

Position of the Health Care Committee of the European Business Association concerning provision of medical drugs to Ukrainian population and also, the issues of medical drugs accession, circulation and circulation control

The Health Care Committee of the European Business Association has been a consistent proponent of introducing the European standards on accessibility of products to consumers, which are based on the factors of effectiveness and safety, pharmacotherapy optimization, control over drug prescriptions and use of funds.

The key criteria affecting provision of effective and safe medical drugs to Ukrainian population are as follows: registration of medical drugs, control over their circulation, pricing policy and also, promotion and advertisement of medical drugs.

Medical drug registration

In execution of the requirements of negotiation processes on Ukraine's accession to World Trade Organization, appropriate amendments were made to the laws of Ukraine, including the ones concerning **accession** and circulation of medicines in Ukraine. Major changes are related to the protection of intellectual property rights and quality of the medicines (amendments to Art. 9, Law of Ukraine On Medical Drugs), admitted for the use in Ukraine, as follows:

- state protection of the information contained in applications for state registration of medical drugs and attachments thereto from disclosure and unfair commercial use;
- 5-year ban, upon registration of a medical drug in Ukraine, (despite the term of validity of any patent pertaining to the medical drug) to use registration information in submitting an application requesting state registration of another medical drug, apart from where the right to refer to or use such information has been duly obtained;
- disciplinary, administrative, civil and/or criminal responsibility, according to the laws of Ukraine, of responsible parties for disclosure, unlawful use of registration information;
- submission of appropriate documents associated with the declaration concerning holding third parties indemnified where registration of medical drugs is concerned, and also, submission of a copy of a patent or license allowing manufacture and trade of registered medical drugs (for state registration of medical drugs, which are based on or pertain to objects of intellectual property);
- issuing decision concerning a complete or temporary ban on the use of the medical drugs by the Ministry of Health or an authorized entity where unsafe features, as unknown before, have been identified;
- refuse state registration, where such registration will violate the current property rights of intellectual property, as protected by a patent, including during the manufacture, use and trade of medical drugs.

Amendments to Resolution N 376, of CMU of 26.05.05 On Approval of State Registration (re-registration) Procedure for Medical drugs and Fees for their State Registration (re-registration) were associated with the level of expertise and independence of expert examination of registration materials, medical drugs submitted for registration, and also, pre-qualification of medical drugs manufacture. Such amendments have made another step toward harmonization with global practices: that kind of inspection is a standard procedure in accordance with the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S). The pre-qualification tool will enable more stringent control over medical drugs at the stage of accession of such drugs to the Ukrainian market.

Presently, additional changes are being prepared to almost fully harmonize both the Procedure of Medical Drugs Registration in Ukraine (Order MOH N 426 of 26.08.05 On Approval of Procedure for Conducting Expert Evaluation of Materials Pertinent to Medical drugs which are Submitted for State Registration (Re-Registration) and Expert Evaluation of Materials about Introduction of

Changes to the Registration Documents during the Validity Period of Registration Certificate) with the European standards and WHO recommendations. The definitions of «generic medical drug» (article 10 (b) of the EC Directive 2001/83/1) and «innovational medical drug» will be incorporated to be in full compliance with Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medical drugs for human use. The definition of “independent”, “full-time” and “part-time” expert will prevent potential unfair commercial use of the information submitted for registration in the future. The new regulation concerning requirements to applicants (marketing authorisation holder) will eliminate the current gaps in possibilities to register imported medical drugs by entities having no appropriate resources to support pharmaceutical supervision in Ukraine, i.e., being incapable of ensuring a required level of responsibility for the effectiveness, quality and safety of medical drugs according to the current laws of Ukraine and international recommendations.

Control over the quality of medical drugs

Ukraine has resumed membership negotiations with the secretariat of Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S²). If Ukraine gains membership in PIC/S, Ukrainian authorized entities will obtain access to the Co-operation Scheme database, which will enable cutting away unqualified drugs at the stage of registration. Such procedure will also help to improve coordination between the quality assurance and market accessibility entities. The PIC/S membership benefits for regulatory authorities are as follows: international harmonization of GMP requirements, high standards, trainings, Rapid Alert System, exchange of information, involvement in drafting and execution of other agreements, including benefits for the industry, membership of regulatory authorities, reduced duplications in evaluations, cost efficiency, increase of export operations, enhancement of market accessibility.

The statements of CMU Resolution N 902 and MOH Order N 391 On Approval of Order on Medical Drugs Production Certification have created conditions of inequality between importers of medical drugs to Ukraine and local manufacturers. The procedure for state control over the quality of medical drugs imported to Ukraine, approved by CMU Resolution N 902 of 14.09.05 On the Approval of the Order of the State Control over the Medical Drugs Quality Imported in Ukraine, contains specific statements (a mandatory requirement for having a GMP (good manufacturing practices) Certificate of Compliance of a manufacturer/fabricator), which do not meet the requirements and general principles of the World Trade Organization, of which Ukraine is a member.

MOH Order N 391 defines certification of manufacturing medical drugs compliance with good manufacturing practice, including recognition of GMP certificates, issued by PIC/S member nations as an optional, i.e., not mandatory, requirement. The requirement for manufacturing of medical drugs to comply with good manufacturing practice will become mandatory for Ukrainian manufacturers on 1 January 2009 according to CMU Resolution N 1419 of 28.10.04 «Specific activities pertaining to quality assurance of medical drugs», which will eliminate existing discrimination.

Therefore, presently we are facing unequal business conditions for Ukrainian manufacturers and importers of medical drugs. To settle this issue, we propose suspension of paragraph 5, Item 5, and paragraph 7, Item 9 until Item 1 of Resolution N 1419 of CMU of 28 October 2004 «Specific activities related to quality assurance of medical drugs» comes into force.,

¹ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code Relating to Medical drugs for Human Use (amended by Directive 2002/98/EC, Directive 2004/24/EC and Directive 2004/27/EC)

² The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) are two international instruments between countries and pharmaceutical inspection authorities, which provide together an active and constructive co-operation in the field of GMP. PIC (Pharmaceutical Inspection Convention) was founded in October 1970 by EFTA (European Free Trade Association) under the title of “The Convention for the Mutual Recognition of Inspections in Respect of the Manufacture of Pharmaceutical Products”.

Promotion of medical drugs

A divergence between the consumption structure and sickness rate in Ukraine resulting from, *inter alia*, ineffective regulation of promotion and advertisement of medical drugs, is a problem area in the industry. The European Business Association has fostered development and implementation of the Rules of promotion of medical drugs and medical purpose items by pharmaceutical companies to health care professionals by the State Service of medical drugs and medical purpose items. The Rules, which are based on corresponding Directive 2001/83/EC, will enable settlement of the issues of drug prescriptions and cease unjustified motivation and influencing doctors.

Besides, improvement of the system of coordination of advertisements of nonprescription drugs in mass media will enable optimization of the consumption of drugs of this group and reduce the impact of advertisement on consumption. Such system of approval and coordination of advertisement messages should not create another center of corruption and restrict the right of consumers to obtain information concerning this group of drugs via mass media.

The implementation of treatment standards and Rules of promotion in accordance with EC Directive and corresponding European regulations will establish a foundation for countering excessive prescriptions and unjustified shift of consumption.

Pricing

A growing medical consumption in recent years following the increasing purchasing capacity of the population, increasing public funding of health care and additional funds require a systematical approach to the effective use of resources in the industry, as well as rendering effective and safe medical services to Ukrainian patients.

Besides regulation of drugstore mark-ups, which have been reconciled within the MOH working group including the public and EBA, there are other factors affecting these issues. The process of growing consumption due to higher quality and more effective products clearly reflects the tendency to prescribe more effective and recognized from the pharmaceutical perspective drugs. It's important to note that prices on medical drugs in the segment of imports from EU countries have hardly changed, and higher prices in national currency have resulted from changing rates of EURO to UAH.

The subject of registration of prices on medical drugs has been continuously discussed at meetings. Taking into consideration the European experience, it is possible to state that state regulation of prices on medical drugs (less trade mark-ups) can only exist, when there is a system of reimbursement of outpatient consumption of medical drugs in place – a so-called reimbursement system.

Compensations in outpatient consumption of vitally important drugs – a reimbursement system

Introduction of the system of reimbursement in outpatient consumption of vitally important drugs (like the so-called reimbursement system existing in European countries) will enable introduction of the system of declaration/registration of prices on the drugs to be consumed within the framework of this reimbursement system.

The first steps toward development and implementation were made in 2008. The Ministry of Health of Ukraine established a working group to develop a state system of reimbursement for drugs (insulin) for diabetes patients (endorsed by Order of the Ministry of Health of Ukraine No. 188 of 8 April 2008). The EBA Health Care Committee is a member of this working group. During the first meeting on 8 April 2008 the parties agreed to establish two sub-groups (consisting of

members of this working group) for medical, economic and organizational issues. Up to date a Draft Resolution of CMU has been developed to approve the following:

1. Procedure for reimbursement of drug-related (insulin preparations and its analogues) costs to drugstores;
2. Regulation concerning a Public register of diabetes patients;
3. Regulation concerning a Public register of registered (re-registered) drug prices (insulin preparations and its analogues).

The implementation of this project in pilot regions in 2009 will help to finalize the reimbursement mechanism and introduce such reimbursement mechanism of using budgetary resources on the national level in 2010.

According to the Health Care Committee of the European Business Association, presently there is a clear procedure of drug registration in place, and it has almost been harmonized with the European one. What needs improvement is to identify the level of production of drugs to be submitted for state registration, and also, the system of drug circulation upon their registration in Ukraine.

To settle the above problem areas, we propose the following:

1. to align protection of the term of validity of data exclusivity for a medical drug registered in Ukraine (adopt the 10+1-year scheme) with the European standards;
2. pass amendments to MOH Order N 426 (they are currently going through the final approval phase);
3. consolidate procedures for registration and expert evaluation of manufacture of medical drugs to be submitted for registration, via incorporation of the outcomes of GPM inspection conducted by the State Service of medical drugs and MPI's or a correspondent PIC/S member nation institution. Develop and adopt a medical drugs manufacturing inspection procedure during expert examination of registration materials, and where a GMP certificate issued by the State Service or a PIC/S member nation is not available – conduct manufacturing re-qualification;
4. obtain membership in Pharmaceutical Inspection Co-operation Scheme (PIC/S);
5. develop and adopt a new Law of Ukraine «On Medical Drugs» taking into account the current environment;
6. improve the procedure of importing medical drugs to Ukraine and their authorized accession to retail system (CMU Resolution N 902 and Order, MOH Ukraine N 391);
7. introduce the system of reimbursement in outpatient consumption of vitally important drugs;
8. introduce medical treatment standards;
9. introduce mandatory medical insurance and foster development of private insurance.