INDUSTRIAL COMMITTEES

HEALTH & PHARMACEUTICALS COMMITTEE

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EXPANDING LOCALIZATION IN THE PHARMACEUTICAL INDUSTRY: INITIATIVES AND RESTRAINTS

This decade, the pharmaceutical industry is starting a new development phase: the Pharma-2020 Strategy is coming to its end, and the Pharma-2030 comes in its wake, including three vectors, namely: localization, focus on innovation, and demand/access to markets. At the same time, one of the main goals of the Strategy is to ensure national security (import independence in critical niches, e.g. in regard to substances) and technological enhancement (maintaining further growth of production capacities in pharmaceuticals and related industries).

Obviously, to complete the tasks set forth by the government and to further develop localization, it is necessary to overcome existing restraints impeding the development of sales markets. This applies to export in the first place. European companies with production facilities in Russia that export to other EAEU countries often face the situation when the national laws of these countries (e.g. of the Republic of Kazakhstan) place the products made in Russia on an unequal footing with goods of national manufacturers providing the latter with preferences, in particular, in public procurement. At the same time, the Russian laws provide goods originating from the EAEU countries with the same preferences in public procurement, e.g. when applying the "third one out" rule, price preferences in case of localizing an active pharmaceutical ingredient (API), etc.

Another obstacle to the further localization of medicines, including innovative ones, is inadequate intellectual property protection. Compulsory licensing mechanism application, unscrupulous generic companies entering the market prior to the expiration of the originator's patent, and sometimes inefficient judicial mechanisms in this regard, the risks of parallel import legalizing are considered by international pharmaceutical manufacturers as a stop signal for further investment in the production expansion.

Lastly, a significant obstacle to the Pharma-2030 strategy implementation is the regulatory environment instability. Moreover, a "second one out" initiative broadly discussed can top up the above-mentioned intellectual property issues. Once it is implemented, pharmaceutical manufacturers who previously localized their production in Russia to the stage of the finished pharmaceutical dosage form are at a high risk of not being allowed to participate in public procurement. In its turn, failure to participate in public procurement intrinsically means narrowing sales markets down, export slowing, and localization becoming economically inexpedient.

RECOMMENDATIONS

Obviously, there are no simple solutions for the above restraints, and to remove them efficiently, businesses and government should join their efforts.

- Thus, to facilitate exports growth, it seems advisable to hold negotiations at the level of the EAEU member states with the governments and businesses involved to level national laws up to provide equal conditions to all manufacturers of the EAEU member states, regardless of the country of origin, in public procurement. Monitoring of law enforcement at the level of the EAEU member states could also be effective.

- Developing measures to reinforce intellectual property rights protection is already laid down in the concept of the Pharma-2030 Strategy. Joint actions of the government and businesses can be aimed at creating additional legal mechanisms both at the level of Russia and the EAEU to eliminate infringement of patent rights in compliance with the interests of all bona fide market players.

- To improve regulation stability, regarding the "second one out" initiative, in particular, it is recommended to consider primarily incentive (tax, etc.) rather than prohibitive measures and to use the existing legal mechanisms ("third one out", price preferences, etc.).

- Lastly, it is important to create conditions and develop new forms and methods of localization, such as original design manufacturing, offset contracts, regional support measures, etc.

INCREASING THE AVAILABILITY OF INNOVATIVE MEDICINES WITHIN THE FRAMEWORK OF STATE MEDICINE SUPPLY PROGRAMS FOR CITIZENS OF THE RUSSIAN FEDERATION

Access to innovative medicines is the most important topic for the future of the healthcare system of Russia. Innovative medicines radically change the lives of patients with severe illnesses and enable them to pursue active lifestyles. Including innovative medicines into the state programs is an investment into the quality of life and life expectancy.

Over the last years, the Government of the Russian Federation has intensified regulatory activities to improve access to innovative medicines whose key producers are foreign ones. However, the level of innovative therapy provision is still insufficient. Over the last three years, only a quarter of innovative medicines approved by the European Medicines Agency (EMA) during the same period has entered the Russian market.

The main issue is the current regulation of the system of incorporating innovative medicines into the public system, which focuses on the cost of medicines rather than on their clinical efficiency and their impact on the quality of life and life expectancy.

The state program for the treatment of high-cost nosologies (hereinafter the "HCN Program") adopted in 2008 under Decree of the Government of the Russian Federation No. 1416 led to a revolutionary breakthrough in the availability of innovative medicines for treating the most severe high-cost diseases. Today, this program still needs further development and optimization. The criterion of "no negative impact on the current budget of the HCN Program during the first year and the three-year planning period" when considering proposals for including medicines in the expensive medicines list (Resolution of the Government of the Russian Federation No. 871 of August 28, 2014) is a significant and often insurmountable obstacle for innovation.

Another obstacle is the features of the current procurement system. In accordance with the provisions of Federal Law No. 44-FZ of April 5, 2013, procurement of medicines is carried out mainly via electronic auctions by reducing the initial (maximum) price. The auction method only makes it possible to have the lowest possible bid price if there are several participants offering a medicine that has the same international non-proprietary name (hereinafter the "INN") and is most suitable for purchasing generic (biosimilar) medicines. An innovative medicine has a unique INN. In this regard, organization of tender procedures is not efficient in its goal of reducing the price yet holding the auction requires time and organizational costs on the customer's part.

RECOMMENDATIONS

- Introduce a differentiated approach to assessing innovative medicines when preparing lists of medicines for human use and the minimum range of medicines required for healthcare delivery, taking into account their long-term impact on the quality of life and life expectancy and excluding the criterion of negative impact on the budget for this category of medicines.

- Develop and implement a mechanism enabling the transfer of medicines that have registered analogs in the Russian Federation from the HCN Program to other medicine supply programs in accordance with their profile (hospital, outpatient segment) while maintaining their availability in accordance with the actual need.

- For innovative medicines under patent protection, provide a differentiated mechanism for setting prices stipulated by law: the maximum selling price according to the current rules when included in the list of vital and essential medicines, and a separate confidential maximum selling price when included in the HCN list which is not public and is not taken into account when registering in the State Register of Maximum Selling Prices.

- Establish an interdepartmental platform on the basis of the Ministry of Health of the Russian Federation for the purpose of negotiating with manufacturers to enter into agreements of various models for innovative medicines procurement.

- Develop a legal instrument that makes it possible to prepare proposals and set the obligations of the parties when entering into agreements supported by the interdepartmental platform.

- Complement and improve the laws on procuring medicines: introduce long-term contracts between government customers and medicine manufacturers, risk-sharing and cost-sharing contracts as well as procurement of reference patented medicines without electronic auctions.

- Implement a flexible mechanism for setting the budget of state programs based on the assessment of medical technologies as well as of patients' actual needs as reflected in the single register of beneficiaries while applying digital data processing technologies.

OTHER ISSUES

- Impact of the COVID-19 pandemic on the pharmaceutical industry.
- Implementation of the automated medicine circulation monitoring system.
- Issues related to registration of orphan medicines.
- Possibility of recognizing the results of clinical trials held abroad following assessment (examination) of lack of scientifically grounded need for participation of local clinical centers in a clinical trial.
- Ensuring free circulation of medicines registered in accordance with the EAEU requirements in the Customs Union.
- Lack of uniformity in the EAEU's certificates of GMP conformity issued by the authorized agencies of Belarus and the Russian Federation.
- Ways to improve the methodology for calculating the maximum selling prices of manufacturers for medicines included in the list of vital and essential medicines.
- Public procurement of medical equipment: application of items in the catalog of goods, work, and services to meet governmental and municipal needs.
- Confirmation of Russian production of medical equipment.
- Harmonizing descriptions of medical devices with the nomenclature directory of medical devices by type.

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