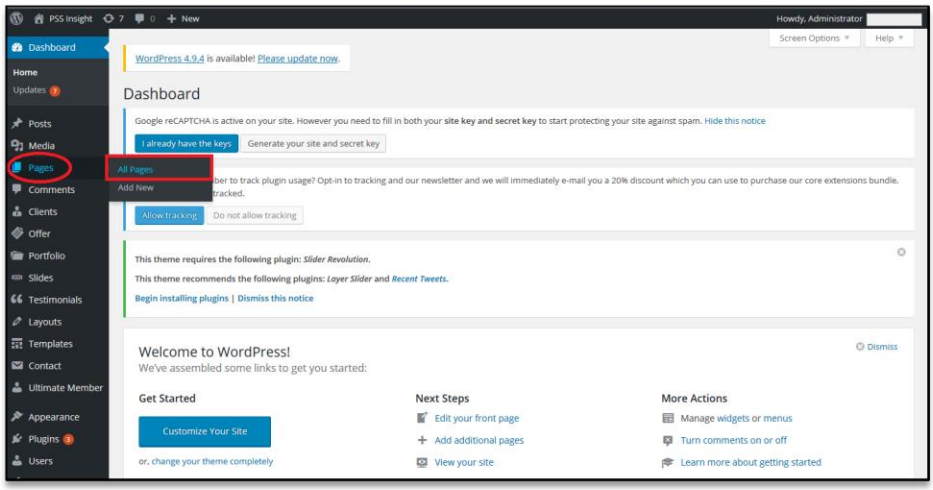


Figure: H-3

User will see the following page…

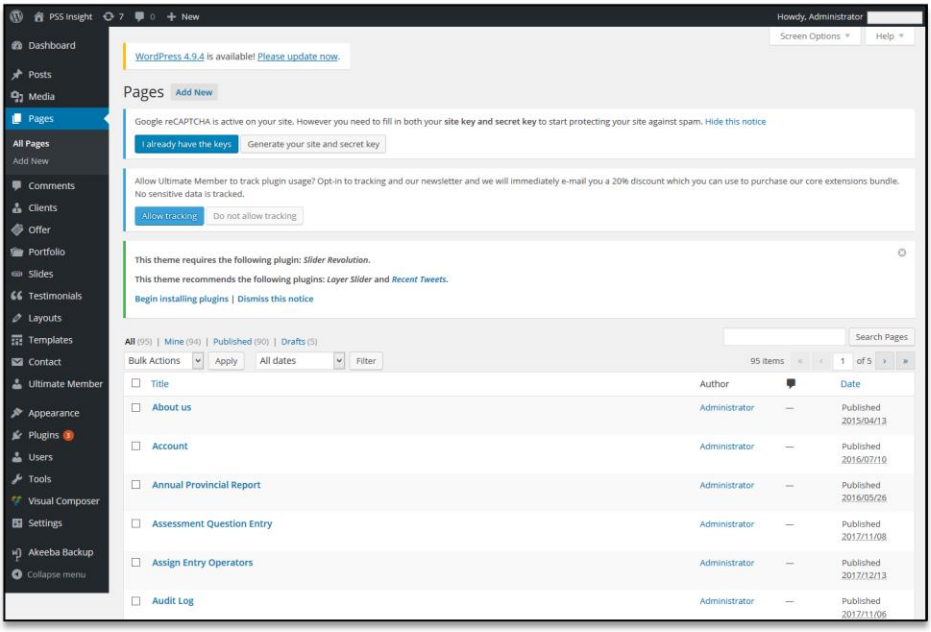


Figure: H-4

Enter home in the search box and then click "**Search Pages**" button then the page will appear…

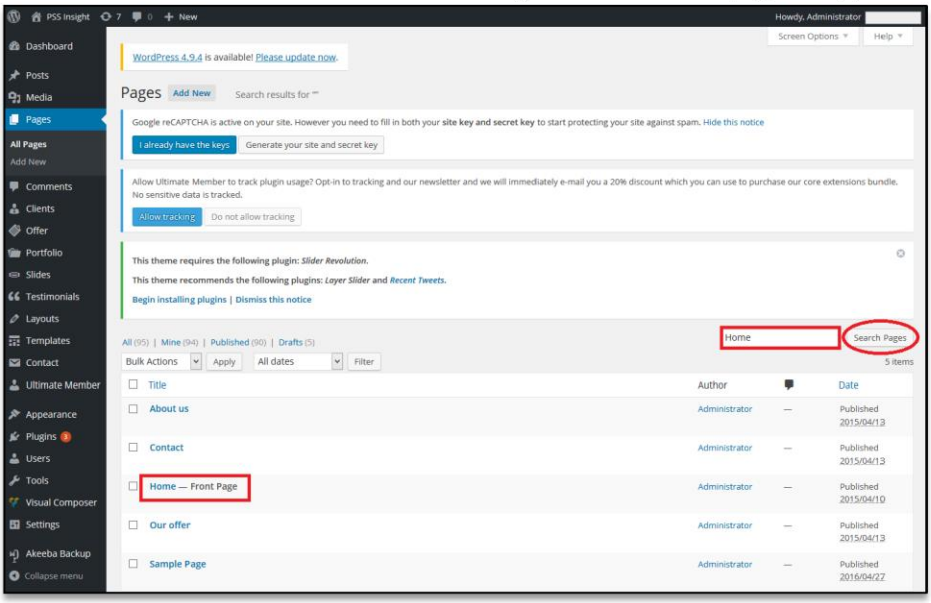


Figure: H-5

When you put cursor over the Home – Front Page link, some more links will show below. Click on "**Edit**".

Figure: H-6

User will see the following page with many **edit icons** to edit the home page content.

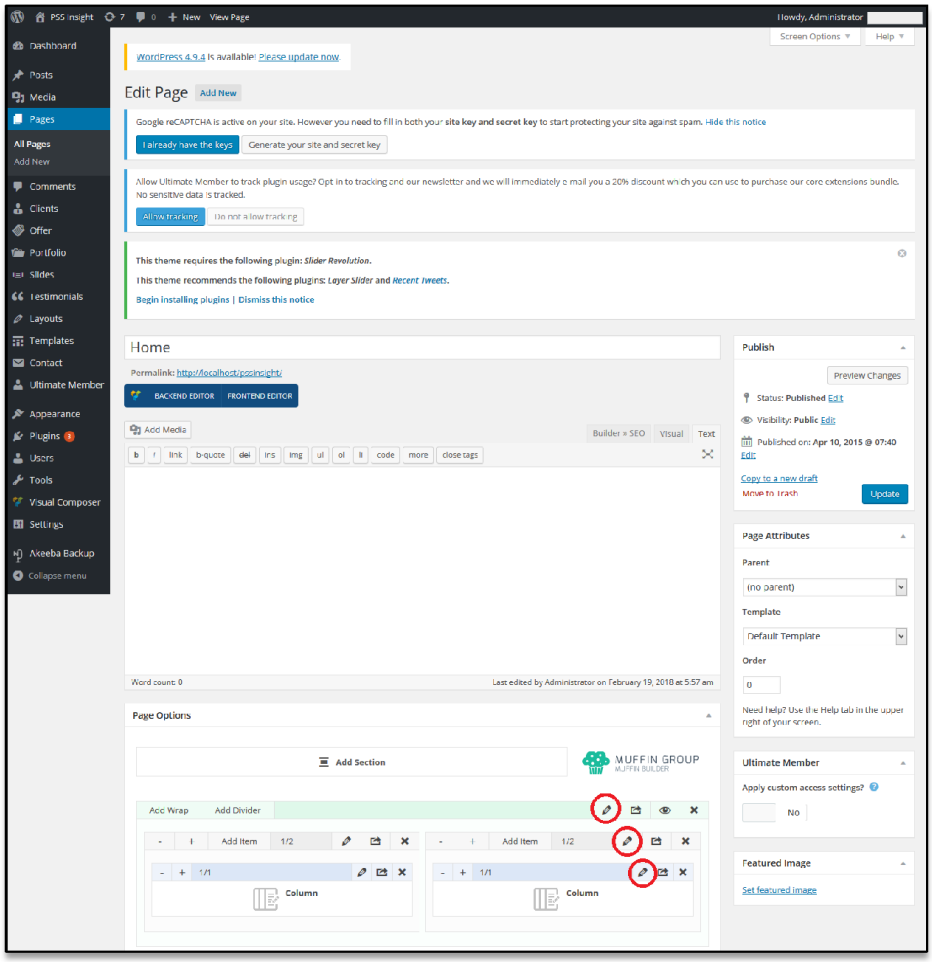
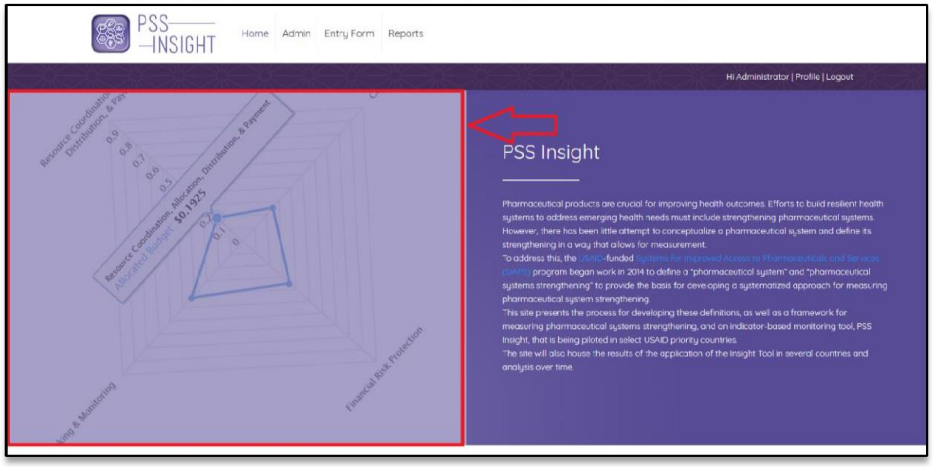


Figure: H-7

9.1. How to change the Home Page Background Image



Click on the first **edit pencil icon** into "**Page Options**" section from "**Figure: H-7**" look like following screen –

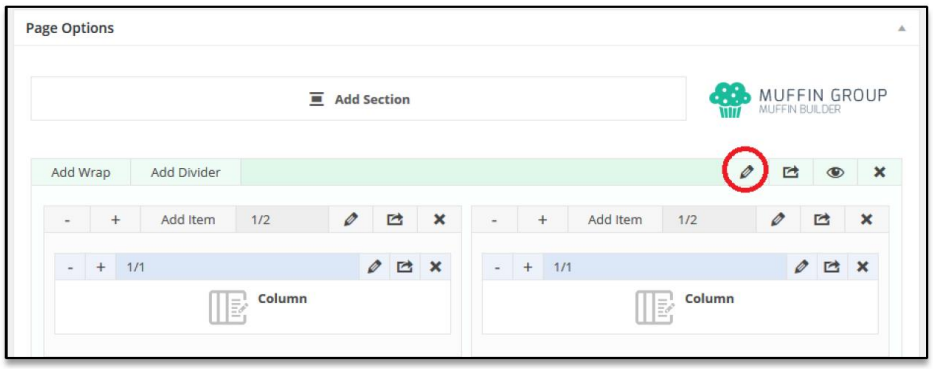


Figure: H-8

User will see the following page…

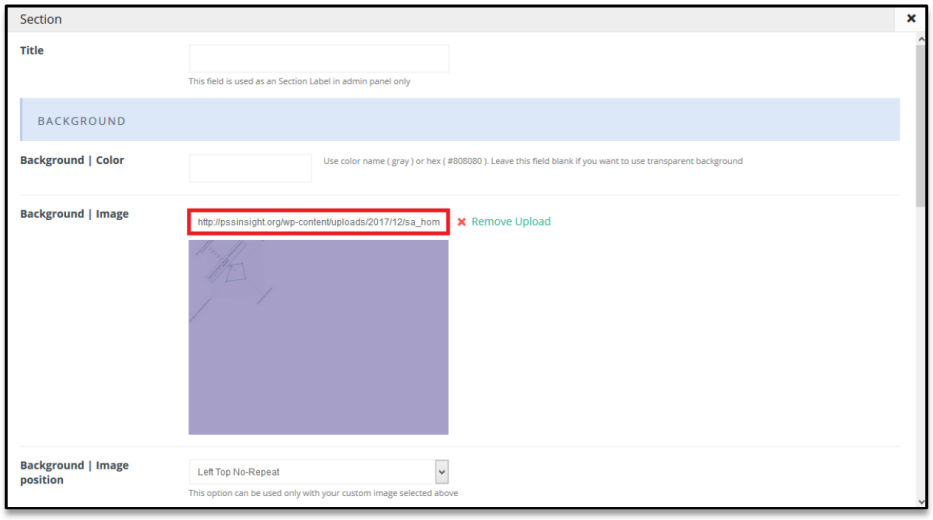


Figure: H-9

Set the home page image URL that is taking from web site media library (described into section-9.1.1).

9.1.1. How to upload image in the media library

Following section explains how to upload image in the media library

Click on the "**add New**" submenu of the "**Media**" menu-

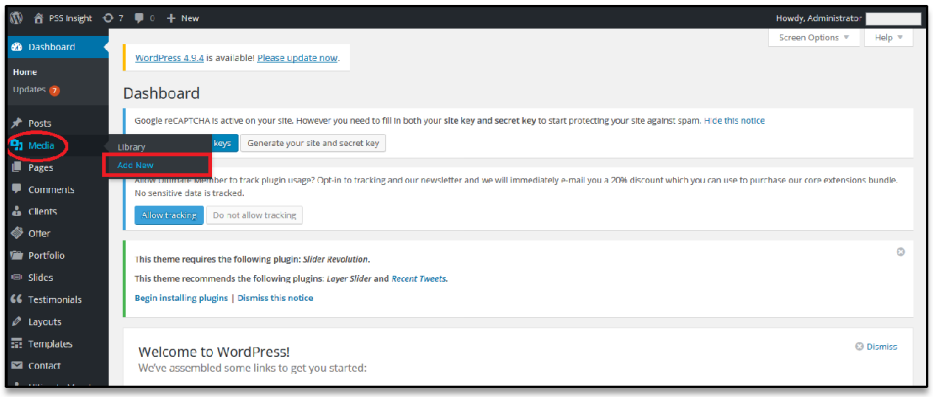


Figure: H-10

Then the following page will appear-

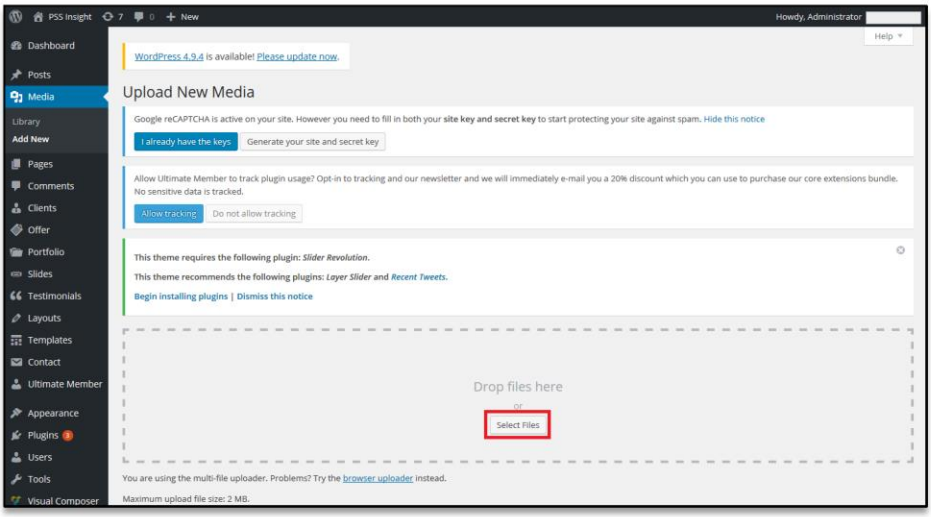


Figure: H-11

Click on the "**Select Files**" button and browse the file from your local drive then click to "**Open**" button as follows-

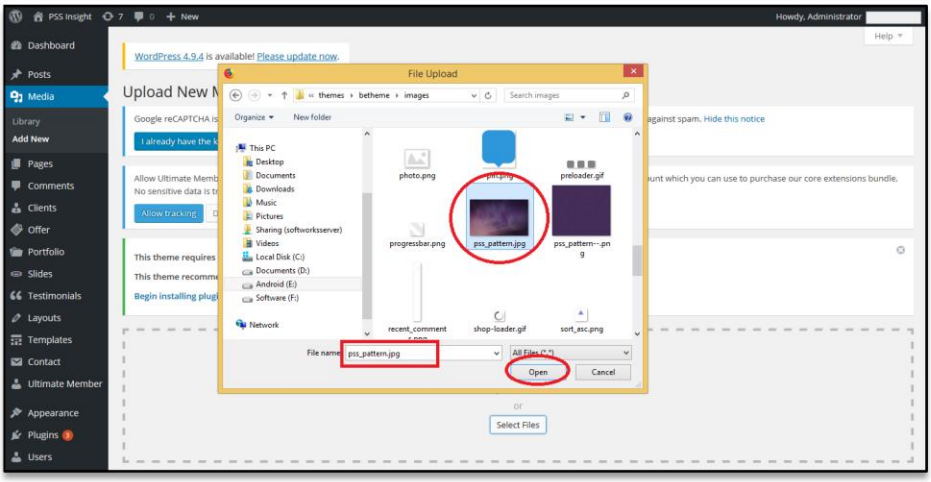


Figure: H-12

Then Click "**Library**" submenu under "**Media**" menu and the user will see the following page as user's uploaded file as indicated.

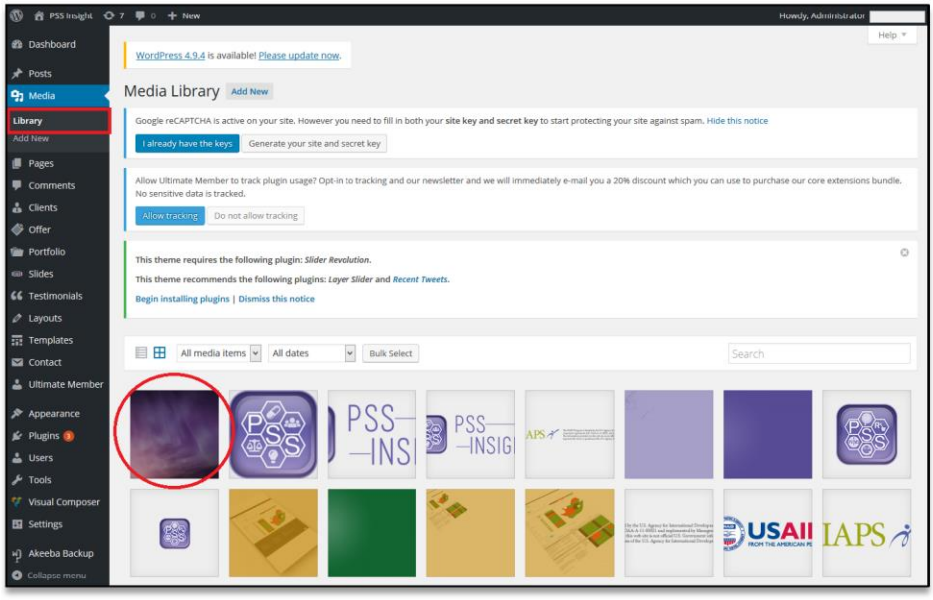


Figure: H-13

Click on the selected file and the following page will appear with indicated URL.

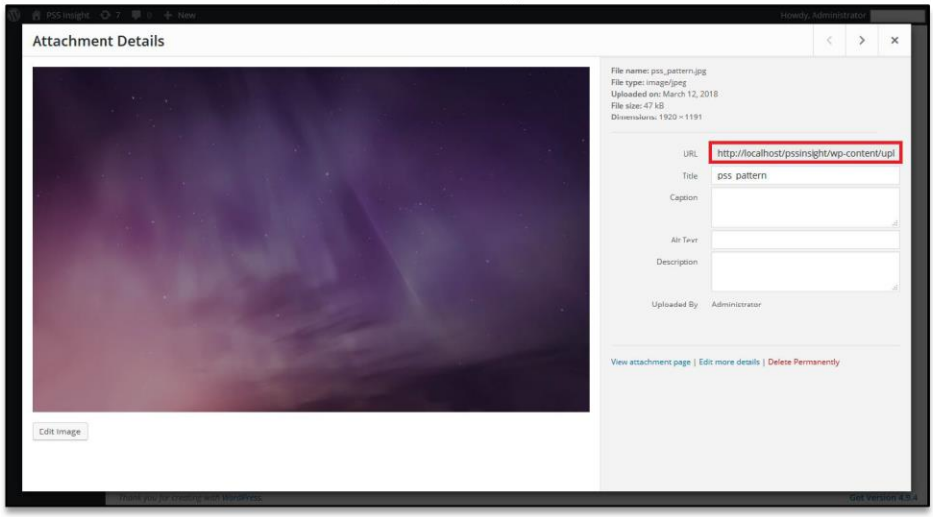


Figure: H-14

Copy the indicate URL from **Figure: H-14** and paste into **Figure: H-9** home page content image URL field and click on "**Save Change**" button to save. After that following screen will appear-

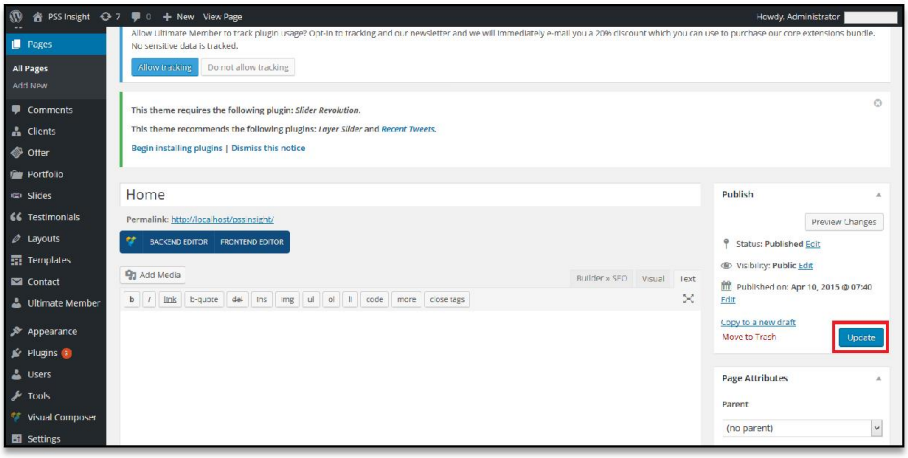


Figure: H-15

Now click into "**Update**" button to update home page information.

Then the content will be changed as following screen-

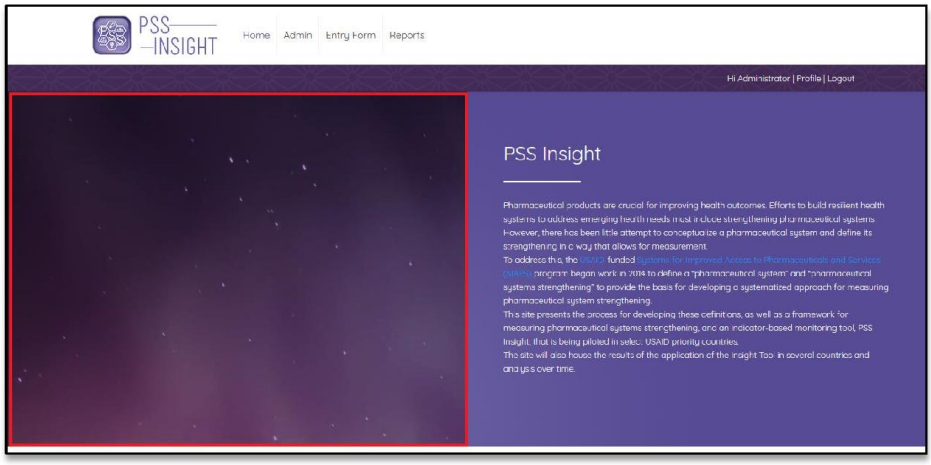


Figure: H-16

9.2. How to change the Home Page Title and Description

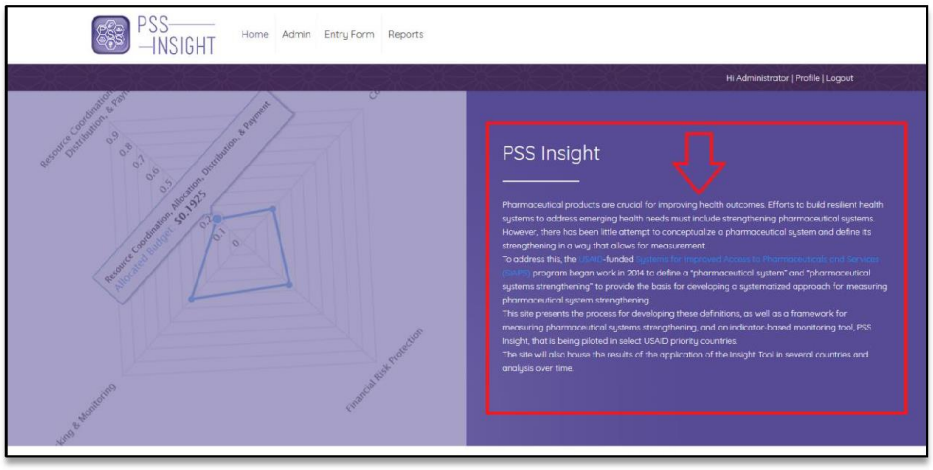


Figure: H-17

Click on the third **edit pencil icon** into "**Page Options**" section from "**Figure: H-7**" look like following screen –

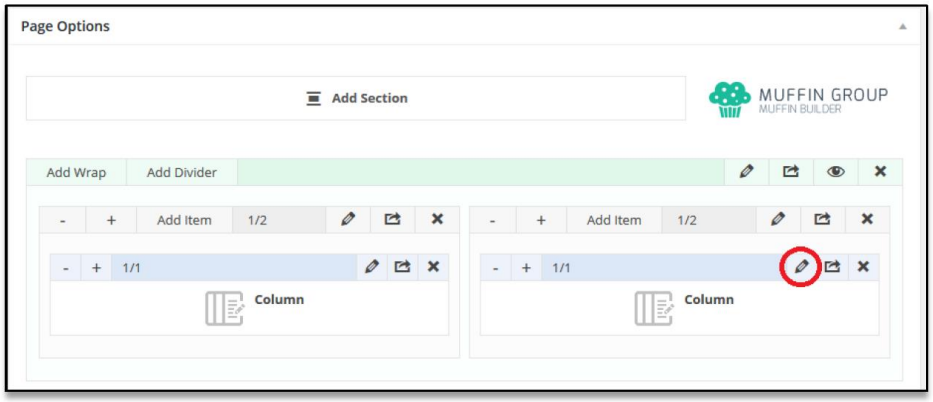


Figure: H-18

User will see the following page-

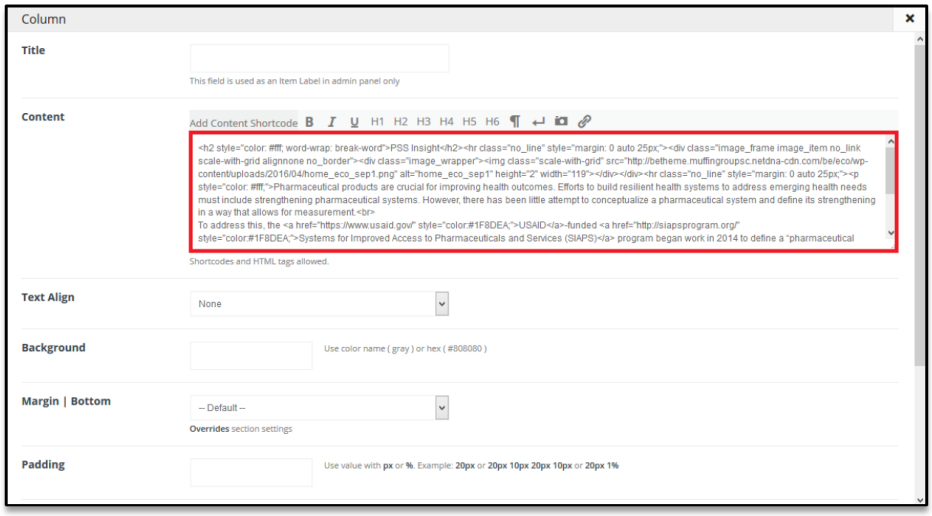


Figure: H-19

Now change the title and description from the indicated section. To save the all changes click to the **Save changes** button from the bottom right side. After that following screen will appear-

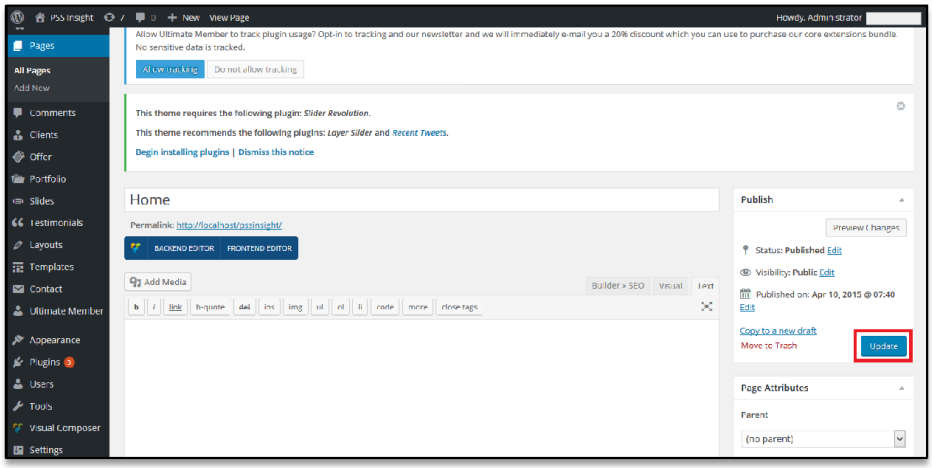


Figure: H-20

Now click into “Update” button to update home page information.

9.3. How to change the background of description

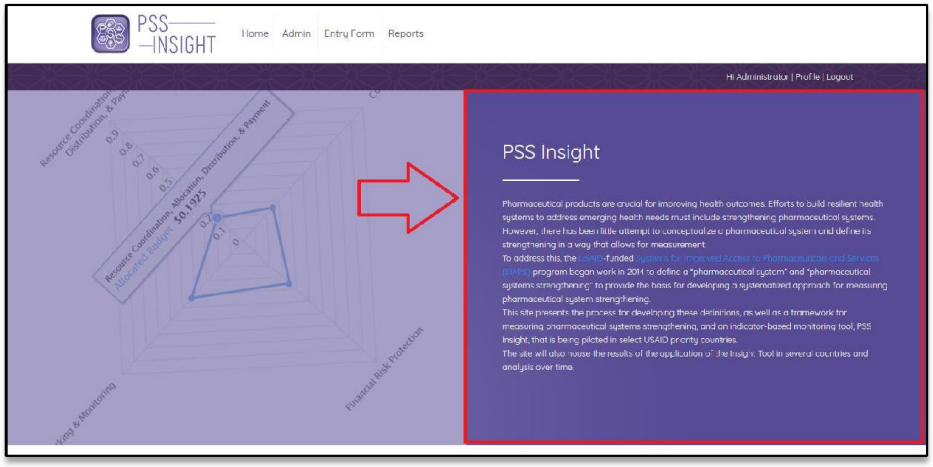


Figure: H-21

Click on the second **edit pencil icon** into "**Page Options**" section from "**Figure: H-7**" look like following screen –

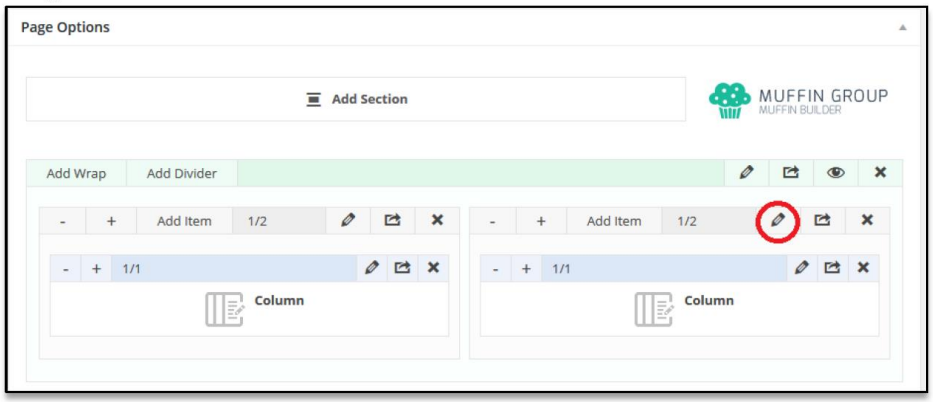


Figure: H-22

User will see the following page-

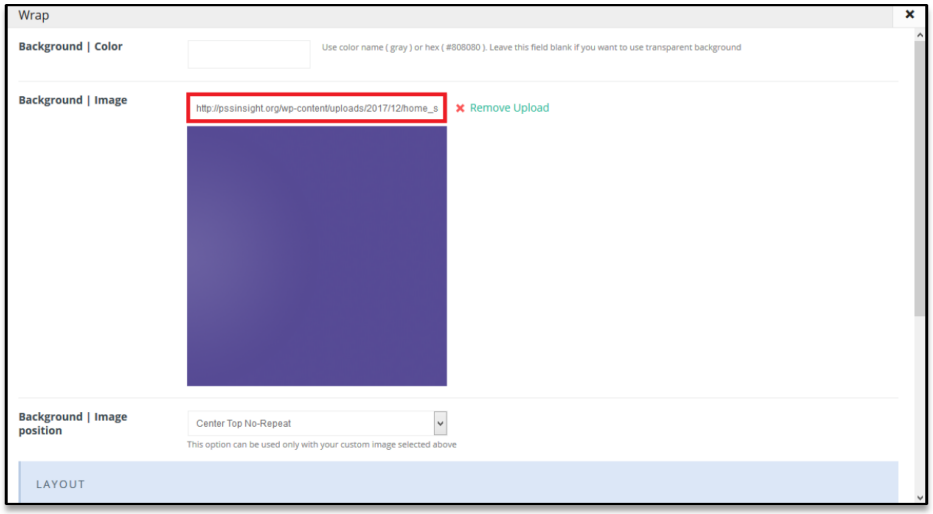


Figure: H-23

Now change the image link from the indicated content section. For this users have to bear in mind that the image URL must be taken from **Media Library,** upload image process describe into (**7.1.1. How to upload image in the media library**). To save the all changes click to the 

button from the bottom right side. After that following screen will appear-

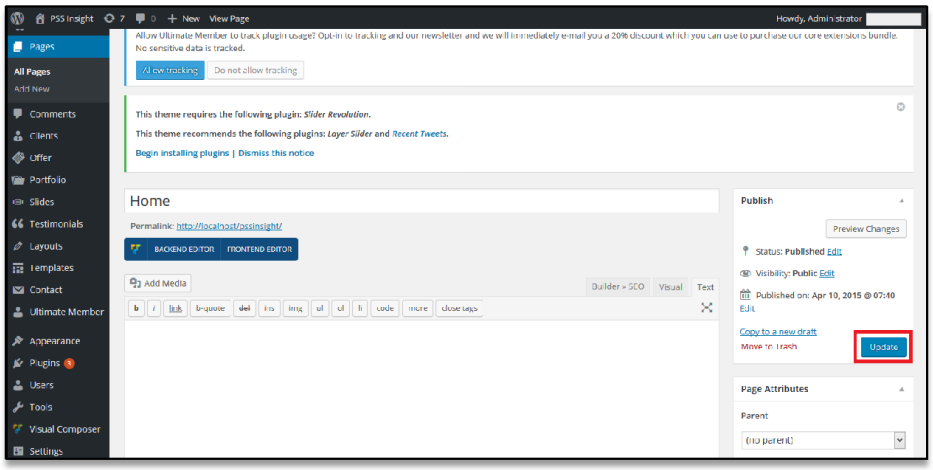
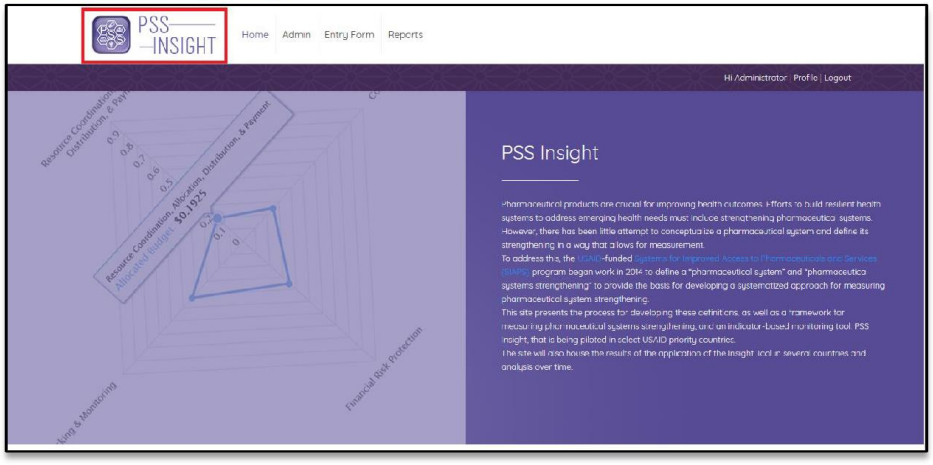


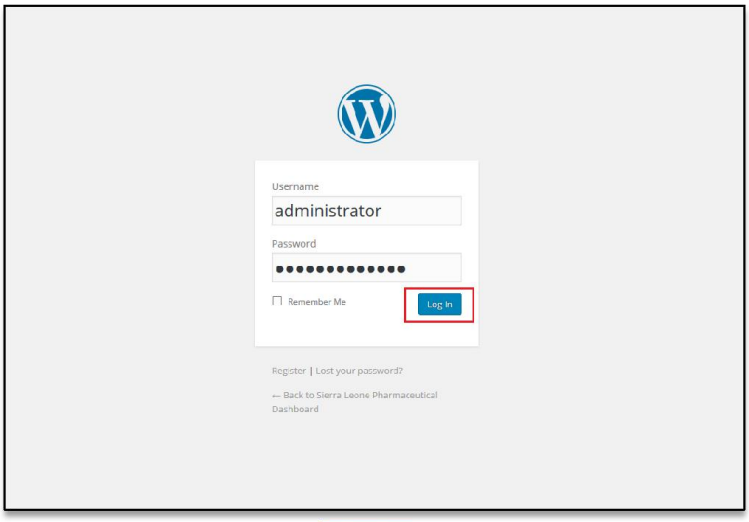
Figure: H-23

Now click into "**Update**" button to update home page information.

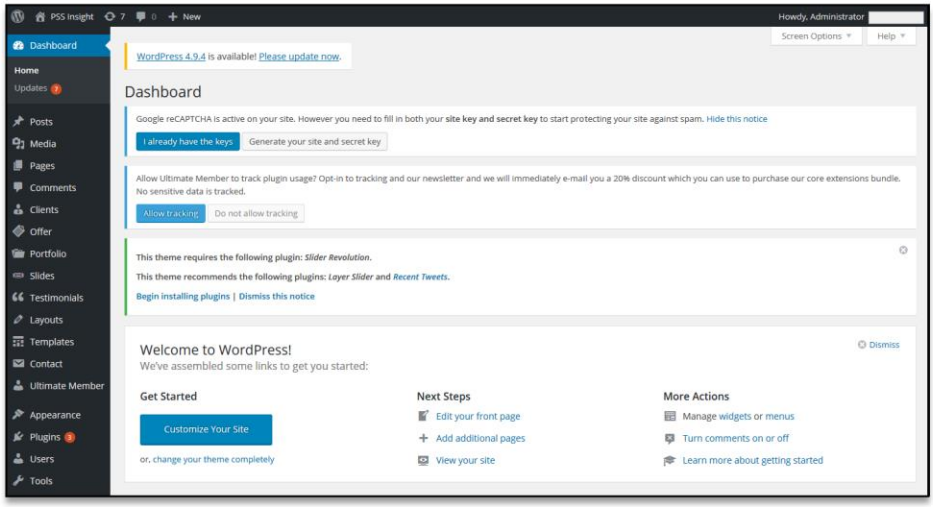
9.4. How to change Logo



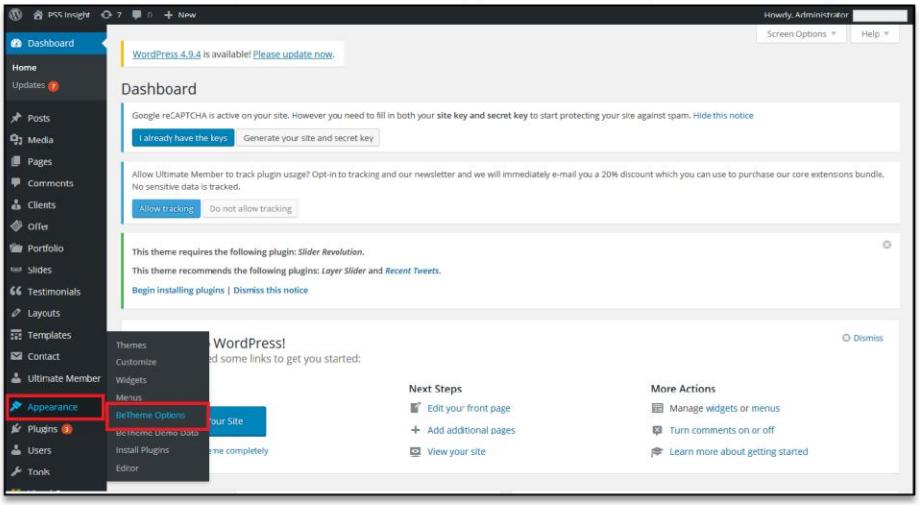
Open any internet browser (Google Chrome, Mozilla Firefox) then type http://pssinsight.org/wp-admin which shows the following screen –



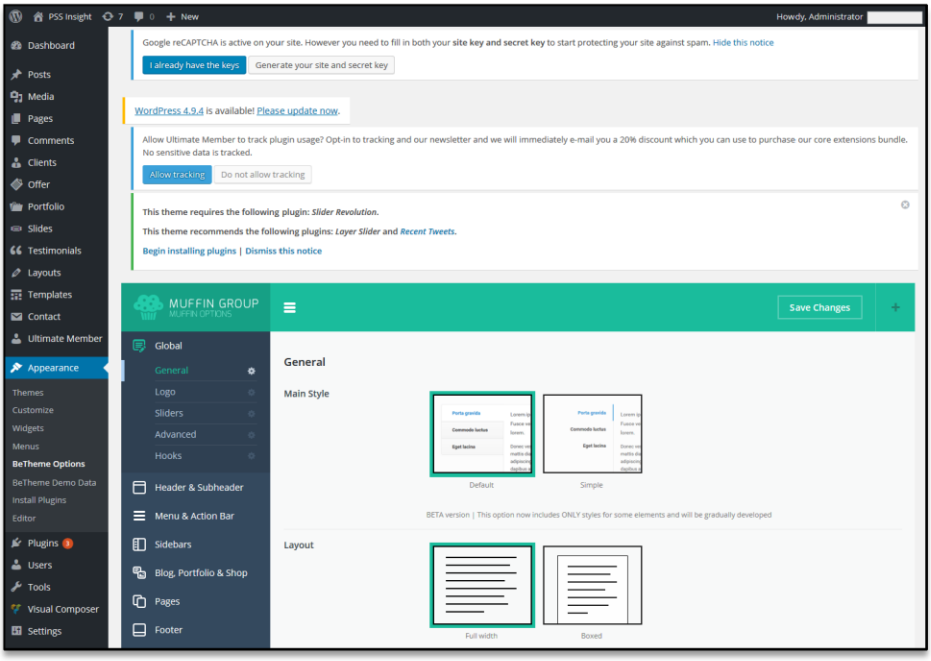
Input Username and Password and click into Log In button. Then the following screen will appear -



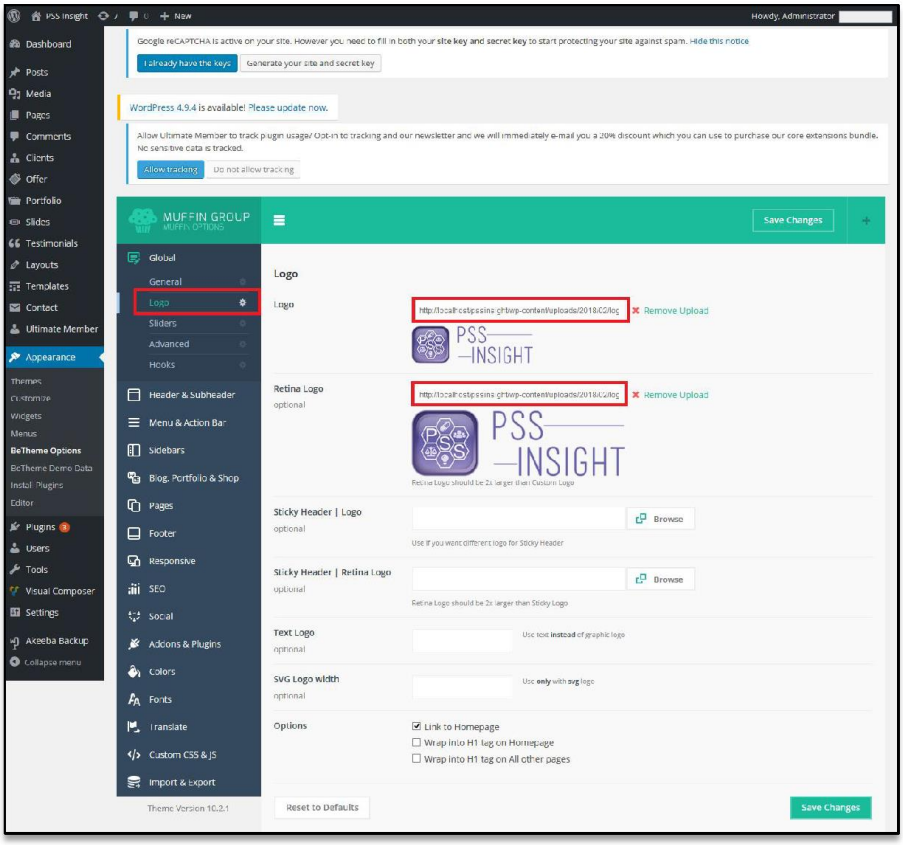
Now click into "**BeTheme Options**" submenu of "**Appearance**" menu, look like following screen-



Then the following screen will be appear-



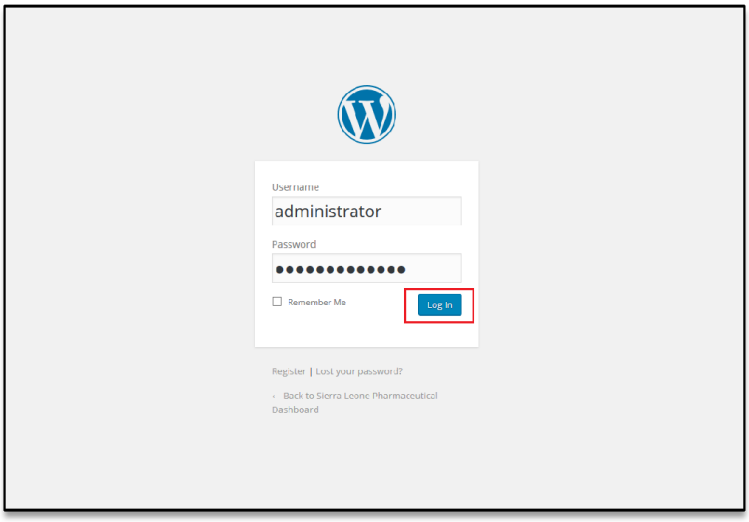
Then click into "**logo**" submenu indicates in the following page with Logo and Retina Logo URL that is also indicated.



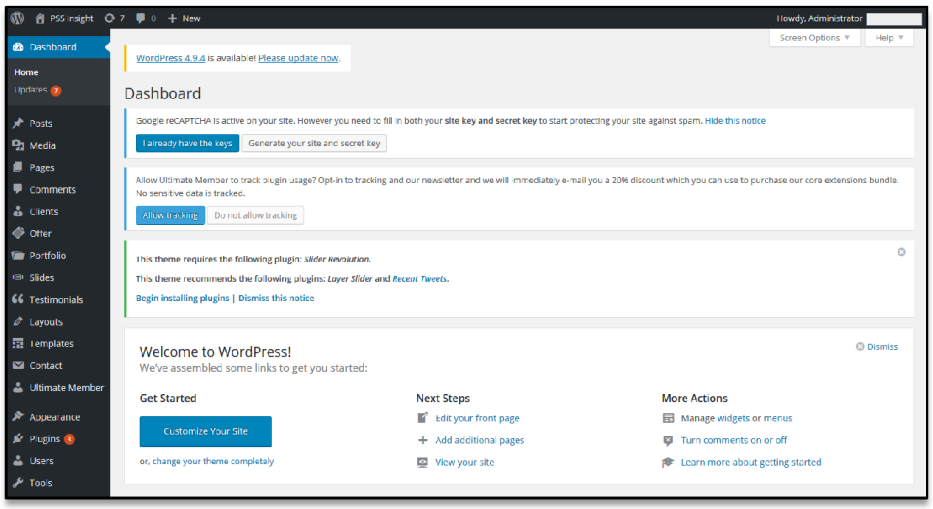
Enter Logo and Retina Logo URL and click "**Save Changes**" button to save logo. Browse http://pssinsight.org/ home page to see the changes in effect.
Note: The images have to be already available in the Media Library.

9.5 How to change Footer

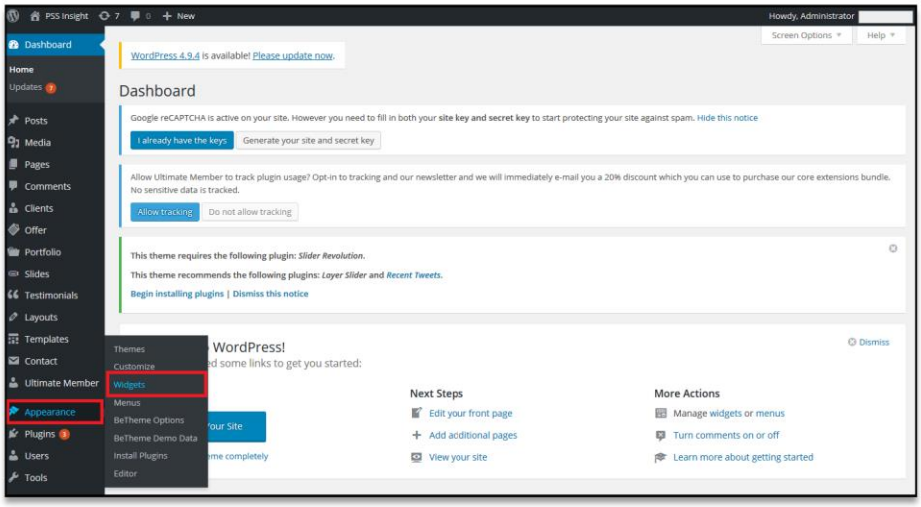
Open any internet browser (Google Chrome, Mozilla Firefox) then type http://pssinsight.org/wp-admin, which shows the following screen –



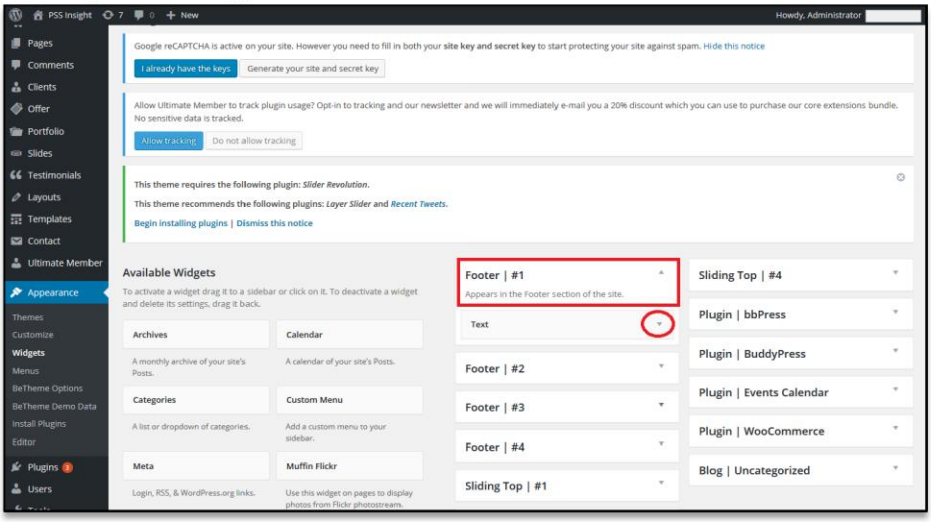
Type Username and Password and then click "**Log In**" button. After clicking "**Log In**" button user will see the following page-



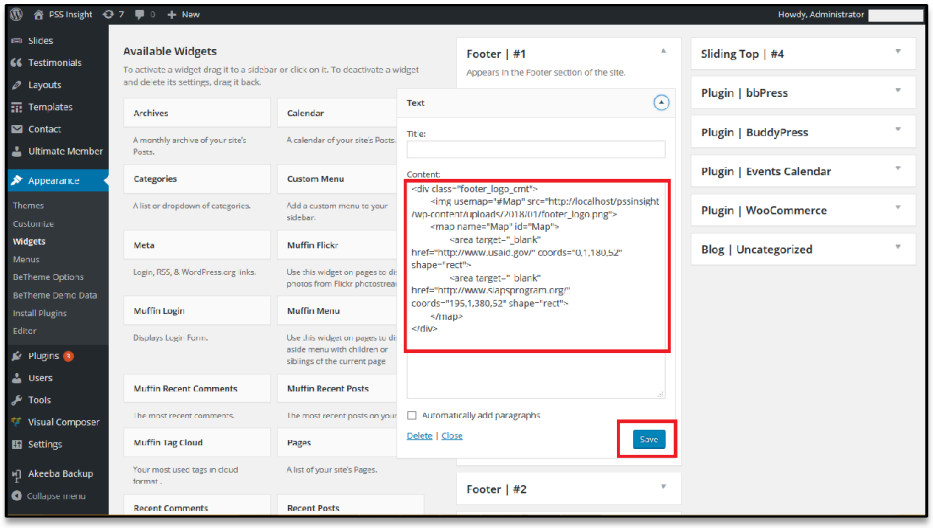
Click on the "**Widgets**" submenu of "**Appearance**" menu



The following screen will appear with indicated footer-



Click on the down arrow key beside the "**Text**" from "**Footer | #1**" and following html content will appear with URL.



The HTML has an image link from "**Media Library**" – USAID and SIAPS logo. If you want to change the logo you can type in the URL of the new image, which has to be already uploaded in the media library. If you want to add more images, you have to edit the HTML template of the footer as indicate in above figure and after that click on "**Save**" button to save.

9.6. How to Create a Menu?

Open any internet browser (Google Chrome, Mozilla Firefox) then type http://pssinsight.org/wp-admin, which shows the following screen –

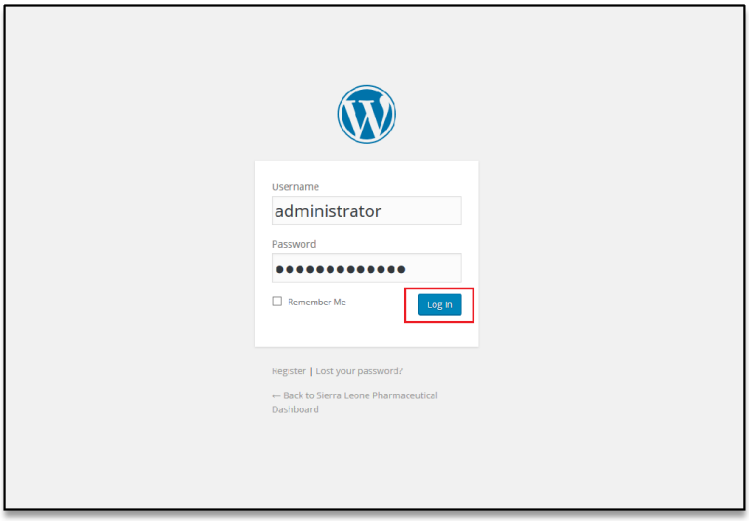


Figure: M-1

Type Username and Password and then click "**Log In**" button. After clicking "**Log In**" button user will see the following page-

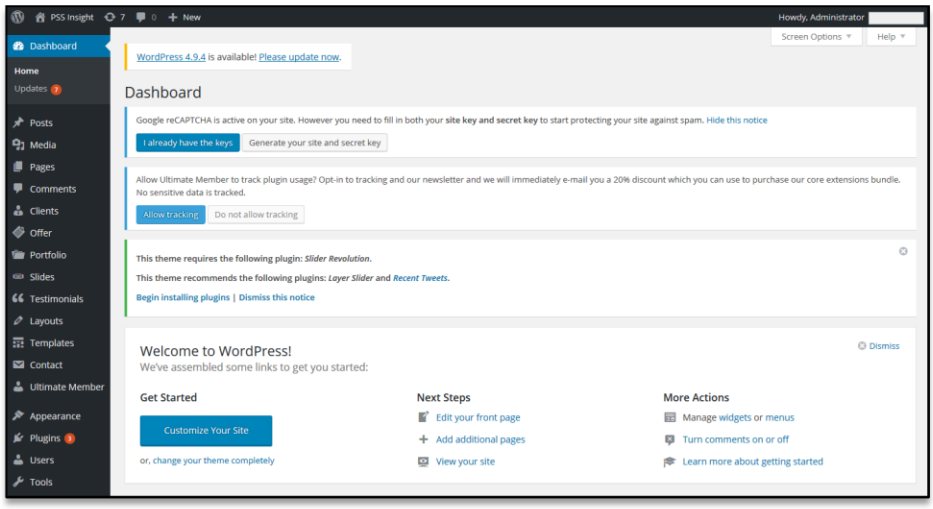


Figure: M-2

Click on "**Add New**" submenu of "**Pages**" menu.

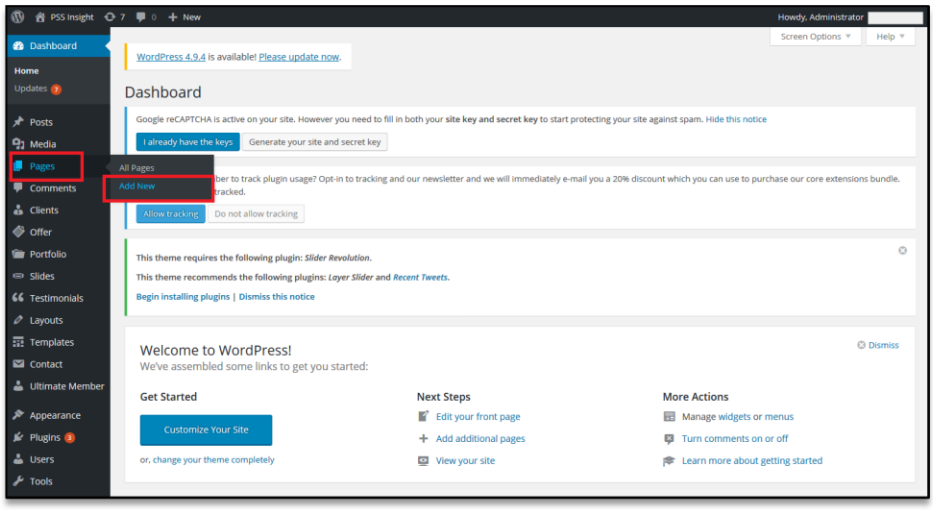


Figure: M-3

Then the following screen will appear-

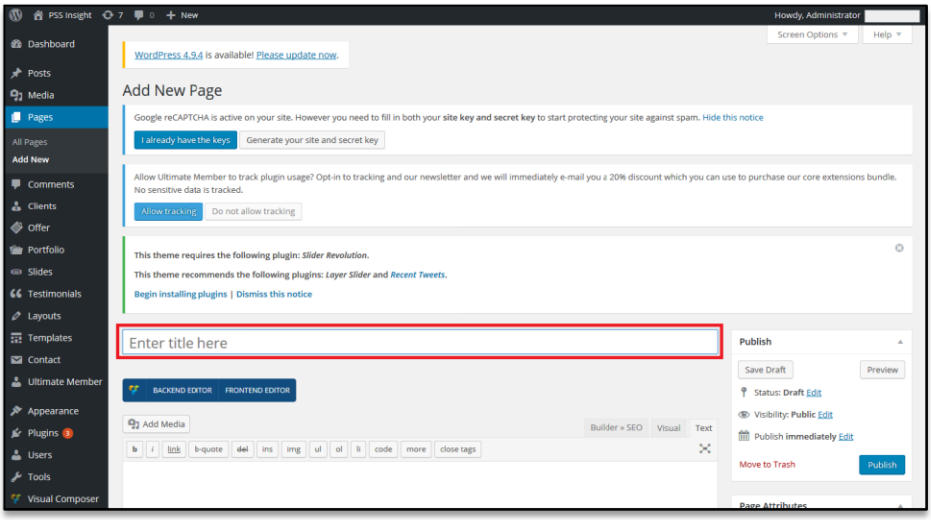


Figure: M-4

Enter Page name indicated the above screen "**Enter title here**"-

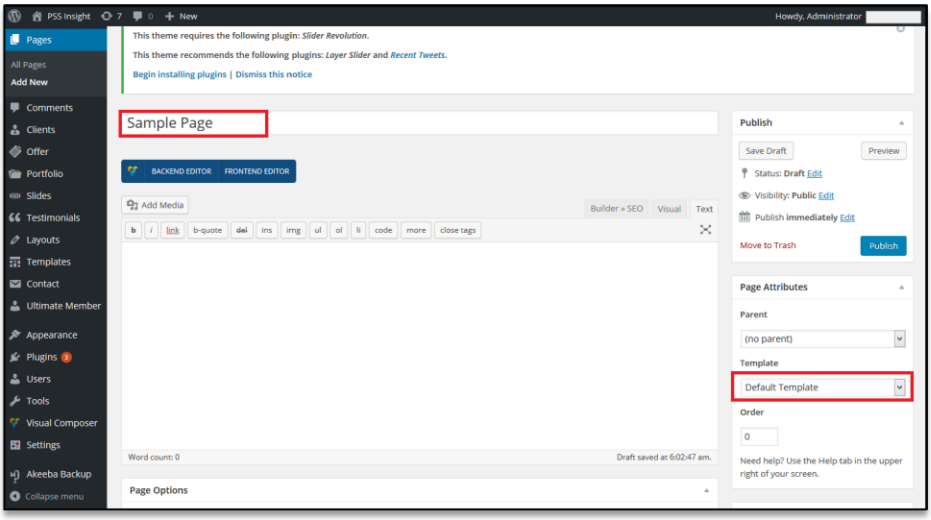


Figure: M-5

Put page title such as "**Sample Page**" then select "**Default Template**". Click on "**Publish**" button to create a page and page will be successfully created.

Click on "**Menus**" submenu under "**Appearance**" menu

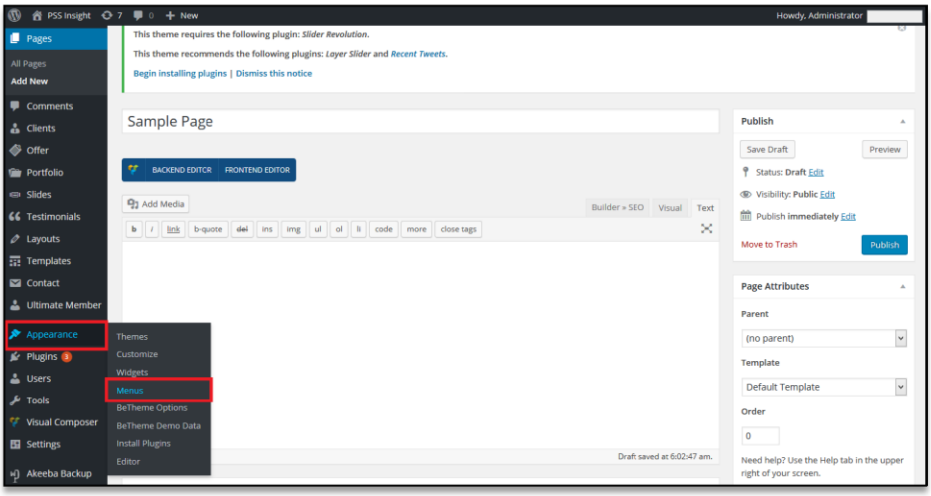


Figure: M-6

Then the user will see the "**Sample Page**" appear in the Page list.

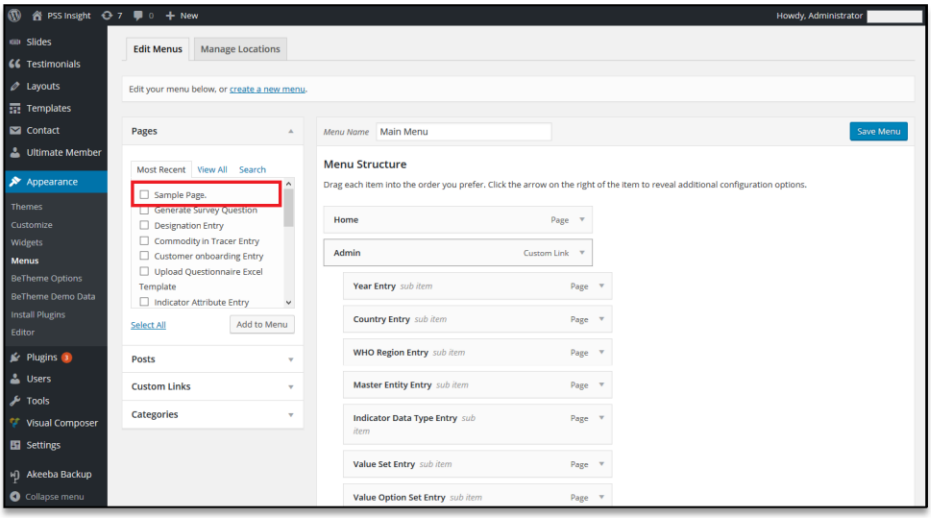


Figure: M-7

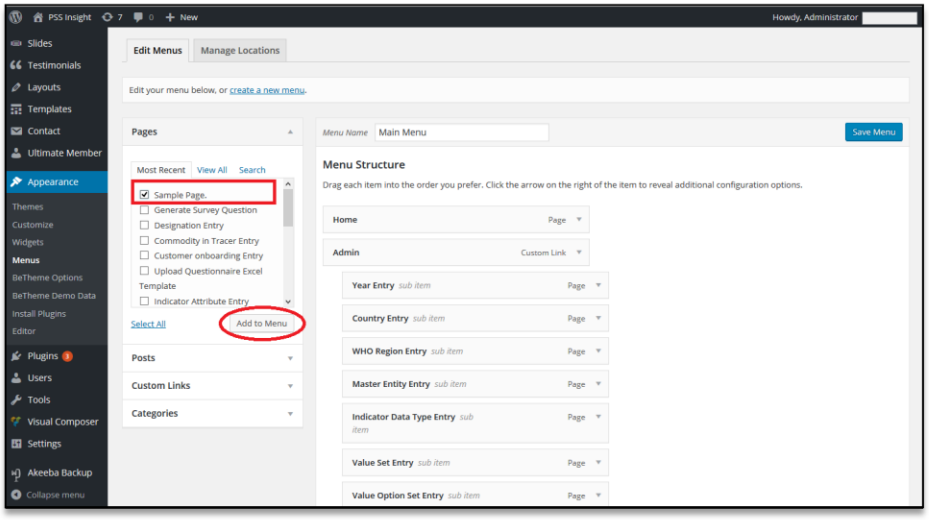


Figure: M-8

Select "**Sample Page**", Click "**Add to Menu**" then the sample Page will appear in the Menu Structure then click on the "**Save Menu**" button to create menu. You can drag the menu to place it in the main menu or to appear under any menu.

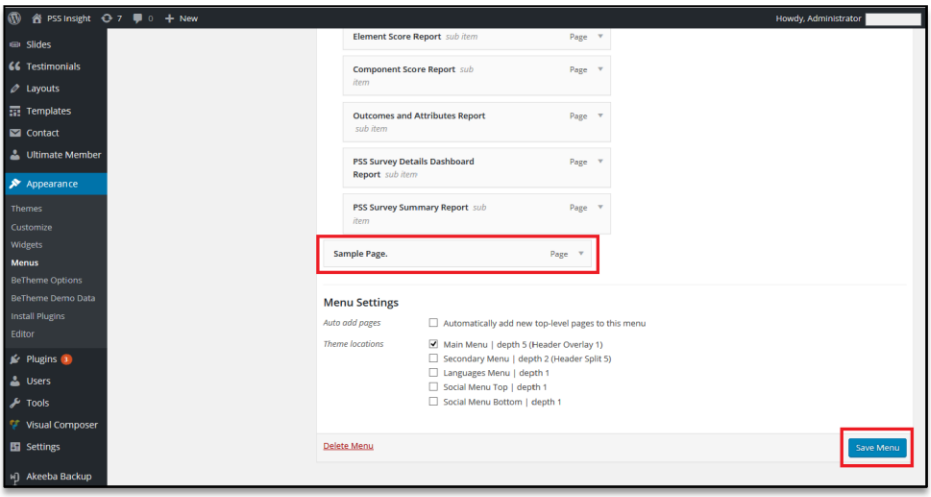
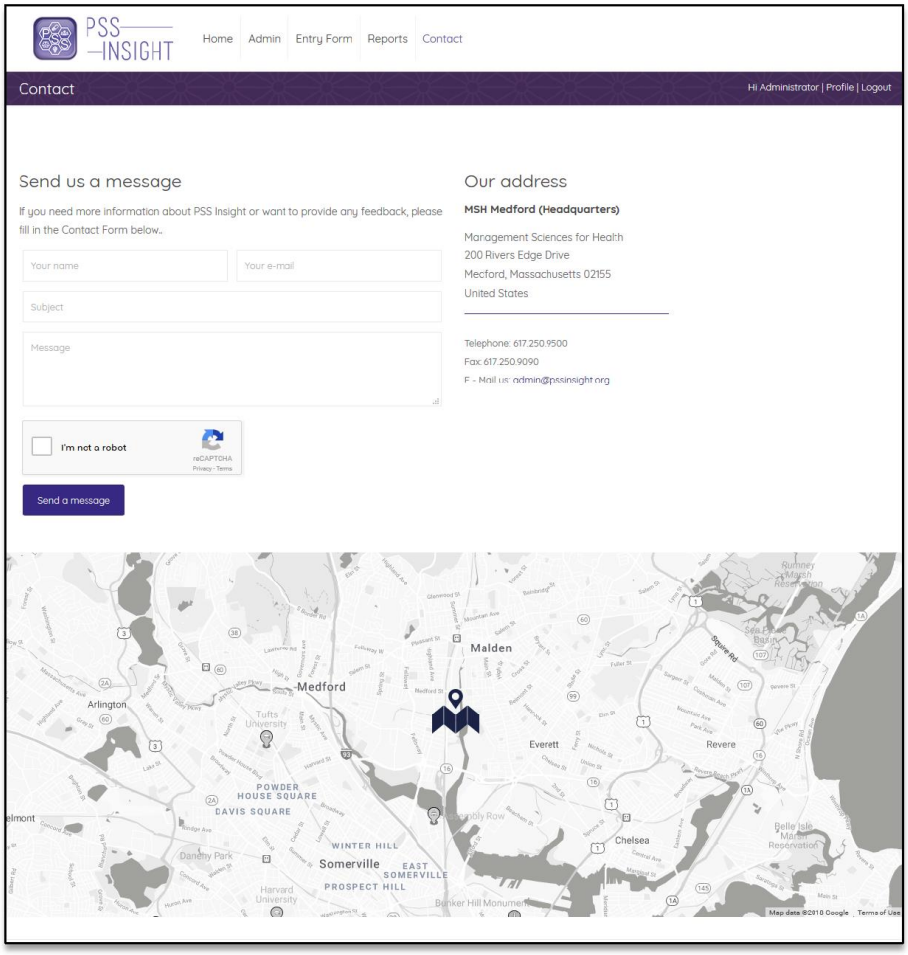


Figure: M-9

Finally, the user will see the menu from front end after login.

Figure: M-10

Chapter-10: How to change Contact Us



Open any internet browser (Google Chrome, Mozilla Firefox) then type http://pssinsight.org/wp-admin/, which shows the following screen –

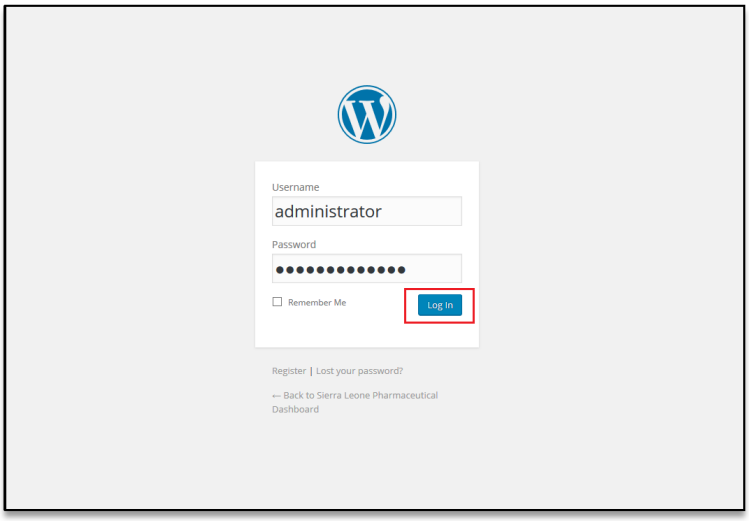


Figure: C-1

Type Username and Password and then click **"Log In"** button. After clicking **"Log In"** button user will see the following page-

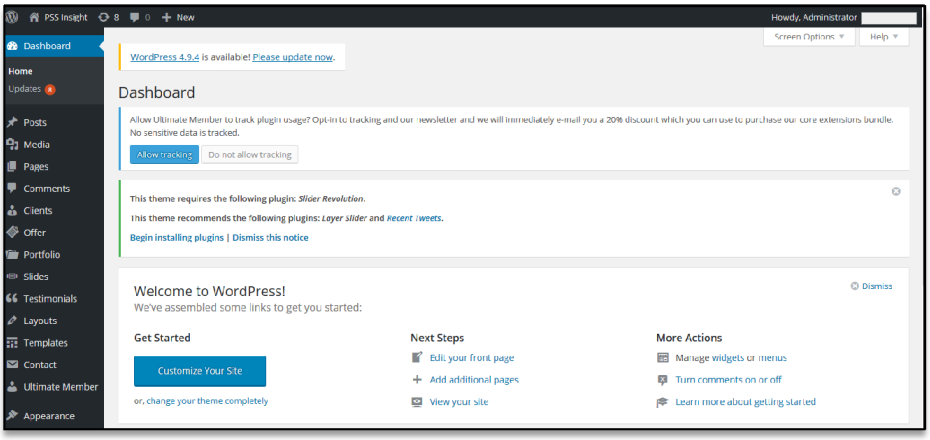


Figure: C-2

Now, Click **All Pages** submenu of **Pages** menu from left side menu bar.

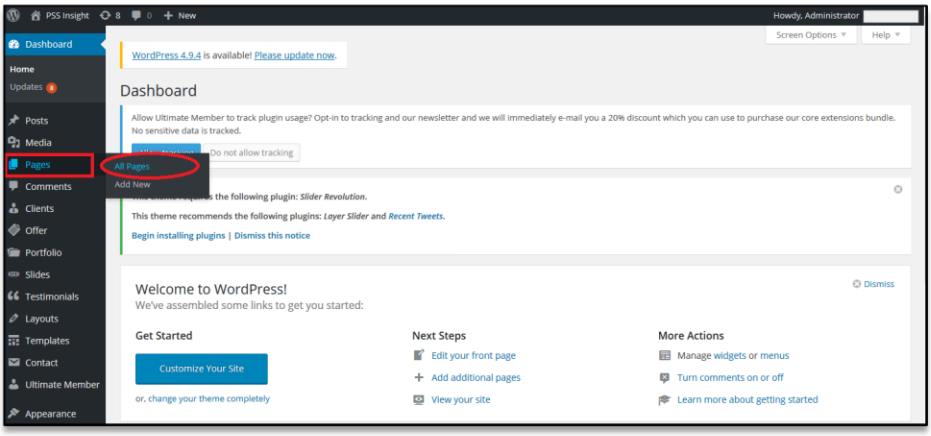


Figure: C-3

User will see the following page…

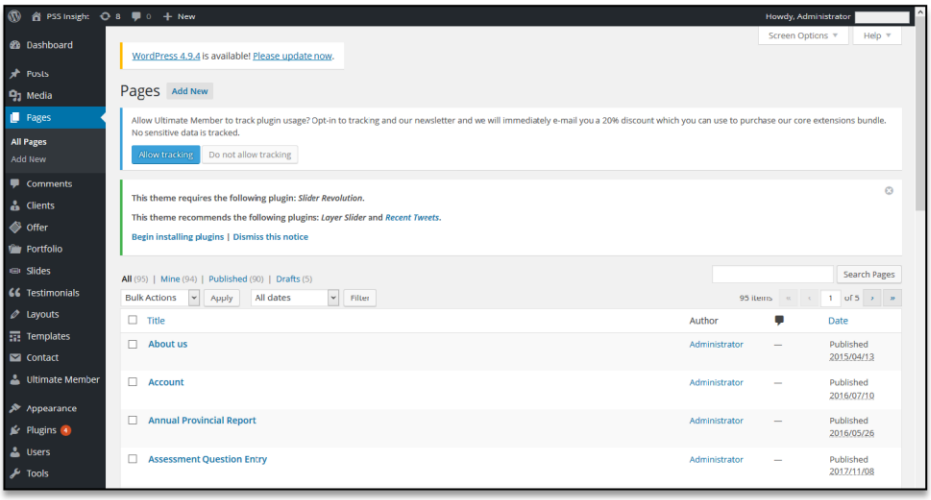


Figure: C-4

Enter home in the search box and then click "**Search Pages**" button then the page will appear…

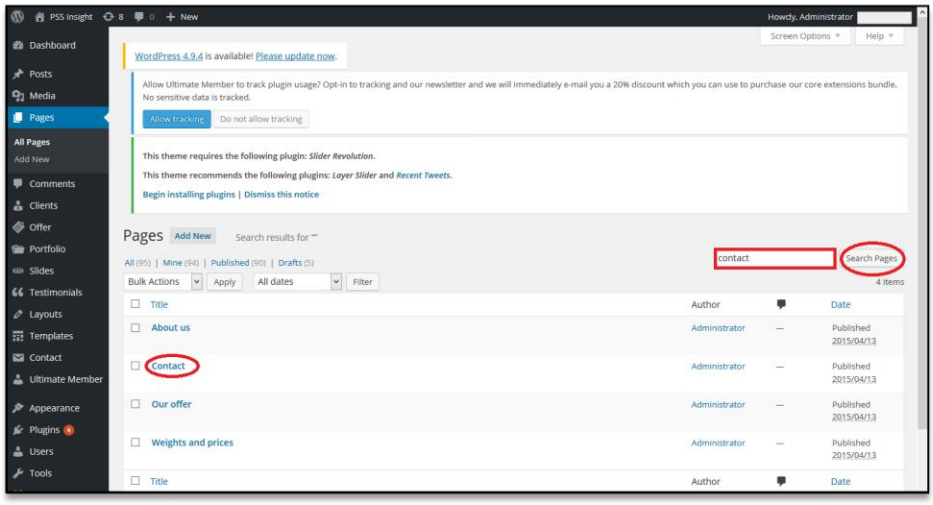


Figure: C-5

When you put cursor over the Contact Page link, some more links will show below. Click on "**Edit**" link.

Figure: C-6

User will see the following page with many **edit icons** to edit the home page content.

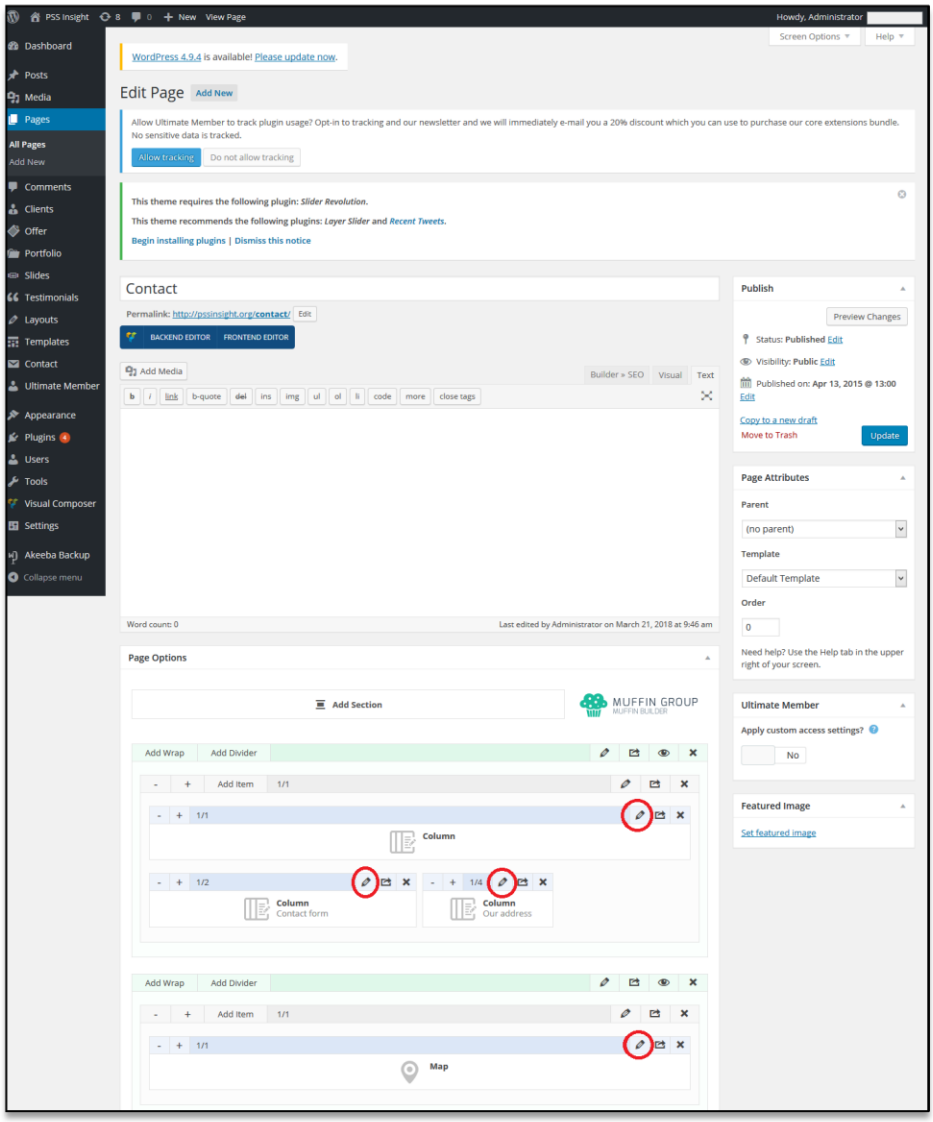


Figure: C-7

10.1. Change Contact page Description

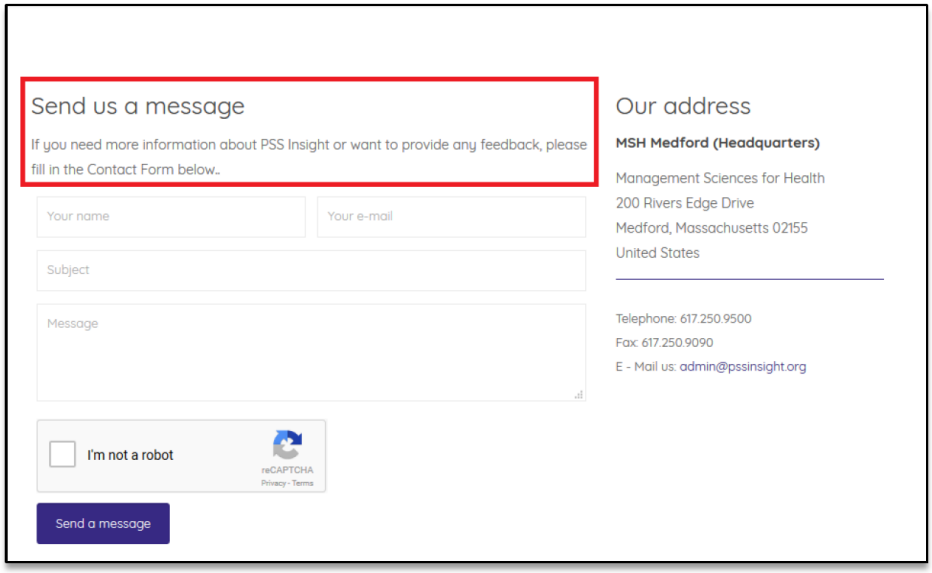


Figure: C-8

Click on the **edit pencil icon** into "**Contact Form**" section from "**Figure: C-7**" look like following screen –

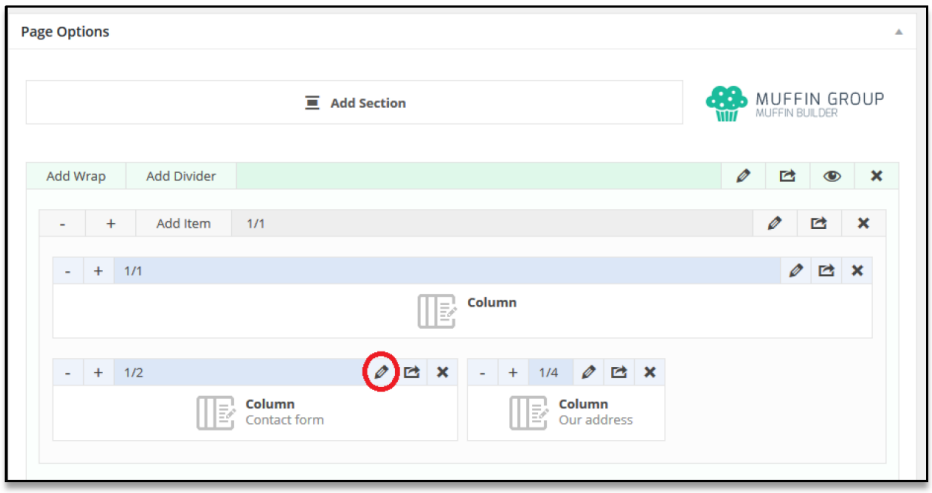


Figure: C-9

User will see the following page-

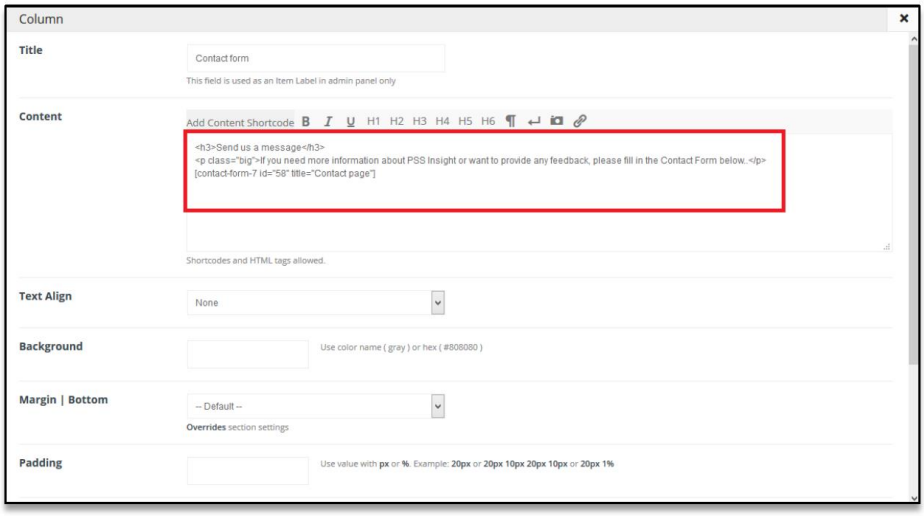


Figure: C-10

Now change the description from the indicated section. To save the all changes click to the **Save changes** button from the bottom right side.

10.2. Change Contact Address

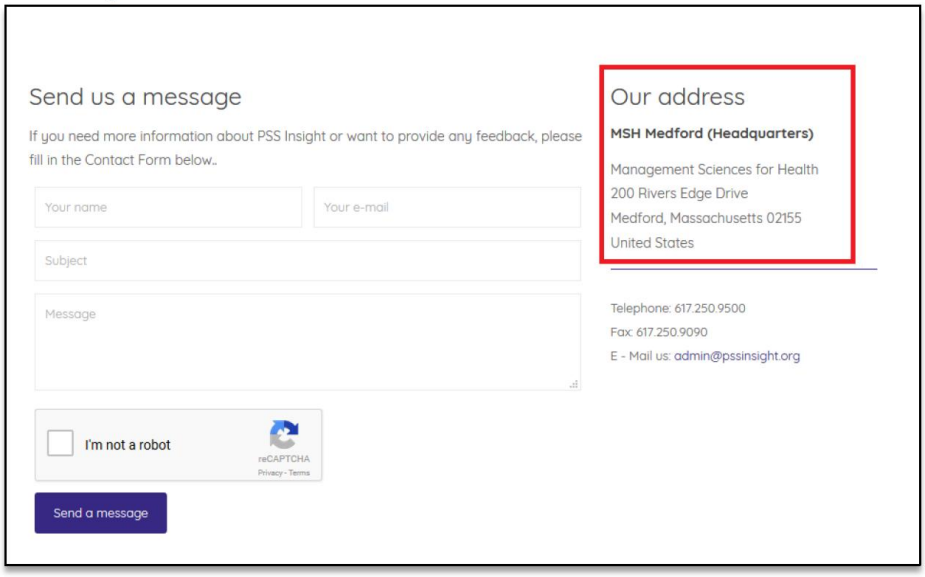


Figure: C-11

Click on the **edit pencil icon** into "**Our address**" section from "**Figure: C-7**" look like following screen –

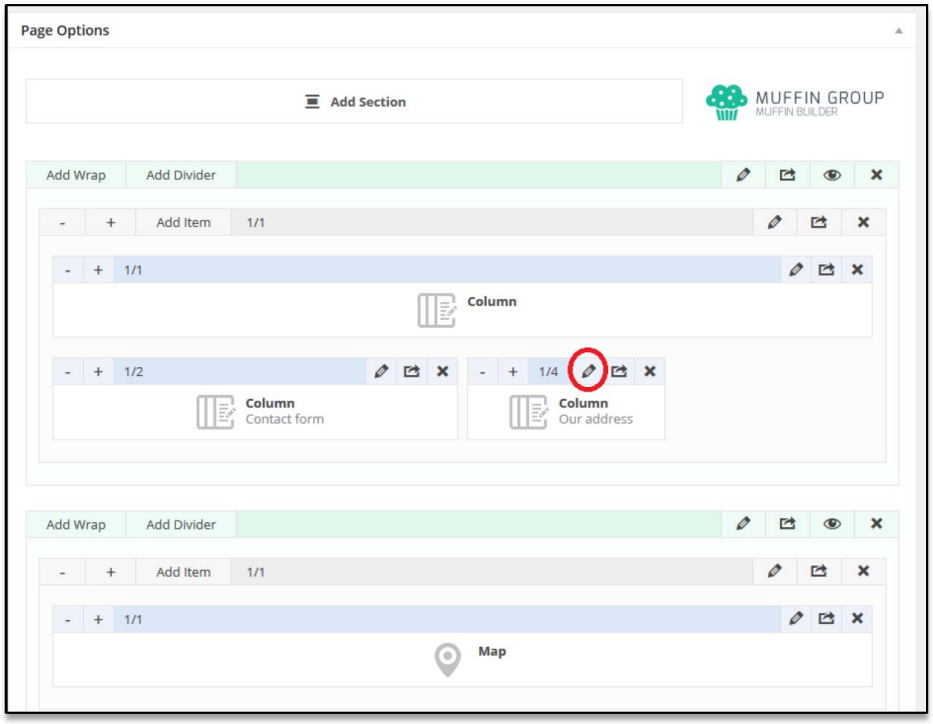


Figure: C-12

User will see the following page-

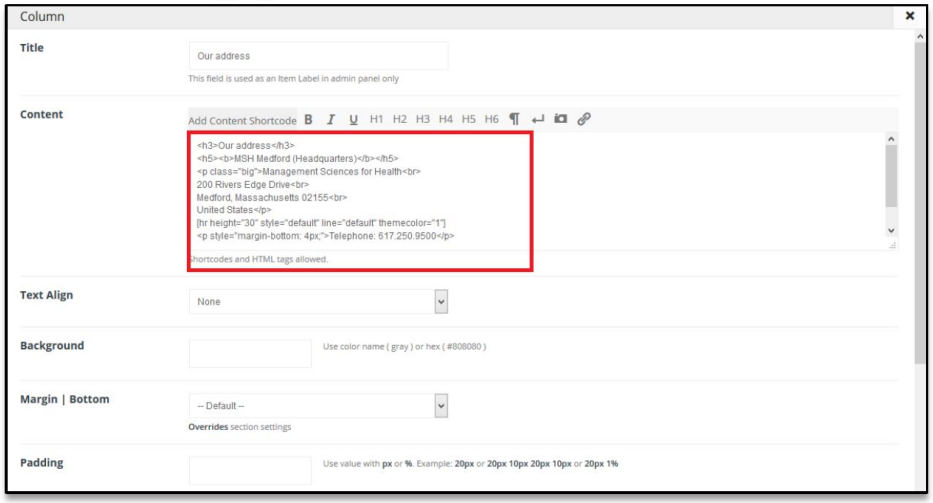


Figure: C-13

PSS Insight Technical Guide

Now change the description from the indicated section. To save the all changes click to the Save changes button from the bottom right side.

10.3. Change Google Maps latitude, longitude, Marker Icon

Figure: C-14

Click on the **edit pencil icon** into "**Map**" section from "**Figure: C-7**" look like following screen –

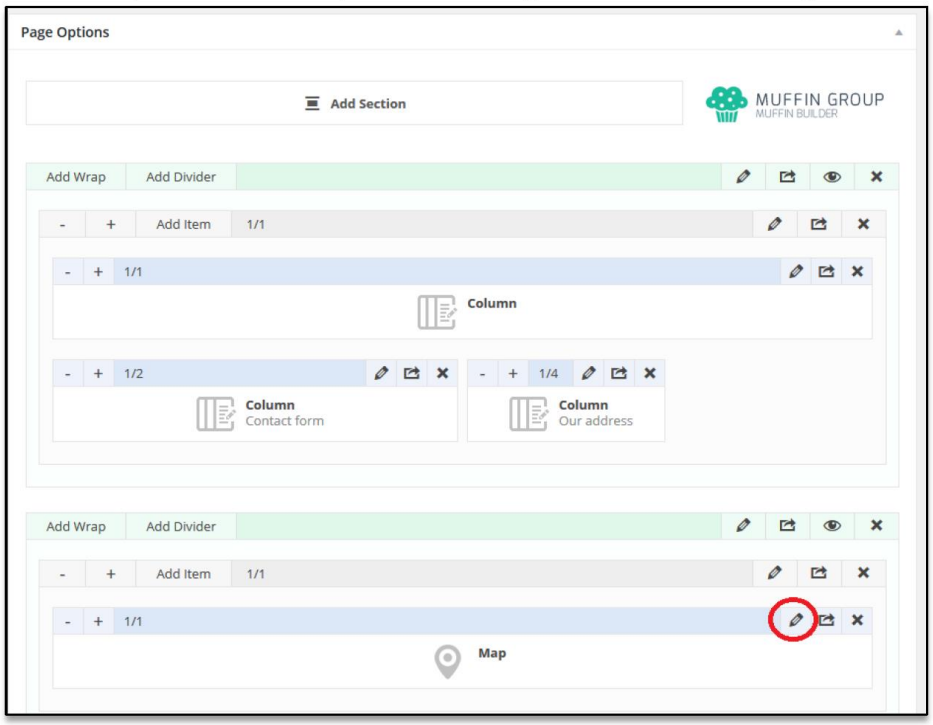


Figure: C-15

User will see the following page-

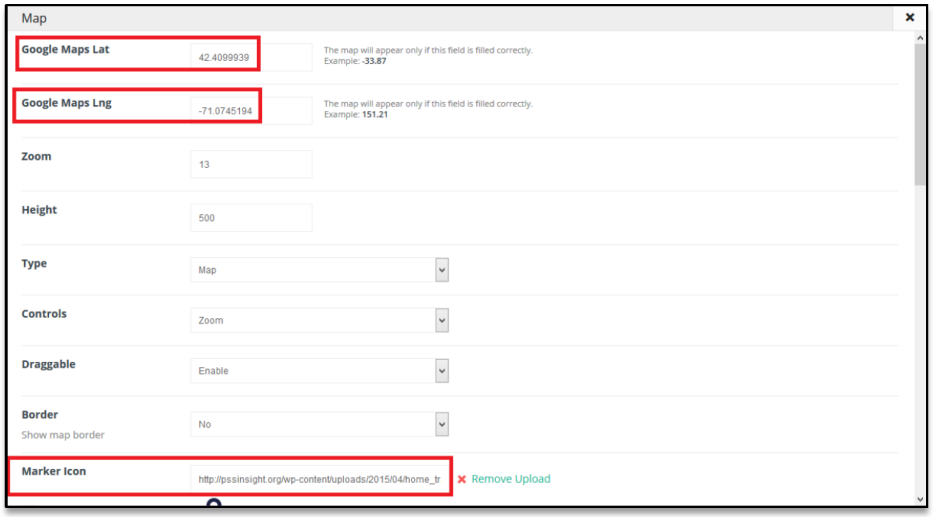


Figure: C-16

Now change the Google Map Lat, Lng and Marker icon link from the indicated section. To save the all changes click to the **Save changes** button from the bottom right side. After that following screen will appear-

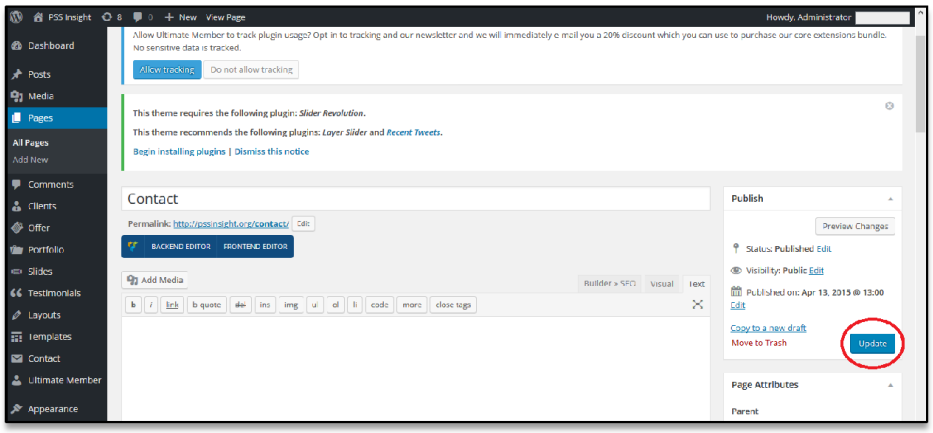


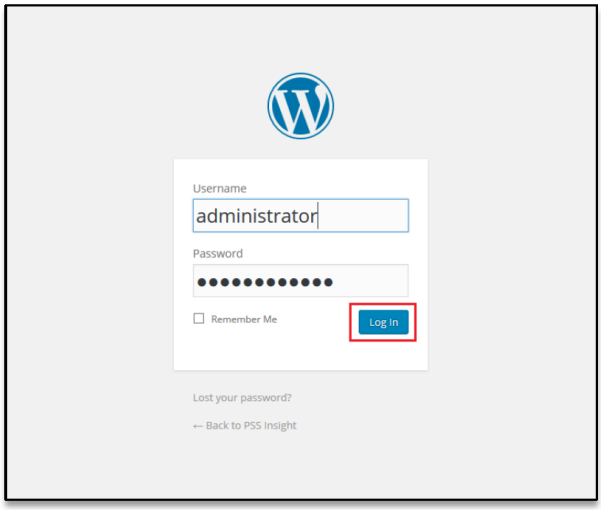
Figure: C-17

Now click into "**Update**" button to update contact page information.

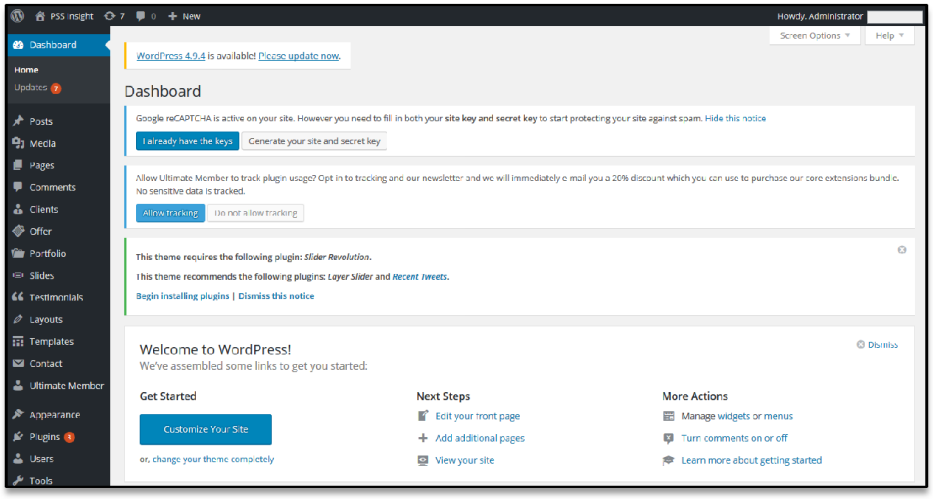
Chapter-11: How to Update WordPress Version:

Wordpress is a content management system and there are version updates pushed towards every wordpress installation. The administrator has to check periodically if there is any version update pending, he can update by just clicking a link.

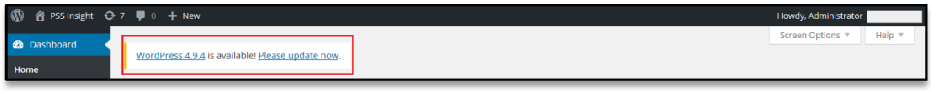
Open any internet browser (Google Chrome, Mozilla Firefox) then type http://pssinsight.org/wp-admin which shows the following screen –



Type Username and Password and then click Log In button. After clicking Log In button user will see the following page-



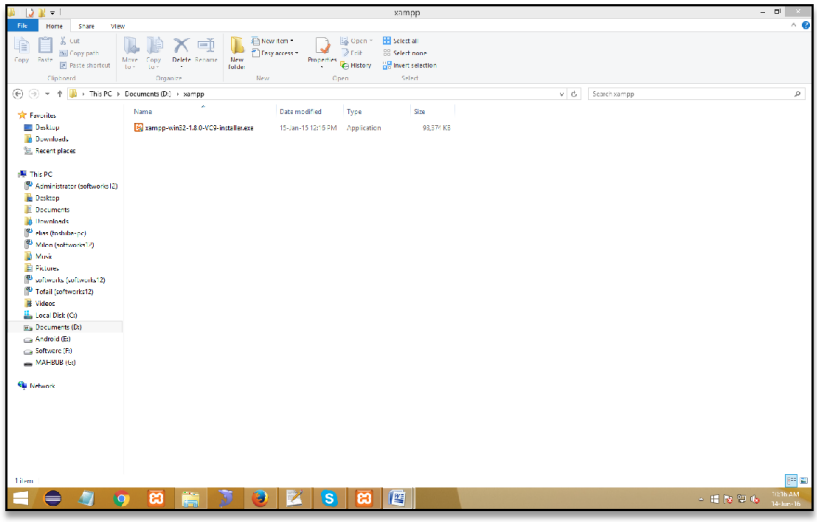
If there is any update pending, right side you will see a line above "Plugins". Press "**Please Update Now**" link and Wordpress will update to latest version.



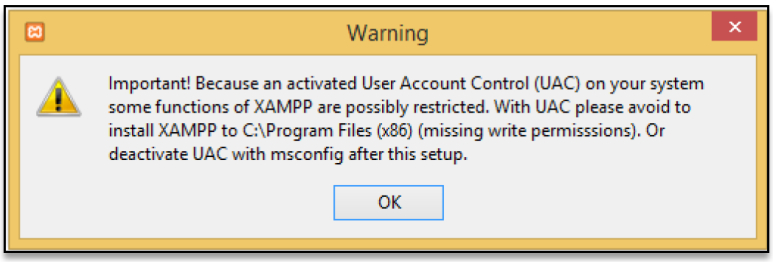
Chapter-12: PSS Insight Local Installation

12.1. XAMPP Installation

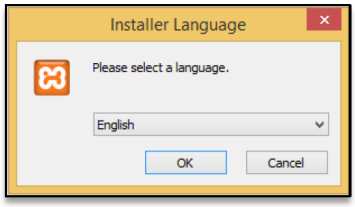
This is a web based system, so it would require a web server and database engine to run. One of the popular packages to run web sites locally is Xampp. You can download the latest version xampp-win32-1.8.0-VC9-installer.exe from here
https://sourceforge.net/projects/xampp/files/XAMPP%20Windows/1.8.0/



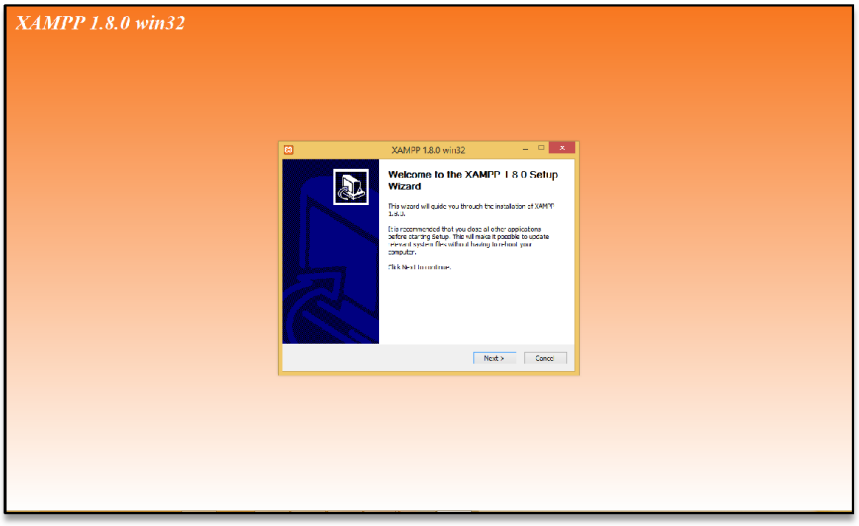
Then double click on the file, if you get a warning as shown in the next picture-



Press OK and the following dialog is shown –

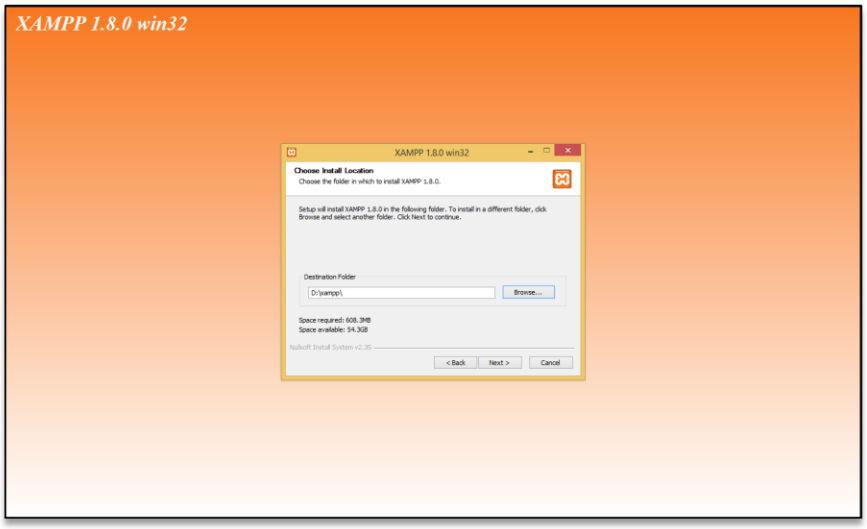


Press OK and the following windows will show –

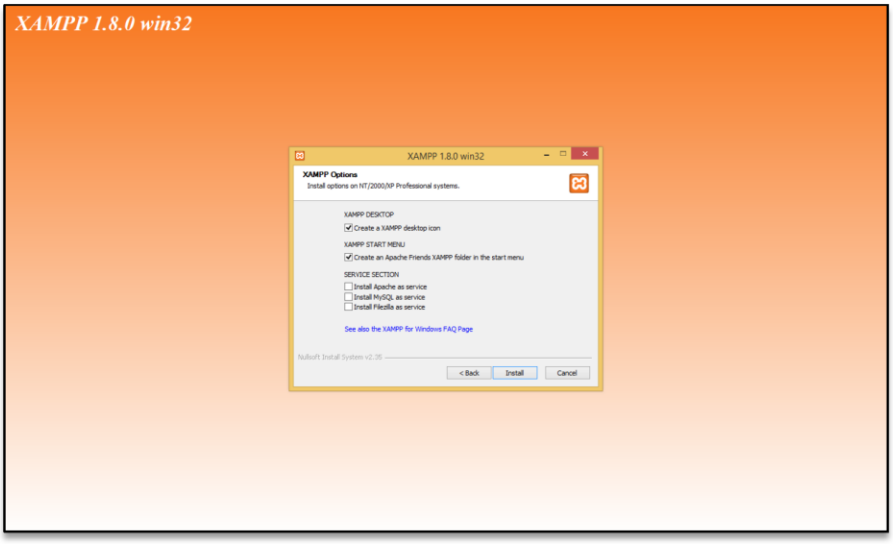


Click *the* Next button *to* continue *the* setup process –

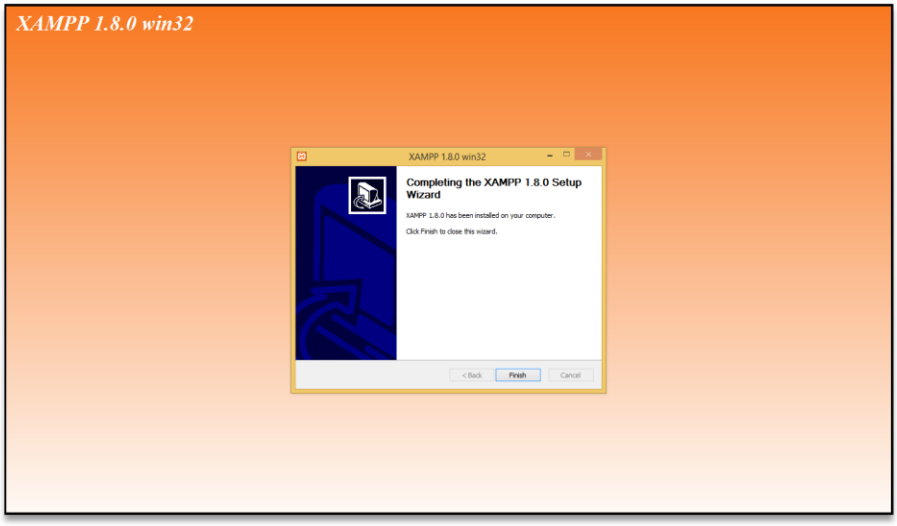
A dialog of installation location setting will appear with default location.



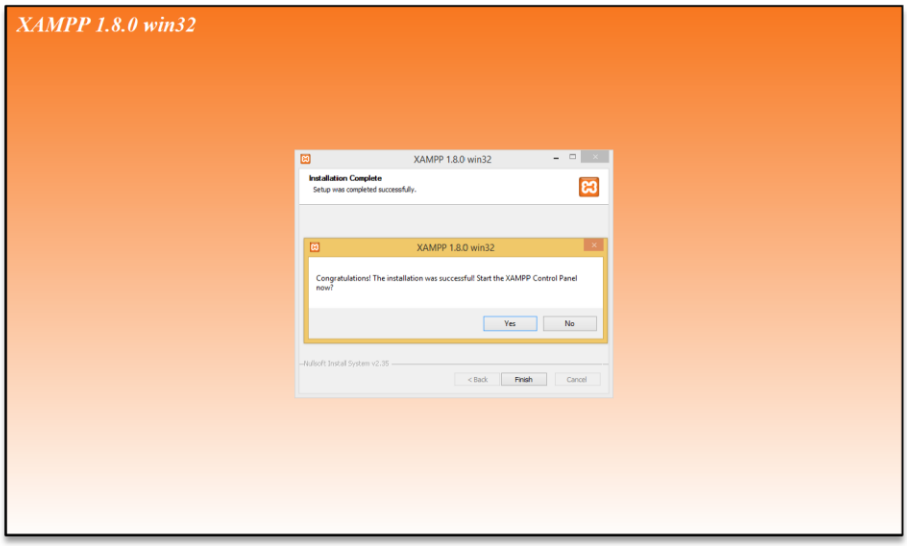
Then click to the “Next” button, which will bring the following screen –



Have the top two check boxes ticked and click on Install button. Wait a while to complete. After completing installation new dialog will appear as below –

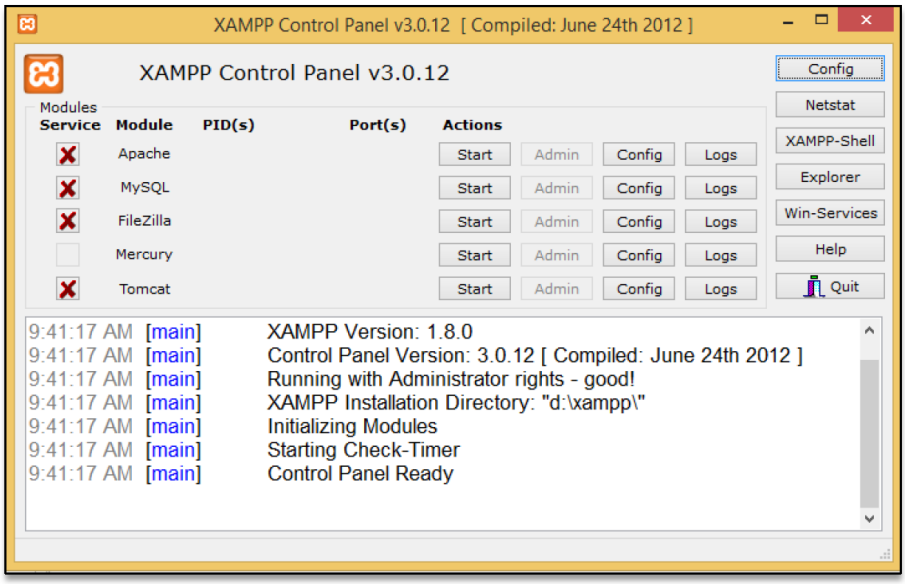


Click on Finish button. The following windows will pop up –

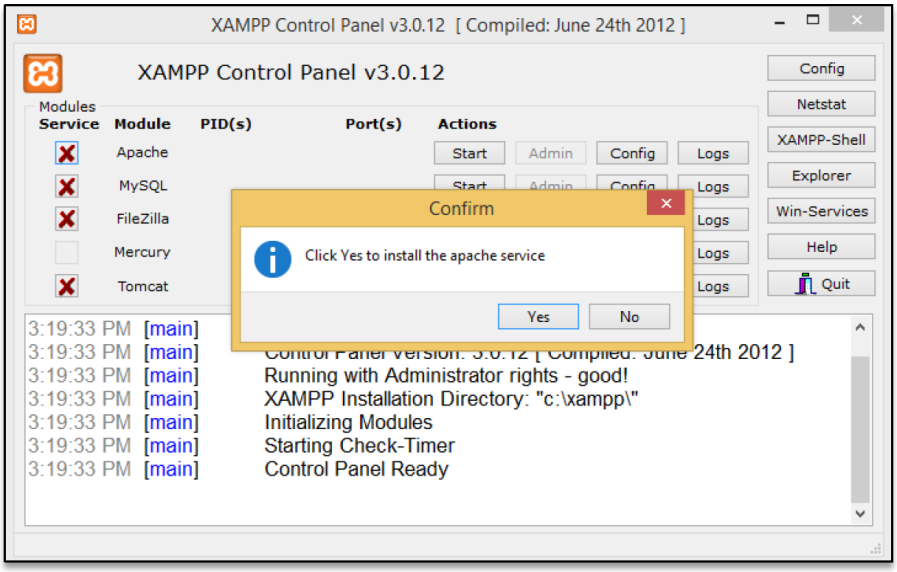


Click “Yes”, and the following windows will show –

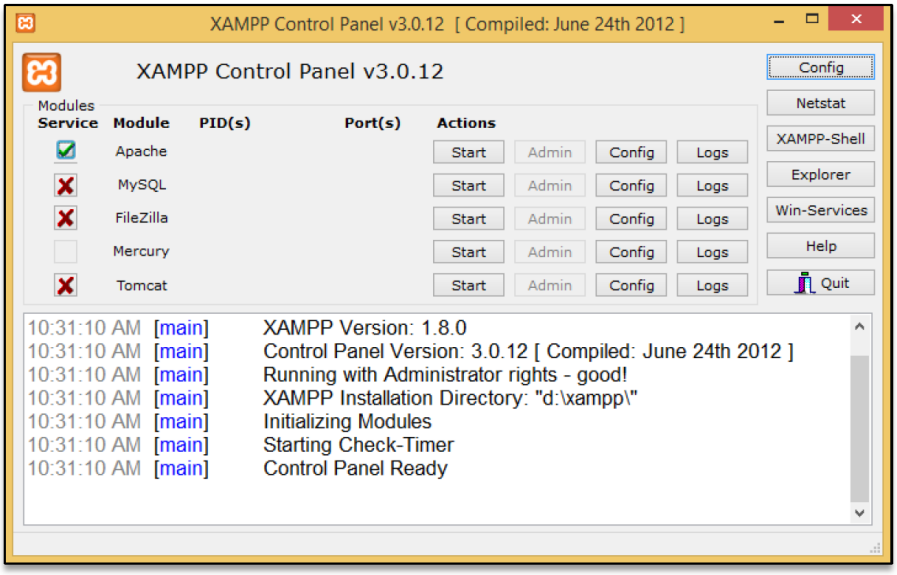
Select OK, the following screen will show –



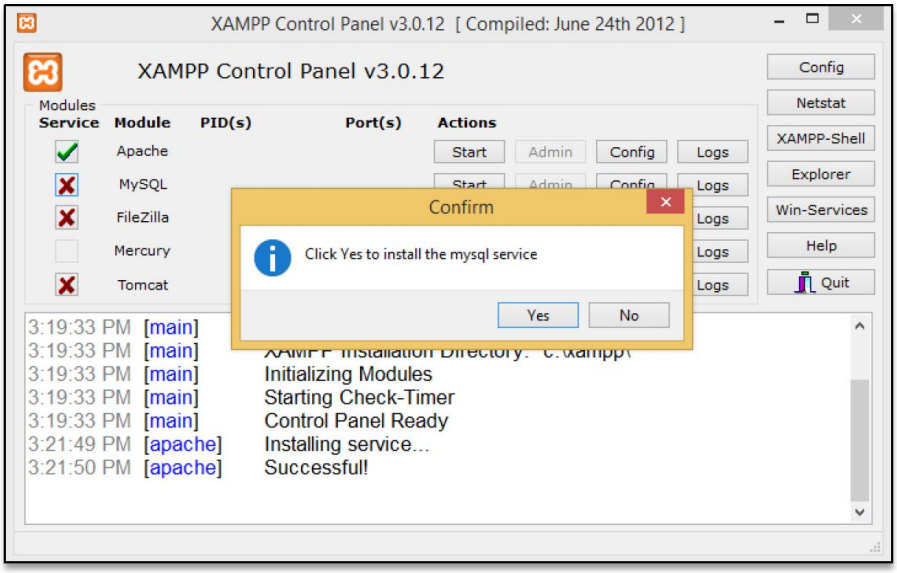
Tick on the first check box titled Apache, The following window will pop up –



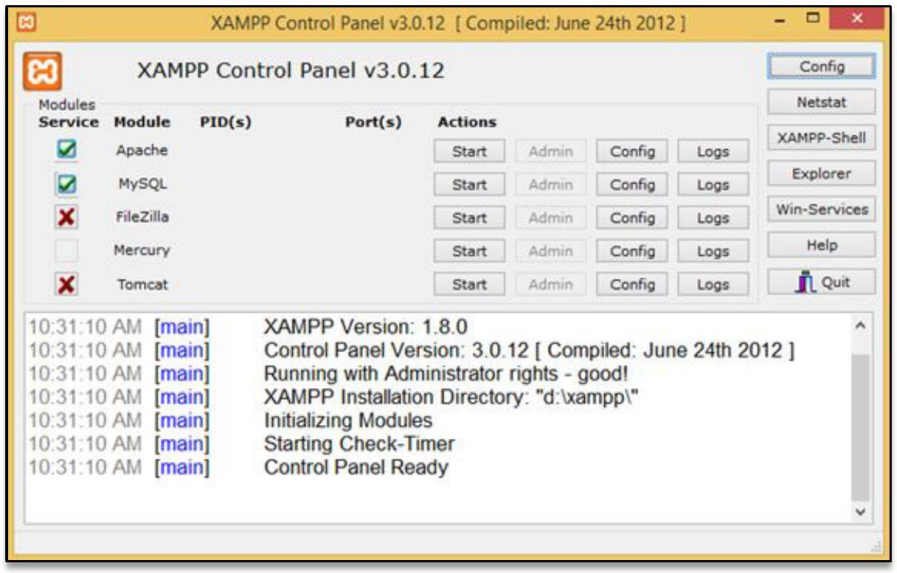
Click "Yes", and the following screen will show –



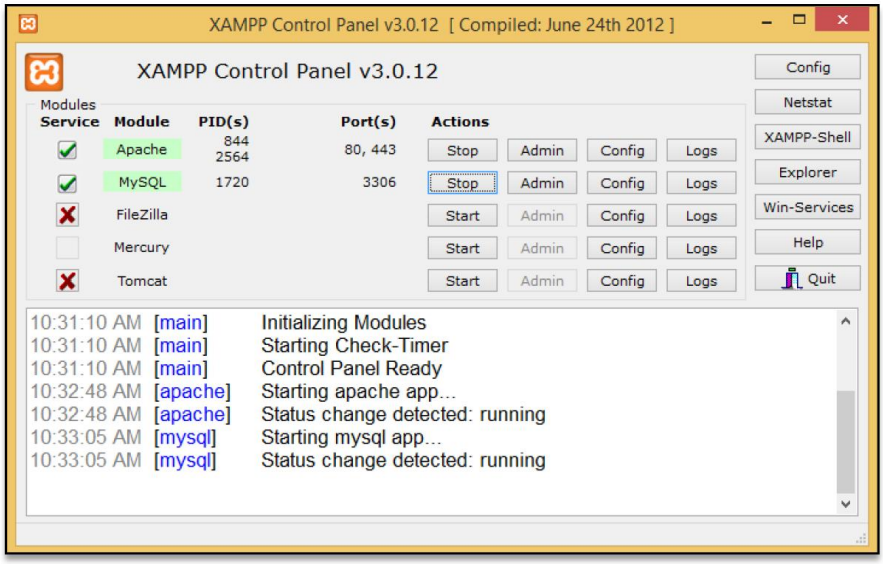
Tick on the second check box titled MySQL, The following window will pop up –



Click "Yes", and the following screen will show –

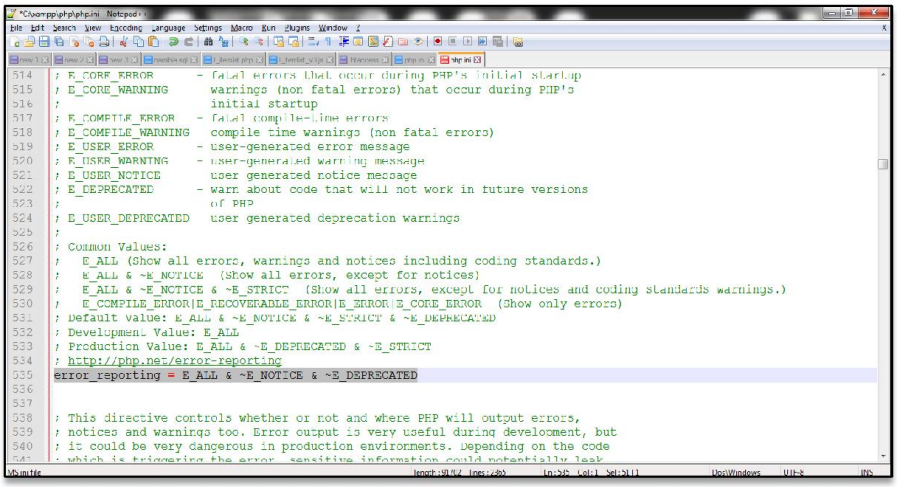


Click on the first two start button titled Apache and MySQL, which will make the screen look like the following –



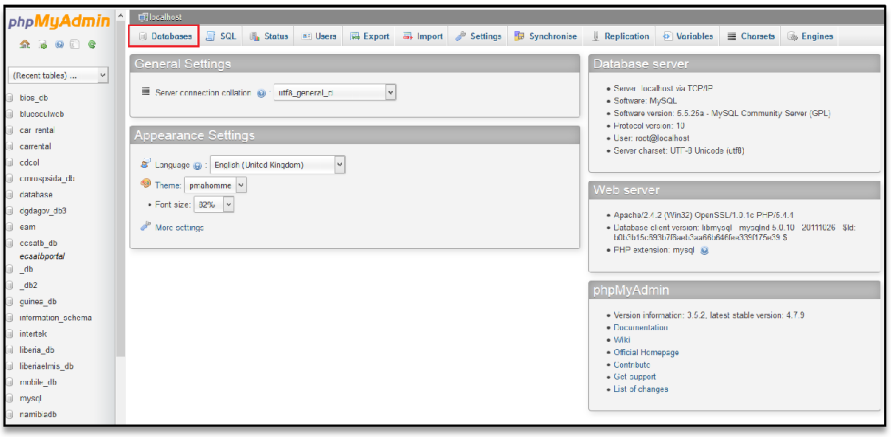
Press “Quit” button to close the dialog box.

Open **php.ini** from XAMPP installed folder (C:\xampp->php->php.ini). Here replace **error_reporting = E_ALL | E_STRICT** this line by **error_reporting = E_ALL & ~E_NOTICE & ~E_DEPRECATED**and restart your computer. This will make the screen look like the following –

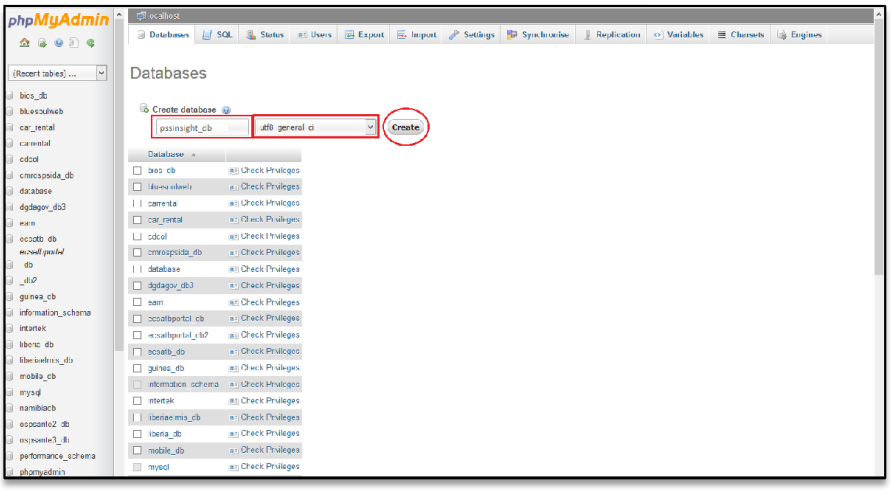


12.2. Create Database:

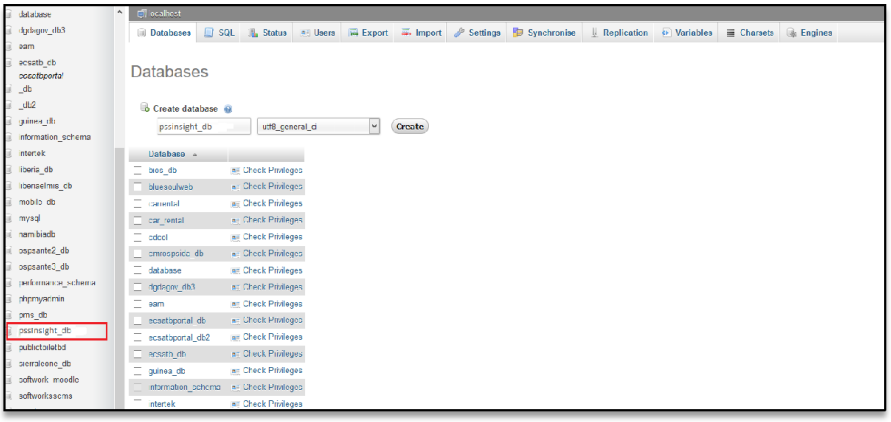
For Database create - Go to **http://localhost/phpmyadmin/**then you will see the following screen:



Click on the Databases (Database tab) then you will see the following screen:

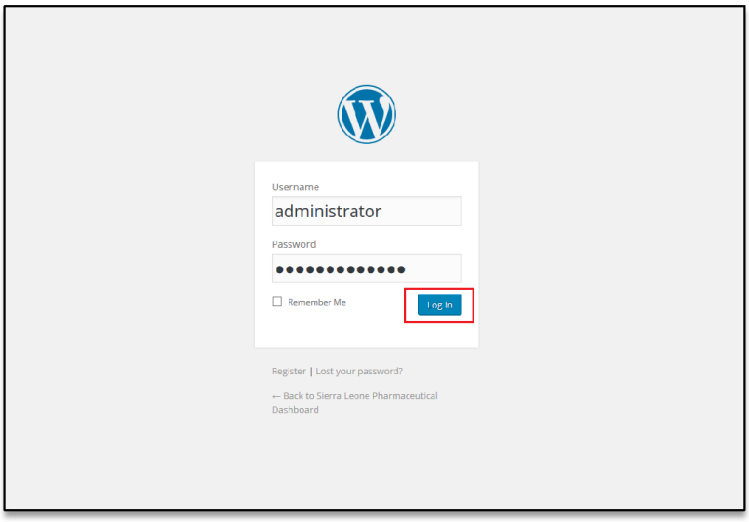


Now type Database Name "**pssinsight_db**" and select "**utf8_general_ci**" from Create database option then click on Create button, finally database "**pssinsight_db**" will be created look like the following screen.

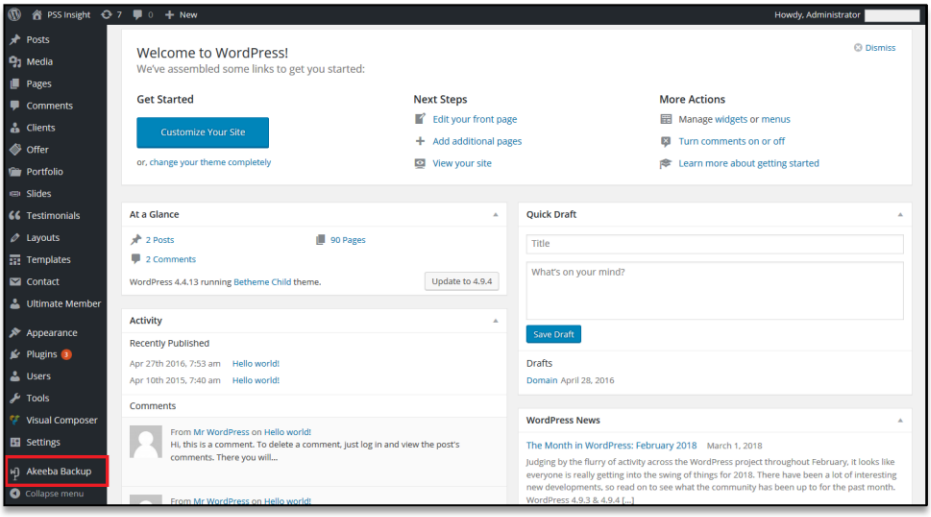


12.3. Create PSS Insight Backup in Web Server

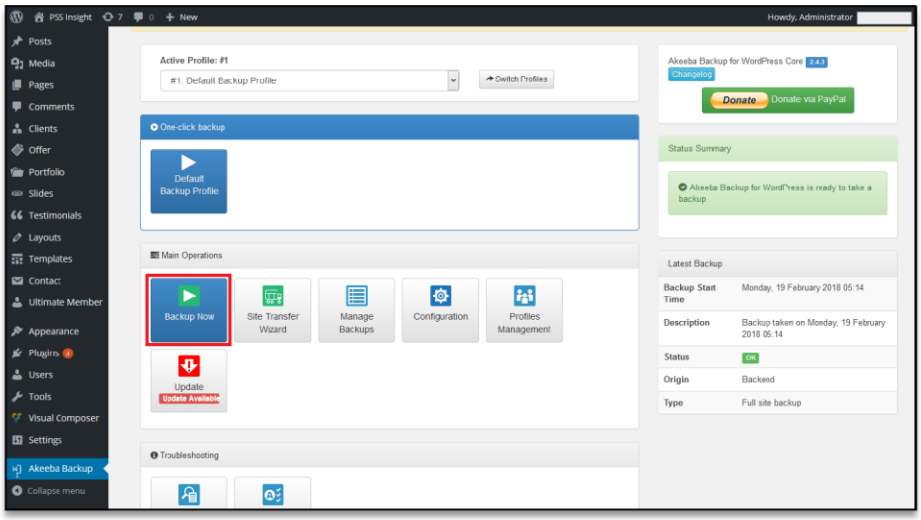
Go to http://pssinsight.org/wp-admin/ and login with your administrator Username and Password following the screen:



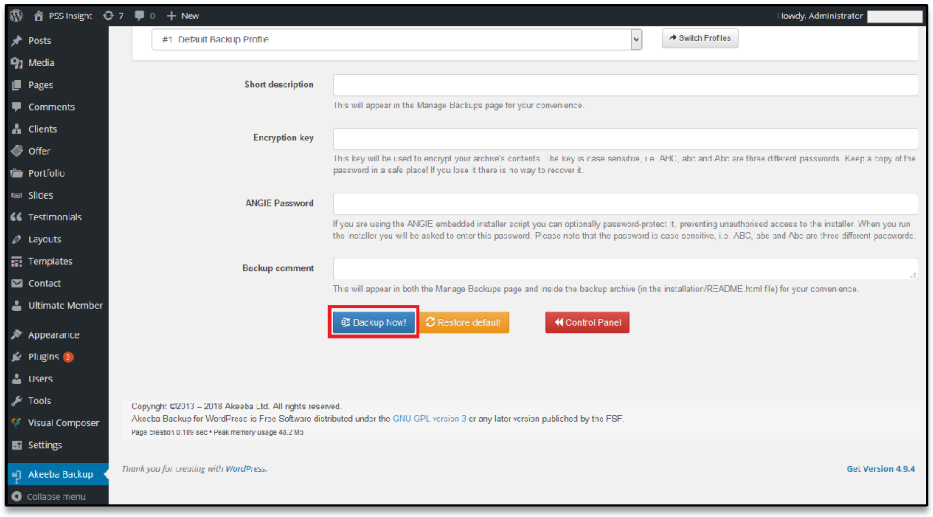
After click on "**Log In**" button then the user will see the following screen with **Akeeba Backup** menu-



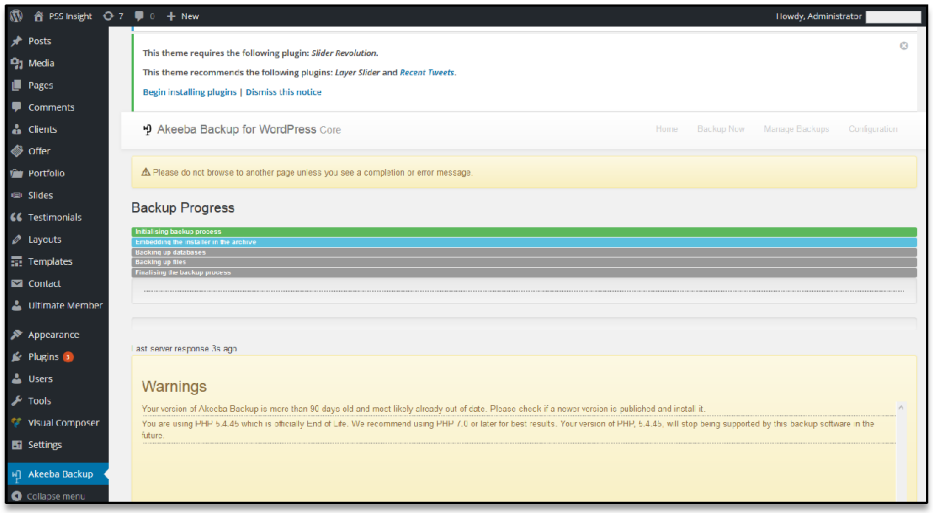
Click on the "**Akeeba Backup**" menu then the following screen will appear:



Click on the "**Backup Now**" button indicated by red square then in the following screen again press "**Backup Now**" button indicated by red rectangular in below screen-

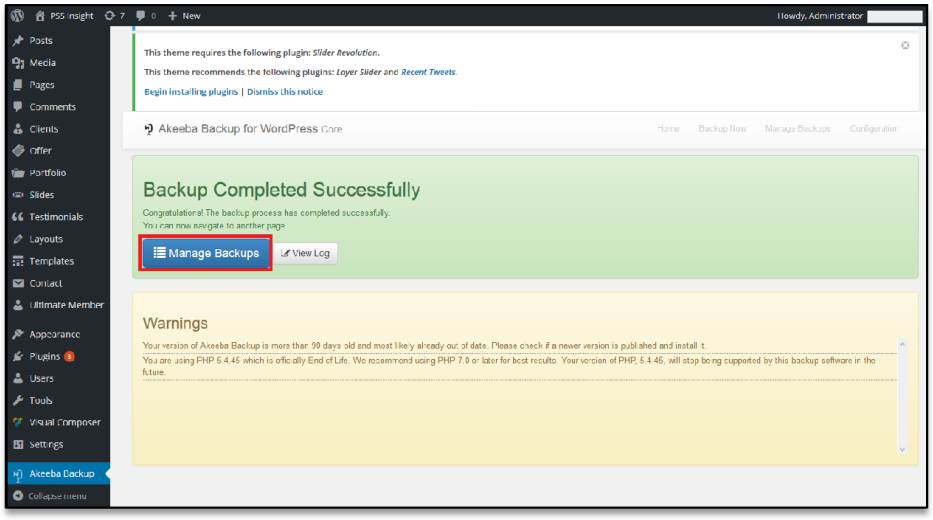


After that the user will see the following backup process screen…

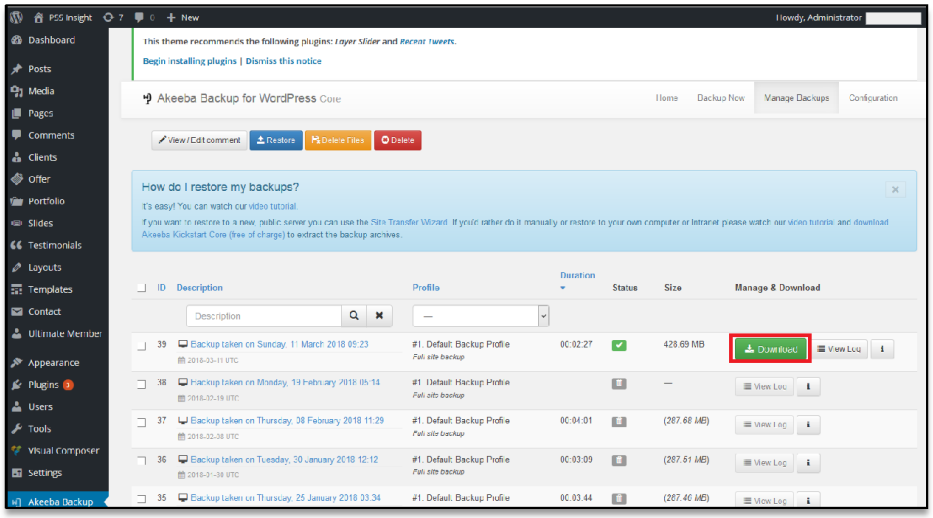


Important! Do not close this browser window unless the backup is completed. Doing so will interrupt the backup creation process and it will not be completed successfully!

After sometimes the user will see the following screen successful message with "**Manage Backups**" button-

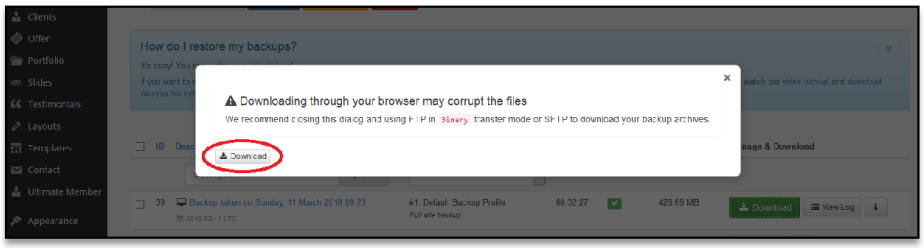


Click on the "**Manage Backups**" button to proceed. Then the following screen will be appear-

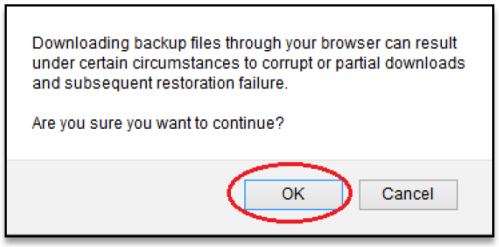


12.4. Download and install PSS Insight Backup

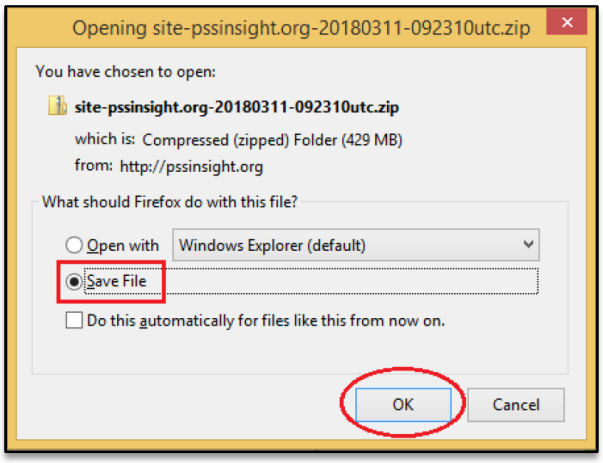
Click on the "**Download**" button of the above page. Then the following page will be appear-



Now click into "**Download**" button then following message will be shown-

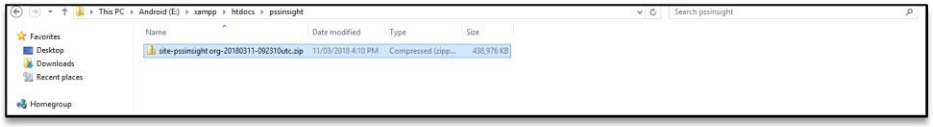


Click "OK" to continue download process.

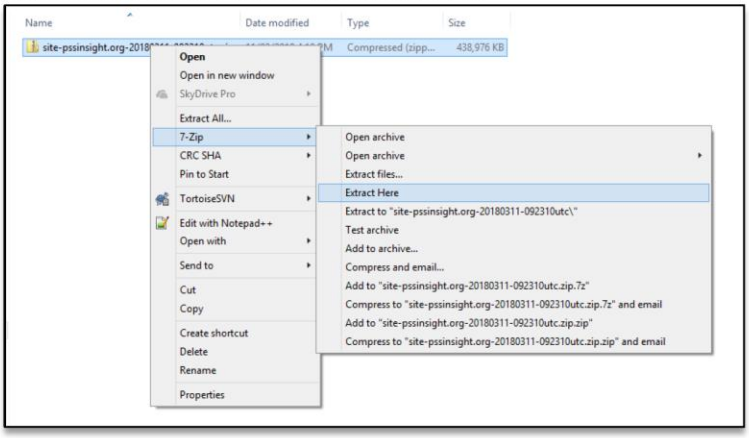


Now click "**OK**" and save the file in your local drive.

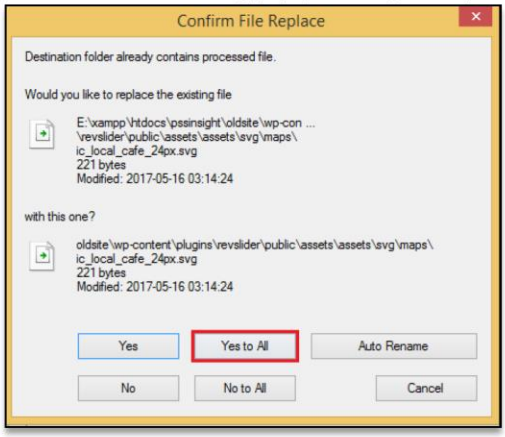
Create folder **'pssinsight`** under **[Drive]:\xampp\htdocs**
Now Copy the downloaded backup file (e.g. **site-pssinsight.org-20180311-092310utc.zip)** under **[Drive]:\xampp\htdocs\pssinsight –**



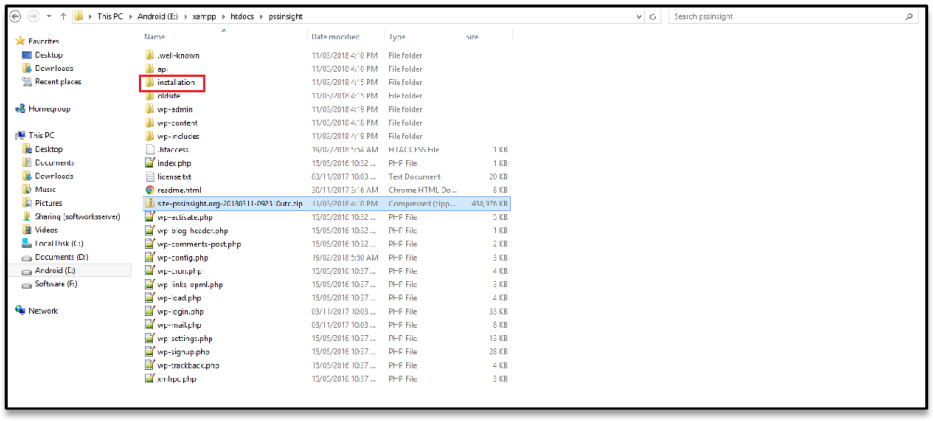
Right click on **.zip** file then the user will see the below screen.



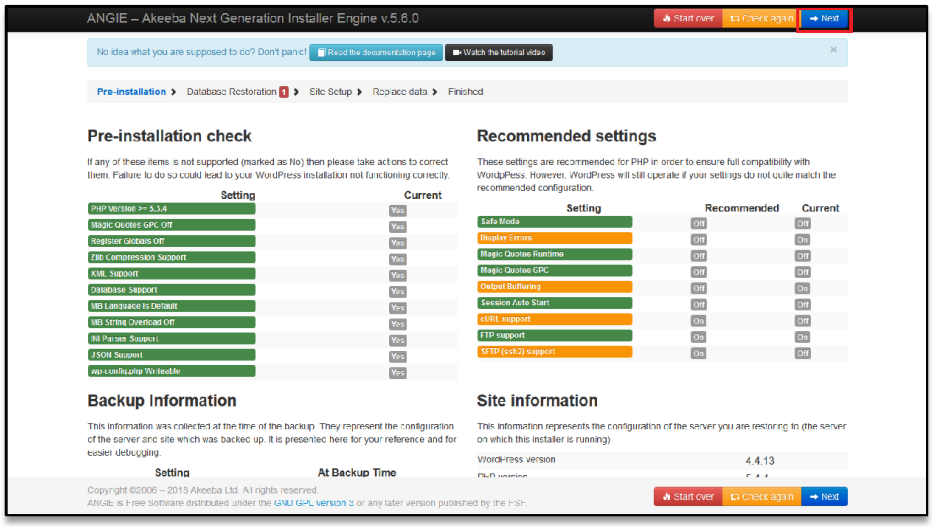
Click on "**Extract Here**" option. If shown following popup message then press "Yes to All" button-



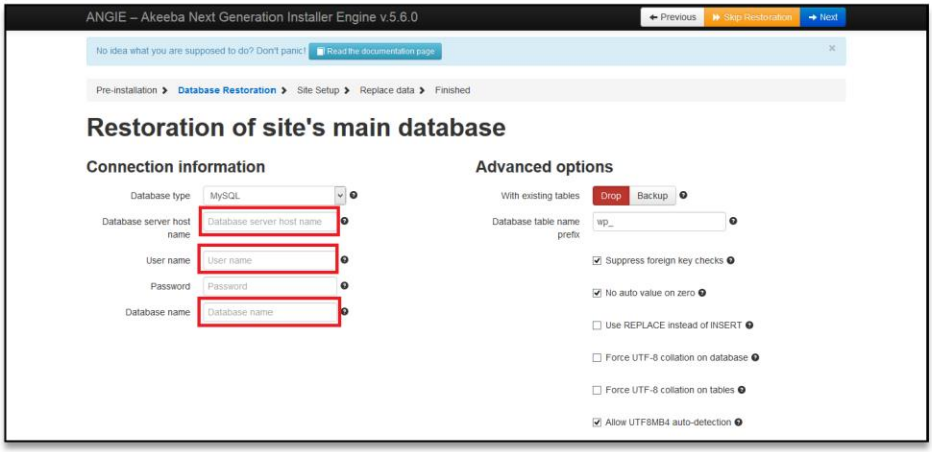
Then the zip archive will be extracted as like following screen–



Now open web browser. Type http://localhost/pssinsight/installation to the address bar. Following screen will appear.



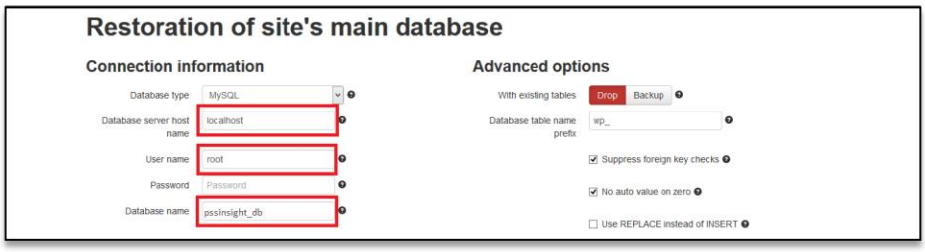
Click on the "**Next**" button then the screen will appear-



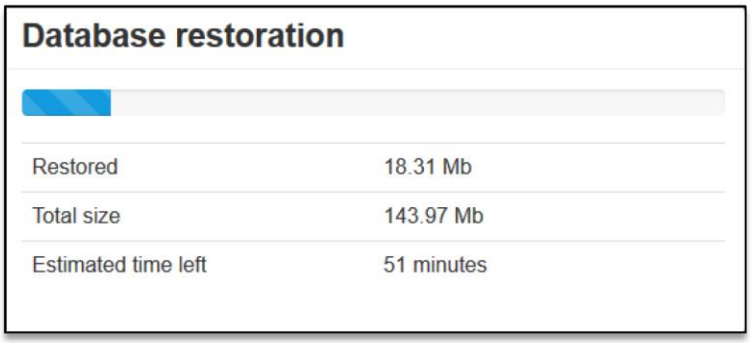
In the connection information section, type –

- **Database server host name** = localhost
- **User name** = root
- **Database name** = pssinsight_db

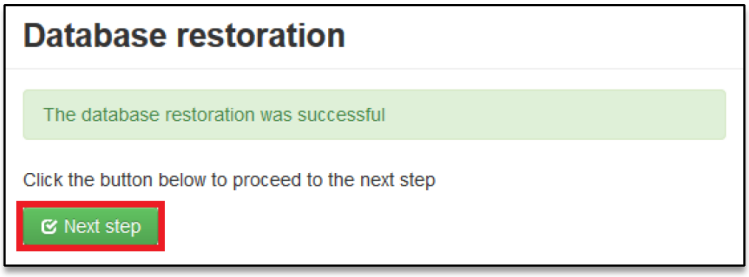
Like as the below screen.



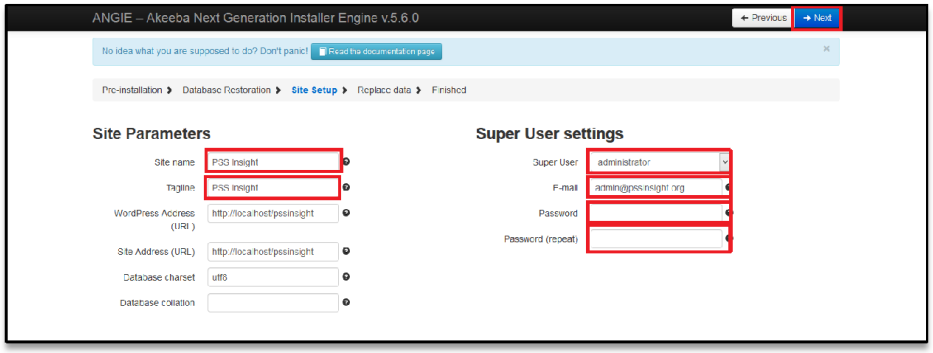
Click on the "**Next**" button then the Database restoration is shown below…



After sometimes database will be successfully restore as following with "Next step" button.



Click on the "**Next step**" button then the screen will appear…



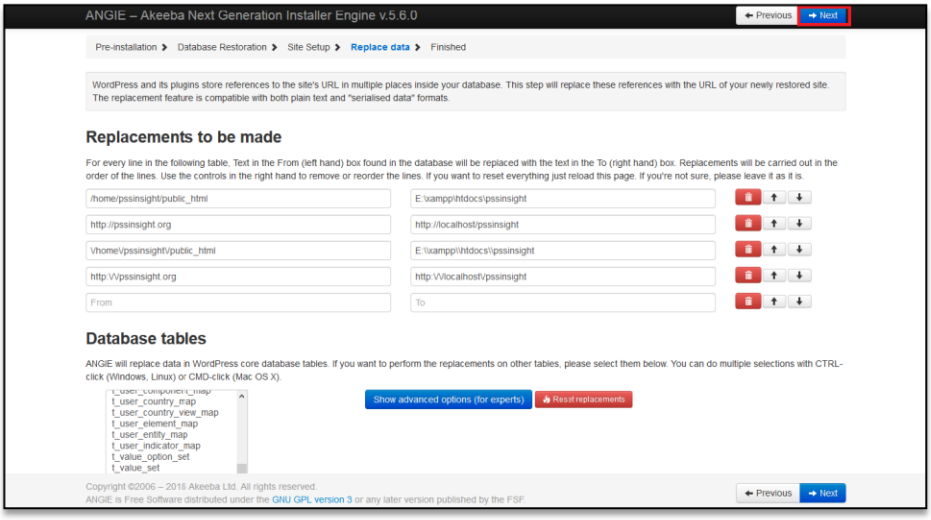
In **Site Parameters-**

1. **Site Name:** Your site name.
2. **Tagline:** Your site name

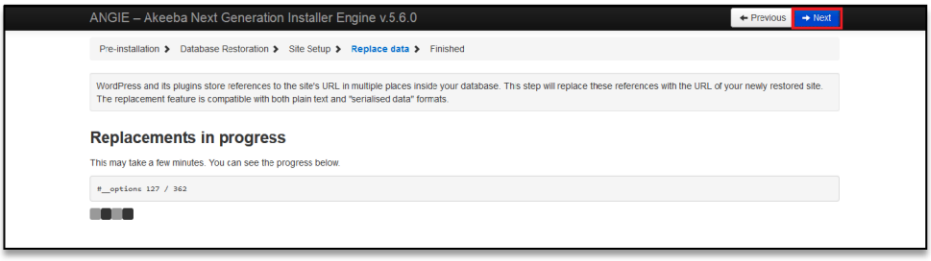
In **Super user Settings-**

1. **Super User:** administrator
2. **Email:** Email address of the administrator
3. **Password:** Any suitable password
4. **Password(repeat):** Re-enter password

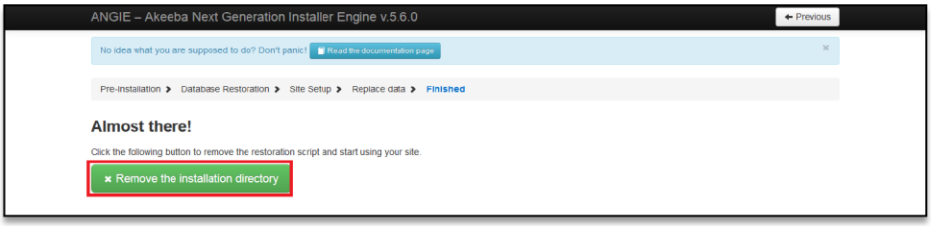
Click on the "**Next**" button then the following screen shown below…



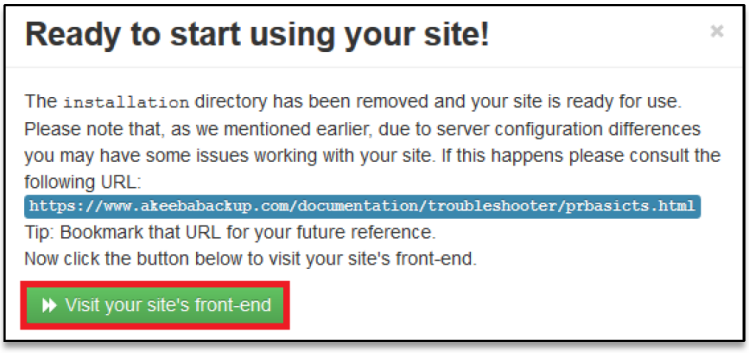
No need to change anything. Click on the "**Next**" button then the following screen shown below…



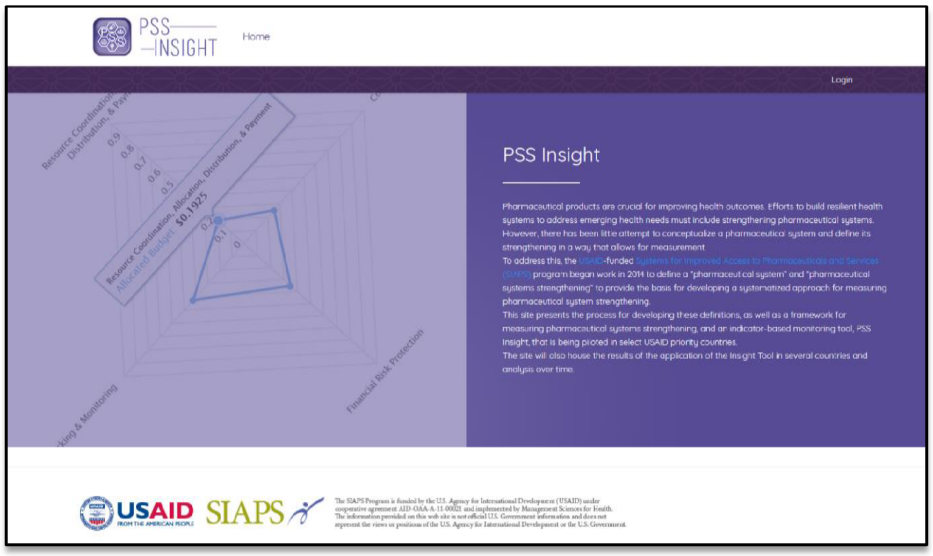
Wait few minutes then the following screen shown below with "**Remove the Installation directory**" button



Click on the **"Remove the Installation directory"** button then the screen will appear**.**



Click on the "**Visit your site's front-end**" button. Then the following PSS Insight home page will be shown:



To access the homepage, go to **[Drive:]\xampp\htdocs\pssinsight \wp-content\themes\betheme** folder and open **settings.ini.php** file at any code editor as follow…

```
1  ;<?php return; ?>
2  [SQL]
3  host = localhost
4  user = pssinsig_user
5  password = WoT5G52U3t8Kx90
6  dbname = pssinsig_db
7
```

Update the above code as following code-

```
;<?php return; ?>
[SQL]
host = localhost
user = root
password =
dbname = pssinsight_db
```

Now save changes with above code look like following screen-

```
;<?php return; ?>
[SQL]
host = localhost
user = root
password =
dbname = pssinsight
```

Now go to **[Drive:]\xampp\htdocs\pssinsight** open **.htaccess** file at any code editor-

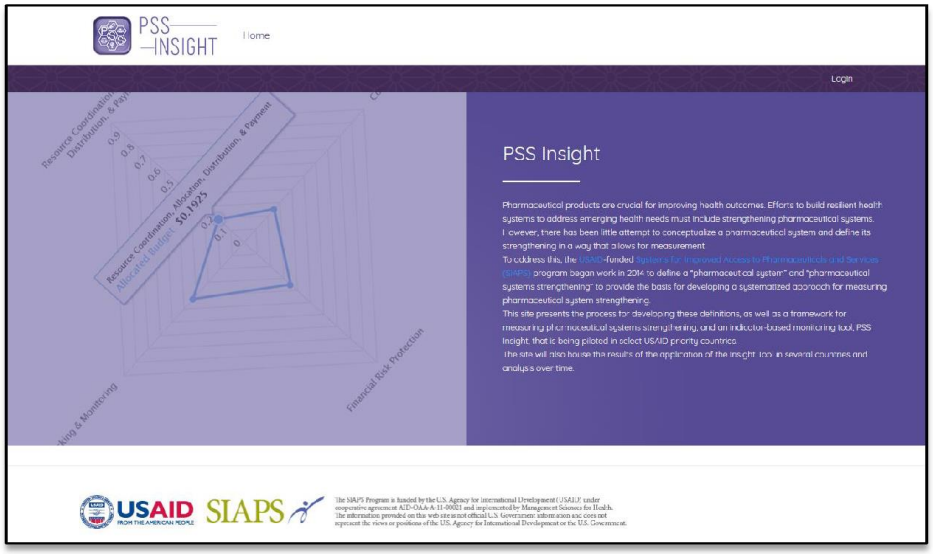
Update the code as following —

```
# BEGIN WordPress
<IfModule mod_rewrite.c>
RewriteEngine On
RewriteBase /pssinsight/
RewriteRule ^index\.php$ - [L]
RewriteCond %{REQUEST_FILENAME} !-f
RewriteCond %{REQUEST_FILENAME} !-d
RewriteRule . /pssinsight/index.php [L]
</IfModule>

# END WordPress
```

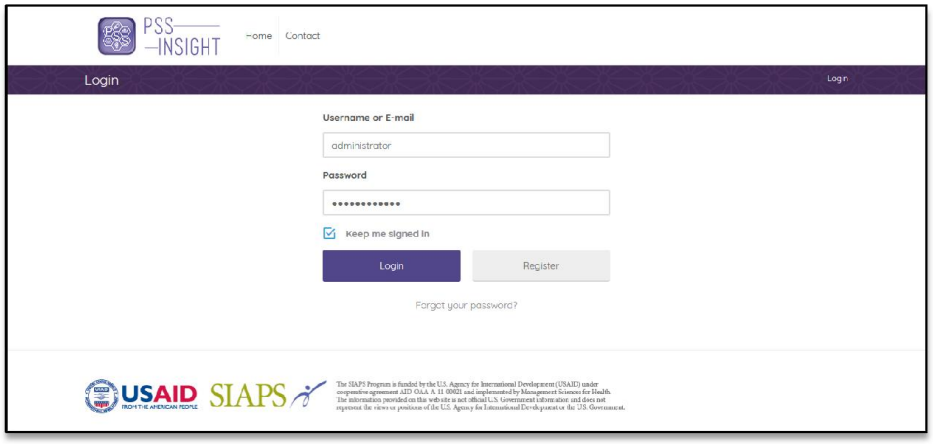
```

# BEGIN WordPress
<IfModule mod_rewrite.c>
RewriteEngine On
RewriteBase /pssinsight/
RewriteRule ^index\.php$ - [L]
RewriteCond %{REQUEST_FILENAME} !-f
RewriteCond %{REQUEST_FILENAME} !-d
RewriteRule . /pssinsight/index.php [L]
</IfModule>

# END WordPress

```

Now save changes the above code.

After changing to save changes then the parameters will be saved. Now browse **http://localhost/pssinsight/**



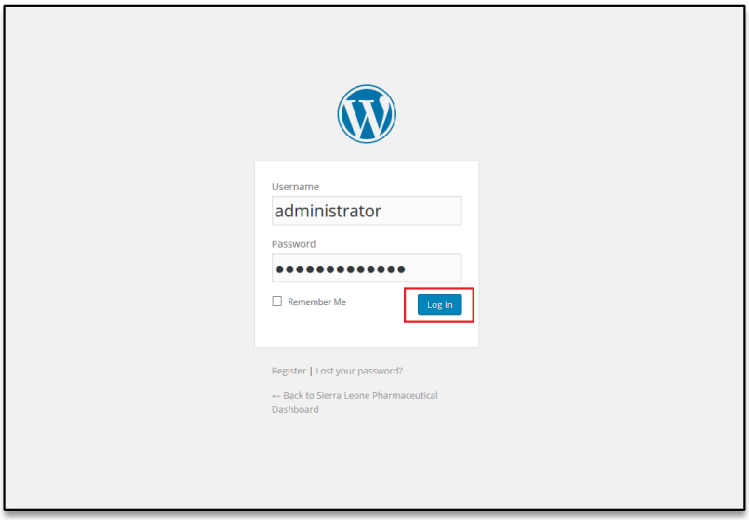
Login to PSS Insight with valid user name and password then you can access PSS Insight in local server.



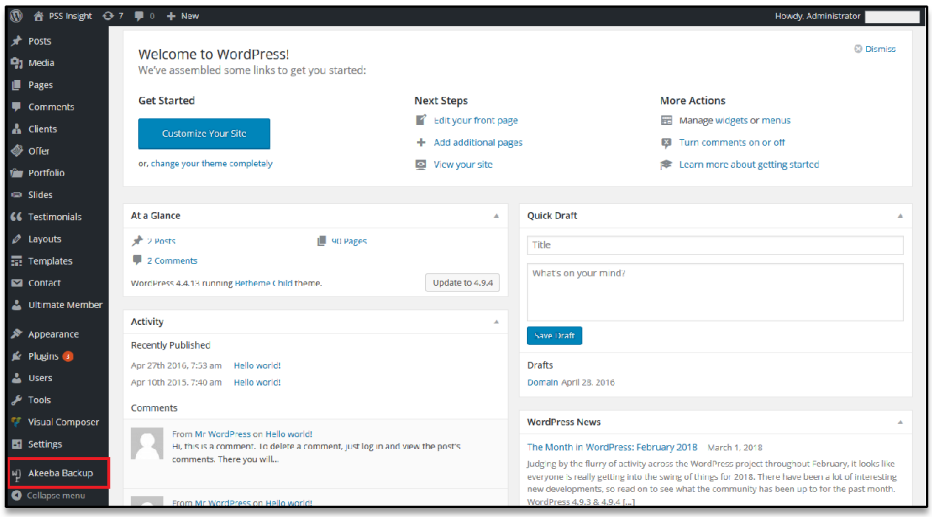
Chapter-13: Install PSS Insight Backup in CentOS server

13.1 Create PSS Insight Backup in webServer

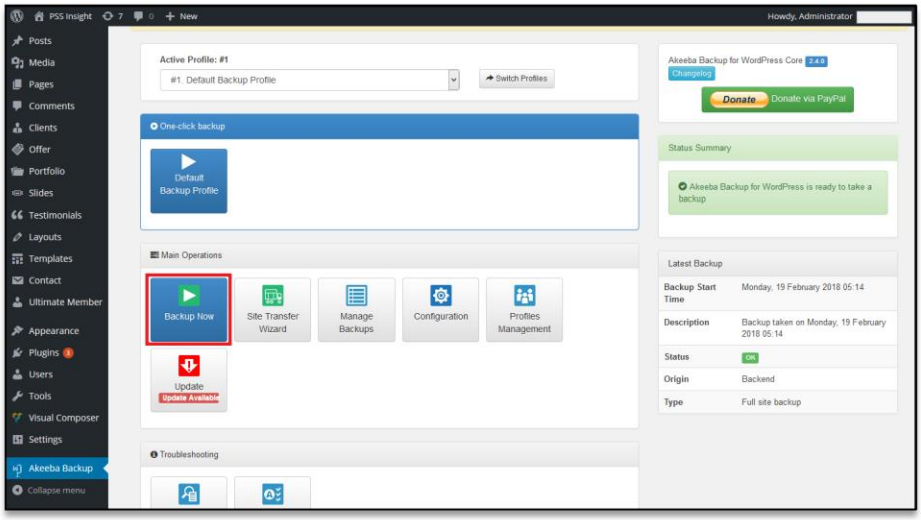
Go to http://pssinsight.org/wp-admin/ and login with your administrator Username and Password following the screen:



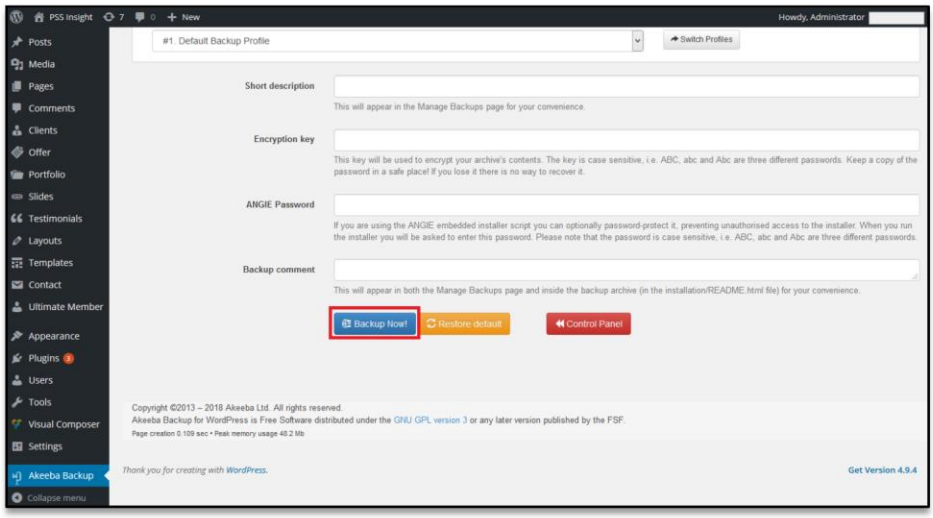
After click on "**Log In**" button then the user will see the following screen with **Akeeba Backup** menu-



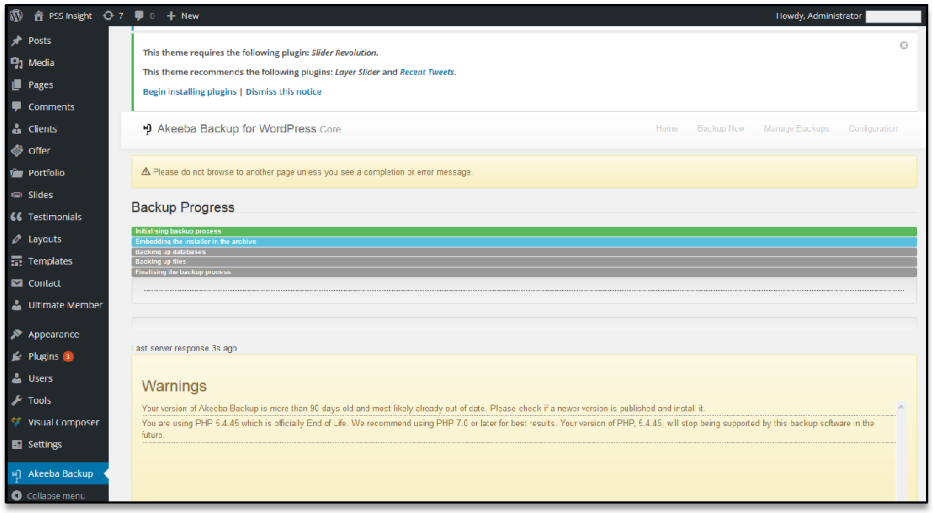
Click on the "**Akeeba Backup**" menu then the following screen will appear:



Click on the "**Backup Now**" button indicated by red square then in the following screen again press "**Backup Now**" button indicated by red rectangular in below screen-

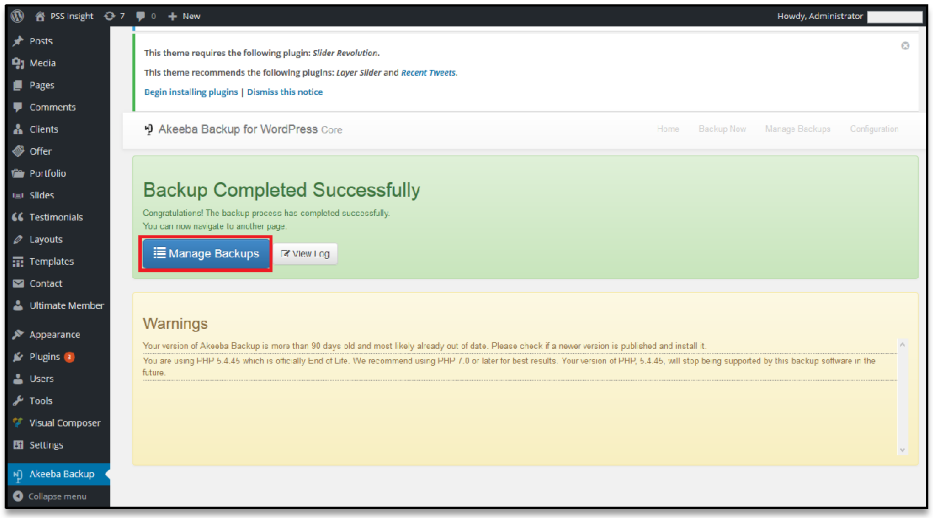


After that the user will see the following backup process screen…

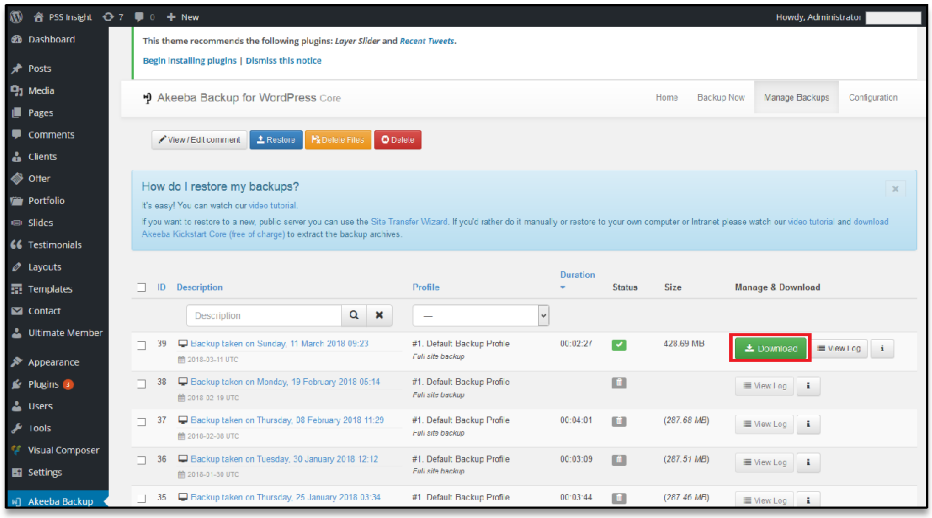


Important! Do not close this browser window unless the backup is completed. Doing so will interrupt the backup creation process and it will not be completed successfully!

After sometimes the user will see the following screen successful message with "**Manage Backups**" button-

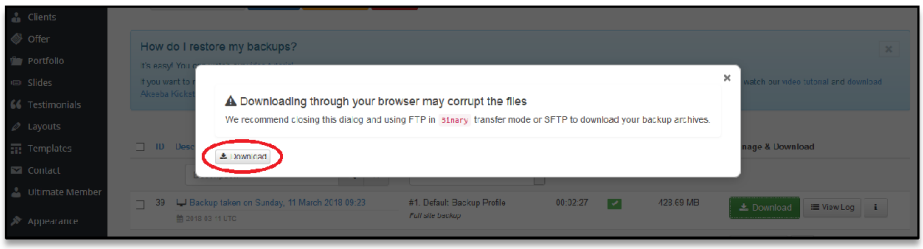


Click on the "**Manage Backups**" button to proceed. Then the following screen will be appear-

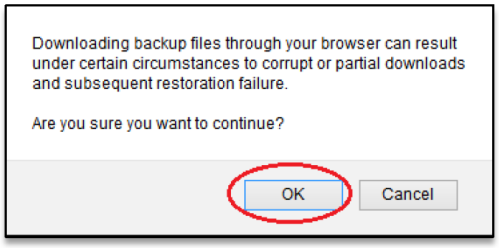


13.2. Download PSS Insight Backup

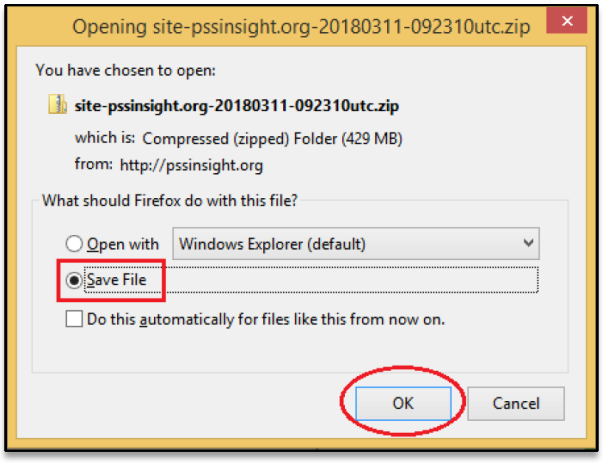
Click on the "**Download**" button of the above page. Then the following page will be appear-



Now click into "**Download**" button then following message will be shown-



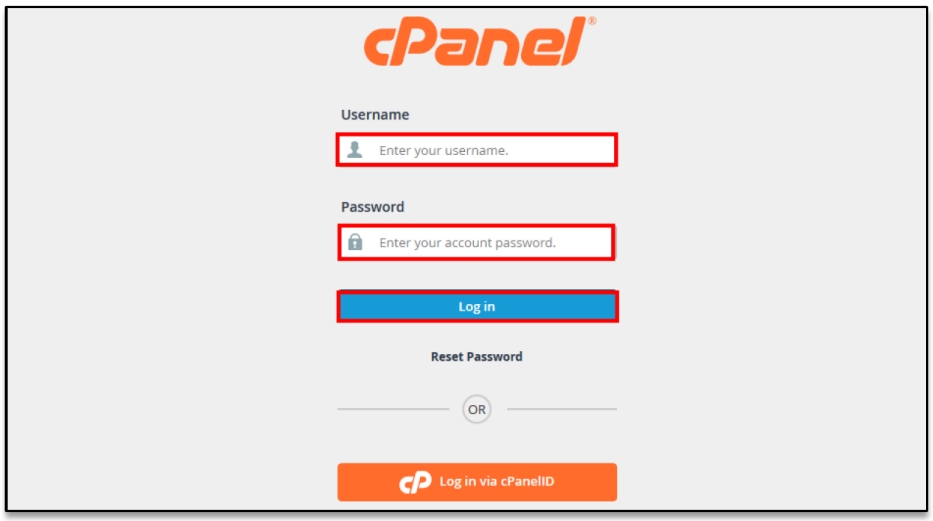
Click "OK" to continue download process.



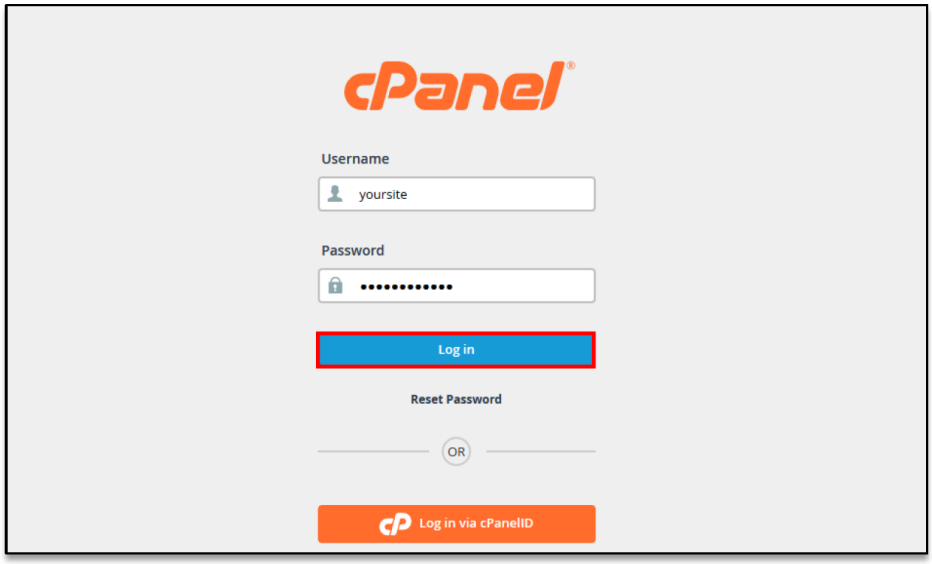
Now click "**OK**" and save the file in your local drive.

13.3 Create database and User name

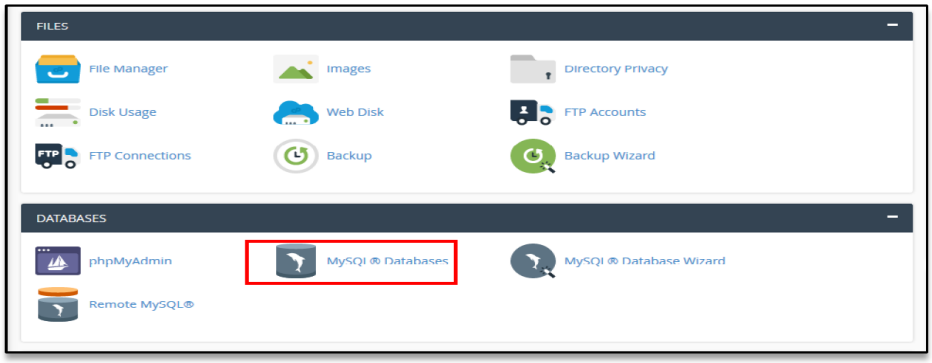
Go to the Control Panel URL of the new web server and you will see the following screen -



Login with your administrator **Username** and **Password** and click on Log In button.

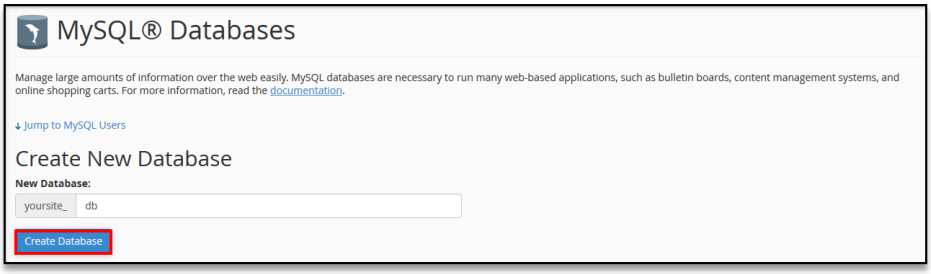


After that a screen will appear like below:

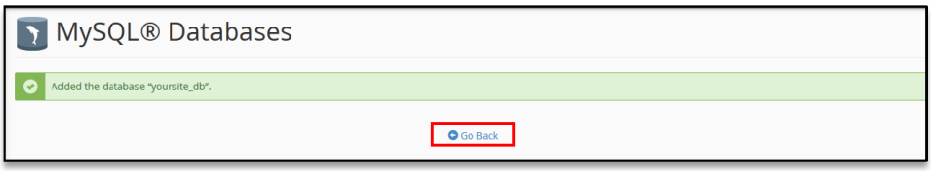


Click on the "**MySQL Databases**" link then the screen will appear like below.

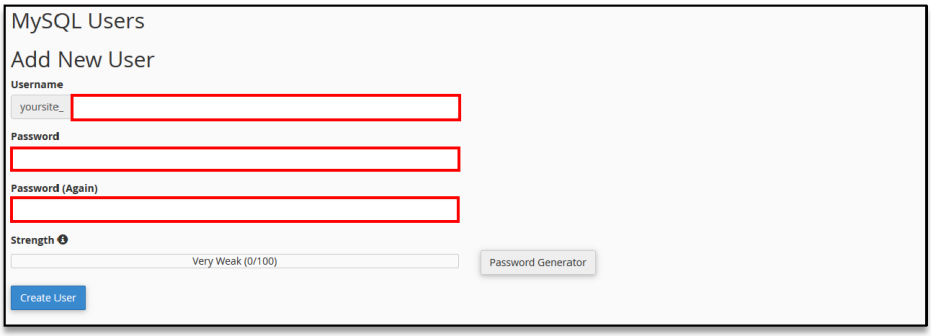
Now, Type new database name and Click on the **"Create Database"** button. Following the below screen.



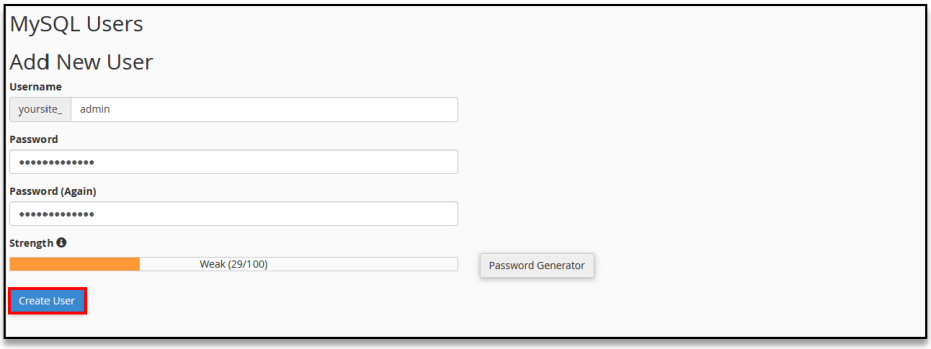
After click on the **"Create Database"** button then the screen will appear with successful message then click on "**Go Back**" button-



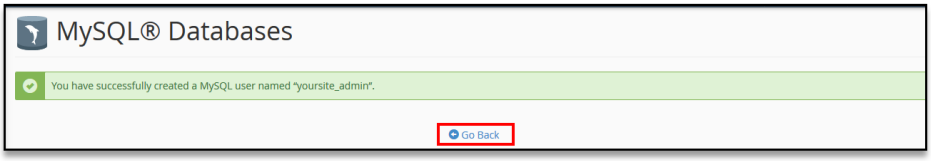
Add new user follow the below screen of the same page-



Type Username, Password, Password (Again) and click on the **"Create User"** button then the following screen will appear-

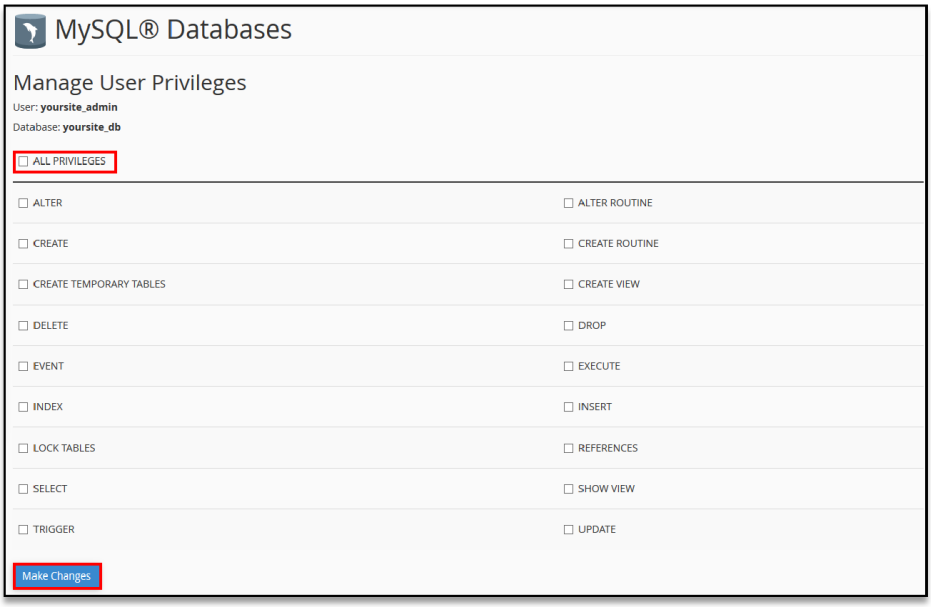


After click on the "**Create User**" button then the screen will appear…then click on "**Go Back**" for main page

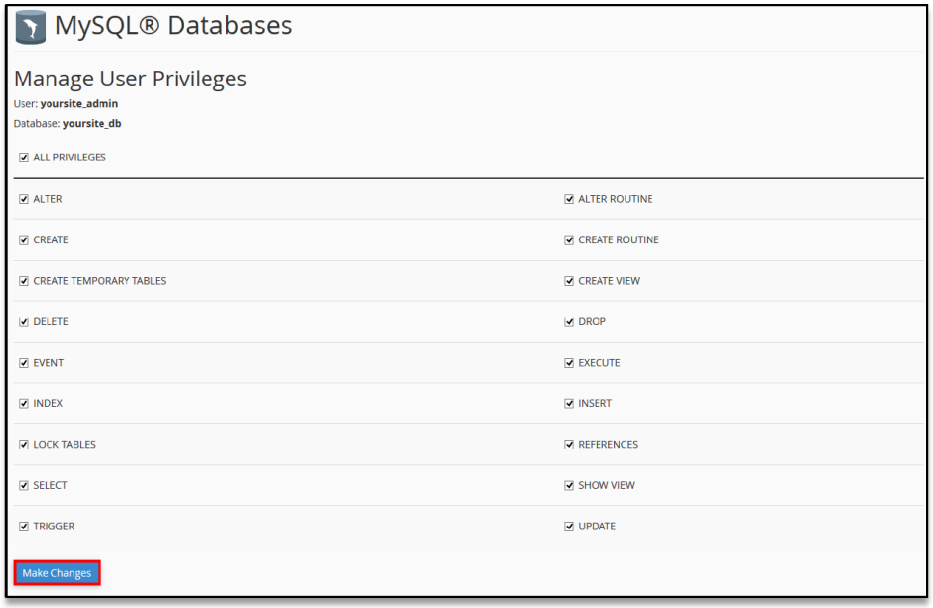


Assign user of this current database follow the below screen of the same page-

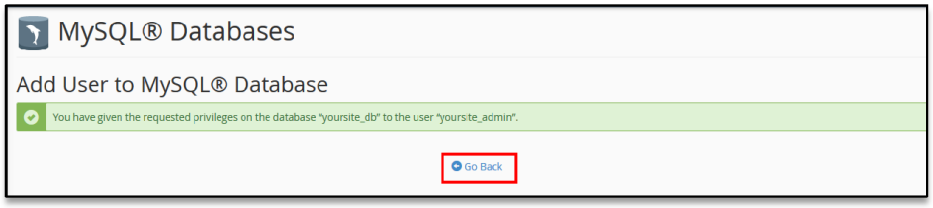
Click on "**Add**" button then following the screen will appear-



Select "**All PEIVILEGES**" then the below screen will appear-



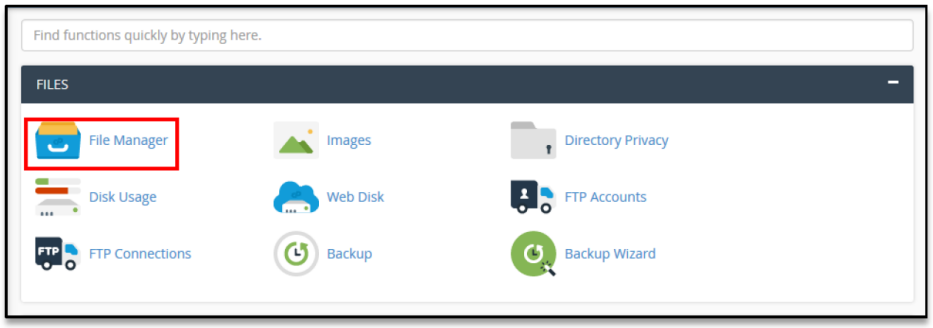
After click on "**Make Changes**" then the screen will appear-then click on "**Go Back**" for main page



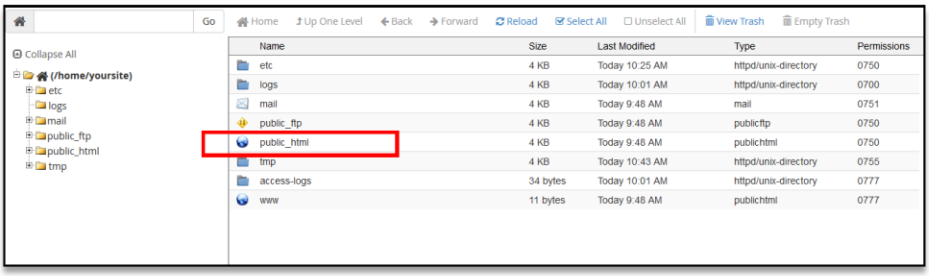
Database creation and assign it to user is complete.

13.4 Install PSS Insight Backup in Centos Server

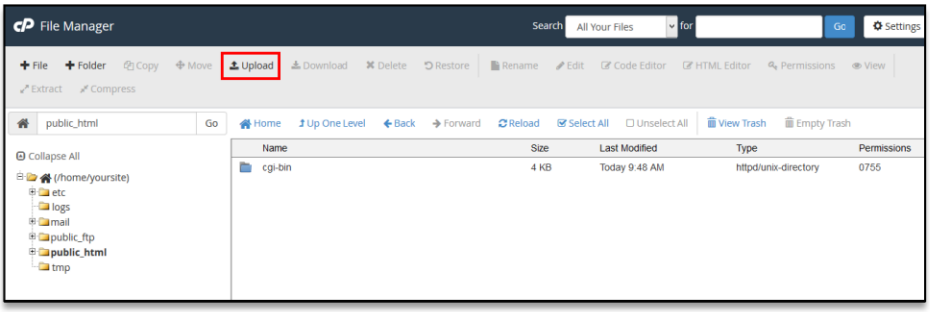
Go to **cPanel** Home page then the following screen will appear-



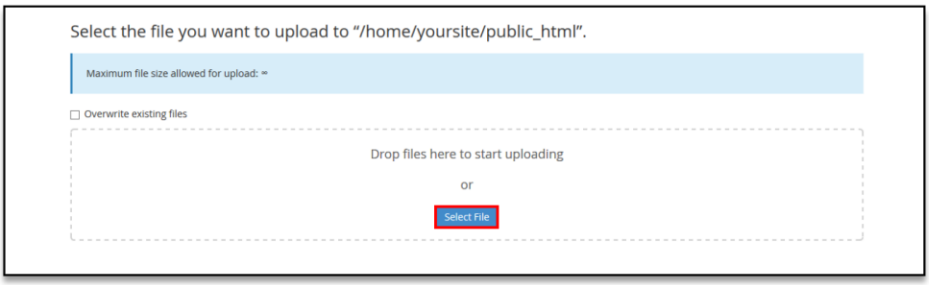
Click on the "**File Manager**" then the screen will appear-



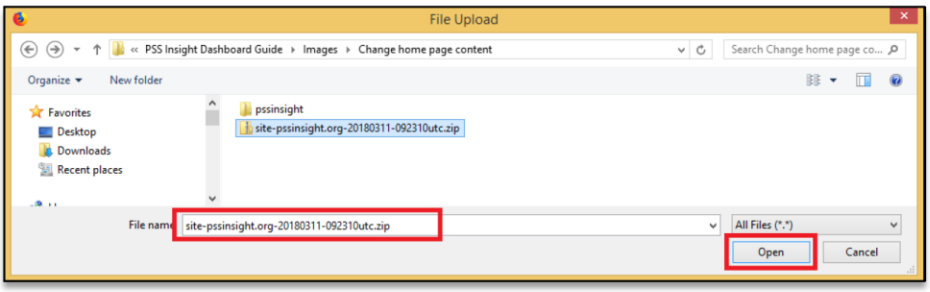
Double Click on the "**public_html**" then the screen will appear-



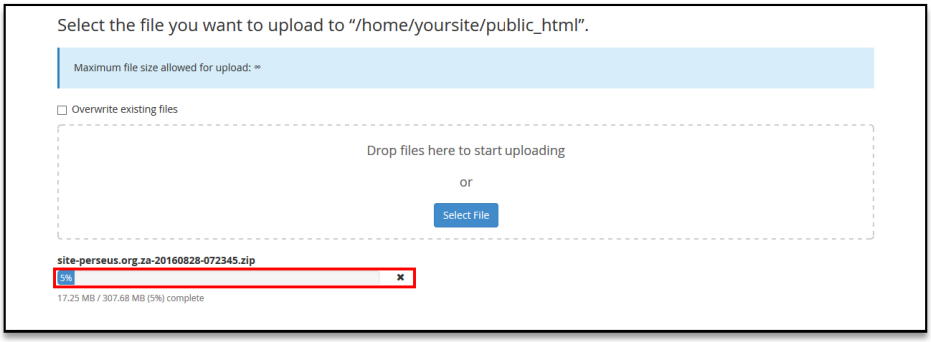
Click on the "**Upload**" link that is indicated by red color rectangular then the screen will appear-



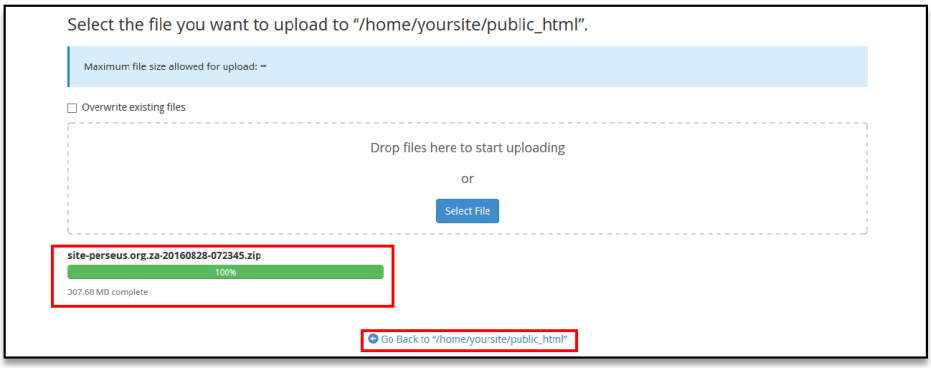
Click on "**Select File**" that is indicated by red color rectangular then the screen will appear-



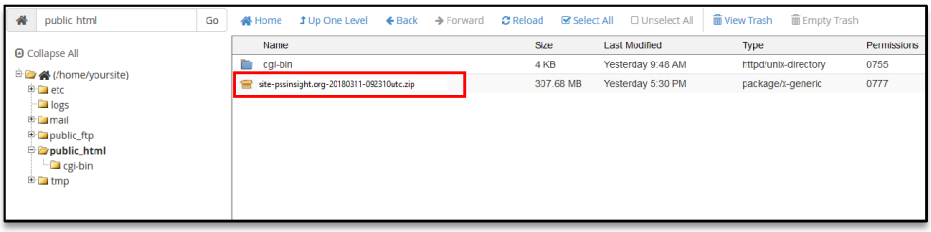
After selection Click on the "**Open**" button that is indicated by red color rectangular then the screen will appear-



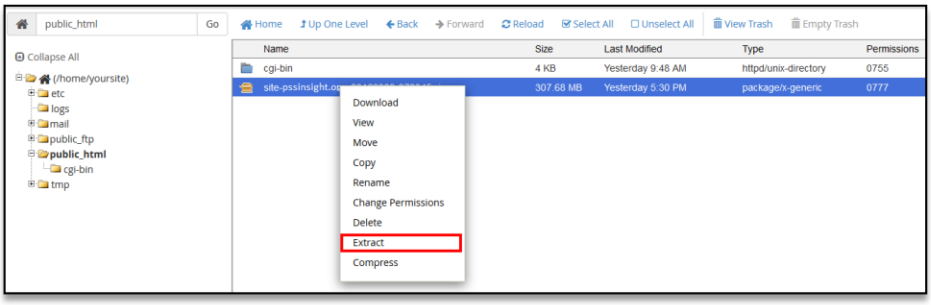
File upload is progress wait until finish 100%. After completing 100% then the below screen will appear…



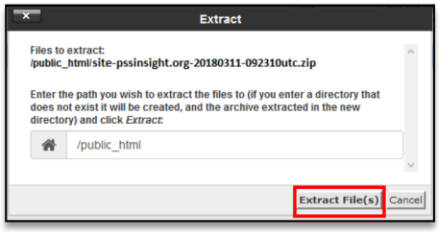
Then click on "Go Back" link to go public_html. In public_html directory you will see uploaded .zip file as below screen.



Now right Click on the selected option then user will see the below screen.

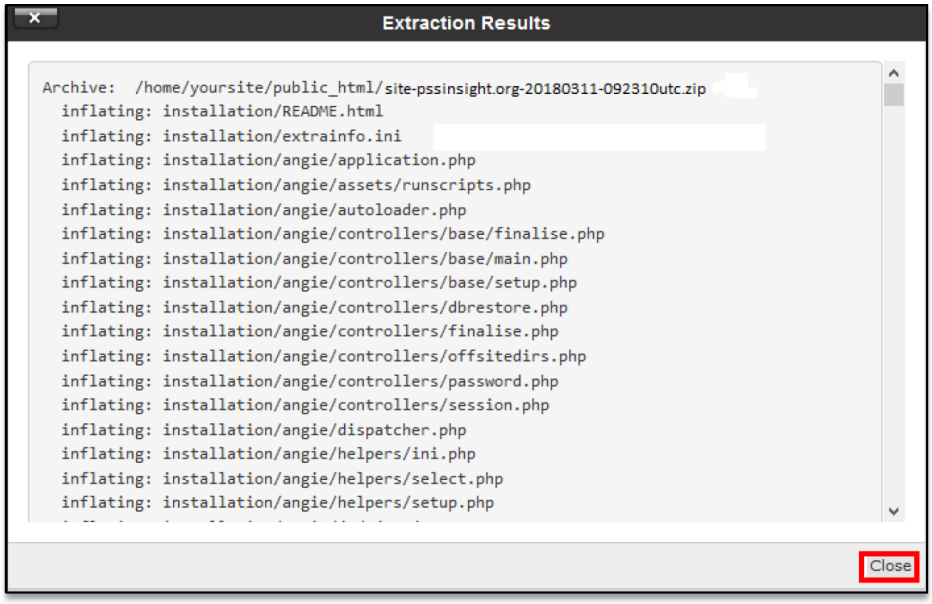


Click on the "**Extract**" button that is indicated by red color rectangular then the screen will appear...

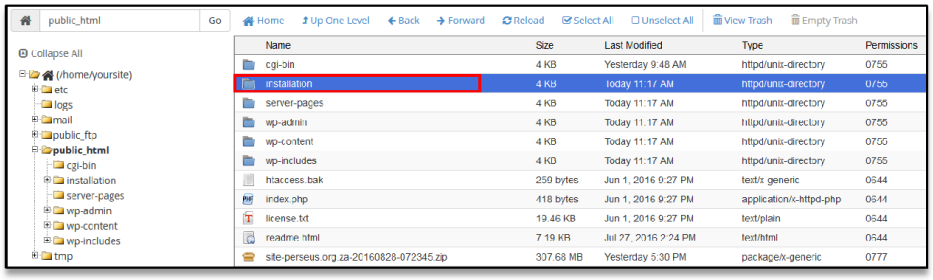


After that click on the "**Extract Files(s)**" button that is indicated by red color rectangular then the screen will appear. File is extracting now.

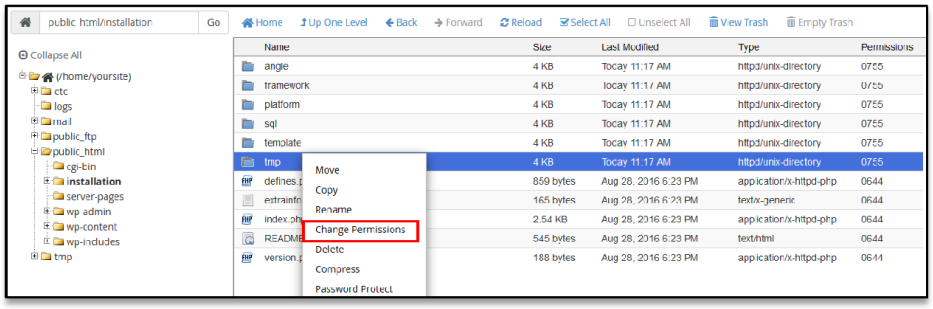
Sometime later the screen will appear as follows -



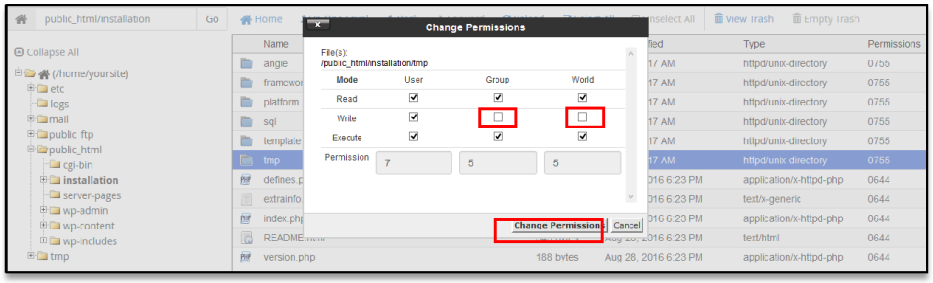
Click on the "**Close**" button that is indicated by red color rectangular bottom of the right corner then the screen will appear and you will see installation folder.



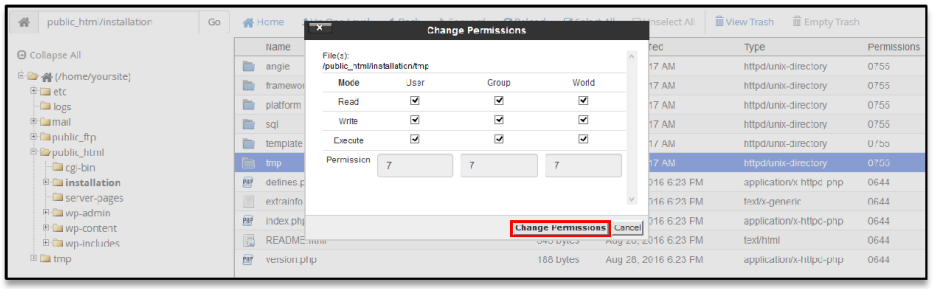
Double click on installation folder then you will see "**tmp**" folder. Right click on tmp folder and the screen will appear.



Now, Click on the "**Change Permission**" option then the screen will appear.

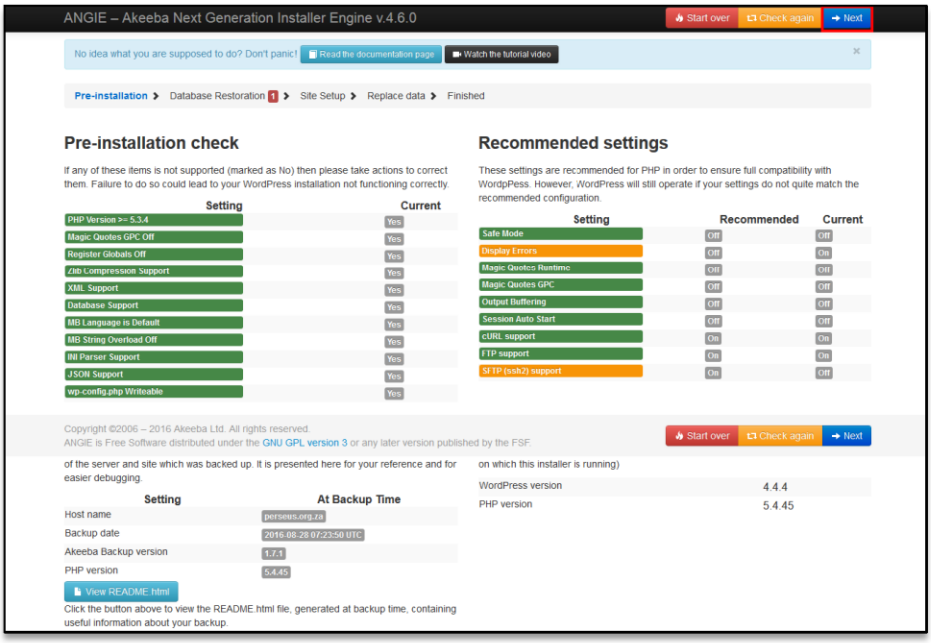


Checked the selected uncheck box then click on "**Change Permission**" button then the screen will appear

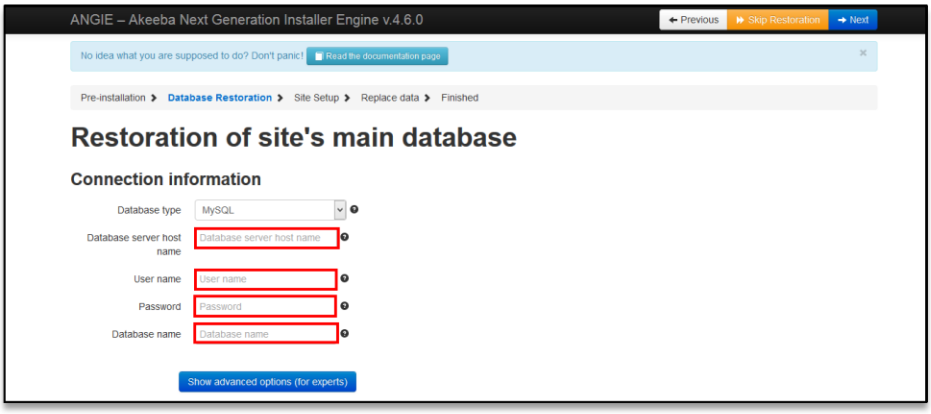


Successfully permission set to "**tmp**" file.

Now, go to http://[your new web site IP]/~[your site name]/installation/then the screen will appear as below screen.

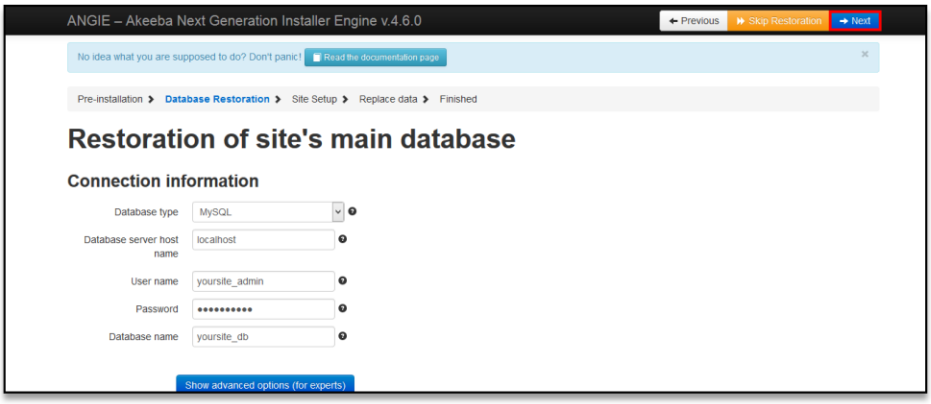


Without Changing, Click on the "**Next**" button that is indicated by red color rectangular top of the right corner then the screen will appear.

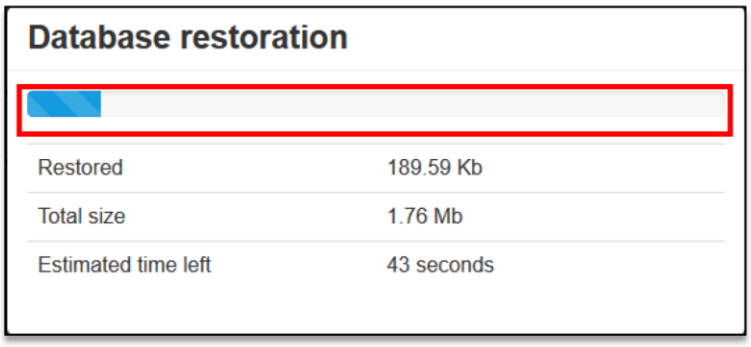


Now fill the select field as below…

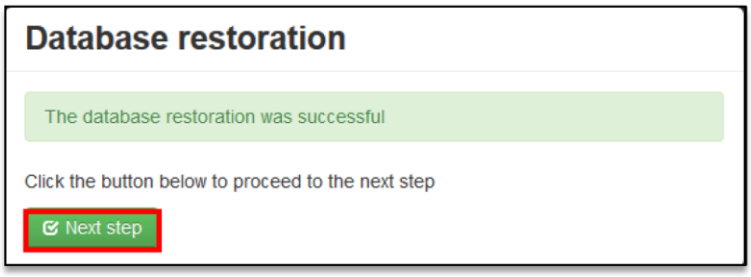
- **Database server host name**: localhost
- **User name**: yoursite_admin
- **Password**: **********
- **Database name**: yoursite_db



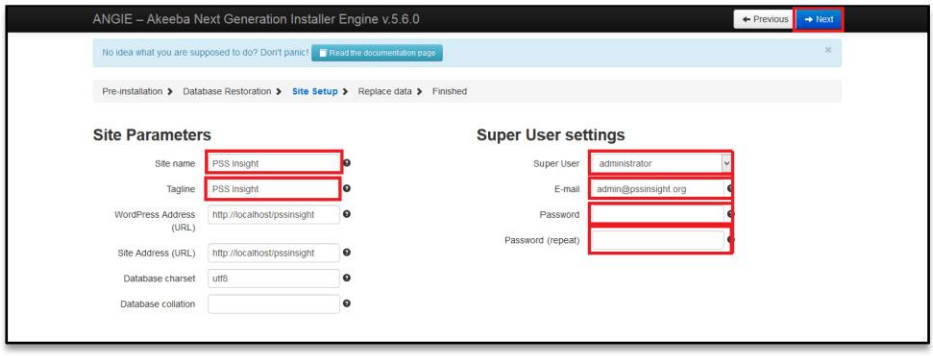
Click on the "**Next**" button that is indicated by red color rectangular top of the right corner then the screen will appear…



After sometime the below screen will appear automatically.



Click on the Next step button that is indicated by red color rectangular then the screen will appear…



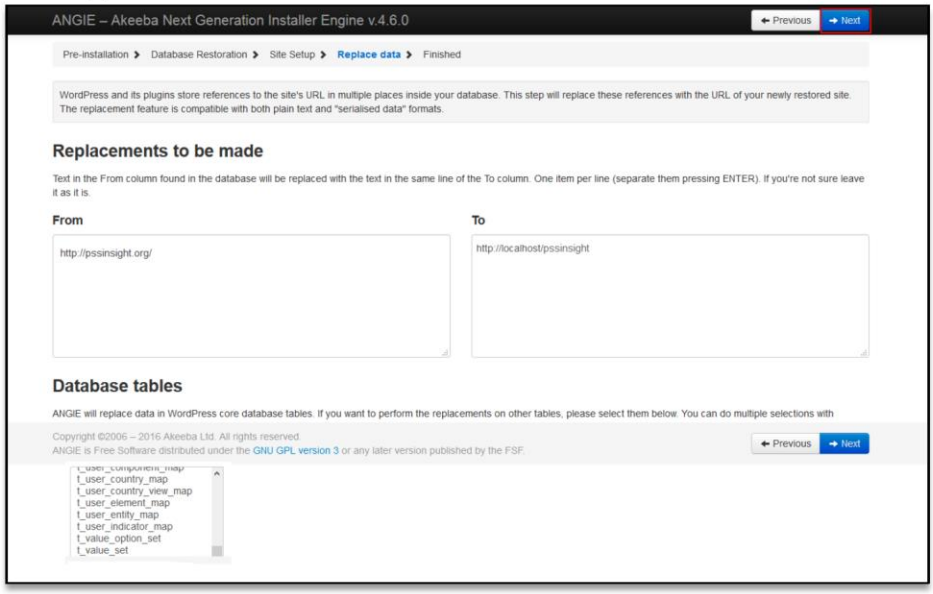
In **Site Parameters-**

3. **Site Name:** Your site name.
4. **Tagline:** Your site name.

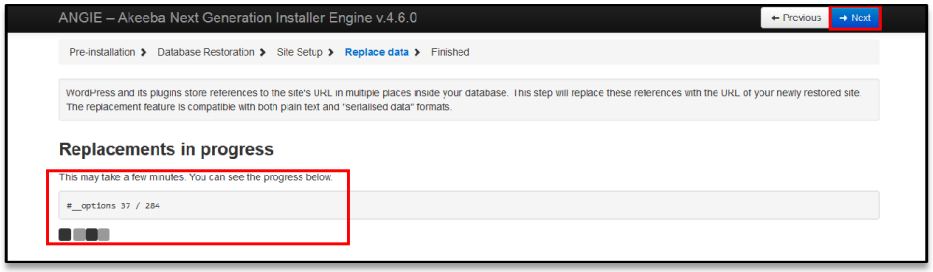
In **Super user Settings-**

5. **Super User:** administrator
6. **Email:***********
7. **Password:***********
8. **Password(repeat):***********

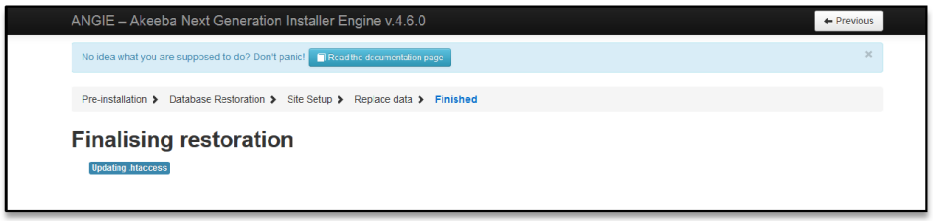
Click on the "**Next**" button that is indicated by red color rectangular top of the right corner then the screen will appear.



Without Changing, Click on the "**Next**" button that is indicated by red color rectangular top of the right corner then the screen will appear.

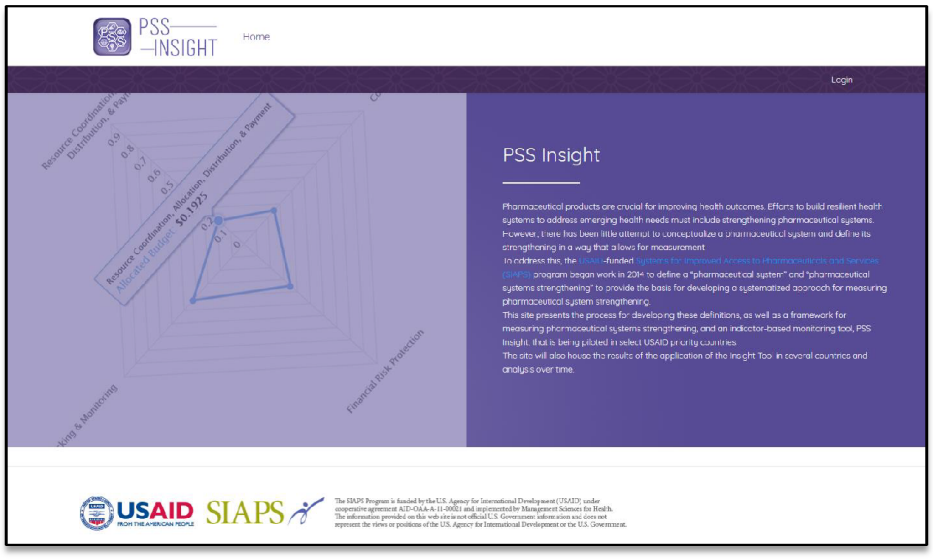


Wait until the progress is finished. After finish progress, Click on the "**Next**" button that is indicated by red color rectangular top of the right corner then the screen will appear.



Install process is finished.

Finally, go to http://pssinsight.org/ which should run from the new server –



END

REFERENCES

[i] Hafner T, Walkowiak H, Lee D, Aboagye-Nyame F; Defining pharmaceutical systems strengthening: concepts to enable measurement, Health Policy and Planning, Volume 32, Issue 4, 1 May 2017, Pages 572–584.

[ii] Kruk ME, Myers M, Varpilah ST, Dahn BT. What is a resilient health system? Lessons from Ebola. The Lancet. 2015 May 9;385(9980):1910-2.

[iii] Masten, AS. Ordinary magic: resilience processes in development. Am Psychol. 2001; 56: 227