



**How Public Funds Were Spent on Procurement of
Medicines in Ukraine's Hospitals?**
Interim Analysis for the Ministry of Health, Ukraine

June 2015

Technical Brief # 1



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Systems for Improved Access
to Pharmaceuticals and Services

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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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ACRONYMS

ATC	Anatomical Therapeutic Chemical classification system
DALY	disability-adjusted life years
EML	essential medicines list
INN	international nonproprietary name
MOH	Ministry of Health
NPH	neutral protamine Hagedorn
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
SMD	Support in Market Development
UAH	Ukrainian hryvnia
USAID	US Agency for International Development
USD	US Dollars
WHO	World Health Organization
YLD	years of healthy life lost due to disability
YLL	years of life lost due to premature mortality

BACKGROUND

Pharmaceuticals may constitute as much as 40% of the health care budget in developing countries, yet large portions of the population may lack access to even the most essential medicines.¹ Public pharmaceutical budgets can be sizeable and hence vulnerable to corruption. The impact of corrupt practices, weak governance, and mismanagement in the pharmaceutical sector can be substantial.² The limited funds available are frequently spent on ineffective, unnecessary, or even dangerous medications.

In collaboration with the State Expert Center (SEC) and the Ministry of Health (MOH) of Ukraine, the United States Agency for International Development (USAID) funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) program has been advocating the adoption of a national essential medicines list (EML) as the sole basis for public sector procurement in Ukraine. The World Health Organization (WHO) promotes the EML strategy as a powerful policy instrument to help national decision-makers select medicines with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. An analysis of past spending patterns on procurement of medicines will help MOH policymakers and key government stakeholders in Ukraine for decisions on adopting the national EML in practice.

The purpose of this technical brief is twofold:

- 1) Demonstrate the need to rationalize limited public funds for maximum health impact.
- 2) Emphasize the need for proper selection of medicines based on WHO recommendations and the rationale for an EML as the sole basis for public sector procurement in Ukraine.

Scope and Source of Data

The high-level analysis of data presented in this brief covers three levels of the Ukrainian hospital tender purchasing system: (1) MOH central tenders, (2) regional health authority tenders (all oblasts and the city of Kiev and Sevastopol—referred to in this brief as 26 regions), and (3) hospital-level tenders. Data were not extrapolated and cover 95% of the Ukrainian hospital market (i.e., 547 hospitals and 54 regional administrative bodies). SIAPS received the data from Support in Market Development (SMD), a market research agency based in Ukraine.

METHODS

Data analysis in this technical brief is based on the ABC value analysis, a powerful tool used to select, procure, and manage distribution of medicines, while promoting rational medicines use. The basic principles of the ABC analysis, typically based on the value of the medicines annual (or multiyear) usage may be applied to a variety of situations in which attention can be given to only a subset of issues or concerns. A well-known fact in medicines expenditure analysis is that a relatively small number of medicines account for most of the spending. This phenomenon, also known as the Pareto Principle, is based on observations by an Italian economist, Vilfredo Pareto. It is also referred to as “separating the vital few from the trivial many” because for any group of things that contribute to a common effect, a relatively few contributors account for a majority of the effect.³

Based on findings from the ABC analysis, this technical brief takes a close look at some of the medicines or therapeutic classes that account for the most expenditure.

Findings

In 2013, just nine medicines accounted for 20% of 2.87 billion Ukrainian hryvnia (UAH) spent on procuring 4,285 medicines (figure 1).

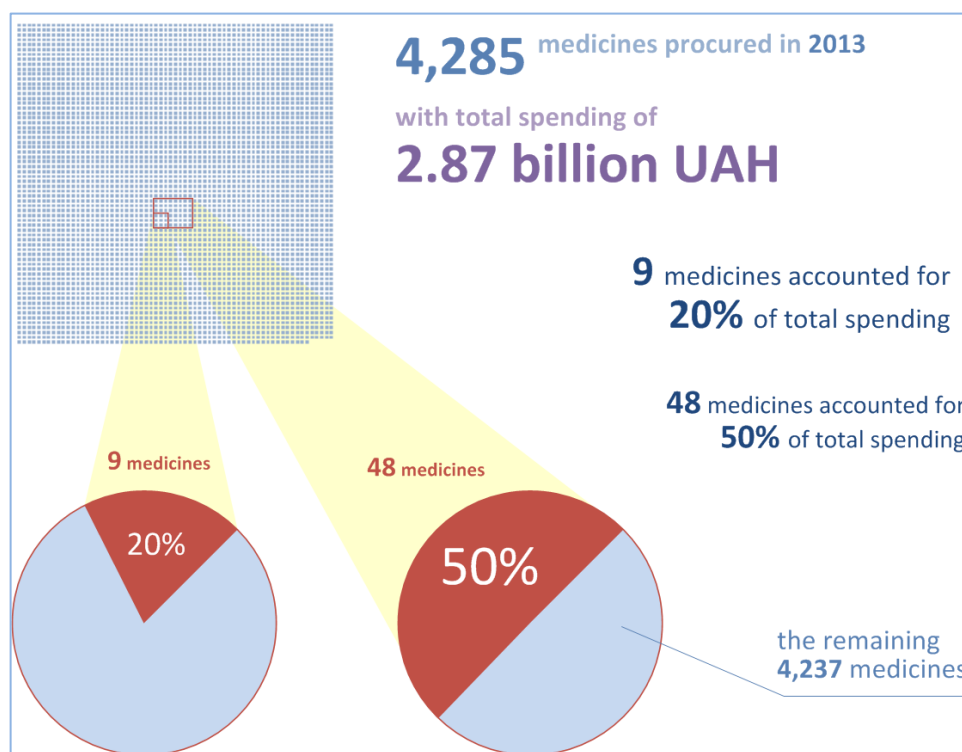


Figure 1. Analysis of spending, 2013

From another perspective, 1.1% (48) of 4,285 medicines procured accounted for half of 2.87 billion UAH spent in 2013. A closer look at spending revealed the top nine medicines procured in terms of spending (table 1). Among the main drivers of spending were vaccines and medicines to treat HIV and other chronic diseases.

Table 1. Top 9 of 4,285 Medicines Procured Nationwide 2013

Trade name	INN	UAH (million)	% total UAH	Units
Pentaxim	DTaP, polio, Hib vaccine	139	4.84%	892,406
Aluvia	Lopinavir and ritonavir	124	4.34%	268,319
Infanrix	DTaP vaccine	72	2.51%	672,995
Rituksim	Rituximab (oncology)	51	1.79%	6,555
Glivec	Imatinab (oncology)	45	1.59%	17,441
Farmasulin HNP	Human insulin semisynthetic (diabetes)	43	1.50%	373,811
Lantus Solostar	Insulin glargine (diabetes)	38	1.34%	44,111
Metalyse	Tenecteplase (thrombolytic)	37	1.31%	2,679
Immunate	Human coagulation factor VIII (hematology)	36	1.26%	23,331
Sub-total (9 medicines)		585 million UAH		
Grand total (4,285 medicines)		2.87 billion UAH		

Abbreviations: DTaP = diphtheria, tetanus, pertussis; Hib = *haemophilus influenzae* type b

The top cost driver in 2013 was Pentaxim[®], presented in a prefilled syringe of 0.5 mL. The acellular pertussis vaccine component is present in Pentaxim. UNICEF/Ukraine does not procure the latter and instead purchases the much cheaper whole cell pertussis component of the vaccine from other manufacturers. The results of a separate analysis on Pentaxim[®] will be presented in a future technical brief.

A vast majority (98% by value) of lopinavir/ritonavir (Aluvia[®]) was purchased in 200 mg/50 mg tablet form (120-pack) versus the 100 mg/25 mg form.

The 51 million UAH spent on procuring rituximab (Rituksim[®]) for 6,555 units indicates its relatively high price (12,312 UAH for 1 500 mg, 50 ml vial). This is also the case for tenecteplase (Metalyse[®]), in which 37 million UAH were spent on 2,679 units of one 50 mg/prefilled syringe with 10 mL (cost per syringe was UAH 14,106). Tenecteplase is indicated for dissolving blood clots during a heart attack.^{4,5}

In 2014, nine medicines accounted for 20% of 3.68 billion UAH spent on procurement of 4,643 medicines (figure 2).

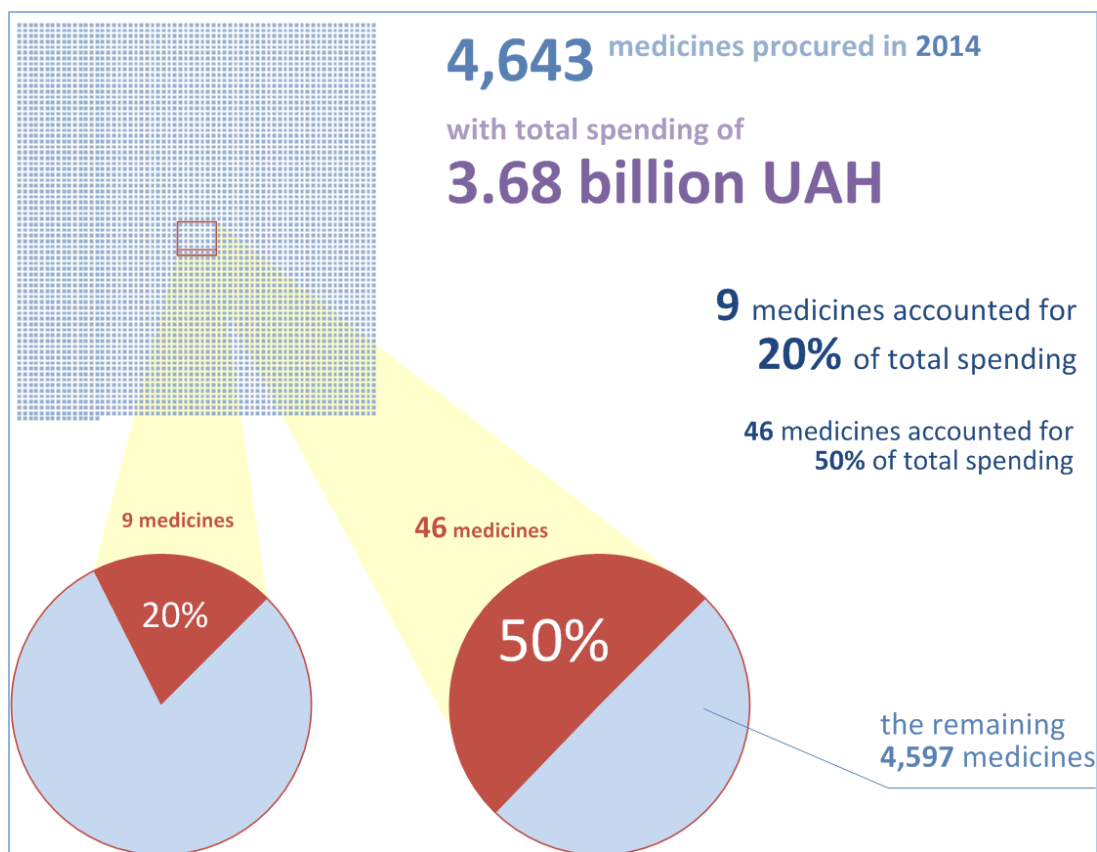


Figure 2. Analysis of spending, 2014

Cumulatively, a mere 1% (42) of 4,643 medicines procured in 2014 accounted for 50% of spending.

The names of the nine medicines are listed in table 2. Peritoneal dialysis solution (Dianeal[®] PD-4) accounted for 5.25% of total 3.68 billion UAH spent. This included solutions procured in various forms such as 1.36% w/v, 2.27% w/v and 3.86% w/v. However, by volume, peritoneal dialysis was also among the top 5 procured medicines.

Both the 50 mg and 100 mg powder for infusion forms of micafungin (Mycamine[®]) were purchased, which are used for treatment of invasive and esophageal candidiasis and as a prophylaxis for patients undergoing stem cell transplantation.⁶ The 50 mg form of Mycamine[®] was procured with a unit cost of 5,332 UAH (467 US Dollars [USD]) while the 100 mg form was procured for 10,933 UAH (or USD 885).

Other medicines with a relatively high unit cost were rituximab (Rituksim[®]), human immunoglobulin (Octagam[®]) and imatinib (Glivec[®]).

Table 2. Top 9 of 4,634 Medicines Procured Nationwide 2014

Trade name	INN	UAH (million)	% total UAH	Units
Dianeal PD-4 + dextrose	Peritoneal dialysis solution	193	5.25%	1,296,761
Pentaxim	DTaP, polio, Hib vaccine	118	3.21%	471,800
Aluvia	Lopinavir and ritonavir	106	2.89%	182,775
Mycamine	Micafungin	75	2.06%	9,857
Rituxim	Rituximab	56	1.54%	6,056
Lantus Solostar	Insulin glargine	56	1.53%	59,813
Infanrix	DTaP vaccine	55	1.50%	492,773
Octagam	Human Immunoglobulin	52	1.44%	14,772
Glivec	Imatinab	49	1.35%	2,823
	Sub-total (9 medicines)	760 million UAH		
	Grand total (4,643 medicines)	3.68 billion UAH		

Abbreviations: DTaP = diphtheria, tetanus, pertussis; Hib = haemophilus influenzae type b

Regional Expenditures

As seen in figure 3, 6 of 26 regions accounted for 54% of spending on medicines in 2013 and 2014 (24 months). These 6 regions cover approximately 42% of the population in Ukraine. Of the 26 regions, Kyiv and Dnipropetrovsk region alone accounted for nearly a third (27%) of 6.55 billion UAH (USD 664 million) spent on procuring medicines in 2013 and 2014 (24 months). Whereas data on health spending across Ukraine is well known, it may be useful to identify major oblasts where targeted interventions related to selection, pricing, and procurement of medicines can be applied for maximum impact. Further analysis will be done at the oblast level by hospital and regional tender as well as therapeutic class, and will be presented in a future technical brief.

In terms of spending by tender type, MOH tenders accounted for 50% of 6.55 billion UAH spent on medicines (figure 4), followed by 32.2% for hospital tenders and 17.7% for regional tenders, in 2013 and 2014 (24 months). Further analysis will be done for each of these specific tenders in a future technical brief with comparison for any potential patterns in medicines selection and pricing.

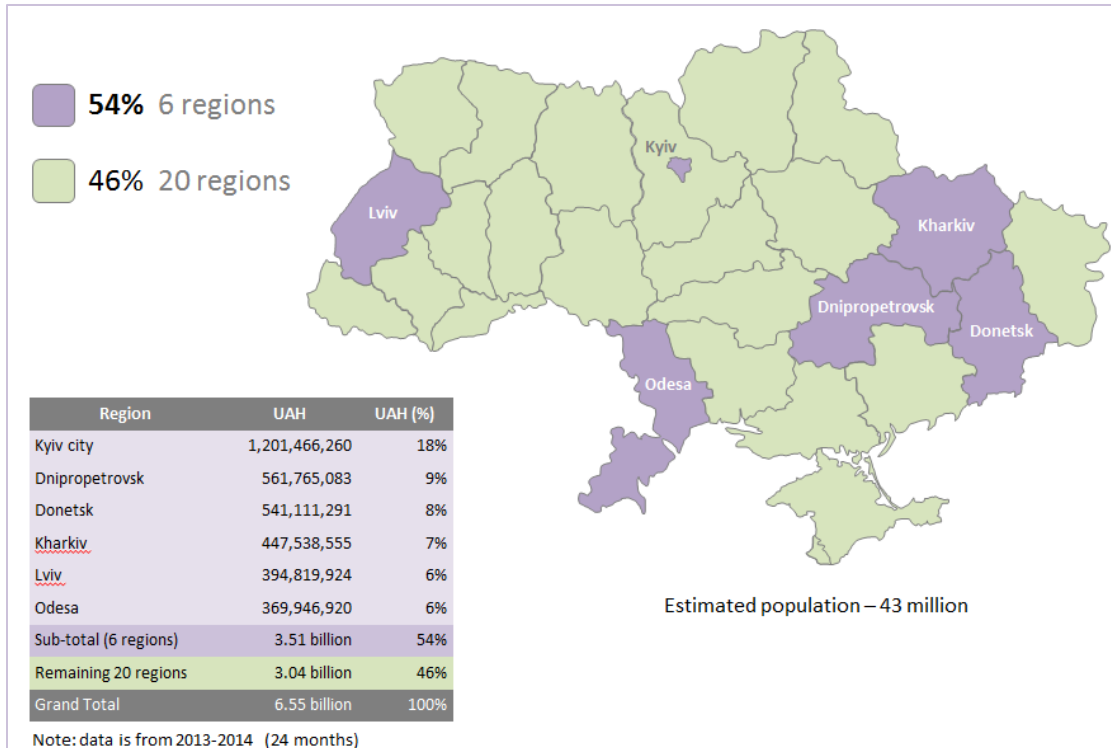


Figure 3. Percentage of spending by region

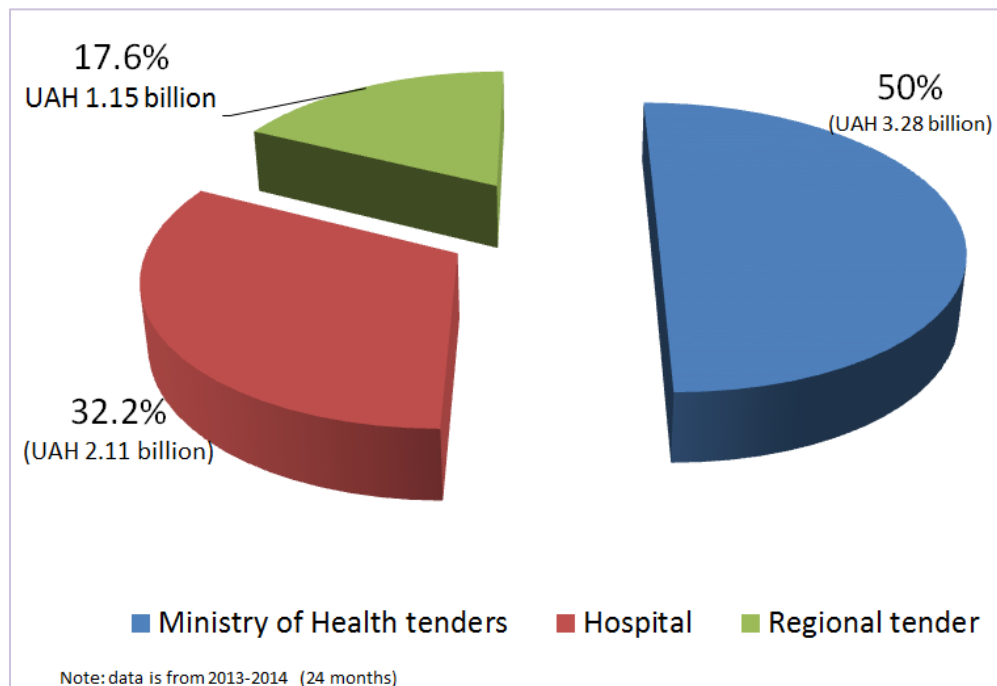


Figure 4. Percentage of UAH 6.55 billion spending by tender type

The pharmacological category analysis based on the Anatomical Therapeutic Chemical (ATC) classification system revealed that 8 of 283 ATC categories accounted for 52% (3.37 billion UAH) of total spending on medicines (6.55 billion UAH) in 2013 and 2014 (24 months).

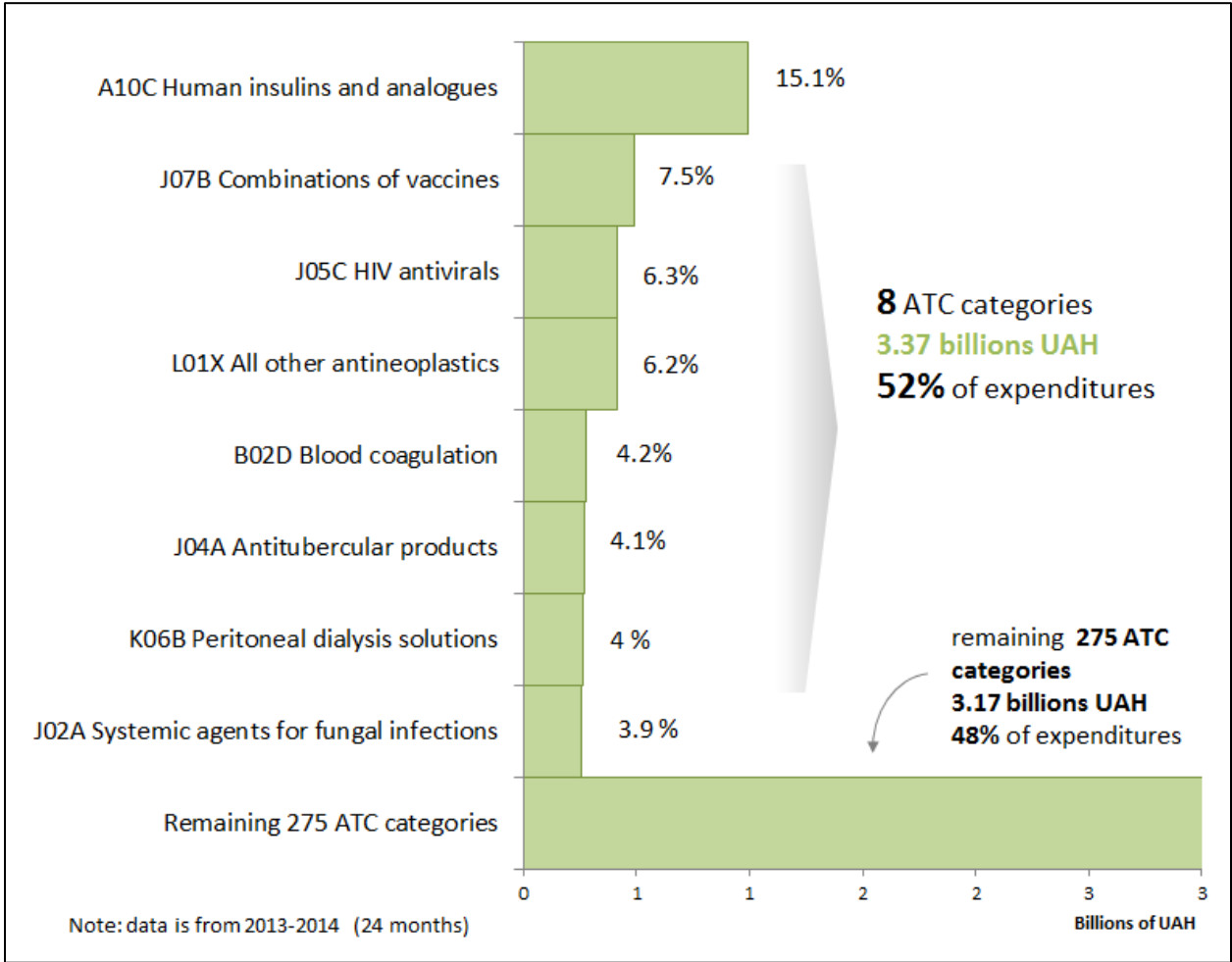


Figure 5. Percentage of spending by ATC category

Notably, human insulins and analogues accounted for a significant 15.1% (990 million UAH) of total spending (6.55 billion UAH) in 2013 and 2014 (24 months). Nine products categorized as “combinations of vaccines” together accounted for 7.5% (491 million UAH) of total spending. HIV antivirals accounted for 6.3% (416 million UAH) of total spending.

Does Spending on Medicines Correspond With Disease Burden in Ukraine?

It is worth examining patterns of spending on medicines and disease burden in Ukraine. Clearly, chronic non communicable diseases are of significant burden (figure 6).

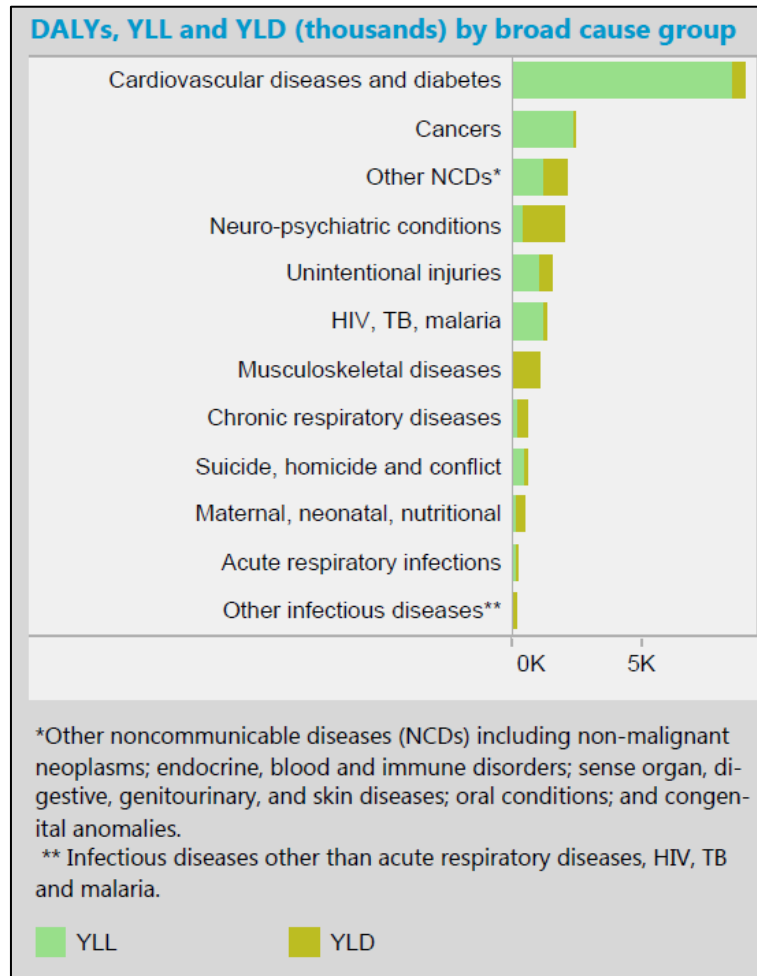


Figure 6. DALYs, YLL, and YLD (thousands) by broad cause group, 2012⁷

Abbreviations: DALYs = disability-adjusted life years; YLL = years of life lost due to premature mortality; YLD = years of life lost due to disability.

It is important to consider aspects of medicines selection, pricing, procurement, and value for money, particularly for medicines used to treat cardiovascular diseases, diabetes, and cancer. With limited funds and public health needs, all eligible patients must have timely access to lifesaving therapies at an affordable cost that the MOH can provide. Yet, despite significant public sector spending on medicines (6.55 billion UAH in 2 years), over 90% of spending on pharmaceuticals and other medical devices are financed by households—more than two to three times the amount of spending in other European Union nations.⁸

Expenditure on Insulins and Analogues: A Focus

This section examines why insulins, both fast-acting and intermediate-acting, accounted for 990 million UAH (15.1%) of total spending on medicines procurement in 2013 and 2014 (figure 5). Formulation-level analysis is also presented to reveal any potential cost drivers.

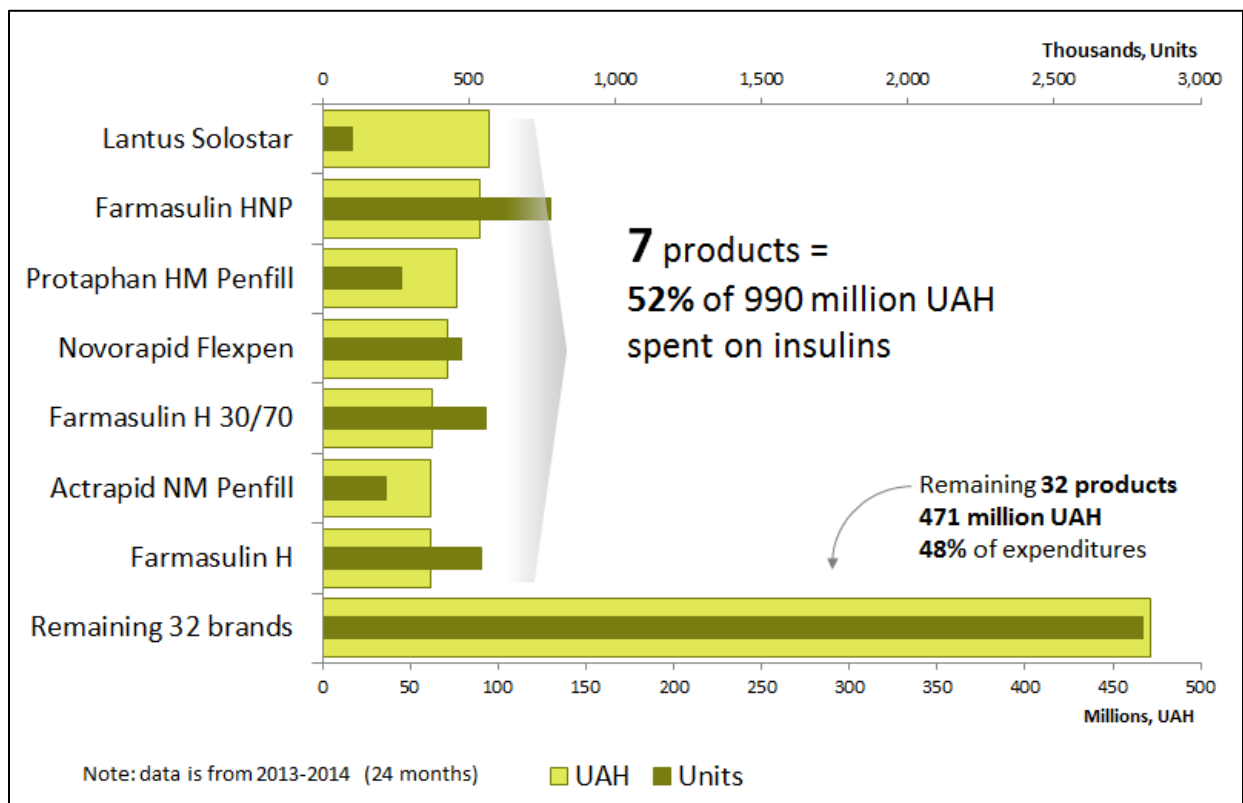


Figure 7. Analysis of spending on human insulins and analogues by product name, 2013–2014

Figure 7 shows that just 7 of 39 brand name products accounted for 52% (519 million UAH) of 990 million UAH total spending on insulins. All 7 products were purchased in the form of either prefilled syringe pens (Lantus Solostar and Novorapid Flexpen[®]) or cartridges for insulin pen refills (Farmasulin HNP, Protaphane HM Penfill[®], Farmasulin H 30/70[®], Actrapid NM Penfill[®], Farmasulin H[®]).

Only Farmasulin products were purchased in the form of vials, besides cartridges. The remaining 32 of 39 products accounted for 48% of spending.

As can be seen in figure 7, Lantus Solostar, a long-acting human insulin analogue containing insulin glargine, accounted for 94 million UAH (9.6%) of 990 million UAH total spending for 103,923 units. Available as a prefilled 100 IU/mL, 3 mL disposable syringe pen, a 5-pack Lantus Solostar disposable syringe pens cost 912 UAH (USD 93) with a unit cost of 182.40 UAH (USD 18.6) for each insulin pen. By contrast, the listed price for the same 5-pack of 3 mL pens in the 2013 *British National Formulary* was 41.5 GBP (USD 64), using 2013 exchange rates.⁹ While the latter price is indicative, it is worth reflecting on whether the USD 93 that was spent in Ukraine was a good value compared to the listed price of USD 64 in the United Kingdom.

Furthermore, the unit cost of US \$116 spent in Ukraine, for a 3 mL, 5-pack Lantus® cartridge was nearly two times that of the listed price of 41.5 GBP (about USD 64) in the UK National Health Service.¹⁰

Figure 8 illustrates spending by form, with a breakdown by vials, cartridges, and cartridge in syringe-pens.

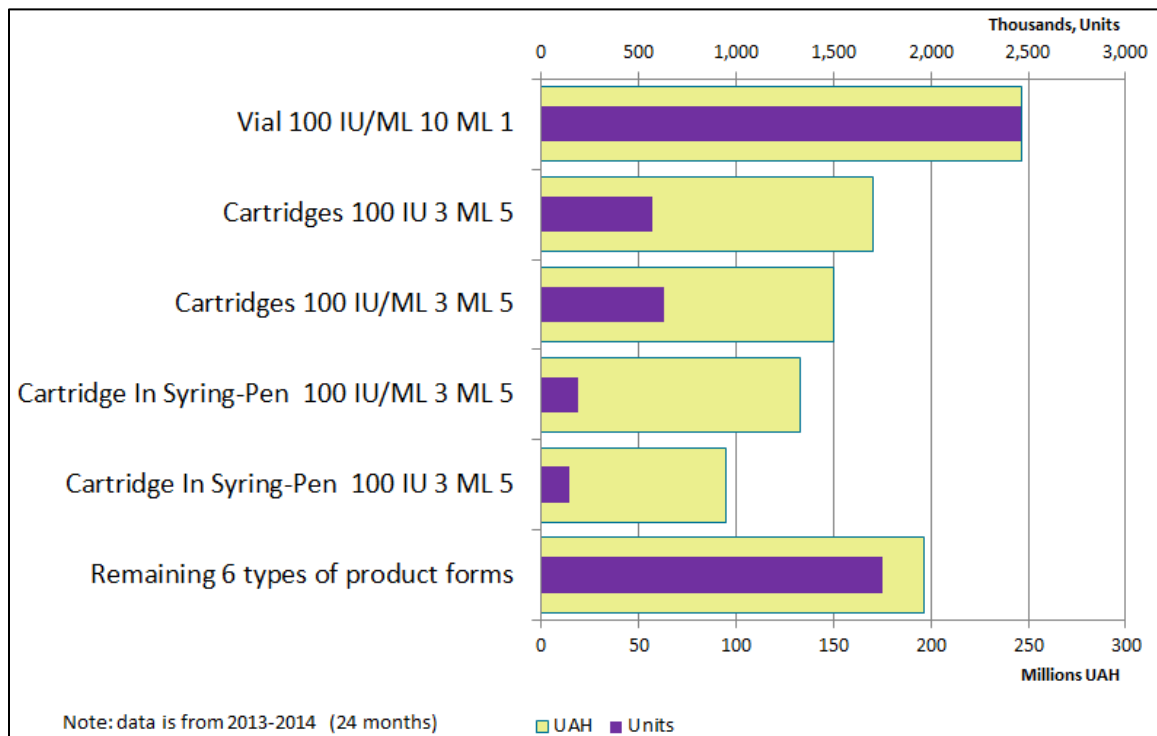


Figure 8. Analysis of spending by form of insulin, 2013–2014

Insulin purchased in the form of 10 mL vials accounted for nearly 25% of 990 million UAH total spent on insulins and analogues in 2013 and 2014. Although figure 8 shows two similar entries for cartridges (100 IU, 3 mL, 5-pack and 100 IU/mL, 3 mL, 5-pack), they are essentially the same but coded as such by SMD, based on the manufacturer’s presentation of their individual product. Likewise, the same applies for products coded as “cartridge in syringe-pen” in figure 8.

Figure 8 shows the significant millions of UAH spent on cartridges and pens relative to the number of units. Of the 11 product forms as presented by the manufacturers, insulin cartridges and pens together accounted for 627 million UAH (64%) of the total 990 million UAH spent on procuring insulins and analogues in Ukraine in 2013 and 2014 (24 months data). A significantly high amount was spent for a relatively small number of units for all cartridges and pens as a sub-group (as seen in figure 7 for Lantus Solostar).

Table 3 shows the breakdown of 990 million UAH spent on insulins by international nonproprietary names (INNs), which provides a different perspective.

Table 3. Spending on Insulins by INNs, 2013–2014

INN	UAH (million)	% total UAH	Units	% total units
Insulin human semisynthetic	548	55.35%	3,693,708	64.29%
Insulin human recombinant	130	13.16%	1,040,397	18.11%
Insulin glargine	102	10.23%	110,980	1.93%
Insulin aspart	92	9.27%	508,739	8.85%
Insulin detemir	58	5.87%	202,981	3.53%
Insulin glulisine	32	3.29%	68,284	1.19%
Insulin lispro neutral	15	1.53%	27,831	0.48%
Insulin human recombinant + insulin isophane	13	1.30%	92,777	1.61%
Grand Total	990 million UAH			

Note: Data is from 2013-2014 (24 months)

Semisynthetic human insulins with 23 products accounted for 55.3% of the total 990 million UAH spent. Recombinant human insulins with five products accounted for 13.6% of total spending and all analogue insulins (glargine, aspart, detemir, glulisine, and lispro) together accounted for 30.19% of total spending. The Lantus Solostar accounted for a significant proportion of the 101 million UAH spent for insulin glargine alone.

In summary, there are two major considerations from table 3 and figure 8:

- Analogue insulins and human insulins: Is the percentage spent on human insulins, recombinant, semisynthetic, and combinations (70%) in line with treatment protocols? Conversely, is the percentage spent on analogue insulins (30%) justified and are eligible patients receiving it?
- Insulin pens and cartridges together accounted for 64% (628 million UAH) of total spending compared to spending on vials (362 million UAH). Is this spending (or cost) justified on the grounds of convenience and comfort?

Before elaborating on the points above, it is necessary to highlight the source of tender purchases. Insulin products were primarily purchased at the regional and hospital levels, with the MOH tender accounting for only 1 million UAH in 2013 and 2014 (table 4). This may not be surprising given the decentralization of insulin tenders in recent years.

Table 4. Source of insulin purchase by tender type

Source of insulin purchase	UAH (million)	Percentage total UAH
Regional tender	638	64.5%
Hospital tender	351	35.5%
MOH tender	1	0.01%
Total	990	

WHO, Cochrane Systematic Reviews, and the European Association for the Study of Diabetes have found no evidence of significant clinical benefit of analogue insulins over human insulins.^{11,12} Internationally, analogue insulins can cost 40 times more than cheaper human insulins, which offer the same clinical benefit. The Scottish Medicines Consortium placed insulin glargine in the “restricted use” category, especially for patients who are at risk of or experience severe nocturnal hypoglycemia.¹³ The UK’s National Institute for Health and Care Excellence guideline recommends starting all new patients diagnosed with type 2 diabetes with human isophane insulin (NPH) and switching to analogue insulins only in certain conditions.¹⁴

In 2010, Germany stopped reimbursing insulin analogues, particularly rapid-acting analogues, on economic grounds alone due to significant budgetary impact.¹⁵ While the European Medicines Agency provides market authorization, pricing and reimbursement are left to countries to decide the best value for money.

In the United States, a budget impact analysis in just one hospital found savings of USD 117,236 by switching from 3 mL pens to 3 mL vials. Switching from either 10 mL insulin vials or 3 mL insulin pens to 3 mL vials found reductions in both cost and waste.¹⁶ If a similar budget impact analysis were done in Ukraine, findings may have significant budgetary implications, given the spending on 3 mL cartridges and pens. In light of the growing diabetes burden in Ukraine, one needs to consider if the available public sector budget can accommodate such choices from a payer perspective.

Insulin Use—Emerging Implications for Ukraine

In Ukraine, what types of patients are being prescribed insulin analogues? Is there an overuse, particularly among type 2 diabetic patients? Why is there such a strong preference for insulin pens compared to vials? Following is a summary translation from the Ukraine Diabetes Guidelines (2014). It is included in this technical brief for the purpose of correlating tender purchases with that of local guidelines.¹⁷ No attempt is made to compare the Ukraine diabetes guidelines with guidelines from WHO or other high-income countries.

A detailed analysis will need to be undertaken on insulin use, taking into account data from tender purchases, medicines selection, and review of evidence-based guidelines. In addition, interviews will be needed from diabetologists and endocrinologists to understand prescribing patterns and factors driving use of insulin pens and analogue insulins.

Summary Guidelines for Type 1 Diabetes

Epidemiology: Based on the MOH Medical Statistics Center report (2012), 212,134 patients required insulin therapy, which comes to 466 patients per 100,000 people.

Insulin Therapy for Adults

Insulin injections during meals can be provided in the form of unmodified (soluble) insulin injections or short-acting insulin analogue injections before major meals.

Short-acting insulin analogue shall be used as an alternative of unmodified insulin.

Table 5. Insulins for Adults and Young People

Patients	INN	Type of insulin	Form
Adults and young people	Lispro, aspart, glulisine	Analogues (short-acting)	<ul style="list-style-type: none"> • Pens: 3 mL (100 MO per 1 mL) • Pens with replaceable cartridges: 3 mL (100 MO per 1 mL) • Bottles: 100 MO per 1 mL
	Human insulin recombinant	Insulins (short-acting)	
	Human insulin recombinant (NPH Insulin)	Insulins (medium-acting)	
	Glargine, detemir	Long-acting	
	Human insulin recombinant (lispro, aspart)	Combination of insulins and analogues (short-acting and medium-acting)	

Table 6. Insulins for Pregnant Women

Patients	INN	Type of insulin	Form
Pregnant women with pregestational diabetes during pregnancy	Lispro, aspart	Analogues (short-acting)	<ul style="list-style-type: none"> • Pens: 3 mL (100 MO per 1 mL) • Pens with replaceable cartridges: 3 mL (100 MO per 1 mL) • Bottles: 100 MO per 1 mL
	Glargine, detemir (as alternative NPH)	Long-acting	
Pregnant women with gestational diabetes during pregnancy	Lispro, aspart	Analogues (short-acting)	
	Human insulin recombinant	Insulins (short-acting)	

Insulins for Children

Protocol: Medical assistance to children suffering from diabetes. Approved by MOH of Ukraine Order 27.04.2006 N 254

Epidemiology

In Ukraine, the total number of children under 18 years old suffering from diabetes comes to 8,178. Annual scale-up of new diabetes patients among children is 0.5%; in 2012 the disease was newly diagnosed in 1,131 children under the age of 17 inclusive.

Insulin Therapy

Only human genetically altered insulins or analogues are recommended for use in children. These include ultrashort-acting, short-acting, medium-acting, and long-acting insulins and their combinations in different proportions.

Table 7. Insulins for treatment of children

Insulins
Short acting (<i>Actrapid HM, Humulin Regular, Insuman Rapid</i>)
Short acting analogues (<i>NovoRapid, Apidra, Humalog</i>)
Long acting (<i>Protaphane HM, Humulin NPH, Insuman Basal</i>)
Preformulated 30/70 (<i>Mixtard 30/70, Humulin M3</i>)
Preformulated 50/50
Preformulated analogue (<i>NovoMix 30</i>)
Long acting analogues* (<i>Lantus, Levemir</i>)

* Not used for children under 6 years old.

Different short-acting analogues have different chemical characteristics; however, there is no significant difference in the time of the beginning of the effect or its duration. Their advantages in comparison to simple (soluble) insulin remains the subject of discussions.

Summary Guidelines for Type 2 Diabetes

Epidemiology

In Ukraine, based on the MOH Medical Statistics Center report (2011), the number of registered diabetes cases was 1,813,000. Of these cases, 90% to 95% were type 2 diabetes. However, the number of people with undiagnosed diabetes exceeded the number of detected cases by two- or threefold.

According to the global statistical data, the number of diabetes cases doubles every 13 to 15 years. There is a similar tendency in Ukraine—the morbidity rate has grown from 115.6 in 1993 to 248.4 in 2008 per 100,000 people. The prevalence rate has grown accordingly from 699.2 to 2,354.7 per 100,000 people.

Insulin Therapy

- Start from basal insulin before bed or two to three times a day as necessary.
- As an alternative, consider long-acting analogue.

Table 8. Insulins for Treatment of Patients with Type 2 Diabetes

Type of insulins	INN	Form
Ultra short acting	Insulin lispro aspartate glulisine	Pens 3 ml (100 MO per 1 mL)
Short acting	Recombinant insulin	
Medium acting	Human isophane recombinant (NPH insulin)	Pens with replaceable cartridges 3 mL (100 MO per 1 mL)
Long acting	Glargine detemir	Bottles 100 MO per 1 mL
Combination of short acting and NPH insulin	Two phase human insulin – genetically altered	
Combination of ultra-short acting and protamine ultra-short acting	Two phase insulin lispro Two phase insulin aspart	

Concluding Remarks

WHO promotes the EML strategy as a strong policy instrument to assist national decision-makers manage costs by helping them identify priority medicines to meet their country’s health needs. In high-income countries that have their own National Reimbursement Medicines List, the EML helps to provide insurance agencies with a neutral, gold-standard list for reimbursement. Recent research on the implementation of multiple WHO Essential Medicines Policies in low- and middle-income countries was found to have a strong correlation with quality use of medicines composite scores.¹⁸

Ukraine’s immediate neighbors, Belarus and Moldova, are effectively using their approved national EMLs as the basis for public sector procurement to provide their citizens access to cost-effective and safe essential medicines.^{19,20} Given that health sector decentralization is a priority for Ukraine, the strategy to link the EML to procurement will need to consider the interests and incentives of a wide variety of stakeholders. The MOH needs to make informed decisions based on unbiased and transparent health technology assessments for specific products, therapeutic categories, and health services.

Ukraine needs a robust national pharmaceutical policy that includes multifaceted measures, particularly on pricing and promotion of generic policies. Since the 2008 financial crisis, pharmaceutical spending has fallen in Organisation for Economic Co-operation and Development member countries. However, the share of the generic medicines market grew by 20% between 2008 and 2012, particularly in Spain (100%), France (60%), Denmark (44%), and United Kingdom (28%).²¹ Given public sector budgetary constraints in Ukraine, there is a need to further investigate selection, pricing, and sourcing of medicines including formulations.

If the Cabinet of Ministers approves the Decree on mandating the EML as the sole basis for public sector procurement, there are opportunities to rationalize spending and choose only effective medicines that are safe and offer the best value for money.

The selection of expert committee members governed by an MOH Order must be transparent with a vetted process covering aspects of conflict of interest and declaration of confidentiality during medicines selection process. There is a need to have checks and balances in place to minimize the vulnerability to corruption and measures in place to improve transparency in decision-making.

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