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01 REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

(Ivan Loboda, Senior Technical Advisor Pharmaceutical Finance, USAID | SAFEMed)

1. What are the regulatory authorities with jurisdiction over drugs, biologicals, and medical devices in your country?

- the Ministry of Health of Ukraine ("Ministry")
- the State Service of Ukraine on Medicines and Drugs Control ("SSM")
- the National Health Service of Ukraine ("NHSU")
- Quality control authorities accredited by the Ministry of Economic Development and Trade of Ukraine

2. What is the regulatory framework for the authorization, pricing, and reimbursement of drugs, biologicals, and medical devices?

The authorization, pricing, and reimbursement of drugs, biologicals, and medical devices is regulated by the following laws and regulations:

1. LAWS OF UKRAINE:
   - On Medicinal Products
   - On Licensing of Certain Types of Economic Activity
   - On Technical Requirements for Products and Conformity Assessment
   - On Price and Pricing
   - On the Basis of the State Regulation of Economic Activity

2. DECREES OF THE CABINET OF MINISTERS OF UKRAINE:
   - "On Approval of the Procedure for State Registration (Re-registration) of Medicinal Products and Amounts of Fees for Their State Registration (Re-Registration)" No. 376 dated 26.05.2005
   - "On the State Register of Medicinal Products" No. 411 dated 31.03.2004
   - "On Approval of License Conditions for Conducting Business Activity of Medicinal Products Production, Wholesale and Retail Trade, Import (except active pharmaceutical ingredients)" No. 929 dated 30.11.2016
   - "On Approval of the Technical Regulation for Medical Devices", "On Approval of the Technical Regulation for in vitro Diagnostic Medical Devices", "On Approval of the Technical Regulation for Active Implantable Medical Devices" No. 753, 754, 755 dated 02.10.2013
   - "On Reference Pricing for Medicines and Medical Products, Purchased with Funds of the State and Local Budgets" No. 240 dated 02.07.2014
   - "On State Regulation of Prices on Medicines" No. 862 dated 09.11.2016
   - "On Introduction Reimbursement of Medicines" No. 863 dated 09.11.2016
   - "On Ensuring Access to Medicinal Products" No. 152 dated 17.03.2017
   - "On Some Issues of State Regulation of Prices for Medicines and Medicinal Products" (National List of Essential Medicines) No. 333 dated 25.03.2009

• "On the Implementation of Pilot Project on State Regulation of Insulin Products Prices" No 73 dated 05.03.2014
• "On Certain Issues of Insulin Products Costs Reimbursement" No. 239 dated 23.03.2016

3. A NUMBER OF ORDERS OF THE MINISTRY OF HEALTH OF UKRAINE:

• "On Approval of the Procedure for State Registration (Re-registration) of Medicinal Products" No. 426 dated 26.08.2005
• "On Approval of the Procedure of Maintaining the Register of Persons Responsible for the Introduction of Medical Devices, Active Implanted Medical Devices, and Medical Devices for in vitro Diagnostics in Turnover, Forms of Communication and List of Data Stored therein and Access to Them" No. 122 dated 10.02.2017
• "On Approval of the Register of Margin Wholesale and Trade Prices for Medicinal Products"No. 2 dated 02.01.2018
• "On Approval the Procedure for Calculation of the maximum Wholesale Prices for Medicinal Products Based on Reference Prices" No. 1423 dated 29.12.2016
• "On Approval of Form of the Register of Medicinal Products Subject to Reimbursement" No. 298 dated 21.03.2017
• "On Approval of Regulation on Register of Reference (Reimbursement) Prices for Insulin Products and the Procedure for Calculation of Reference (Reimbursement) Price for Insulin" No. 453 dated 07.03.2018
• "On Approval of Rules of Writing Prescriptions for Medicines and Medicinal Products, the Procedure for the Dispatch of Medicines and Medicinal Products from Pharmacies and their Structural Subdivisions, Rules on Storage, Recording and Disposal of Prescription Forms" No. 360 dated 19.07.2005, etc.

3. What are the steps to obtaining authorization to develop, test, and market a product?

In cases relating to a finished medicinal product:

PRODUCTION, MARKET ACCESS AND DISTRIBUTION:

1. Undergo the procedure of state registration of medicines (for registration of medical devices, the applicant should submit the necessary documents based on the requirements of the Ministry)
2. Obtain a state registration certificate for medicinal products (issued by the Ministry)
3. Obtain a license for economic activity on import of medicines/manufacturing of medicines (issued by the SSM)
4. Receive confirmation of GMP compliance (issued by the SSM)
5. Complete the quality control procedure (controlled by the SSM)
6. Receive a license for wholesale trade of medicinal products (issued by the SSM)
7. Conclude agreement with drug manufacturer (for procurement)
8. Conclude agreement with pharmacy (for sale)

RETAIL

1. Obtain a license for retail trade in medicinal products (for direct sale to patients)
2. Conclude a medicine supply agreement with a distributor

Economic entities must subsequently undergo, in the terms set by the legislation, a check for the observance of the licensing conditions for medicinal product manufacturing, wholesale and retail trade in medicinal products (carried out by the SSM)

4. What are the approximate fees for each authorization?

MEDICINE STATE REGISTRATION:

State registration (re-registration) fee:

1. for state registration (re-registration) of medicinal products, including medical immunobiological drugs, in addition to radioactive drugs, diagnostic agents, simple or complex (galenical) herbal medicinal products, in the amount equivalent to EUR 100 for each dosage form, EUR 10 for each subsequent dose, and EUR 10 for each subsequent package of a medicinal product.
2. for state registration (re-registration) of radioactive drugs, diagnostic agents, simple or complex (galenical) herbal medicinal products, active restricted drugs and those produced in accordance with the regulations approved by the Ministry (information about the composition, formulation (manufacturing technique), quality control, and application of a medicinal product), and donated blood or plasma products equivalent to EUR 25 per item, EUR 5 for each subsequent dose, EUR 5 for each subsequent package of the medicinal product

The registration fee does not include the cost of medicinal product expertise as well as additional expertise.

Information on the cost of expertise procedures for the state registration of medicinal products submitted for state registration (re-registration) is available on the website of the State Expert Center ("Center") at **www.dec.gov.ua/index.php/ua/1**

LICENSING OF ECONOMIC ACTIVITIES:

The license fee is payable once at one minimum subsistence income, based on the minimum subsistence income of able-bodied persons valid on the day the licensing body takes the decision to issue the license.

The procedure for assessing the conformity of medical products/confirmation of conformity of the production conditions of medicinal products with the GMP requirements:

The cost of the specified procedures is specified in the contract between the applicant and the appropriate body depending on the performed works (to determine an estimated cost of the procedures, the applicant must consult the appropriate body).

5. For how long are marketing authorizations/registrations valid? How are marketing authorizations/registrations renewed?

The registration certificate for a medicinal product is valid for five years; after re-registration, the validity is unlimited.

The validity of the conformity assessment certificate for medical products according to the decision of the relevant body that assesses for conformity for a period of up to five years, after the re-assessment of medical products for conformity, is unlimited.

The license validity is unlimited.

6. How does the authorization process differ between brand-name products and generic products? Are there differences for local manufacturers versus foreign-owned manufacturers?

The original (innovative) medicinal products are patented.

There is a simplified state registration procedure for medicinal products, in particular, those registered by the competent authority of the United States of America, Switzerland, Japan, Australia, Canada, those registered by the competent authorities of the European Union according to the centralized procedure, to be applied in the territories of these countries or member states of the European Union which are subject to procurement on the basis of the procurement procedure conducted by a specialized organization that makes purchases for the Ministry.

7. How are combination products (drug + drug, drug + biologic, drug + device, biologic + device, drug + biologic + device) regulated?

Medicinal products (including combination products (drug + drug, drug + biologic, drug + device, biologic + device, drug + biologic + device) are allowed for medical application after they are registered with the state and a registration certificate is obtained for them, for example, a solution for injection in a cartridge within an injection pen.

Medical devices are allowed to apply after they are assessed for conformity and a corresponding certificate is obtained for them. A medical product may be in the form of a device + a product and is allowed for use as a medical product. If an active component contained in a medical product has a therapeutic effect, it must be registered as a medicinal product.

8. How is compliance with regulations monitored and evaluated?
Is the regulatory regime comparable with the U.S. Food and Drug Administration or the European Medicines Agency expectations and requirements?

FOR MEDICINAL PRODUCTS:

The Department of Pharmacovigilance of the State Expert Center of the Ministry takes measures to inform the Ministry regarding decisions on market access and registration of medicinal products adopted by the FDA or the European Medicines Agency, in particular, regarding adverse reactions.

Physicians and patients can also fill in a notice of a product's adverse reaction on the website of the State Register of Medicinal Products.

Based on the relevant recommendations, the Ministry may decide to cancel the state registration of a medicinal product.

Within the terms established by the legislation, business entities are tested for compliance with the license provisions of business activity on the production

of medicinal products, wholesale and retail trade in medicines, as well as control of the quality of medicinal products carried out by the SSM.

The Ministry maintains the State Register of Medicinal Products.

The SSM maintains the Register of Licensed Business Entities.

The SSM issues decisions on the prohibition of medicinal product circulation for the duration of their quality control. It supervises the medicinal product market operations and prevents adulterated products from entering circulation.

FOR MEDICAL DEVICES:

The SSM carries out market surveillance of medical device circulation, inspections of manufacturers and medical-purpose products.

It maintains a register of persons responsible for introduction of medical devices, active implantable medical devices, and medical devices for in vitro diagnosis.

Control over the circulation of food products on the market does not fall within the competence of the Ministry and the SSM; it is carried out by the State Service of Ukraine on Food Safety and Consumer Protection.

9. What is the potential range of penalties for noncompliance?

Administrative or criminal liabilityas established by the current legislation.

10. Is there a national healthcare system? If so, how is it administered and funded?

The Law of Ukraine "On State Financial Guarantees for Medical Care of the Population" has recently come into force. In accordance with the law, a program is introduced that determines the list and scope of medical services (including medical products) and medicinal products, the full payment for which the state guarantees patients at the expense of the state budget of Ukraine according to the tariff, for prevention, diagnostics, treatment, and rehabilitation with regard to illnesses, injuries, poisonings, and other health issues, as well as pregnancy and childbearing. An an electronic health-care system is also undergoing trials featuring electronic prescriptions in five pilot regions in Ukraine.

The NHSU has now been established, which is a central executive body implementing state policy in the area of state financial guarantees for the population's medical care and performing the functions of a client of medical services and medicinal products under the program of medical guarantees.

Financing is at the expense of funds allocated from the state budget to pay for medical services for the population.

Medical institutions (those that have undergone automation) which have entered into agreements with the NHSU will receive payments for services rendered.

The NHSU will control the quality of provision of medical services to patients by appropriate health facilities. Patients make, at their own discretion, a declaration with a physician from whom they intend to receive treatement. If a patient is not satisfied with the physician, he can change and make a declaration with another one at another institution, regardless of the place of residence of the patient.

Patients will receive a (benefit) package of guaranteed medical services (under the specified list), the cost of which is compensated from the state budget.

In addition, from the beginning of 2018, medical institutions funded from the state budget should provide in full the needs of patients in medicinal products included in the National List of Essential Medicines. The cost of these drugs is completely compensated from the state budget. If a medical institution did not purchase medicinal products to satisfy the patients' needs according to the National List, it has no legal grounds to purchase other medicinal products that are not included on the List.

The National List is a guaranteed list of medicinal products reimbursed to patients at the expense of the state budget, which is formed in accordance with the recommendations of the WHO (the 20th Edition of the WHO Model List of Essential Medicines).

11. How does the government (or public) healthcare system function with private sector healthcare?

To carry out medical practice, business entities (private or public) must obtain an appropriate license issued by the Ministry.

The difference between a public medical institution and a private one is that public (state) medical institutions provide medical services, treatment to patients on a preferential basis or free of charge and are financed from the budget, while in the private sector, patients get medical services at a tariff established by private medical institutions and pay for the services rendered on their own. Provision of such services is not compensated for from the state budget.

A patient chooses independently a medical institution (private or public) to receive medical care.

In addition, patients who are prescribed medicinal products within the "Affordable Medicines" state program that are reimbursed by the state budget can get them at a public or private pharmacy (participation of pharmacy institutions in the program is voluntary).

12. Are prices of drugs and devices regulated and, if so, how?

No, they are not. Prices for medicinal products and medical devices are not regulated by current legislation.

For medical devices purchased in whole or in part at the expense of the state and local budgets, marginal supply and sale mark-ups are set that are no higher than ten percent-charged for medical devices and added to the wholesale factory price, taking into account taxes and duties. Marginal trade (retail) mark-ups are no higher than ten per cent charged to the purchase price, including taxes.

13. How are the drugs and devices used by patients paid for? What roles do public and private payers play?

To date, patients who, according to legislation, have benefits or a certain illness, receive medicinal products and medical devices free of charge or with an additional payment. There is also a state system of reimbursement of medicinal products for patients with bronchial asthma, type II diabetes, and cardiovascular diseases, as well as the reimbursement of insulin preparations. Patients

receive medicinal products under the reimbursement program free of charge or with an additional payment.

In addition, from the beginning of 2018, medical institutions funded from the state budget should provide in full for the needs of patients in medicinal products included in the National List of Essential Medicines. The cost of these medicinal products is completely compensated from the state budget. If a medical institution did not purchase medicinal products to satisfy the patients' needs according to the National List, it has no legal grounds to purchase other medicinal products that are not included in the List.

Also, medicinal products and medical devices are purchased by specialized organizations under special state programs by order of the Ministry to be supplied to the medical institutions of the regions of Ukraine in accordance with the needs declared by these institutions.

Financing for the purchase of medicinal products and medical devices is done at the expense of the state budget.

Private sector patients receive medical services at tariffs set by private medical institutions and pay the cost of services rendered on their own. Provision of such services is not compensated for from the state budget.

14. Who dispenses drugs and devices to patients and how are those dispensers compensated?

Medicinal products and medical devices are prescribed to patients by physicians who work at a medical institution, work for a sole proprietor, or are sole proprietors themselves. Narcotic and psychoactive drugs are prescribed by physicians on a special Form 3 prescription blank.

Medicinal products are delivered to patients by a pharmacy (according to the prescription if they are prescribed) or its structural subdivisions (according to the license obtained).

Patients undergoing inpatient treatment receive medicinal products and medical devices in accordance with the medication administration records prescribed by physicians.

The cost of the medicinal products included in the National List of Essential Medicines purchased by medical institutions financed from the budget and purchased by specialized organizations under special state programs by order of the Ministry is compensated to patients in full at the expense of the state budget.

Medicinal products that are reimbursed by the state under the "Affordable Medicines" and insulin reimbursement programs are prescribed to patients at an outpatient level and delivered free of charge or with additional payment (within the "Affordable Medicines" program, patients decide for themselves whether to obtain the medicinal product for free or get another (alternative) one with additional payment).

In addition, patients who receive care at outpatient level and relate to reimbursement population categories, or have a certain illness in accordance with Resolution No. 1303 of the Cabinet of Ministers of Ukraine dated August 17, 1998, obtain medicinal products either free of charge or with an additional payment (50% reimbursement), which is compensated from the state budget.

15. What are the professional and legal responsibilities of those who dispense drugs and devices? What role do they play in providing patient care, information, and safety?

Medicinal products and medical devices are administered and prescribed to patients by physicians in accordance with medical specialties. Physicians must follow the prescription rules established by the Ministry when prescribing medicinal products to patients. They must familiarize patients with the directions for use of a medicinal product and make sure that patients do not have issues with the active ingredients. They must provide qualified medical assistance to patients and maintain medical records (medical histories, patient cards).

In cases provided for by current legislation, medical personnel are administratively and criminally liable while carrying out their professional activities.

Dispensing medicinal products to patients is carried out by pharmaceutical sales representatives (pharmacists) at pharmacies and their structural subdivisions. A pharmaceutical sales representative working at a pharmacy must meet the qualification requirements provided for in the Licensing Conditions for the production of medicinal products and wholesale and retail trade.

When dispensing OTC medicines, a pharmaceutical sales representative must hold a conversation with a patient (pharmaceutical care) in order to find out the causes of his disease and provide guidance on the choice of the medicinal product.

When dispensing prescribed medicines, a pharmaceutical sales representative must make sure that the prescription is written out without violation of the prescription rules and dispense the medicine to the patient. If the prescription is written out in violation of the rules, the pharmaceutical sales representative must refuse to dispense the medicine to the patient (in this case, the prescription is considered invalid and is returned to the patient).

In cases provided for by the current legislation, pharmaceutical sales representatives are administratively and criminally liable while carrying out their professional activities.