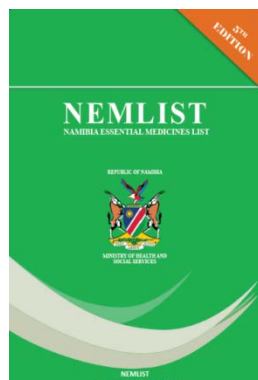


Supporting the Development and Implementation of Essential Medicines Lists



The careful selection and implementation of a limited list of essential medicines is a proven effective intervention that enhances access to and rational use of pharmaceuticals, improves quality of care, and supports cost-effective use of resources. This essential medicines concept has become an established approach in the field of international public health and is supported by governments and health care providers around the world. To date, at least 156 countries have adopted national essential medicines lists (EMLs).

WHO Model List of Essential Medicines

The WHO Model List of Essential Medicines is a guide for the development of national and institutional EMLs. First published in 1977, the WHO Model List is updated every two years. The most recent list comprises over 350 medicines, including those for malaria, HIV/AIDS, tuberculosis, reproductive health, and chronic diseases. A country decides which medicines are regarded as essential based on its most pressing health care needs. National EMLs should be used to guide procurement, supply, and use of medicines in the public and private sectors; schemes that reimburse medicine costs; medicine donations; and local medicine production¹. The national list can also be used to create more limited lists of medicines for use at lower levels of health care, such as the health center.

The most recent version of the WHO Model EML for adults is available at http://whqlibdoc.who.int/hq/2011/a95053_eng.pdf. The model list for children is available at http://whqlibdoc.who.int/hq/2011/a95054_eng.pdf.

A Model Process

The essential medicine selection process promotes the use of cost-effective treatments for common diseases and encourages consistency in prescribing practices. The process of updating an EML should be participatory, evidence-based, and transparent. Applications for additions or deletions to the EML are submitted to an expert committee that bases its decisions on a systematic review of the evidence, external review, and links to clinical guidelines. Local stakeholder support and the dedication of a multidisciplinary EML committee are critical building blocks to the successful development or revision of an EML.

The SIAPS Approach

With funding from the United States Agency for International Development (USAID), the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program and its predecessor programs – Strengthening Pharmaceutical Systems (SPS) and Rational Pharmaceutical Management Plus (RPM Plus) – have

¹ Medicines: essential medicines. WHO Fact Sheet N325, June 2010. <http://www.who.int/mediacentre/factsheets/fs325/en/index.html>

Essential medicines are *“those that satisfy the priority health care needs of a population. They are selected with due regard to disease prevalence, efficacy, safety and comparative cost-effectiveness. They are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and community can afford.”*

Source: WHO, 2013



provided technical assistance to 13 countries in sub-Saharan Africa in supporting EMLs to improve medicine access and use, streamline procurement activities, minimize institutional costs, and optimize patient care.

The Work of SIAPS and its Predecessors in Supporting EMLs

Type of Support	Countries
Revision of EML	DRC; Ethiopia; Ghana; Kenya; Lesotho; Liberia; Namibia; Rwanda; Senegal; South Africa; Swaziland; Zambia
Dissemination of EML	Kenya; Liberia; Malawi; Namibia; Rwanda; Senegal; Swaziland; Zambia
Orientation/Training on EML	Kenya; Swaziland

Based on WHO guidance², SIAPS assists in-country stakeholders in following an established series of steps to develop or revise an EML.

Step 1: Develop working principles for the development or revision of the EML

The Ministry of Health (MOH) specifies the purpose of the EML, including information regarding public and private sector use, procurement, and prescriptions. Policies and procedures for the development and use of the EML are clearly stated.

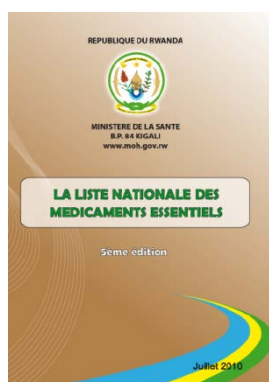
Step 2: Choose members to form a multidisciplinary expert committee

The MOH appoints a *multidisciplinary* expert committee to identify medicines to include in the national EML. It selects committee members based on their relevant backgrounds and previous experience in procurement, supply, or use of medicines. Committee members should be completely separate from any conflict of interest with pharmaceutical companies or suppliers/distributors. In fact, the committee should have procedures in place to help protect against conflict of interest.

Step 3: Initiate activities and develop explicit policies on medicine selection

The expert committee should start by identifying a list of common diseases that would expect to be treated at each level of health care. The next step is to identify the first-line medicine to treat these various conditions. If existing national standard treatment guidelines (STGs) are evidence-based and up-to-date, they should be used as the primary basis for drawing the draft list of medicines to include in the EML. If there are no national STGs or if they are outdated, the WHO Model EML should be used to inform the development of the EML.

The choice of medicines should be supported by evidence-based information from high-level sources (e.g., meta-analyses, systematic reviews, and randomized controlled trials). Other important factors to consider during the selection of medicines include the need for specialized diagnostic or monitoring facilities, qualified human resources, and financial and environmental resources, among others. All medicines must be selected based on *established efficacy, safety, quality, and comparative cost-effectiveness*.



“The first list was a major breakthrough in the history of medicine, pharmacy, and public health.”

Source: Médecins sans Frontières, 2000

² WHO Item 2: How to develop a National Essential Medicines List.

http://www.who.int/selection_medicines/committees/expert/18/policy/policy2/en/



Recipes for Success

- Multidisciplinary EML committee
- Participatory, transparent process
- Link to STGs and formularies
- Clarity on the purpose of the EML (legal and administrative authority)
- Official product launch
- Initial and reinforcement orientations/trainings
- Regular updates
- Monitoring of use

While developing the draft EML, the committee may decide to form subgroups of relevant experts to draw up the list of medicines pertaining to specific organ-systems or therapeutic/chemical categories. Once drafted, the EML should be finalized through a wide consultative process and then approved by MOH authorities.

Step 4: Establish program for revisions, dissemination, and training on the EML

Following publication of the first national list, the EML should be revised periodically, preferably every two years, to keep up with changes to clinical management protocols, health trends, and evidence-based best practices. The committee must develop an ongoing system for updating the EML and clearly lay out procedures for adding to and deleting from the list.

Once a national EML has been finalized and printed, a launch campaign should be organized to raise awareness and emphasize the advantages of the EML. Expansive media coverage, combined with the involvement of high-level government officials, gives the list national prominence and credibility. The dissemination strategy should focus on creating awareness, ensuring that the STGs and EML are readily available, and training health care workers on their proper use. In addition to printed copies, the documents should be made available through CD-ROMs and as downloadable PDF versions from the MOH website. Where possible, the dissemination strategy should involve regional sensitization meetings with dissemination packages for training health care workers provided to provincial- and district-level teams.

Step 5: Develop a monitoring component for the EML

The expert committee should also develop an ongoing monitoring component for assessing the availability, utilization, and impact of the EML. Illustrative indicators to monitor the application of the essential medicines concept include the following³:

- What is the total number of pharmaceuticals (in dosage forms and strengths) on the national EML?
- Is there consistency between the drugs included in the EML and STG?
- What % of public-sector health facilities has a copy of the EML and STG?
- Are the EML and STG used for pre-service and in-service training of health care personnel?
- Has the national EML/formulary been updated and distributed countrywide in the past five years?
- Do drug donations comply with the national EML?
- The value of drugs from the national EML procured in the public sector, out of total value of drugs procured in the same sector.
- The number of drugs from the national EML prescribed, out of total number of drugs prescribed.
- The number of locally manufactured drugs sold in the country from the national EML, out of total number of drugs from the national EML.
- The number of drugs from the national EML among the 50 best selling drugs.

³ Indicators for monitoring national drug policies: A practical manual (<http://apps.who.int/medicinedocs/pdf/whozip14e/whozip14e.pdf>); Systems Assessment Approach: A How-To Manual, 2007. (http://www.usaid.gov/our_work/global_health/hs/publications/hs_manual.html)

Acceptance and Uptake

Acceptance and uptake of a national EML depend on several factors. First, the development of the EML must involve a diverse group of national experts and government stakeholders. Second, a national drug policy framework must be in place and the list must have a purpose. Third, the process of selecting medicines must be transparent, evidence-based, and realistic. Further, there must be an established procedure for making amendments to the EML⁴. The development of an EML is only a starting point; it must be linked with procurement and supply, STGs, training, and monitoring and evaluation of prescribing in order to contribute to better health care.

Implementing the Essential Medicines Concept to Improve Access to Pharmaceuticals in Namibia: A Success Story

The first edition of the Namibia EML (Nemlist) was developed in 1995 and subsequently updated in 1999 and 2003. There was, however, a delay in further revision after the 2003 edition. In 2007, SPS staff collaborated with their national counterparts to develop an implementation plan to update the Nemlist and strengthen the capacity of the committee and its secretariat to review submissions and make decisions on additions and deletions to the list. SPS developed training materials on the concept and implementation of essential medicines and STGs and facilitated sessions at the Namibia essential medicines workshop on review of the Nemlist for 25 senior health professionals and policy makers.

After five years of inactivity, the reestablished committee met to adopt new terms of reference and procedures to ensure a rigorous, transparent, and consistent essential medicines selection process. The committee also approved new medicines for inclusion in the Nemlist including those for HIV/AIDS, tuberculosis and palliative care medicines. SPS also supported the committee secretariat in developing scopes of practice for the selection of essential medicines, which were later included in the fourth edition of the Nemlist. The fourth edition was finalized in 2008 and 2,000 copies of the document were printed and disseminated to all the health facilities.

With SIAPS's support, Namibia made another revision to the Nemlist, leading to the publication of an updated fifth edition in May 2012. The document contains several useful annexes including guidelines and request forms for changes to STGs and the EML, and procurement of non-Nemlist medicines (buy-out). This fifth edition of the Nemlist was officially launched by top MOH officials in October 2012 and subsequently disseminated to all public health facilities in the country.



Dr. Norbert Forster (left), the MoHSS Deputy Permanent Secretary, and Ms. Elzadia Washington (right), the USAID/Namibia Mission Director, display copies of the Nemlist fifth edition during the launch of this document on October 15, 2012. Ms. Jennie Lates the former Deputy Director for Pharmaceutical Services, looks on.

⁴ WHO Item 2: How to develop a National Essential Medicines List.

http://www.who.int/selection_medicines/committees/expert/18/policy/policy2/en/