

# EML Harmonization Process in Ukraine

June 2017



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Systems for Improved Access  
to Pharmaceuticals and Services



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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.

## **Recommended Citation**

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## ACRONYMS

EC	Expert Committee
EML	essential medicines list
HTA	health technology assessment
INN	international nonproprietary names
MOH	Ministry of Health
NEML	national essential medicines list
SEC	State Expert Center
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
UAH	Ukrainian hryvnia
WHO	World Health Organization

## EXECUTIVE SUMMARY

The development of a new essential medicines list (EML) that is based on principles of evidence-based medicine and rational medicine use is a difficult endeavor in any environment, but particularly in a corrupt environment such as Ukraine, where special interest groups have a long history of strong influence over decision making. The initiative to introduce a new EML as the sole basis for public procurement was seen as a corruption fighting measure that inevitably evoked strong political resistance. It was not easy to overcome this resistance, but in the end, the most effective means the project found to counter resistance was ensuring open discussions among all stakeholders that were conducted in an inclusive and transparent manner. For such discussions to be successful, however, an in-depth stakeholder analysis was undertaken early in the process, followed by proactive networking to synergize with allies, disarm/neutralize detractors, and reach consensus. It should be noted that this initial step took much longer than anticipated, and what was originally envisioned as a one-year plan took several years.

A key to working toward consensus was consistently focusing on setting generally acceptable rules and processes for developing and maintaining the EML rather than discussing the list itself. Stakeholders, both manufactures and patient organizations, were often interested in pushing for assurance that their particular medicines would be included. However, we continually brought them back to the discussion of establishing a transparent process for selection rather than discussing the importance of individual medicines or medicine categories that should be included. Because of this, we were eventually able to get consensus and support. However, this process took months of continued discussions.

Another key factor for the successful promotion of the idea that a new EML was needed in Ukraine was the development and utilization of a strong evidence base that was derived from both international best practices and local examples. Building this evidence base started early in the process, was well documented, and was actively used for advocacy purposes.

It was extremely important to align with the Ukrainian legal framework and follow all required bureaucratic procedures for legal document development. While this was a cumbersome, redundant, contradictory, and time-consuming process, it did ensure that reformatory changes were embedded into national legislature and legal practice and made it much more difficult to roll them back. As a result, the bulk of our time and effort was spent on developing a legal process for sustainability rather than a list of medicines.



## BACKGROUND

Pharmaceuticals comprise as much as 40% of the health care budget in developing countries,<sup>1</sup> yet large portions of the population may lack access to even the most essential medicines. Public pharmaceutical budgets can be sizeable and therefore vulnerable to corruption. The limited funds available are frequently spent on ineffective, unnecessary, or even dangerous medications.

In 2013, half of the 2.87 billion Ukrainian hryvnia (UAH) of public-sector funds available for medicine procurement was spent on 48 medicines (1.1%) out of a total of 4,285 medicines procured. In 2014, 20% of the 3.68 billion UAH public-sector procurement budget was used to procure nine of the 4,643 medicines procured.<sup>2</sup>

The World Health Organization (WHO) promotes the EML strategy as a powerful policy tool to help policy makers determine priority medicines to meet public health needs and select medicines based on evidence of efficacy, safety, and comparative cost-effectiveness.

The careful selection and implementation of a list of essential medicines enhances access to and the rational use of pharmaceuticals, improves quality of care, and supports the cost-effective use of resources. National EMLs (NEMs) are used to guide the procurement, supply, and use of medicines in the public sector as well as schemes that reimburse medicines and guide local medicine production.

While the concept of essential medicines had been used in Ukraine, an EML was seen only as a guidance document with no legal mandate for its utilization for decision making. As a result, it was neither regularly updated nor utilized. Table 1 shows the existing documents that could be used at that time as a basis for pharmaceutical procurement at the central, regional, or facility level and the entity in the government responsible for implementation.

**Table 1. Procurement Regulations before EML Harmonization in Ukraine**

Procurement list	Regulation	Approved by
List of domestically manufactured and imported medicines eligible for procurement by health care facilities and institutions partially or cumulatively funded from the state or local budget	Order #1,071	Cabinet of Ministers
National Essential Medicines List	Order #333	Cabinet of Ministers
State Formulary	Regulation #183 (updated annually)	Ministry of Health

The list of medicines that may be procured by health care facilities fully or partly financed by state and local budgets that was approved by government decree #1,071 on September 5, 1996, “On the order of budget financed medicines procurement by healthcare facilities” has numerous medicines with no evidence-based clinical efficacy. The list contains 1,073 international nonproprietary names (INNs) or trade names and is constantly updated.

“The State Formulary of Medicines” addresses standardized health care systems. It covers evidence-based medicines registered in Ukraine of an acceptable safety level that are cost effective. The most recent version contains 983 INNs (7,388 trade names) but does not define any priorities or guidance on public health priority conditions, which contributes to inefficient and corrupt procurement methods.

Order #333 is formal; does not take into account the need for medicines or public health priorities; and does not use the main criteria for the selection of medicines (i.e., clinical efficacy, safety, and cost-efficiency). The regulatory framework adjusts (limits) trade margins on medicines that are included in order #333.

These different and diverging medicines lists made it difficult for procurement entities to rationally make procurement decisions or for the Ministry of Health (MOH) to determine which medicines should be prioritized to be state guaranteed.

### **Purpose of Our Work in this Area**

The availability of a unified EML with evidence-based clinical efficacy to be used by the MOH for the state-guaranteed package of services is an essential part of the successful launch of the health care reform initiative. This required the development and institutionalization of a process to ensure sustainability into the future rather than a one-off list of essential medicines.

The main task of US Agency for International Development-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program was the provision of technical assistance to the Government of Ukraine to solve the problem of medicines list harmonization, which was needed to review and update the NEML to be the sole list for procurement or reimbursement with public funds, and to develop legislative documentation to institutionalize the process. The work was performed in cooperation with the MOH and the State Expert Center (SEC) and included the following:

- Analyzing the existing medicines lists and the legal basis for their use in medicines procurement/reimbursement
- Summarizing the analysis results and holding discussions with key stakeholders to reach consensus on an EML process
- Developing a plan for the MOH to recommend a scheme for unified NEML implementation to replace current lists in the medicines procurement system and drafting the legal documents required to change the system
- Developing a methodology on transparent medicine selection for the NEML and drafting the legal documentation to institutionalized the process
- Advocating for changes to current legislation or rules for a unified NEML to be approved by all parties involved into medicines procurement at the national and regional levels
- Providing training and technical guidance to the new EML Expert Committee (EC)

## THE EML PROCESS

### Stage 1: Information Gathering

As a first step before engaging stakeholders, SIAPS carried out a situation analysis to review existing medicines lists and regulatory frameworks and to identify how they are currently being used by procurement entities. The data analysis was based on an ABC analysis and showed that the expense imbalance in procurement of certain medicines resulted in too much of one medicine and not enough of another being procured. In 2013, nine medicines accounted for 20% of the 2.87 billion UAH spent on procuring 4,285 medicines. From another perspective, 48 (1.1%) of the 4,285 medicines procured accounted for half of the 2.87 billion UAH spent in 2013.<sup>2</sup> A closer look at spending identified the top nine medicines procured in terms of spending.

In 2014, 20% of the total budget for procurement of 4,643 medicines was spent on only nine medicines, and 50% of the budget was spent on 42 medicines.

The procurement of overpriced medicines was found, as was the procurement of medicines with no evidence-based efficacy. For example, 990 million UAH—15.1% of the total budget—was spent on fast- and intermediate-acting insulin in 2013 and 2014. The unit cost of USD 116 in Ukraine for a 3 mL, 5-pack Lantus<sup>®</sup> cartridge was nearly twice that of the listed price of 41.5 GBP (approximately USD 64) in the UK National Health Service.<sup>3</sup> Patients have to pay for approximately 86% medicines and health commodities out of pocket.<sup>4</sup>

The results of the analysis were published in the “How Public Funds Were Spent on Procurement of Medicines in Ukraine’s Hospitals? Interim Analysis for the Ministry of Health, Ukraine” technical brief.<sup>2</sup>

National- and oblast-level meetings were held with representatives of the MOH, state services, SEC, Oblast Health Administration, Central Formulary Committee, WHO, and chief physicians. SIAPS facilitated interviews with these officials, and information was acquired on the actual use of existing medicines lists for procurement and procedures for the selection of medicines for these lists.

A desk review was performed on public procurements to identify the number and potential value of medicines procured by the MOH that are included in different medicines lists, including the WHO-approved EML and the NEML.

Understanding that medicine procurement in Ukraine has a long history of corruption,<sup>5</sup> the process started with the understanding that there would be overt and covert resistance to any changes that would rationalize procurement. To get a better understanding of where this resistance might come from, SIAPS carried out a comprehensive stakeholder analysis to identify both potential supporters for the initiative and potential sources of resistance. This became the basis for reaching out and finding champions to support the process.

## **Stage 2: Formation of Expert Committee**

In 2015, based on the initial stakeholder analysis, SIAPS started identifying stakeholders who would support establishing a new, transparent medicine selection system and creating the NEML during a complicated political situation. Complications included the need for multiple and simultaneous reforms in the absence of stability and political leadership. The Minister of Health and deputies have changed three times since 2014, and the Cabinet of Ministers membership and the Prime Minister have changed twice. In addition, the general director of the SEC, which is a key recipient and partner of SIAPS, has changed three times.

After multiple meetings with stakeholders and in light of the current political situation, it was decided that the most influential supportive force to assist in the initiation of the new NEML process would be the Parliament of Ukraine and the heads of the three parliamentary committees: health care, entrepreneurship, and international relations.

The political support of members of Parliament helped SIAPS to obtain signed memoranda of collaboration and acceptance from key partners, including the MOH, SEC, and Medical University (pharmaceutical management department), to support the NEML implementation. The specialists of these organizations were actively involved in establishing the NEML process. The actual signing of the memoranda with stakeholders was important because it meant official approval of the project activities for NEML development and implementation and support of the activities at the national level regardless of leadership changes.

In addition to stakeholder engagement, SIAPS started working on the technical aspects of establishing the process, including:

- Developing the legal base for NEML implementation. SIAPS hired a law firm with experience in pharmaceutical legislation to support the NEML legislation development and implementation.
- Developing the terms of reference for the new EC and secretariat and the methodologies for how the initial list would be determined:
  - Drafting the orders required and moving them through the bureaucratic process to set up an independent structure (the EC) in charge of medicine selection
  - Supporting the MOH in carrying out a transparent recruitment process for committee members
  - Identifying funding sources to initially support EC activities
  - Training the EC and national stakeholders (e.g., MOH, SEC) on the health technology assessment (HTA) used for medicine selection
- Developing a regulatory framework for the system of medicine selection

While the technical work was under way, outreach activities with patients, physicians, and manufacturers were ongoing to build their support for the new, transparent approaches to ensuring access to medicines. Orders and other legislation were shared for comment, and multiple meetings were held for stakeholders to voice concerns and provide feedback.

Beginning in April 2014, SIAPS conducted eight public round table meetings at which stakeholders were able to raise issues concerning the NEML development. SIAPS Ukraine representatives and local experts spoke on the NEML at three national conferences. Through these activities, SIAPS has been actively engaged in building public acceptance to set up a new medicines selection system and create the NEML.

The process recommendations made by SIAPS experts on approaches to NEML implementation were adapted by local experts to fit with the national environment and became a standard legal base that was later approved. This legal base regulates NEML development and mandates its use as a single list for procurement and/or reimbursement to ensure that public needs are met with essential medicines that have evidence-based efficiency, safety, and cost effectiveness, with the limited public health budget of Ukraine taken into account. The legal base includes the following documents (see annexes A–C):

- Regulations on the NEML
- Regulations on the NEML EC, approved by MOH order #84 in February 2014
- Regulations of medicines selection to the NEML, approved by MOH order #1,050 on October 7, 2016
- The Decree of the Cabinet of Ministers of Ukraine #180 of February 2017 on the mechanisms of provision with essential medicines listed in the NEML

Decree #180 annuls all lists that were effective prior to the establishment of the NEML and mandates the use of the NEML to meet the needs of patients for procurement and reimbursement with public funds.

Developing and getting approval of this legal base took SIAPS two years. Challenges included the resignation of three Ministers of Health during the two-year period. The resulting changes at the Deputy Minister level required establishing new relationships and getting new buy in for the process.

Despite this, an efficient communication and technical strategy has given SIAPS consistent support from patient organizations, manufacturers, national stakeholders, and international organizations. As a result, in 2016 the NEML and NEML EC regulations were approved.

In July 2016, MOH order #690 to establish the EC membership based on transparent selection principles was approved. Every applicant for EC membership had to file a conflict of interest declaration that was reviewed by the selection committee. Only those applicants determined to have no conflicts of interest were selected for the EC. The requirement of filing a declaration of conflict of interest was seen by locals as a new and innovative approach. Prior to this legislation,

Ukraine had no transparent procedures for decision maker selection, particularly for those in charge of state budget medicines list development. These positions were always appointed from within the government in a non-transparent process.

Immediately following approval of the EC membership, SIAPS organized and conducted a training for members on methods and principles of medicines selection for the NEML. The training was also attended by a local pharmaceutical journal reporter, and materials have been published in the media to transparently highlight Ukraine's new approaches for state budget medicines selection.<sup>6</sup> The regulations on medicines selection for the NEML, which specified the basic selection criteria (clinical efficiency, safety, and cost effectiveness) were approved on October 7, 2016. Only medicines that meet the established criteria can be listed in the NEML. The HTA trainings and technical support from SIAPS have contributed to developing the experts' medicines selection skills.

### **Stage 3: The Work of the Expert Committee**

On August 1, 2016, the 12 EC members officially started their activities to draft the NEML. It should be noted that despite a significant effort by international technical assistance projects to move public health reforms forward, including the establishment of the NEML, deeply imbedded corruption within the government often hampered progress. Despite the efforts of SIAPS and its partners for a transparent process for EC member selection to increase the level of public confidence in the new system of medicines selection and comply with the best global practices, after two months of work, the newly established EC was unable to move forward because of obstacles placed by the then Acting Minister of Health, who had questionable ties to the pharmaceutical industry. It was only upon the appointment of a new, unbiased Acting Minister that the EC could resume its work. EC members who had ties to the former Acting Minister and had been the source of obstruction within the committee and its progress resigned when the Acting Minister left, and a new round of selection was carried out to replace them. Since December 1, 2016, the renewed EC has proceeded with NEML development activities based on the WHO EML.

The EC currently includes 14 experts. The team is multidisciplinary and consists of experts in pharmacoeconomics, medicine, and pharmaceuticals. The EC secretariat comprises three members from within the SEC. EC regulations (approved by MOH order #84) require that EC activities be transparent. An EC website was developed to highlight the process of EC work on the NEML.

The EC regulations also provide guidance on the participation of invited experts in EC work to ensure that their participation also adheres to the principles of transparency and mitigation of conflicts of interest.

Representatives of patients, international organizations, and the MOH were regularly invited to observe EC meetings as the first draft of the NEML was written. These observers were not entitled to vote, but the experts could take their recommendations into consideration when making decisions.

The measures taken by SIAPS are actively supported by other international partners and patient organizations. The Renaissance Foundation in Ukraine strongly supports public health reforms, and efforts are aimed at improving patients' access to safe and quality medicines. The Foundation also provided financial support to SIAPS to support the EC's work and training of members and to develop the EC website.

After public discussion, the NEML was approved by the Decree of the Cabinet of Ministers of Ukraine #180 on March 16, 2017. Pursuant to the Decree, beginning on July 1, 2017, the NEML will be used for regional- and central-level procurements. The medicines listed in the first NEML draft will be procured with the state budget to fully meet the need.

#### **Stage 4: Next Steps**

The NEML includes 346 INNs as a basis for state budget procurements (or reimbursement) and is a significant development for the health system in Ukraine. Approval of the NEML undermines the corruption procurement schemes that have existed for years because the mechanism for NEML use approved by the Cabinet of Ministers Decree allows for:

- Efficient and transparent planning of procurement volumes, thereby eliminating the corruption risks when forming the procurement nomenclature list
- Procurements that are controlled by both fiscal agencies and patients.

The NEML's sustainability will be ensured only if it is implemented in a way that ensures patients' access to medicines, particularly those patients who traditionally receive medicines through state programs. The overall health financing system has not undergone any significant changes (although this is on the agenda for health care reform) and funding for medicines procurement is currently obtained through several mechanisms, including national procurements (central budget), regional and subregional procurements (subventions from central and local budgets), and procurements by the Academy of Sciences (central level). Because of the compressed timeline required for the implementation of the NEML and the levels of procurement that have different medicine requirements, it was decided that there would be a transition period for NEML implementation. The first approved NEML focused on the categories of medicines required for regional and Academy of Sciences procurements. These are generally off-patent medicines that would be part of the WHO EML, which was used as the basis for developing the first version of the NEML. At the same time, a new order was passed requiring all regions to use morbidity-based forecasting for all medicines on the NEML. This is the first time forecasting will be done without it being tied to budgets received.

The categories of medicines usually procured by the 18 national programs that are currently being procured by international organizations represent an additional phase of the transition. This was done to allow the EC to conduct a more in-depth HTA of the clinical efficiency, safety, cost effectiveness, and budget impact for national program medicines, many of which are covered by patents. The requirement that manufacturers must submit evidence to the EC for consideration for inclusion in the NEML allows the committee to evaluate the cost effectiveness and budget

impact of these often very expensive medicines. It also gives the MOH an opportunity to negotiate with manufactures before a final decision is made on NEML inclusion.

The EC secretariat has started collecting manufacturer applications for listing medicines in the NEML. As of April 1, 2017, 15 applications had been submitted.

The transition period is scheduled to continue through 2019. In 2018, a second amended NEML draft is scheduled for approval that will add medicines that will be reimbursed with state budgets for outpatient and inpatient treatment. This will help expand the new reimbursement system that has been initiated this year as part of health care reform. Changes are also expected in health system financing mechanisms, and the NEML will transition to address these changes as they occur.



## RESULTS AND ACHIEVEMENTS

The Ukraine NEML development process achieved the following results by creating awareness, involving stakeholders in consensus building, using a strong evidence base, and developing a sound legal framework:

- Existing medicines lists and the legal base for their use for procurement have been analyzed. The lists revealed the divergence in medicines and the lack of criteria for rationalizing medicines to be guaranteed by the state.
- A public discussion of the analysis results was held to bring stakeholders to consensus.
- The EC was established for essential medicines selection and use.
- The assessment criteria and the mechanisms for transparent selection of medicines for the NEML have been developed and adopted into legislation. The first phase of the NEML has been developed and implemented.
- Recommendations on further elaboration and updating of the NEML have been implemented, which is the basis for HTA implementation into the public health system of Ukraine.
- The NEML had been adopted as a sole list for procurement and reimbursement at the regional level.

## LESSONS LEARNED

### ***What went well?***

- The recommendations from the initial assessments and discussions highlighted the need for a new NEML. Stakeholders eventually supported these recommendations.
- To overcome initial political resistance, open discussions and round tables were held with all stakeholders, which helped remove barriers to moving forward.
- The SEC and Medical University signed MOUs to officially collaborate with SIAPS.
- The development process was legally approved and institutionalized.
- There was strong collaboration between project and technical and legal experts, as well as with the government and the Prime Minister.
- All stakeholders were actively involved in reviewing all stages in the development of legal documentation.
- The process has been carried out within the legal framework required by the Government of Ukraine for legislation development.

### ***What did not go well?***

- Early on, there was strong resistance both from the government and the private sector.
- There were repeated delays in the process because of political issues.
- The government did not understand the timeframe for NEML development and initially insisted that it be a rapid process.
- Because of the political situation, the required counterparts in government were initially blocked from working with us.

### ***How well was the plan executed?***

- The plan has been significantly delayed because of multiple political issues and resistance, but ultimately the NEML was developed and approved.

### ***How well were key stakeholders involved in the implementation?***

- We have worked hard to involve stakeholders through the entire process.

***What tools or techniques worked well?***

- Round tables with tele-bridges with international experts
- Close collaboration between US and Ukraine technical teams
- Focusing on process development rather than discussing the list itself
- Formal MOUs with key stakeholders
- Leveraging funding from difference sources
- Utilizing tools and technics that have been successful in other countries

***What key factors contributed to successes?***

- Extreme flexibility in a changing political environment
- Networking
- Strong support from the headquarters office on technical and administrative issues
- Understanding and adhering to the local legal and cultural environment
- A supportive donor that understands the need for flexibility

***What key factors contributed to failures?***

- Pressure from special interest group that led to delays and challenges
- Underestimating the time required to address political and bureaucratic issues

***What obstacles or unanticipated circumstances made it difficult to accomplish goals/objectives?***

- Multiple personnel changes within MOH leadership

***How well were issues resolved?***

- The issues noted above were resolved. We have worked to deal with all political issues by being open and transparent about all aspects of the development process, which has earned the confidence of and support from entities who originally opposed this work.

***What data are available to support our experiences?***

- How Public Funds Were Spent on Procurement of Medicines in Ukraine's Hospitals? Interim Analysis for the Ministry of Health, Ukraine
- High Cost of Medicines in Ukraine: Factors and Price Components (technical report)
- Number of approved orders, which define the NEML development process

***What is missing?***

- The MOH has not yet developed a financing mechanism for the EC's work, and the committee still depends on donor support.

***What is worth replicating?***

- The entire process of open and transparent discussion, which was a key factor for success
- Do a key stakeholder analysis early in the process and use it to develop champions and understand risks
- Start with gathering evidence to document why an EML is needed, and use that information to advocate

***Is the recommendation for action clearly linked to what was learned?***

- Yes

## **CONCLUSION**

The NEML is a vital part of national reforms to combat basic threats to public health and to prevent and treat priority diseases in Ukraine. The NEML specifies the life-saving medicines that will be guaranteed by the state as free to all patients who need them. Implementation of the NEML empowers the state to efficiently control resource use of quality and safe medicines to ensure medical care to more people and to influence economically sound medicine pricing. The state program on NEML implementation will enhance access to medicine.

## ANNEX A



### MINISTRY OF HEALTH OF UKRAINE ORDER

February 11, 2016

Kyiv

#84

On approval of the Regulations on National Essential Medicines List and Regulations on the National Essential Medicines List Expert Committee

In accordance with the paragraphs second and third of Subclause 1 Clause 2 of the Decree of the Cabinet of Ministers of Ukraine as of 09.12.2015 No 1134 “On Amending the Decrees of the Cabinet of Ministers of Ukraine as of 17 October, 2008 No 955 and as of 25 March, 2009 No 333,” Subclause 6 Clause 4 of the Regulation on the Ministry of Healthcare of Ukraine, approved by the Decree of the Cabinet of Ministers of Ukraine as of 25.03.2015 No 267,

#### **WE HEREBY ORDER:**

1. Approve:
  - Regulations on National Essential Medicines List, which is enclosed;
  - Regulations on the National Essential Medicine List Expert Committee, which is enclosed.
2. To declare to be no longer in force the Order of the Ministry of Healthcare of Ukraine as of 24.05.2005 No 226 “On approval of Regulations on National Essential Medicines List and medical products and Regulations on the Expert council for formation, amendments and additions to National Essential Medicines List and medical products,” registered in the Ministry of Justice of Ukraine on 07.06.2005 with No 635/10915.
3. To the Pharmaceutical Activities and Quality of Pharmaceutical Products Department to ensure application of this Order for state registration to the Ministry of Justice of Ukraine.
4. Deputy Minister, Victor Shafranskiy, shall be charged with supervising the execution of this Order.
5. This Order shall come into effect from the day on which it is published.

**Minister/signature/**

**Oleksandr Kvitashvili**

APPROVED

By Order of the Ministry of Health of Ukraine of February 11, 2016, #84

**REGULATIONS**  
**On the National Essential Medicines List**

**I. General Provisions**

1. These Regulations define the structure and tenor of the National Essential Medicines List (herein after – the NEML), as well as the procedure and criteria of amending it.
2. The NEML includes quality, effective and safe medicines required to meet the priority needs of medical care provided to population in healthcare facilities regardless their form of ownership.
3. Medicines are selected to the NEML taking into account burden of disease, morbidity and mortality rates, evidence of comparative effectiveness, safety and cost effectiveness, as well as industrial standards in the area of healthcare and levels of funding.
4. Medicines shall be available at healthcare facilities at any time, in adequate quantities and dosage forms (for medicines) to ensure adequate level of functioning in the area of healthcare.
5. Proposals regarding amendments to the NEML are reviewed by the National Essential Medicines List Committee (herein after – the NEML Committee) established by the Ministry of Health of Ukraine (herein after – the MOH).
6. The NEML Committee shall operate based on the Regulations approved by the MOH.

**II. Structure and Tenor of the NEML**

1. The structure and tenor of the NEML is based on the most current version of the Model Essential Medicines list of World Health Organization (herein after – WHO).
2. The NEML comprises:
  - Core list that includes the most efficacious, safe and cost-effective medicines for priority conditions that are determined based on the current and expected significance for healthcare;
  - Supplementary list that includes medicines for priority conditions that require specialized diagnostic or monitoring equipment and/or specialized medical assistance and/or training of specialists. In case of doubt such medicines may also be listed to the core list as supplementary upon condition of consistent high cost or poorer cost-effectiveness in various settings.
3. The NEML includes registered and unregistered in Ukraine medicines.

Medicines are approved for use in Ukraine, procured and reimbursed from the state and local budgets after their state registration.

4. Medicines are included into the NEML by International Non-proprietary Names.

### **III. NEML Amending Procedure**

1. The NEML is amended once a year by the initiative of the NEML Committee, private or legal entities.
2. The NEML Committee initiates amendments to the NEML based on the most current version of WHO Model Essential Medicines List and when necessary, based on disease prevalence, morbidity and mortality rates, as well as healthcare sector standards.
3. If amendments to the NEML are initiated, private persons or legal entities shall submit application according to the form established by current legislation and evidence of comparative effectiveness, safety and cost effectiveness of medicines.
4. Information regarding received applications (proposal initiator, date of submission, content of the proposal) is published on the official web-site of the Expert Committee for consideration and suggestions within ten days after submission of the application.
5. Applications and documents submitted to the NEML Committee shall be reviewed within two months from the day of their submission in the order of precedence.

Information on the status of review is published on the official web-page of the NEML Committee.

6. In case if submitted application does not meet the set requirements, the NEML shall inform the applicant about this fact in writing and the applicant shall reconcile such inconsistencies within twenty days. In case if the applicant fails to meet the requirements within the identified term, the NEML Committee does not review the application and informs the applicant about it in writing.
7. In the process of the consideration of amending the NEML, the NEML Committee shall perform evaluation of comparative effectiveness, safety and cost effectiveness of medicines. The NEML Committee may ask applicants to provide additional information, needed for such evaluation.
8. Based on the results of evaluation of comparative effectiveness, safety and cost effectiveness of medicines the NEML Committee shall make a decision to recommend or not recommend the medicine for inclusion or exclusion to/from the NEML.
9. For each submitted decision the NEML Committee shall develop a report with conclusions and recommendations based on the requirements outlined in Annex 1 hereto. Based on the results of its operations the NEML Committee shall develop Annual Report and submit it to the MOH, Annual Report requirements are set in Annex 2 hereto.
10. The NEML publishes reports mentioned in Clause 9, Section III hereto on its official web-page.
11. The MOH publishes draft decision about amendments to the NEML on its official web-page and according to the established procedure submits it to the Cabinet of Ministers for the review.



#### **IV. Criteria for Amendments to the National Essential Medicines List**

1. Medicines are included and excluded to/from the NEML based on the following criteria:

- Prevalence, morbidity and mortality rates (based on MOH data);
- Evidence of comparative effectiveness, safety and cost effectiveness;
- Medicine stability in various settings;
- Need of special medicines for diagnostics or treatment (for medicines);
- Budget impact analysis results;
- Pharmacokinetic properties of medicines;
- WHO recommendation for use of such medicines.

2. Mostly, the NEML includes mono preparations.

Combinations are included in case if there is evidence of their clinically proven advantage over mono preparations.

3. The evaluation of comparative cost effectiveness shall be performed considering the cost of medicine and the cost of total treatment for population.

4. Medicine being original or generic shall not be selection criteria for inclusion or exclusion to/from the NEML.

**Acting Head of Pharmaceutical**

**Activities and Products Department**

**Taras Liaskovskiy**

Annex 1  
To the Regulations  
On the National Essential Medicines List

(Clause 9, Section III)

**Requirements to Report of the National Essential Medicines List Committee**

1. List of people that participated in the evaluation of comparative effectiveness, safety and cost effectiveness of medicines from the NEML:
  - NEML Committee members;
  - Invited experts.
2. Information regarding conflict of interests and decisions made with this regard.
3. Information about proposals for amendments to the NEML:
  - Proposal initiator;
  - Essence of proposal;
  - Information about evaluation of effectiveness, safety and cost effectiveness of medicines, including information about average cost per one patients (in total) and **cost of total treatment for population**;
  - Information about the review of comments received in the course of public discussion of the proposal (if any);
4. Conclusions and recommendations of the NEML Committee, including text of proposed amendments to the National Essential Medicines List (if any).

Annex 2  
To the Regulations  
On the National Essential Medicines List

(Clause 9, Section III)

**Requirements to Annual Report of the National Essential Medicines List Committee**

1. List of people that participated in the evaluation of comparative effectiveness, safety and cost effectiveness of medicines from the NEML:
  - NEML Committee members;
  - Invited experts.
2. Information regarding conflict of interests and decisions made with this regard.
3. Information about proposals for amendments to the NEML:
  - Proposal initiator;
  - Essence of proposal;
  - Information about evaluation of effectiveness, safety and cost effectiveness of medicines, including information about average cost per one patients (in total) and **cost of total treatment for population**;
  - Information about the review of comments received in the course of public discussion of the proposal (if any);
  - NEML Committee conclusions and recommendations.
4. Brief description of all conclusions and recommendations of the NEML Committee with regard to:
  - Inclusion of medicines to the NEML;
  - Exclusion of medicines for the NEML;
  - Applications that were not relieved.

**Annexes to the Report**

1. Draft of the National Essential Medicines List
2. Anatomical Therapeutic Chemical (ATC) Classification codes of medicines included to the NEML.
3. List of medicines in alphabetical order (with Anatomical Therapeutic Chemical (ATC) Classification codes).

APPROVED  
Order of the Ministry of Health of Ukraine of  
February 11, 2016, #84

## **REGULATIONS**

### **On the National Essential Medicines List Expert Committee**

#### **I. General Provisions**

1. These Regulations shall govern the procedure of establishment and functioning of the National Essential Medicines List Expert Committee (herein after – the NEML Committee).
2. The NEML Committee is a permanent advisory body established by the Ministry of Health of Ukraine (herein after – the MOH) to provide evaluation of comparative effectiveness, safety and cost effectiveness of medicines with the purpose of their inclusion in the National Essential Medicines List (herein after – the NEML).
3. The purpose of the NEML Committee is to perform transparent selection of high quality, effective, safe medicines with the highest cost effectiveness indicators, required to meet the priority needs of medical care provided to population in healthcare facilities for treatment covered from the state and local budgets.
4. While performing its tasks the NEML Committee shall apply principles of independence, impartiality, transparency and competence.

#### **II. NEML Committee Membership**

1. The NEML Committee shall consist of 12 – 18 members.

The NEML Committee shall consist of specialists with university education in medicine, pharmaceuticals or economics.

2. Members of the NEML Committee are appointed by the Minister based on competitive selection results for four year term.
3. The NEML Committee candidates shall meet the following requirements:
  - Have university education in medicine, pharmaceuticals or economics;
  - Work in a healthcare facility or higher medical educational establishment or scientific and research institution;
  - Not to serve as a government official;
  - Have no real conflict of interests as provided by the Law of Ukraine “On Combating Corruption” and these Provisions, not to have labor or any other contractual relations with manufacturers or marketing authorization holders or persons associated with them;
  - Have experience in the evaluation of comparative effectiveness, safety and cost effectiveness of medicines.
4. Members of the NEML Committee may be citizens of Ukraine or other countries.

5. The Head of NEML Committee is appointed by the Minister. The Deputy Head is selected from the NEML Committee members by an open majority vote of members present at the first meeting.

### **III. Conflict of Interests**

1. NEML Committee candidates shall submit Conflict of Interest Statement to the Selection Board mentioned in Clause IV hereof according to the form in Annex 1 hereto.

Before members are appointed all the Statements provided by NEML Committee candidates shall be reviewed by the Selection Board for conflict of interests.

2. In case if any conflict of interests is identified, NEML Committee candidate shall not be selected to be a member of the NEML Committee.

In case if any potential conflict of interests is identified, the selection board, by vote, shall make a decision about participation of such candidate in the process of amending the NEML.

3. NEML Committee members shall submit to the NEML Committee Conflict of Interest Statements: annually according to the form in Annex 2 hereto and before each meeting according to the form in Annex 2 hereto.

Submitted Statements shall be reviewed by the NEML Committee Secretariat.

4. In case if real conflict of interests is identified regarding Agenda items, NEML Committee member shall not be present during the consideration of such items.
5. In case if potential conflict of interests is identified, the NEML Committee by vote shall make a decision about:
  - Member`s presence during consideration of the issues where there is the conflict of interests;
  - Member`s participation in the decision making regarding the issues where there is conflict of interests without participation in the discussion of such issues.
6. In case if an NEML Committee member has not submitted the Conflict of Interest Statement or provided false data regarding real conflict of interests, the NEML Committee shall make a decision to remove such member from the Committee.
7. Before each meeting to which experts are invited, such experts shall submit the Conflict of Interest Statements to the NEML Committee according to the form in Annex 2 hereto.

Submitted Statements shall be reviewed by the NEML Committee Secretariat.

In case if potential or real conflict of interests is identified, if invited experts fail to submit

Conflict of Interest Statement or provide false information, the NEML Committee shall make a decision to prohibit participation of such expert in the relevant meeting by vote.

8. Description of information regarding NEML Committee members` and invited experts` conflicts of interests based on the submitted statements shall be published on the official NEML Committee web-page together with information on the decisions made with this regard.
9. NEML Committee members are prohibited from direct (outside of NEML Committee meetings) contact with stakeholders regarding issues associated with amending the NEML.

#### **IV. Procedure of Competitive Selection of NEML Committee Members**

1. Competitive selection of NEML Committee members shall be performed based on the principles of equal access of the candidates to participation in the competition.
2. The Selection Board shall be established by MOH Order.
3. The Selection Board includes representatives of HR and Legal Departments, other MOH Departments and MOH Public Council.

The Selection Board is chaired by the Minister.

4. Competitive selection announcement shall be published on MOH web-page. The announcement shall list key requirements to the candidates, submitted documents, place and terms of their submission (within twenty calendar days from the day of the announcement).
5. Persons that desire to participate in the competition shall submit to the Selection Board the following documents:
  - Free-format cover letter stating that they meet the requirements set for NEML Committee candidates;
  - Conflict of Interest Statement according to the form in Annex 2 hereto;
  - Copy of ID;
  - Information and documents that prove the level of education, professional experience and responsibilities, including, medicines comparative effectiveness, safety and cost effectiveness evaluation experience.
6. Documents from specialists that desire to participate in the competition are collected by the Selection Board Secretary. Submitted documents and Selection Board materials are stored at the MOH HR Department.
7. The Selection Board Secretary shall verify whether submitted documents meet the requirements set out in Clause 3 of Section II hereof.

Information about the receipt of applications for participation in the competitive selection shall be published on the official web-page of the MOH.

8. Based on the review of the submitted documents and the interview with candidates the Selection Board shall select NEML Committee members during its meeting.

Preference is given to the candidates with the most extensive proved experience in the evaluation of comparative effectiveness, safety and cost effectiveness of medicines.

9. Selection committee meeting shall be deemed quorate if minimum two thirds of its members are present.

The Selection Committee makes its decisions by majority vote. In case of equally divided votes, the Chairman casts the deciding vote.

10. Meeting notes shall be developed based on the Section Board meeting results and signed by all NEML Committee members present at the meeting.

The Selection Board shall make a decision appointing NEML Committee members and formalize this decision in MOH Order.

11. The Selection Board Secretary shall inform NEML Committee candidates about the results in writing within three business days after such decision has been made.

Selection Board decision shall be published on official MOH web-page.

## **V. Functions of the NEML Committee**

1. The NEML Committee shall:

- Identify priority conditions;
- Initiate amendments to the NEML;
- Review propositions regarding amendments to the NEML;
- Perform evaluation of comparative effectiveness, safety and cost effectiveness of medicines for their inclusion or exclusion to/from the NEML;
- Prepare reports with conclusions and recommendations regarding each suggested amendment into the NEML;
- Prepare and submit to MOH annual reports with conclusions and recommendations regarding amendments to the NEML;
- Review Conflict of Interest Statements submitted by NEML Committee members and invited experts;
- Inform public about its activities through publishing information on its official web-page.

2. NEML Committee members shall:

- Participate in the NEML Committee operations, including its meetings and discussing Agenda issues according to the rules;
- Fulfill assignments of the Head of NEML Committee;
- Act professionally in the patients` interest;

- Have access to all materials reviewed by the NEML Committee, including documents provided by applicants;
  - Meet conflict of interest and confidentiality requirements, particularly, sign Confidentiality Statement (free form);
  - Make collegial decisions;
  - Sign NEML Committee meeting notes.
3. The Head of NEML Committee shall:
- Summon NEML Committee meetings;
  - Chair NEML Committee meetings;
  - Make decisions regarding inviting non-members to NEML Committee meetings;
  - Sign NEML Committee meeting notes;
  - Monitor compliance with NEML Committee decisions.
4. The Head of NEML Committee shall charge NEML Committee members with separate tasks associated with the evaluation of comparative effectiveness, safety and cost effectiveness of medicines.

## **VI. The NEML Committee Secretariat**

1. The Secretariat shall be coordinated through the Head of NEML Committee.

Secretariat personnel are not NEML Committee members.

2. The NEML Committee Secretariat shall:
- Provide organizational support of the NEML Committee operations;
  - Coordinate search of data, required for the evaluation of comparative effectiveness, safety and cost effectiveness of medicines suggested for inclusion to the NEML;
  - Provide work flow management of the NEML Committee, including registration of correspondence, preparation of draft conclusions in response to requests submitted to the NEML Committee;
  - Keep a record of applications to amend the NEML and other requests received by the NEML Committee;
  - Develop Draft Agenda for an NEML Committee meetings and send it out together with information about meeting dates to all NEML Committee members no later than five days prior to the meetings;
  - Keep and formalize NEML Committee meeting notes within maximum ten business days after the meeting;
  - Formalize reports with conclusions and recommendations regarding each suggested amendment to NEML and annual NEML Committee reports;
  - Keep a record of NEML Committee decisions;
  - Ensure publication and update of information regarding NEML Committee operations on the NEML Committee official web-page.
3. Members of the Secretariat shall be liable for disclose of confidential information.



## **VII. NEML Committee Meetings**

1. NEML Committee meetings are held as and when needed, but at least once a month.
2. NEML Committee meeting is deemed quorate if at least two thirds of its members are present.

NEML Committee members shall in advance inform the NEML Committee Secretariat about their inability to attend the meeting.

3. NEML Committee meetings are closed for public.

Non-members of the NEML Committee may participate in the meeting upon invitation. Based on the Head of NEML Committee decision experts, civil society and Mass Media representatives may be invited to the meetings, save those parts of the meetings when decisions are made based on the results of the review of applications for amending the NEML.

4. NEML Committee meetings are convened by the decision of the Head of NEML Committee. The Head of NEML Committee shall chair the meetings and in case of his/her absence – the Deputy Head of NEML Committee.
5. Information shared with NEML Committee members and as a result of such membership and the Secretariat shall be confidential. NEML Committee members and the Secretariat shall not disclose such information in any manner, except in cases when such information is published on official web-pages of the NEML Committee of MOH.

In case of unlawful disclosure of confidential information, NEML Committee members are removed from the Committee and members of the Secretariat are suspended from work in the NEML Committee.

6. NEML Committee Agenda is developed based on the issues within the competence of the NEML Committee that the Committee needs to consider.

The Head of the NEML Committee approves Agenda and meeting date.

Information about day and time of meetings and Agenda shall be published on the official NEML Committee web-page at least 5 days prior to the day when its held.

7. Review of each issue during an NEML Committee meeting is culminated with a relevant decision formalized in meeting notes.

## **VIII. NEML Committee Decision**

1. NEML Committee decisions based on the review of suggestions to amend the NEML shall be made by open vote.

2. The decisions shall be made by majority vote of members present at the meeting.

The Head of NEML Committee shall be the last one to vote. In case of equal distribution of votes of the Expert Committee members and the Head's vote is negative, such a decision is not made.

3. NEML Committee meeting notes shall be signed by the Head and all NEML Committee members present at the meeting.

NEML Committee members that signed meeting notes may state their opinion in writing. Such written opinion shall be enclosed to the meeting notes.

4. Meeting notes and all meeting materials shall be stored in the NEML Committee archives for 3 years.
5. The NEML Committee shall publish extracts from relevant meeting notes on its official web-page within 10 business days after such meetings.

### **IX. Suspension of Membership**

1. NEML Committee membership is suspended by Minister's decision in the following cases:
  - Based on the written request of an NEML Committee member;
  - In case of violation by a member of the requirements set out herein, including requirements regarding conflict of interests and confidentiality of information;
  - If an NEML Committee member does not participate in two or NEML Committee meetings in a row unreasonably.
2. In case if a member is removed from the NEML Committee, such member may appeal the decision in court.

**Acting Head of Pharmaceutical  
Activities and Products Department**

**Taras Liaskovskiy**

Annex 1  
To the Regulations On the National Essential  
Medicines List Expert Committee

(Clauses 1, 3 Section III)

**Conflict of Interests Statement of a Candidate or a Member of the National Essential  
Medicines List Expert Committee**

Name, Last name: \_\_\_\_\_  
Place of work: \_\_\_\_\_  
Phone: \_\_\_\_\_  
E-mail: \_\_\_\_\_

1. Within last four years did you or your relatives receive any payments from business entities or other organizations, which can have interest in objects of the work of the Expert Committee:

- Labor relations;

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_ Yes ☐ No ☐

- Consulting?

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_ Yes ☐ No ☐

2. Within last four years did you, your relatives or organization, where you work, receive from business entities or other organizations, which can have interest in objects of the work of the Expert Committee:

- Research support, including grants, sponsorships and other funding;

\_\_\_\_\_  
\_\_\_\_\_ Yes ☐ No ☐

- Non-monetary support, including in the form of equipment, facilities, research assistants, payment for travel etc;

\_\_\_\_\_  
\_\_\_\_\_ Yes ☐ No ☐

- Support for presentations or trainings for business entities or other organizations, which have interest in the object of the work, including in the form of payment for provided services?

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_ Yes ☐ No ☐

## Annex 1 Continued

3. Whether your current investments into business entities, which may have interest in objects of the work of the Expert Committee, in particular direct or indirect investments (for example, in the holding company), except investments in investment funds, non-state pension fund and other similar investments, which are not controlled by you:

- Stocks, bonds and other securities;

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_ Yes ☐ No ☐

- Commercial business interests (for example, joint venture, partnership)?

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_ Yes ☐ No ☐

4. Are you an owner of intellectual property rights, which can be expanded or narrowed according to the results of the work of the Expert Committee:

- Patents, trademarks for goods and services, copyright (including applications which are considered);

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_ Yes ☐ No ☐

- Patented know-how?

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_ Yes ☐ No ☐

5. Within the past four years have you provided an expert evaluation related to the state registration, clinical/pre-clinical trials (research) of the medicines, which can be related to the objects of the work of the Expert Committee?

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_ Yes ☐ No ☐

6. Within the past four years have you been taking the position, where you represented or defended the interests, which can be related to the objects of the work of the Expert Committee?

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_ Yes ☐ No ☐

## Annex 1 Continued

7. Whether the results of the Expert Committee's work have positive or negative influence on the interest of persons, you have common personal, professional, financial or business interests with (such persons are adult children or brothers, sisters, colleagues with whom you work closely, structural units etc.) ? Yes ☐ No ☐
8. Have you received any payments (except refund for a trip) or fees for public speaking/publication, which can be related to the objects of the work of the Expert Committee? Yes ☐ No ☐
9. Are there other circumstances, which can be understood as an influence on your objectivity and independence have place? Yes ☐ No ☐

If the answer is "yes", explain above.

I hereby certify that to the best of my knowledge and belief the above information is true and correct.

I hereby give my consent to disclosure of the information provided in this Statement to other NEML Committee members and to be shared in public domain on the MOH official web-page.

**Note:**

1. In this Statement stated circumstances that may pose real or potential conflict of interest. Conflict of interests includes financial, professional or other interests associated with participation in the review of proposals to amend the NEML as well as interests that may have impact on the results of such activities.

Potential conflict of interests is a personal interest of a person in the area in which he/she carries out his/her official or representative functions, which may have impact on fairness or impartiality of decisions this person makes or does or fails to do while carrying out the above mentioned functions.

Annex 1 Continued

Real conflict of interests is a conflict between personal interest of a person and his/her official or representative functions, which may have impact on fairness or impartiality of decisions this person makes or does or fails to do while carrying out the above mentioned functions.

In addition please, state such interests of your relatives (persons that reside with you, persons with whom you share household and share rights and obligation of family nature, including persons, that reside with you, but are not married to you, and – regardless identified circumstances – husband, wife, father, mother, step-father, step-mother, son, daughter, step-son, step-daughter, brother, sister, grandfather, grandmother, great grandfather, great grandmother, grandson, granddaughter, great grandson, great granddaughter, son-in-law, daughter-in-law, mother-in-law, father-in-law, adopting parent of adopted child, guardian, person under your guardianship) and in case if there are other persons with whom you have joint interests that may be deemed as interference with your NEML Committee member activities (e.g., employer, employees, etc).

2. Positive answer does not mean automatic suspension or limitation of participation in NEML Committee activities.

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Name

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Signature

Annex 2  
To the Regulations  
On the National Essential Medicines List  
Expert Committee  
(Clause 3, 7, Section III)

**Conflict of Interests Statement of NEML Committee Members and Invited Experts**

Name, Last name: \_\_\_\_\_  
Place of work: \_\_\_\_\_  
Phone: \_\_\_\_\_  
E-mail: \_\_\_\_\_

1. Within last four years did you or your relatives participate, provide commercial services or received payments from manufacturer or distributor of medicines reviewed during this NEML Committee meeting?  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_ Yes ☐ No ☐
2. Within last four years did you or your relatives participate, provide commercial services or received payments from manufacturer or distributor of medicines within the competition circle of medicines reviewed during this NEML Committee meeting?  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_ Yes ☐ No ☐
3. Did the information regarding conflict of interests you provided in the last NEML Committee Conflict of Interests Statement change \*?  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_ Yes ☐ No ☐

\* Not applicable for invited experts

If the answer is “yes”, explain above.

I hereby certify that to the best of my knowledge and belief the above information is true and correct.

I hereby give my consent to disclosure of the information provided in this Statement to other NEML Committee members and to be shared in public domain on the MOH official web-page.

**Note:**

1. In this Statement stated circumstances that may pose real or potential conflict of interest. Conflict of interests includes financial, professional or other interests associated with participation in the review of proposals to amend the NEML as well as interests that may have impact on the results of such activities.

Potential conflict of interests is a personal interest of a person in the area in which he/she carries out his/her official or representative functions, which may have impact on fairness or impartiality of decisions this person makes or does or fails to do while carrying out the above mentioned functions.

Real conflict of interests is a conflict between personal interest of a person and his/her official or representative functions, which may have impact on fairness or impartiality of decisions this person makes or does or fails to do while carrying out the above mentioned functions.

In addition please, state such interests of your relatives (persons that reside with you, persons with whom you share household and share rights and obligation of family nature, including persons, that reside with you, but are not married to you, and – regardless identified circumstances – husband, wife, father, mother, step-father, step-mother, son, daughter, step-son, step-daughter, brother, sister, grandfather, grandmother, great grandfather, great grandmother, grandson, granddaughter, great grandson, great granddaughter, son-in-law, daughter-in-law, mother-in-law, father-in-law, adopting parent of adopted child, guardian, person under your guardianship) and in case if there are other persons with whom you have joint interests that may be deemed as interference with your NEML Committee member activities (e.g., employer, employees, etc).

2. Positive answer does not mean automatic suspension or limitation of participation in NEML Committee activities.

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Name

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Signature



## ANNEX B



### MINISTRY OF HEALTH OF UKRAINE O R D E R

October 7, 2016

Kyiv

#1050

On the Regulations on  
the Selection of Medicines  
to the National Essential Medicines List

According to Clause 8 of the Regulations on the Ministry of Health of Ukraine approved by the Decree of the Cabinet of Ministers of Ukraine of March 25, 2015 to #267, and the paragraph to the fourth the subparagraph 1 of Clause 2 of the resolution of the Cabinet of Ministers of Ukraine of December 9, 2015 #1134 "On Introduction of Amendments to Decrees of the Cabinet of Ministers of Ukraine of October 17, 2008 #955 and of March 25, 2009" #333,

#### **HEREBY IT IS ORDERED:**

1. To approve **Selection of Medicines to the National Essential Medicines List** which is enclosed.
2. To provide to management of pharmaceutical activities and quality of pharmaceutical products submission of this order on state registration in the Ministry of Justice of Ukraine.
3. Deputy Minister Roman Ilyk shall be charged with supervising the execution hereof.
4. This order becomes effective from the date of its official publication.

*Acting minister*  
*V. Suprun*

APPROVED  
Order of the Ministry of Healthcare of Ukraine  
October 7, 2016, No 1050

**REGULATIONS**  
**on the Selection of Medicines to the National Essential Medicines List**

1. These Regulations determine the procedure of medicines selection for inclusion to the National Essential Medicines List (herein after referred to as the NEML) performed by the National Essential Medicines List Expert Committee (herein after referred to as the NEML Committee) which acts according to Regulations on the National Essential Medicines List approved by Order of the Ministry of Health of Ukraine of February 11, 2016, No 84, registered at the ministry of Justice on February 18, 2016, No 258/28388, by establishing and introducing amendments to the NEML on annual basis.
2. The NEML Committee shall develop the NEML according to the following procedure:
  - Identifies priority conditions taking into account the following factors:
    - Population (epidemiological) and burden of disease factors (economic and social manifestation of the repercussions and issues caused by the disease);
    - Regulatory requirements according to sector, National State Programs, social guarantees;
    - Specific aspects of medical care provision to population.
  - In accordance with the identified priority conditions list the NEML Committee establishes recommended version of the NEML based on the most recent edition of the Model List of Essential Medicines recommended by World Health Organization (herein after referred to as WHO);
  - Completes the recommended version of the NEML based on the healthcare sector standards (unified clinical protocols for medical services, State Formulary of Medicines), that include medicines based on budget impact analysis among other indicators as well as submits it to the Ministry of Healthcare of Ukraine.
3. The NEML Committee shall review the NEML on the annual basis adhering to the following procedure:
  - By October 1 of each year the NEML Committee shall review the priority conditions based on set indicators;
  - By November 1 of each year the NEML Committee shall develop NEML Draft for the following year according to the defined list of priority conditions, the most recent edition of the WHO Model Essential Medicines List, healthcare sector standards (unified clinical protocols for medical services, State Formulary of Medicines) developed with due account to budget impact analysis results;
  - By April 1 of the year following after current, the NEML Committee Secretariat accepts the applications to amend the NEML. Template of such application is provided in Annex 1, hereto (herein after referred to as the Application) Specific aspects of completion of such Application are set out in Annex 2 hereto;
  - By June 1 of the year following after current, reviews the applications regarding changes to the NEML, makes decisions on them and submits recommended version of the NEML to the Ministry of Health of Ukraine.

4. The application includes documents that prove comparative effectiveness, comparative safety and cost-effectiveness.
5. Information from points 1-4 and 14 of the Application shall be published on the NEML Committee web-page.

Information from points 5-13 of the Application and from the documents included with it is confidential.

6. The Applicant is responsible for reliability of information in the Application and documents submitted to the NEML Committee.
7. The Application and documents enclosed shall be reviewed by the NEML Committee according to the procedure and within the terms set out in the Regulations on the Essential Medicines List approved by the Order of the Ministry of Health of February 11, 2016, No 84, registered in the Ministry of Justice on February 18, 2016, No 258/28388.

Annex 1  
To Regulations on Selection of Medicines for  
National Essential Medicines List

**APPLICATION**  
**for Amendments to the National Essential Medicines List**

1	Name of the Applicant   Location   Telephone/fax _____  E-mail _____
2	Brief description of a proposal to amend the National Essential Medicines List including clinical indicators, target population and place in therapy     
3	Medicine name _____  Formula     Pharmacologic action     Pharmacotherapeutic class     
4	Dosage form suggested for inclusion     

5	<p>Details about existence and availability in Ukraine and around the world of formulations and presentations of the proposed product with references, manufacturers and trade names</p> <hr/> <hr/> <hr/>
6	<p>Details whether the medicine is suggested as an exemplar of a class</p> <hr/> <hr/> <hr/>
7	<p>Details about the need within the healthcare system based on prevalence and incidence indicators and potential impact of the proposed medicine on disease or condition course</p> <hr/> <hr/> <hr/>
8	<p>details regarding specifics of treatment of priority conditions or a disease, in particular, suggested dosages and duration of treatment with reference to WHO Model Essential Medicines List and healthcare sector standards (<b>if available</b>) (other sources may be indicated)</p> <hr/> <hr/> <hr/>
9	<p>Details of comparative effectiveness and comparative safety with regard to suggested indications:</p> <ul style="list-style-type: none"> <li>• Clinical evidence identification (literature search strategy, systematic review of findings, rationale for selection or exclusion of clinical trials data)</li> </ul> <hr/> <hr/> <hr/> <ul style="list-style-type: none"> <li>• Summary of the data (quality evaluation, indicators and description of the results)</li> </ul> <hr/> <hr/> <hr/> <ul style="list-style-type: none"> <li>• Aggregated clinical trials data</li> </ul> <hr/> <hr/> <hr/>
	<ul style="list-style-type: none"> <li>• Brief description of comparative effectiveness for suggested indications (when head-to-head direct clinical trials are not possible, provide rationale of indirect comparative studies relevance)</li> </ul> <hr/> <hr/> <hr/>

10	<p>Brief description of comparative safety:</p> <ul style="list-style-type: none"> <li>• Patient characteristics</li> </ul> <hr/> <hr/> <hr/> <ul style="list-style-type: none"> <li>• Evidence on adverse events and details on their frequency and severity</li> </ul> <hr/> <hr/> <hr/> <ul style="list-style-type: none"> <li>• Differences between the safety profile of the medicine under review and comparator</li> </ul> <hr/> <hr/> <hr/>
11	<p>Details on comparative cost and cost effectiveness of the medicine under review in relation to the comparator within treatment group (or outside):</p> <ul style="list-style-type: none"> <li>• Range of prices for the medicine under review in countries where it is registered</li> </ul> <hr/> <hr/> <hr/> <ul style="list-style-type: none"> <li>• In case of comparison of the medicinal product within the framework of treatment group – the approximate range of costs in routine use: <ul style="list-style-type: none"> <li>○ cost of a treatment course</li> </ul> <hr/> <ul style="list-style-type: none"> <li>○ cost of a month's treatment</li> </ul> <hr/> <ul style="list-style-type: none"> <li>○ cost per case prevented (if appropriate)</li> </ul> <hr/> </li> </ul>
	<ul style="list-style-type: none"> <li>• In case of comparison of the medicinal product outside the framework of treatment group – information about incremental cost effectiveness or cost utility</li> </ul> <hr/> <hr/> <hr/> <ul style="list-style-type: none"> <li>• Information on average cost of expenses for one patient (in general) and general cost of treatment for the population, including any expenses for introduction of the medicine and treatment of the adverse reactions</li> </ul> <hr/> <hr/> <hr/>

12	<p>Information on:</p> <ul style="list-style-type: none"> <li>Registration and permitted indications of the medicine under review in the following countries:</li> </ul> <p>EU countries <input type="checkbox"/></p> <p>Japan <input type="checkbox"/></p> <p>USA <input type="checkbox"/></p> <p>Canada <input type="checkbox"/></p> <p>Switzerland <input type="checkbox"/></p> <p>Australia <input type="checkbox"/></p> <p>WHO pre-qualified <input type="checkbox"/></p>
13	<p>Whether the medicine under review is included to the following pharmacopoeias:</p> <p>The British Pharmacopoeia <input type="checkbox"/></p> <p>The International Pharmacopoeia <input type="checkbox"/></p> <p>The United States Pharmacopeia <input type="checkbox"/></p> <p>The European Pharmacopoeia <input type="checkbox"/></p> <p>The State Pharmacopoeia of Ukraine <input type="checkbox"/></p>
14	<p>Proposal regarding brief product description of the medicine under review in the renewed version of the NEML</p> <hr/>

Annex 2  
to Regulations  
on Selection  
of Medicines for  
National Essential Medicines List  
(Sub clause 3, Clause 3)

**REQUIREMENTS**

**To the Preparation of Applications for Amendments to the National Essential Medicines List**

1. In p. 1 indicate title or name of the applicant, correspondence address shall be listed in Ukrainian and English (if necessary).
2. In p. 2 provide brief description of a proposal to amend the National Essential Medicines List including the following information:
  - Brief overview of the condition/disease to be treated (brief overview of etiology, pathogenesis, diagnostics, treatment and prevention options around the world and in Ukraine);
  - Brief description of the target population;
  - Rationale for inclusion of the medicine in the NEML including gaps in therapy that potentially may be eliminated through including the proposed medicine in the NEML, and underlying pharmacological and/or pharmacokinetic principles;
  - The suggested place in therapy for this treatment (diagnostics, treatment, prophylaxis, rehabilitation) with respect to treatments currently available;
  - Indication(s) for the medicine use, according to information provided in instruction for medical use (if available);
  - Details of the registration status of the product in Ukraine for the indication(s) detailed in the application including dates of granted or expected marketing approval;
  - Granted or expected validity terms of marketing approval of the product in Ukraine for indication(s) detailed in the Application;
  - Details whether the product has been designated an orphan medicinal product for the indication(s) detailed in the application.
3. In point 3 name (trade name, International Nonproprietary Name (INN), generics, chemical name, formula, pharmacological effect, pharmacotherapeutic class of the proposed medicine shall be indicated.
4. In point 4 provide information on formulation(s) of the medicinal product approved for use in Ukraine or which will be approved for indication(s) submitted for the state registration (re-registration/amended registration).

**If data regarding the use of proposed dosage forms of the medicinal product for certain populations (e.g. children, pregnant women) is not available, this fact shall be indicated in the application.**



5. In point 5 provide details about existence and availability in Ukraine and around the world of formulations and presentations of the proposed product with references, manufacturers and trade names.

It should be detailed whether the proposed medicine and nominated comparator(s) have been subject to health technology assessment (HTA) in Ukraine or other countries; or if it is planned to conduct such assessments (it is necessary to indicate the name of organization undertaking the HTA, and the expected date of publication of the results). Also, if possible, provide any available recommendations of completed or ongoing assessments.

6. In point 6 similar clinical effects within the third or fourth level of Anatomical Therapeutic Chemical classification (herein after – pharmacotherapeutic class) shall be denoted with (€) symbol. In some cases the medicine included in the NEML may be an exemplar of a class, in which case it will be one for which the NEML Committee has established the highest indicators of efficacy and safety. In the absence significant difference in the evidence on comparative efficacy and safety of the products, product with the lowest cost shall be selected for inclusion in the NEML (with the prices for equi-effective doses compared where possible), with respect to international price data sources.

Where the use of the (€) symbol is proposed, the application should contain the list of treatment options of the medicinal product, which can be considered as similar by the indicators of efficacy and safety.

7. Point 7 of the application shall include an estimate of the quantity of the product likely to be needed within the healthcare system according to data of official statistics from the Ministry of Health of Ukraine and the State Service of Statistics of Ukraine. Other sources, which contain the appropriate information regarding Ukraine (WHO, UNICEF, World Bank and others), may also be provided (with references) with relevant justification of using such sources.
8. In Point 8 details regarding specifics of treatment of priority conditions or a disease, in particular, suggested dosages and duration of treatment, recommended by WHO Model List of Essential Medicines and healthcare sector standards<sup>1</sup> developed with respect to the results of budget impact analysis, and other tertiary sources of scientific information (international clinical guidelines) shall be submitted in the original version with the relevant references.
9. Point 9 of the Application shall contain details of comparative effectiveness and comparative safety of the proposed medicine and the appropriate comparator(s), including summary tables with details of key trials and output data (copies of documents on key trials) in electronic PDF format. General information regarding benefits and adverse effects shall be detailed separately and include the following data:
  - In sub point 1 of point 9 the literature search strategy and results should be provided, together with the rationale for the subsequent exclusion of any identified trial.

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<sup>1</sup> The National Formulary and STGs

The most relevant comparative studies (randomized controlled trials) should be listed and described, including information on patient characteristics, baseline risk for basic relevant results in study group, absolute difference or limitations of association. Where an alternative approach is chosen (especially in cases where there are only one or two studies), the applicants should ensure that an appropriate evaluation of the study is available including the extent to which it is generalizable to the Ukrainian population;

- In sub point 2 of point 9, if multiple relevant trials exist, their results shall be aggregated using meta analytic techniques, with a description and justification of the approach taken. It is also acceptable to submit a systematic review, provided there is also an adequate assessment of the quality of clinical trials (researches) and in cases when no additional clinical trials (researches) have been identified in the literature search;

Detailed information on studies to demonstrate the comparative effectiveness of the medicine for the proposed indication(s) relative to the main comparator(s) used in clinical practice shall be provided.

Direct (head-to-head) randomized clinical trials of the proposed medicine with the comparator(s) are the most persuasive. If such trials have not been conducted, then two sets of clinical trials using a common comparator may be presented. The common comparator may be placebo or another active substance (herein after – the common comparator). In this case justification of the relevance of the common comparison should be provided, including the extent to which the baseline patient groups are similar. Placebo-controlled and uncontrolled trials may also be included if they provide relevant clinical results that have not been identified during active-controlled trials of the medicine, but constitute a lower level of evidence and will be less persuasive.

If details regarding one and the same study are provided from different sources, this should be specified and care taken to avoid duplication of results.

It should be detailed, if the studies have been described in publications of regulators, in particular, in medicine evaluation reports (ePARs) of European Medicines Agency (EMA) and in medical reviews of Food and Drug Administration (FDA).

The following information on each clinical study, which materials are provided in annexes shall be specified in the application:

- Name and/or registration number of the study (trial);
- Brief details on trial design, including information about efforts to minimize bias including blinding and randomization, and an assessment of their adequacy;
- Details of inclusion and exclusion criteria including any definitions, especially for potentially ambiguous assessments;
- Details of study drug and comparator(s), namely: with information on strength, including routes of administration and titration schedules where appropriate, whether the strength is approved for use in Ukraine;

- Overview of concomitant medications permitted and contraindicated during the study;
- Details of the primary hypothesis (in particular whether the trial was designed to demonstrate a difference between treatments) and statement about the power of the study including assumptions in the sample size calculation; and the method(s) of statistical analysis used.

Primary outcome measures, including details of the methods of collecting the data and timing of assessments. If the primary outcome is measured on a scoring system, an explanation of this should be provided (e.g. higher scores=better quality of life); and any evidence of prior validation:

- Population details included in the analysis of the primary outcome and methods for handling missing data;
- Details of the statistical test(s) used in the analysis of the primary outcome;
- For any relevant secondary analyses of the primary outcome (e.g. analyses in a subgroup within which the drug is licensed) provide details of the study population included in these analyses, methods for handling missing data and details of the statistical analysis applied;
- Details of the number of patients randomized, treated and discontinued from the study and the number of patients who completed the study or are ongoing in the study (the information is provided in the form of charts and/or diagrams);
- Details of baseline demographics, including age, sex and relevant variables describing disease duration/severity and, if appropriate, previous treatments (if there are any significant differences between study groups, these should be noted);
- Details of results from the primary analysis of the primary outcome with a measure of variance (preferably 95% confidence intervals). Graphical presentation of data may be appropriate, but should be a supplement to the text and tabulated data, not an alternative;
- Details of results of relevant secondary analyses of the primary outcome and any analyses of relevant secondary outcomes in the format described previously for the primary analysis of the primary outcome;
- Details of ongoing studies, or updated analyses of trials that have already been submitted to the NEML Committee, which would provide additional evidence within the next 6 to 12 months for the drug in the indication(s) under review.

If drugs designated as orphan for the indication(s) under review provide details of ongoing studies, which could extend the indication(s) to a larger patient population (e.g. current indication for use in severe disease and ongoing studies in less severe disease). For each trial provide a brief description of:

- the trial design, including details of blinding and randomization;
- the main inclusion criteria, which define the patient population included in the study;
- the primary and/or other relevant outcome(s) measured in the study and likely timescale for reporting of these.

- In sub point 3 of Point 9 provide aggregated clinical effectiveness data:
  - Describe any limitations of the trial methodology and conduct affecting the quality of the evidence under review relative to relevant active comparator(s).
  - Describe the relevance of the outcomes assessed in clinical trials to clinical benefits and adverse effects expected in practice.
  - Provide details of whether trials directly measured clinical outcomes (e.g. death, survival, incidence of disease, functional performance, or quality of life), or whether surrogate or intermediate endpoints were utilized (e.g. reduction in blood pressure, change in LDL cholesterol, FEV1, etc.).
  - Provide details of the extent to which the surrogate or intermediate endpoints have been validated and evidence of the strength of the association between the surrogate or intermediate outcomes and the clinical outcomes of interest.
  - Describe any factors which may influence the generalizability of clinical trial results to patients in routine clinical practice in Ukraine.
  - Provide details of differences between the patient populations included in the studies, which provided evidence of clinical benefits compared to the Ukrainian population. For example, differences in baseline demographics, such as age, performance status, previous treatments, severity of disease; differences in clinical management, such as the dose schedule of comparator(s) or permitted/disallowed concomitant drugs, monitoring or assessment frequency.
- In sub point 4 of point 9 the following questions should be completed to provide an account of the advantages and disadvantages of the drug under review relative to relevant active comparator(s):
  - The main alternative treatment options used for the indication(s) under review within Ukrainian clinical practice;
  - Details on availability of recommendations regarding proposed medicine in healthcare sector standards (STGs and the Stat Formulary), designed taking into account budget impact analysis results and related to indication(s) under review;
  - Details of any indirect comparisons used in the economic model to define clinical benefits and adverse effects to be expected in practice with the drug in the indication(s) under review;
  - Details of the search strategies or rationale for identification of data sources used in the indirect comparison to provide evidence of clinical benefits and adverse effects;
  - Details of any relevant differences between the data sources providing evidence of clinical benefits and adverse effects with the drug in the indication(s) under review and those providing evidence for indirect comparator(s).
- These would include differences in:
  - patient populations, by comparing inclusion/exclusion criteria, baseline demographics, including defining relevant variables such as disease severity and previous treatments;

- drug treatments, by comparing dosing schedules of study drugs and concomitant study medications;
- methodology, by comparing trial methodologies;
- results, by comparing results;
- study limitations, by comparing limitations in methodology and application of results to practice;
- Details of any advantages or disadvantages, other than clinical benefits and adverse effects with the drug in the indication(s) under review compared to usual clinical practice with the relevant active comparator(s).

These would include differences in terms of:

- Necessary tests or investigations for the identification and/or therapeutic monitoring of patients in addition to those used. Provide details of any additional tests or investigations needed for selection or monitoring of patients over and above usual clinical practice with the relevant active comparator(s). In terms of safety, to identify patients in whom the treatment is contra-indicated and/or who are particularly at risk of known adverse effects or monitoring to detect potential adverse effects. If the recommended testing/monitoring regimens are extensive, these may be included as an appendix;
- Routes or schedules of administration. Changes in resource utilization or patterns of care. For example, increase or reduction in use of healthcare facilities, physician visit, numbers of medical staff, hospital admissions etc.

10. Point 10 of the Application should include data on the comparative safety of the medicinal product under review relative to its comparator, including summary tables with details of key trials and output data (copies of key trial documents) in electronic PDF format.

It is also acceptable to use alternative ways to provide details, including systematic reviews, as well as single studies.

The most revealing comparative studies (randomized controlled trials) shall be detailed with providing information on patient characteristics, baseline risk for basic relevant results in a regular treatment group and control group. In case if an alternative approach was chosen (especially in case if there is only one or two studies), then ensure that appropriate evaluation of clinical studies is available or exists the risk of making system error in an individual study and commentaries regarding possibility of using data of such studies. Where multiple relevant trials exist the results should be aggregated using meta analytic techniques, with a description and justification of the approach taken. It is also acceptable to submit a systematic review, provided there is also an adequate assessment of the quality of clinical trials and no additional relevant trials have been identified in the literature search.

- In sub point 2 of point 10 provide evidence on adverse events and details on their frequency and severity. General risks and benefits shall be provided separately and shall include data on clinical trials, adverse effects of medicines, indications for use are considered with comparatives. The most relevant are head-to-head randomized controlled trials directly comparing the proposed drug with the most relevant comparator. However,

if direct head-to-head RCTs are not available, an indirect comparison may be presented using two sets of placebo or active-controlled trials using a common comparator. In this case it is important to demonstrate that the trials populations are similar, particularly, with respect to disease severity.

- In sub point 3 of point 10 provide complete details of trials demonstrating differences between the safety profile of the medicine under review and placebo or comparator.

For active-controlled trials, which primarily assessed an efficacy outcome, provide details of any analyses, indicating significant differences in adverse event rates between the drug under review and an active comparator.

For placebo-controlled and uncontrolled trials, which primarily assessed an efficacy outcome, provide details of the type and frequency of adverse effects that might be expected in clinical practice with the drug in the indication(s) under review.

Also, the information should be taken from complete published reports but if the published trial report is missing, this information should be taken from reports of clinical studies. Clinical study reports should be clearly highlighted in the text by underlining.

In addition, provide details of any additional safety issues for the drug in the indication(s) under review compared to relevant active comparator(s), which were not identified in the trials described previously, for example:

- Details of any additional safety issues identified by the regulatory authorities, e.g. requirements for post-marketing surveillance of possible but rare potential adverse effects;
- Details of adverse effects not yet identified with the drug under review, which have been observed with comparator(s). Similarly details should be provided of adverse effects identified with the drug under review, which have not been observed with relevant comparator(s). Any limitations of available data for these comparisons should also be stated.

11. In point 11 of the Application provide details on comparative cost and cost effectiveness of the medicine under review in relation to the comparator within the context of its proposed use in Ukraine. If the context of any cost effectiveness analysis is broader, provide a rationale for the reasonable interpretation of the results in the Ukrainian context.

- In sub point 1 of Point 11 provide price of the proposed medicine in the countries in which it is registered and/or actual or expected level of declared ex-factory and reference price (if available) of the medicine under review.
- In sub point 2 of point 11 - in case of comparison of the medicinal product within the framework of treatment group – the approximate range of costs in routine use: e.g. cost of a month's treatment (for chronic therapy), cost of a treatment course (for acute therapy), cost per case prevented (if appropriate);

- In case of comparison of medicinal product outside the framework of the treatment group in sub point 3 of point 11 provide information about incremental cost effectiveness:
  - Where there is a clinical meaningful difference in clinical effectiveness, presentation of an incremental cost effectiveness ratio based on data from the key clinical trial(s).
  - Where the evidence supports a finding of similar effectiveness, provide comparison of costs for equi-effective doses.
- In sub point 4 of point 11 provide information on average cost of expenses for one patient (in general) and general cost of treatment for the population, including any expenses for introduction of the medicine and treatment of the adverse reactions.

Description should include description of costs for procurement and use of the medicine under review, and any direct effects of using other medical services, for example, required diagnostic tests, and substitution of parenteral therapy to oral (including costs offsets of substituted therapies, if any).

If the available data are insufficient to allow calculation of a comparative cost-effectiveness (or cost-utility) ratio using clinical outcomes (as opposed to surrogate or intermediate outcomes), a modeled analysis may be presented. Decision-analytic modeling (decision trees or Markov processes) may be used. The model should be presented using MS Excel and the complete model should be submitted with the Application.

The accompanying narrative shall specify:

- Type of model and justification;
- Sources of values of model parameters (should be literature based where possible);
- The time horizon of the model which should include the time to onset of final clinical outcomes;
- Description and diagram of the model structure, explaining how this is consistent with the natural history of the condition in question;
- Transition probabilities and other parameters used in the model;
- Description of the cohort of patients included in the model;
- Description of outcome measures and costs consistent with those described in the preceding sections;
- Presentation and interpretation of the results of the bases case of the model, together with sensitivity analyses, varying the values of key parameters. In the sensitivity analysis, the degrees of variation of the parameters should be justified.

In those cases where data are unavailable, the evaluation of comparative cost and cost effectiveness may be based on assumption.

Where HTAs/health economic evaluations have been undertaken for the candidate medicine in other health systems, descriptions of these could be included (instead of accepting assessments based on the assumptions). The descriptions would include the purpose and type of analysis; compared alternatives in the clinical study; key parameters

(e.g., price); health outcome measures (clinical indicators, quality of life, long term results, etc.); used methods, and models, and results. If these have been made by state institutions or HTA agencies to support decision making within another national healthcare system, the decision should be stated, with any applicable conditions, constraints or qualifications.

In particular decisions of state institutions in Europe such as NICE, HAS, etc. (positive or negative) should be included with the relevant references and the appropriate document containing the final assessment and conclusions annexed to the Application.

In case of positive decision, the reimbursement status of the respective product in the EU, indications, restrictions and level of reimbursement, a summary or recommendations for reimbursement, if reimbursement is valid for any indications or for specific indications only, should be described.

In addition, the following information should be provided:

- Total number of patients in Ukraine, who have disease and have relation to indication(s) under review and the source of provided indicators;
- Number of new patients, who are diagnosed annually, over the first 5 years after introduction of the medicine (the annual incidence) and the source of provided indicators;
- Number of patients annually, over the first five years after introduction of the medicine under review.

In addition to this, the indicator is calculated by the following formula:

$$\begin{array}{l} \text{Net number of} \\ \text{patients each year,} \\ \text{over the first five} \\ \text{years after the} \\ \text{introduction of} \\ \text{medicine under review} \end{array} = \begin{array}{l} \text{Prevalent cases} \\ \text{(in the} \\ \text{beginning of the} \\ \text{year)} \end{array} + \begin{array}{l} \text{Incident cases (in} \\ \text{the end of the} \\ \text{year)} \end{array} - \begin{array}{l} \text{Patients who} \\ \text{recover or die} \\ \text{(in the end of the} \\ \text{year)} \end{array}$$

The net number should, where appropriate, take account of changing patterns associated with the condition under consideration. In some cases, the prevalence may remain constant from one year to the next. In others, it may be likely to change e.g. because of changes in incidence and/or prognosis and survival. There may be assumptions that some of these changes will be influenced by the new treatment. The source of data should be information from the Ministry of Health of Ukraine and/or State Statistics Service of Ukraine. Calculation based on Eastern European countries indicators may be also provided.

Give an estimate of the number of people in Ukraine currently treated for this condition.

Give an estimate of the number of people likely to be prescribed this treatment. It may involve making assumptions about market share and uptake changing with time.



Give the cost of treatment over a defined time period (e.g. the acquisition cost of 30 days' chronic treatment, annual costs or cost per treatment case) for the medicine under consideration and the comparator:

- Average term(s) of treatment;
- Average dose(s) anticipated;
- Whether or not treatment is continuous, one-off or given cyclically but for a finite time;
- Cost per patient per year, or other appropriate time period, stating any assumptions made.

For the product under consideration, identify any direct savings over a defined time period.

In general, direct costs and savings refer only to the acquisition cost of the product and the costs involved in the process of providing the treatment e.g. administration sets and diluents for a parenteral preparation. Other costs and savings should be considered in the economic analysis.

Based on data noted in sub point 4 of point 11 provide a summary of the net resource implications for Ukraine in each of the first five years following introduction. This should take account of acquisition costs associated with the new treatment and with other therapy whose uptake may be influenced by its availability.

12. In point 12 provide information about registration and permitted use of the medicine under review in EU countries, Japan, USA, Canada, Switzerland and Australia; whether the medicine has passed WHO prequalification procedure and been included in the WHO list of prequalified medicinal products, designed for combating HIV/AIDS, tuberculosis, malaria, hepatitis C and other diseases, and also appointed in the field of reproduction and included into the WHO prequalification program and is considered acceptable for procurement by the UN.
13. In point 13 note if the medicine under review is included in pharmacopoeias (The British Pharmacopoeia, The International Pharmacopoeia, The United States Pharmacopeia, The European Pharmacopoeia) and the State Pharmacopoeia of Ukraine.
14. In point 14 note proposal regarding brief product description and position of the medicine under review in the renewed version of NEML.
15. Information in the Application should be brief and use common terminology as well as include data available at the moment of submission.
16. The Application shall be submitted in Ukrainian as paper based and electronic document (in Word). Documents annexed to the application shall be submitted in Ukrainian or English with translation to Ukrainian or Russian (if required) as paper based or electronic document.

## ANNEX C

DRAFT



### MINISTRY OF HEALTH OF UKRAINE O R D E R

\_\_\_\_\_ Kyiv

№ \_\_\_\_\_

On the Approval of the Procedure of  
Quantification of Medicines for Procurement  
by Healthcare Facilities and Institutions that  
are Fully or Partially Funded from the State or  
Local Budgets

According to paragraph two clause 1<sup>1</sup> of Decree of the Cabinet of Ministers of March 25, 2009, #333 “Some Issues of the State Regulation of Prices for Medicines and Medical Products” to ensure rational planning of the need of healthcare facilities that are fully or partially funded from the state or local budgets and effective spending of budget funds while procuring and reimbursing medicines

#### **HEREBY IT IS ORDERED:**

1. To approve the Procedure of Quantification of Medicines for Procurement by Healthcare Facilities and Institutions that are Fully or Partially Funded from the State or Local Budgets (herein after referred to as the Procedure) that is enclosed.
2. Heads of healthcare departments of oblast and Kyiv city administrations shall ensure the implementation and compliance with the Procedure during quantification of the need in medicines that are procured with the funds from the state and local budgets in the facilities that report to them.
3. Pharmaceutical Department (Taras Liaskovskyi) shall ensure that this Order is submitted for the state registration to the Ministry of Justice of Ukraine.
4. Deputy Minister Roman Ilyk shall be charged with supervising of the execution hereof.
5. This Order comes into effect on the day of its publication.

Acting Minister

Uliana SUPRUN

Deputy Minister	R. Ilyk
Acting Director of the Medical Department	A. Havryliuk
Head of Pharmaceutical Department	T. Liaskovskyi
Acting Director of Economic and Financial Policy Department	A. Kuplivanchuk
Head of Legal Department	L. Demshevska
Head of Staff Organization Support Department	I. Velychko
Acting Head of Corruption Risks Evaluation and Mitigation Department	O. Levchenko
Head of the Department of Organization of Ministry Administration Work	S. Antonov

Mailing list:

To be filed	2 copies
Medical Department	1 copy
Pharmaceutical Department	1 copy
Heads of healthcare department of the state (city) administrations	25 copies

N. Ostropolets 253-53-07

APPROVED

Order of the Ministry of Health of Ukraine

\_\_\_\_\_, 2017, # \_\_\_\_

**Procedure of Quantification of Medicines for Procurement by Healthcare Facilities and Institutions that are Fully or Partially Funded from the State or Local Budgets**

**I. General Provisions**

1. This procedure determines the mechanism for quantification of the need in medicines of healthcare facilities and institutions that are fully or partially funded from the state and local budgets, procurement of medicines including those listed in the National Essential Medicines List (herein after the Procedure and the NEML accordingly).
2. The need in medicines which are procured with budget assignments that are additionally allocated by budget fund administrators from July 1, 2017 to December 31, 2017; and medicines funded from the state and local budget for 2018 and following budget years shall be quantified according hereto.
3. Quantification methods shall be applied to identify the need in procurement of medicines procured by healthcare facilities and institutions that are fully or partially funded from the state and local budgets, as well as medicines to be reimbursed from the state and local budgets.
4. Quantification methods are applied to:
  - Prepare and justify budget estimates for procurement of medicines;
  - Plan new and scale up current national medicines procurement programs;
  - Optimize budget estimates to procure medicines based on priority issues of healthcare and rational approached to treatment;
  - Calculation of the need in medicines to provide emergency care in case of natural disasters, environmental accidents and epidemics;
  - Evaluation of current need/demand ratio with regard to medicines.
5. Methods of quantification of the need in medicines used for quantification by healthcare facilities and institutions that are fully or partially funded from the state and local budgets are as follow:
  - Morbidity based method of quantification of the need in medicines (herein after referred to as the morbidity based quantification)- uses data on the number of instances of patients seeking medical assistance, including hospitalization, taking into account morbidity rate dynamics and STGs.
  - Consumption based method of quantification of the need in medicines (herein after referred to as the consumption based quantification) – uses data on volumes of consumption of specific medicines in the past (taking into account stock-out periods and/or changes in consumption volumes).
6. The need in medicines can be determined using one or combination of two quantification methods.

Morbidity based method shall be preferred for public procurement planning, in particular, for new national healthcare programs without long history.

Consumption based method is recommended to identify the need in medicines cost of which is reimbursed from the state or local budgets.

Method/s shall selected by healthcare facilities and institutions that are fully or partially funded from the state or local budgets taking into account base data (quantitative indicators).

7. Because of significant number of variable base values, the results of quantification of the need in medicines are indicative.
8. To prevent deficit of medicines during their quantification it is necessary to consider that circumstances in which it is impossible to use medicines further may occur, in particular, expiration, mechanical, chemical, physical, biological or another type of impact (herein after – possible losses). The level of possible losses may come to 3% annually.

## II. Morbidity based method

1. The following data is required for morbidity based quantification:
  - Information on medicines listed in the NEML (INNs, ATC code, dosage form, strength, quantity in a package, wholesale price per package);
  - Available financial recourses to ensure pharmacotherapy (approved budgets, estimates, etc.; including data about planned expenses and funds used for the procurement of medicines).
  - Standard treatment regimens recommended by STGs on the basis of average doses and average treatment duration (if available);
  - Morbidity rates, including number of treatment episodes for each disease or condition.
2. Morbidity based quantification is performed using the following formula:

$$\text{Total quantity of medicines needed to solve the health issue} = \frac{\text{Number of disease or condition treatment episodes}}{\text{Quantity of medicines needed for standard course of treatment of 1 episode}} \times \text{Quantity of medicines needed for standard course of treatment of 1 episode}$$

3. Using morbidity-based method current International Classification of Disease Codes (herein after – ICD).
4. Required number of medicines shall be quantified according to the procedure outlined on Figure 1 below. **Figure. 1. Morbidity Based Quantification Procedure**

### **Stage 1. Development of the list of diseases/conditions for which calculations will be performed.**

Morbidity statistical data analysis in the service region or patients discharged from the hospital by medical entities is performed in each department of the facility independently

(based on department annual report results) to identify the list of, first of all, the most prevalent and socially dangerous diseases and conditions that amount to 70-80% of bed-days in morbidity patterns.

In case of quantification for NEML medicines Stage 1 shall be omitted.

**Stage 2. Development of the list of medicines recommended for treatment and prophylaxis of the above mentioned diseases/conditions.**

The above mentioned list is recommended to be developed as a spreadsheet which will allow sorting items by INNs as well as by diseases and conditions.

In case of quantification for NEML medicines Stage 2 shall be omitted and the NEML used.

**Stage 3. Preparation of standard treatment/prophylaxis regimens for the diseases/conditions.**

Provided there are sector level medical care standardization system medical and technical documents on the issue under investigation (adopted clinical guidelines, unified clinical protocols), development of local treatment protocol for the treatment facility is the optimal option. In such cases standard treatment regimen is developed based on the local protocol.

If there are no sector level medical care standardization system medical and technical documents on the issue under investigation, it is necessary to perform retrospective analysis of medical care provided to patients with particular disease/condition in the healthcare facility and assess quality of healthcare in these cases based on the results of treatment provided. Treatment regimens with high treatment efficacy indicators may be selected for the development of standard treatment regimens.

In case of quantification for NEML medicines Stage 3 shall be omitted.

**Stage 4. Morbidity data collection.**

This stage includes calculation of treatment/prophylaxis episodes with consideration of the fact that this indicator does not coincide with the number of clinic visits. Visits of patients that require pharmacotherapy should be considered separately from visits of those patients that do not require such treatment.

This stage includes calculation of treatment/prophylaxis episodes with consideration of the fact that this indicator does not coincide with the number of clinic visits. Visits of patients that require pharmacotherapy should be considered separately from visits of those patients that do not require such treatment.

Data on the number of cases of a particular disease may be received centrally, based on official statistical indicators (Form No 12 “Report on Diseases Registered in Patients Residing in Medical Facility Service Area for 20\_\_\_\_”, Form No 20 “Treatment Facility Report” approved

by MOH Order of July 10, 2007, No 378,) or summarized based on separate data from healthcare facility departments as an indicator of number of visits/hospitalizations that required pharmaceutical prophylaxis/treatment in the last reporting period (preferably, at least one year).

The result of this analysis is the list of main diseases or hospitalization causes with the number of cases by each disease/condition during a particular period of time (approximately 1/2 - 2/3 of the number of disease area treated in the department during previous periods).

**Stage 5. Calculation of the total number of each medicine for each disease/condition.**

The calculation shall be done the following way: number of treatment episodes during one year is multiplied by number of medicines required for standard treatment regimen developed during Stage 3.

**Stage 6. Scale up of the quantity calculated during previous stage considering possible expenses.**

The level of possible expenses may come to 3% annually.

Medicines quantity adjustment shall be calculated considering possible expenses and according to the following formula:

$$\text{Need in medicines taking into account possible losses} = \text{Need in medicines} \times 1.03$$

**Stage 7. Quantification of the need in medicines in packages and calculation of total cost of total quantity of medicines planned for procurement.**

Quantification of the need in medicines in packages.

Received quantity of medicines in grams (milligrams) shall be converted to the quantity of medicines in solid oral forms. Quantity of packages of medicines shall be calculated according the following formula:

$$\text{Number of packages needed} = \frac{\text{Total quantity of medicines considering losses (in dosage form units)}}{\text{Number in one package}}$$

Total cost of the calculated required quantity of medicines is calculated using the following formula:

$$\text{Total cost of each medicine} = \text{Required quantity of packages} \times \text{Cost of one package}$$

**Stage 8. Reconciliation of the volume of medicines to be procured with available funds (budget) using ABC/VEN-analysis.**

When the need in NEML medicines has been covered by 100%, facilities and institutions may procure medicines that are registered in Ukraine according to the procedure provided by the law and are not in the NEML according to their indications. Herewith, the preference is given to medicines included to healthcare sector standards.

5. An example of morbidity based quantification use is provided in Annex 1.

### **III. Consumption based quantification**

1. Consumption based quantification of the need in medicines and calculation of funds needed for their procurement shall be performed according to the procedure outlined in Figure 2 on the following page.



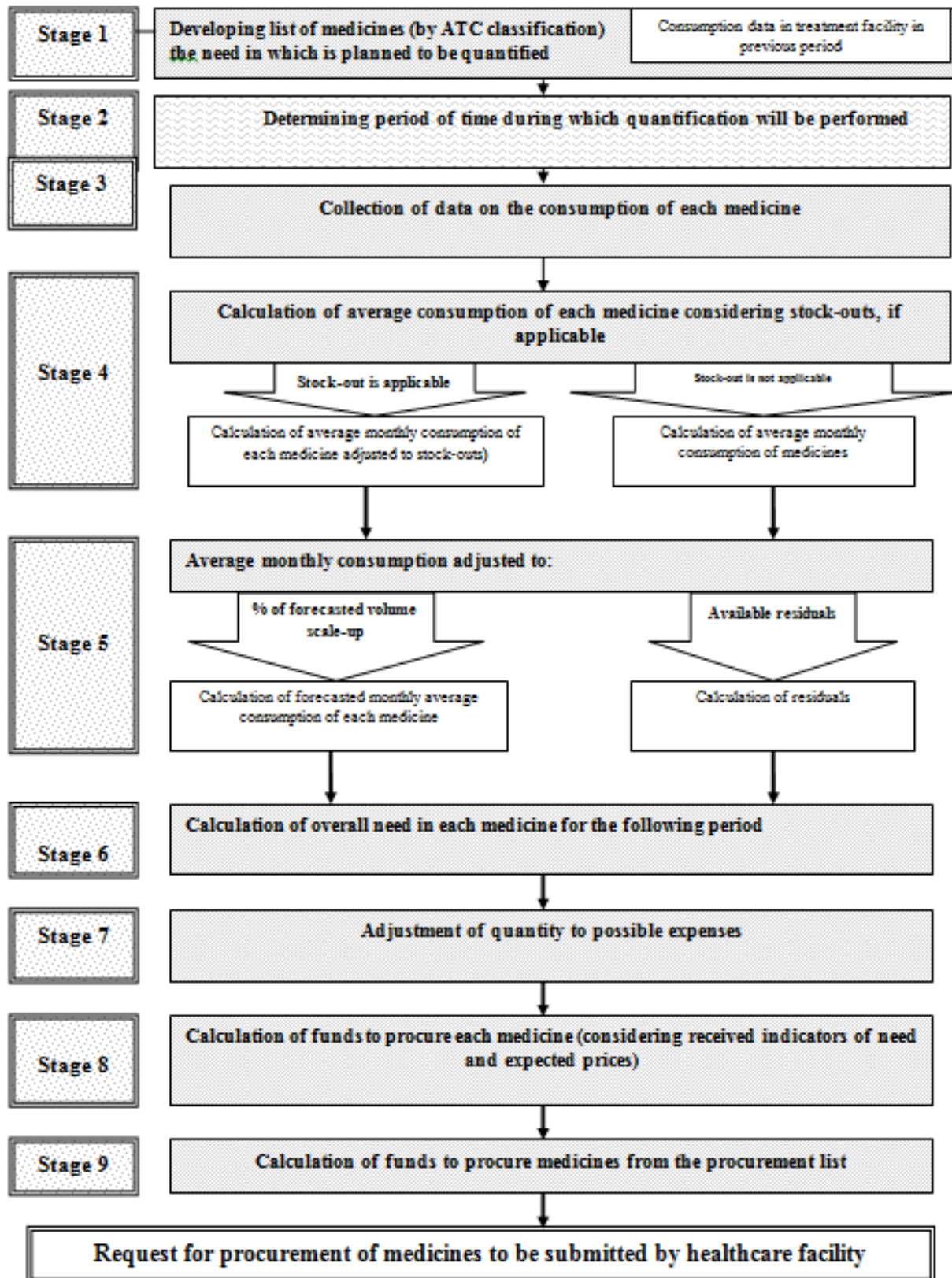


Figure. 2. Consumption Based Quantification Procedure

**Stage 1. Developing the list of medicines the need in which is planned to be quantified**

The list is developed by ATC classification.

To quantify the need in medicines based on consumption it is necessary to make a list of all medicines for procurement taking into account data about consumption during previous periods (months/years).

In case of quantification for NEML medicines Stage 1 shall be omitted and the NEML shall be used instead.

**Stage 2. Determining period of time during which quantification will be performed.**

While quantification it is necessary to consider consumption of medicines during previous periods (months/ years) adjusted to stock outs that happened during these periods.

**Stage 3. Collection of data on the consumption of each medicine.**

For each medicine on the list it is necessary to have the information about the quantity of medicines that was used in the healthcare facility/facilities during reporting (similar) periods (in dosage form units).

If such information is not available in primary healthcare facilities, it shall be taken from pharmaceutical market marketing research data bases.

**Stage 4. Calculation of average monthly consumption of medicines and calculation of forecasted monthly consumption of medicines considering expected changes in the consumption structure.**

- Calculation of average monthly consumption of medicines (if during reporting period there was deficit of medicines).

Average monthly consumption shall be calculated based on the following formula:

$$\text{Average monthly consumption of medicines} = \frac{(\text{volumes of consumed medicines} + \text{Volume of deficit of medicines})}{\text{Number of months}}$$

Calculation of forecasted average monthly consumption taking into account expected changes in the consumption structure (if there was no deficit of medicines).

The result received shall be adjusted to the following:

- Percentage of scale-up of forecasted consumption of medicines that shall be calculated based on the following formula:

$$\text{Forecasted average monthly consumption of medicines} = \frac{\text{Average monthly consumption of medicines}}{\text{Forecasted scale-up (scale-down) of medicines (\%)}}$$

- Available residuals of medicines that shall be calculated based on the following formula:

$$\text{Residuals of medicines} = \frac{\text{Residuals of medicines at the warehouse}}{\text{Residuals of medicines held by patients}}$$

Some consumption indicators are not influenced by the tendency of general use of medicines by patients (for instance, seasonal fluctuations in consumption). If the use of such indicators is necessary, in particular in cases when they are part of consumption data, it is recommended to foresee scale up (scale down) of consumption of the respective medicines.

#### **Stage 6. Calculation of the quantity of medicines required for the next procurement period.**

The total need in medicines shall be calculated based on the following formula:

$$\text{Need in medicines} = \frac{(\text{forecasted average monthly consumption of medicines} - \text{Residuals of medicines})}{12 \text{ months}}$$

#### **Stage 7. Calculation of the increase of total quantity of each medicines taking into account possible losses.**

Possible losses may come up to 3% annually.

It is necessary to calculate adjustment of the quantity of medicines taking into account possible losses. This indicator shall be calculated based on the following formula:

$$\text{Need in medicines taking into account possible losses} = \frac{\text{Need in medicines}}{1.03}$$

#### **Stage 8. Calculation of expenses by each medicine.**

To evaluate expenses for procurement of medicines it is necessary to multiply received indicators of the need by expected future prices using the following formula:

$$\text{Funds required for procurement of medicines} = \frac{\text{Need in medicines adjusted to losses}}{\text{Price of one package of medicines}}$$

#### **Stage 9. Calculation of the total amount of funds needed to procure medicines.**

- An example of consumption based quantification of medicines and calculation of funds for their procurement is provided in Annex 2.

Annex 1

To the Procedure of Quantification of Medicines for Procurement by Healthcare Facilities and Institutions that are Fully or Partially Funded from the State or Local Budgets

**Example of morbidity based quantification**

1. Quantification of each medicine for each disease/condition.

Quantification on the example of the Amoxicillin indicated for urologic, respiratory and skin diseases (Chart 1).

*Chart 1*

ICD	Disease/condition	Medicine	Average therapeutic dose for adults	Administration frequency per day	Number of treatment days	Quantity per treatment course
N30.1	Chronic Cystitis	Amoxicillin	0.50 g	3	7	10.50 g
J01	Acute Sinusitis	Amoxicillin	0.50 g	2	10	10.00 g
L02	Skin abscess, furuncles	Amoxicillin	0.75 g	2	10	15.00 g

$0.5\text{g} \times 3 \text{ (times/day)} \times 7 \text{ days} = 10.50\text{g}$

$0.5\text{g} \times 2 \text{ (times/day)} \times 10 \text{ days} = 10.00 \text{ g}$

$0.75\text{g} \times 2 \text{ (times/day)} \times 10 \text{ days} = 15.00 \text{ g}$

To calculate total quantity of each medicine for treatment/prophylaxis of diseases/conditions in ambulatories it is necessary to consider the following data provided in Chart 2.

*Chart 2*

ICD	Disease/Condition	Number of visits	Number of episodes
N30.1	Chronic Cystitis	5	1
J01	Acute Sinusitis	3	1

To calculate total quantity of each medicine to cover healthcare facility need we summarize and organize data from Charts 1 and 2 as follows (Chart 3):

*Chart 3*

ICD	Disease/Condition	Medicine	Quantity per treatment course	Number of episodes	Total quantity
N30.1	Chronic Cystitis	Amoxicillin	10.50g	350	3675.00 g
J01	Acute Sinusitis	Amoxicillin	10.00g	200	2000.00 g
L02	Skin abscess, furuncles	Amoxicillin	15.00g	500	7500.00 g

2. Calculation of the increase of total quantity of each medicine considering possible losses.

Scale up of the quantity calculated during previous stage considering possible losses as shown in Chart 4.

Chart 4

Medicine	ICD threatened with the medicines	Total quantity of medicines	Total quantity of medicines considering losses (3%)
Amoxicillin	N30.1	3675.00 g	3785.25 g
Amoxicillin	J01	2000.00 g	2060.00 g
Amoxicillin	L02	7500.00 g	7725.00 g

3. Quantification in packages and calculation of the total cost of the medicine that is planned to be procured.

Quantification in packages.

Since to treat Chronic Cystitis Amoxicillin is prescribed at 0.5 g 3 times a day for 7 days, the required quantity and strength is 20 tablets, 250 mg each (based on the example of specific trade names present on the market):

$$3785.25\text{g}/0.25 \text{ g(in 1 tablet)} = 15141 \text{ tablets}$$

Calculation of the number of packages:

$$15141\text{tablets}/20 \text{ tablets}= 757.1 = 758 \text{ packages}$$

Calculation of total cost of medicines that are planned to be procured:

$$758 \text{ packages} \times 43.30 \text{ UAH} = 32821.40 \text{ UAH}$$

To treat acute sinusitis patients are prescribed Amoxicillin at 0.5 g 2 times/day for 10 days.

Using the example of a specific trade name present on the market a package of which contains 20 tablets with 500 mg of active ingredient let's calculate the required quantity of tablets:

$$2060 \text{ g}/0.5 \text{ g (in 1 tablet)} = 4120 \text{ tablets}$$

Required quantity of packages is:

$$4120 \text{ tablets}/ 20 = 206 \text{ packages.}$$

Calculation of total cost of medicines that are planned to be procured:

$$206 \text{ packages} \times 24.20 \text{ UAH} = 4985.20 \text{ UAH}$$

To treat abscess patients are prescribed Amoxicillin at 0.75 g 2 times/day for 10 days. Using the example of a specific trade name present on the market a package of which contains 20 tablets with 500 mg of active ingredient let`s calculate the required quantity of tablets:

$$7725.00 \text{ g} / 0.5 \text{ g (in 1 tablet)} = 15450 \text{ tablets}$$

Required quantity of packages is:

$$15450 \text{ tablets} / 20 = 772.5 = 773 \text{ packages}$$

Calculation of total cost of medicines that are planned to be procured:

$$773 \text{ packages} \times 24.20 \text{ UAH} = 18706.60 \text{ UAH}$$

TOTAL amount of funds needed for procurement of medicines in the future period is 56513.20 UAH.

## Annex 2

To the Procedure of Quantification of Medicines for Procurement by Healthcare Facilities and Institutions that are Fully or Partially Funded from the State or Local Budgets

### Example of morbidity based quantification

1. Quantification on the example of Ampicillin and Amoxicillin.

Input data are provided in Chart 1.

*Chart 1*

Medicine	Dosage form, strength, package	Need in the current year, tablets	Procured in the current period, tablets	Consumed last year, tablets	Residuals at the warehouse from the previous period, tablets	Stock out in the previous period, tablets
Ampicillin	Tablets 250 mg No 10	2400	2000	2000		400
Amoxicillin	Tablets 250 mg No 20	2000	2000	1000	1000	
Amoxicillin	Tablets 500 mg No 20	1500	1000	1000		500

Calculations of average monthly consumption considering deficit:

For Ampicillin:

$$(2000 \text{ tablets} + 400 \text{ tablets}) / 12 \text{ months} = 200 \text{ tablets}$$

For Amoxicillin (250 mg):

$$1000 \text{ tablets} / 12 \text{ months} = 83.33 \text{ tablets}$$

For Amoxicillin (500 mg):

$$(1000 \text{ tablets} + 500 \text{ tablets}) / 12 \text{ months} = 125 \text{ tablets}$$

2. Based on morbidity data for the last year there was an increase in hospitalization cases by 15% (1.15 index), which requires scale up in monthly average consumption in the next year:

For Ampicillin:

$$200 \text{ tablets} \times 1.15 = 230 \text{ tablets}$$

For Amoxicillin (250 mg):

$$83.33 \text{ tablets} \times 1.15 = 95.83 \text{ tablets}$$

For Amoxicillin (500 mg):

$$125 \text{ tablets} \times 1.15 = 143.75 \text{ tablets.}$$

3. At the pharmacy warehouse there are residuals of Amoxicillin (250 mg) - 1000 tablets, for further calculations we need to know monthly average residuals calculated using the following formula

$$1000 \text{ tablets} / 12 \text{ months} = 83.33 \text{ tablets.}$$

4. Based on the data received we can calculate overall need in medicines (in tablets) considering stock outs, at the end of the period:

For Ampicillin

$$230 \text{ tablets} \times 12 \text{ months} = 2760 \text{ tablets}$$

For Amoxicillin (250 mg)

$$(95.83 \text{ tablets} - 83.33 \text{ tablets}) \times 12 \text{ months} = 150 \text{ tablets}$$

For Amoxicillin (500 mg)

$$143.75 \text{ tablets} \times 12 \text{ months} = 1725 \text{ tablets.}$$

5. Adjustment of the result received taking into account the percentage of possible losses that in this particular facility come to 3% (1.03index):

$$\text{For Ampicillin } 2760 \text{ tablets} \times 1.03 = 2842.8 \text{ tablets}$$

$$\text{For **Amoxicillin** (250 mg) } 150 \text{ tablets} \times 1.03 = 154.5 \text{ tablets}$$

$$\text{For **Amoxicillin** (500 mg) } 1725 \text{ tablets} \times 1.03 = 1776.75 \text{ tablets.}$$

6. Calculation of the number of packages to be procured in the next period:

$$2842.8 \text{ tablets} / 10 \text{ tablets in a package} = 284.28 \text{ (285 packages)}$$

For Amoxicillin (250 mg)

$$154.5 \text{ tablets} / 20 \text{ tablets in a package} = 7.73 \text{ (8 packages)}$$

For Amoxicillin (500 mg)

$$1776.75 \text{ tablets} / 20 \text{ tablets in a package} = 88.84 \text{ (89 packages)}$$



7. Total cost of packages in UAH is calculated by multiplying number of packages by wholesale price of 1 package:

Ampicillin 285 packages x 5.47 UAH = 1558.95 UAH

Amoxicillin (250 mg) 8 packages x 17.04 UAH = 136.32 UAH

Amoxicillin (500 mg) 89 packages x 27.22 UAH = 2422.58 UAH.

8. TOTAL amount of funds needed for procurement of medicines in the future period is 4117.85 UAH.

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