REGULATION PHARMACEUTICAL INDUSTRY IN JORDAN

Malek Valid Ahmad Al-Khalaf, Makarova O. E.
National University of Pharmacy, Kharkiv, Ukraine
MakarovaOlgaEv@gmail.com

Introduction. Jordan is considered a pioneer in the Arab world from the perspective of the pharmaceutical industry, since the first pharmaceutical factory was founded in Jordan in 1962. Since then, the volume of the pharmaceutical industry in Jordan has increased significantly: as of January 2016 are 17 pharmaceutical companies, pharmaceutical manufacturers. In Jordan, the dynamically developing production of pharmaceutical and cosmetic products, 70% of which are exported to other countries. Cosmetic products based on Dead Sea salts and dirt are exported to many European countries. In Jordan, there is no local manufacturing capacity for certain therapeutic groups of drugs – such as cancer drugs, vaccines.

Aim. Our research has focused on the issue of theoretical analysis of pharmaceutical industry in Jordan.

Materials and methods. We used empirical methods: observation and comparison; and methods of experimental and theoretical: logical analysis, the hypothetical synthesis of theoretical generalizations.

Results and discussion. Local pharmaceutical manufacturers carry out contract manufacturing for major international pharmaceutical companies, but now it is less than 5% of the revenue of the pharmaceutical sector as a whole.

All 17 of the Jordanian pharmaceutical companies have been certified in accordance with GMP standards of the WHO. Two of pharmaceutical companies have FDA certified, and 7 – EMEA certified. Despite the high level of the local manufacturing sector, pharmaceutical production goes to foreign markets at a lower level in the overall scheme of the world's supply. Major pharmaceutical companies, which owns a number of factories producing medicines in Jordan:

- The Arab Pharm. Mfg. Co. Ltd
- Dar Al Dawa Development & Invst. Co
- Hikma Pharmaceuticals
- The Jordanian Pharm Mfg. Co.
- Arab Center for Pharm. & Chem.
- Hayat Pharm. Ind. Co. Ltd
- Middle East Pharmaceutical and Chemical Industries Company

Organization of Jordan Food and Drug Administration (FDA) is responsible for the registration of pharmaceutical products, including those for the quality assessment of clinical trials, bioequivalence studies for pricing, organization of accreditation of pharmaceutical manufacturers to promote rational use of medicines and pharmacovigilance and post-marketing monitoring.

JFDA put forward stringent requirements for the registration of new drugs and usually attracts for a decision on the registration status of the recognized world authorities such as the U.S. Food and Drug Administration US (FDA) and European Medicines Agency (EMA). Registration of any drug requires the drug sold by at least 1 year in the country of origin, or any system JFDA country. According to the bylaws JFDA, registration of a new drug should be completed in less than 180 working days. The average registration time is about 90 days. The price for registration of drug registration is 1500 JD (about US $ 2,000) for new chemical substances and 400 JD (about US $ 550) for the generic drug. JFDA has a modern well-equipped laboratory for quality control of drugs and substances, which has 56 staff employees.

Pharmaceutical company provides detailed information on the drug, which comprises the chemical structure, pharmacological and chemical properties, classification according to the Anatomical Therapeutic Chemical Classification regarding the therapeutic activity of the drug and its active ingredients on the organs or organ systems, to which they affect

Conclusions. JFDA bylaws regulate the drug, which stayed in the pharmaceutical market for more than two years and the number of issued more than seven consecutive batches of appropriate quality, should not necessarily be subjected to quality control for each party, and shall be subject only to the selective quality control. However, for medicines purchased by public sector institutions, JPD requires quality control of each series. Process pricing controlled JFDA, based on the external reference prices taking into account the price of the drug in the country of origin and in 16 countries studied (particularly in the UK and France), in Saudi Arabia. Therefore, this process can lead to the prices on the products will be higher on average than in some neighboring countries (such as in Egypt). To register a new drug it is analyzed in the laboratory to control the quality of JFDA. After confirmation of the quality of medicines and laboratory tests of collecting complete dossiers, files are transferred in JFDA technical committee to study, review and approval. The approval process for new products takes about 12 months.

Accelerated registration procedure may be requested for essential drugs. In these cases, the approval process can take as little as 6 months. In order to pass the accelerated registration procedure, the drug should be included in Rational Drug List Jordan. If the drug is approved for Rational Drug List, public hospitals can send their requests to the Department of Procurement Jordan. JFDA may issue a special permit for the import of medicines which are not registered in Jordan, but have already been registered by the US FDA or the EMA, if proved urgent need on the basis of a full dossier of the case, including recipes from the specialized doctor. Patients in this case pay the international price of the drug, which is fixed by a pharmaceutical company in the country of origin.