

**20.12.2019 TARİHLİ VE E.220773 SAYILI İLAÇLARIN PIYASADA BULUNABİLİRLİĞİNİN
SAĞLANMASI, ENG**

MINISTRY OF HEALTH OF THE REPUBLIC OF TURKEY Medicines and Medical Devices Agency
of Turkey

Number : 16358815-000-E.220773 Subject : Ensuring Market Availability of Medicines
NORMAL

20.12.2019

ASSOCIATION OF RESEARCH-BASED PHARMACEUTICAL COMPANIES Söğütözü, 2176. Sk.
Platin Tower Business Center No:7 D. 52-55, 06700 Çankaya / ANKARA

Patient complaints are received by the Department of Economic Evaluations and Medicine Supply Management of our Agency regarding non-availability of some medicines on the market despite being registered in Turkey. In order to ensure that patients are not negatively impacted within the framework of annexed circular and considering the interests of our country as well, it is necessary to notify us until the 10 th day of each month the names of the products (of the previous month); - for which registration cancellation has been requested, - which cannot be placed on the market due to the reasons associated with the manufacturing site of the active substance or the manufacturing site of the product, - which have recently received registration but cannot yet be placed on the market as they expect their sales permit, - which expect to receive their price and thus cannot be placed on the market; furthermore, it is necessary to notify us at least 1 month ahead on when these products will be placed on the market to ensure that no negative impact is incurred. It was communicated with all relevant stakeholders via the letter dated 22.06.2017 that in case of failure to supply products which are on the market, it is necessary to notify us at least 3 (three months) before product stock-out. However, it was identified that some companies do not duly make such notifications. I hereby submit for your information and kindly request for the relevant action to ensure that due care is displayed regarding this topic and that the referred matters are communicated to the member companies of your association.

Dr. Hakkı GÜRSÖZ President of the Agency

Annex: 1- Circular on Market Availability of Medicines (2 pages)

DISTRIBUTION: 1- Pharmaceutical Manufacturers Association of Turkey (IEIS) 2- Association of Research-Based Pharmaceutical Companies of Turkey (AIFD) 3- Turkish Pharmaceutical Industry Association (TISD) 4- Self-Care Products Association (SURDER) 5- Association of Innovator Pharmaceutical Companies (GIFD)

MINISTRY OF HEALTH OF THE REPUBLIC OF TURKEY Medicines and Medical Devices Agency
of Turkey

Internal Correspondence No. : İY 20459 – 1499501 Internal Correspondence Date :
20.11.2014 Number : 75642246-506.99 Subject : Market Availability of Medicines

CIRCULAR 2014/11 As known, article 56 of the Constitution guarantees the “right to health” and the State is assigned with the duty to plan healthcare institutions and provide healthcare services for the purpose of fulfilling this right. This task assigned to the State for “healthcare services” with the referred provision is executed via our Ministry and its affiliated institutions as per Decree Law dated 11/10/2011, with No. 663, on the Organization and Duties of the Ministry of Health and its Affiliated Institutions. Within this scope, the following statement is stipulated in items (a) and (d), respectively, of clause two, article 2 of the Decree Law No. 663, where the duties of the Ministry are indicated: (a) “Protection and development of public health, mitigation and prevention of disease risks”; (d) “Ensuring availability of the medicines, special products used in healthcare services, substances subject to national and international control, active substances and excipients used in pharmaceutical production, cosmetics and medical devices in a safe and high quality manner, their provision to the public and designation of their prices”. Also the following tasks, stipulated in items (a) and (d), respectively, of clause two of article 27 of the same Decree Law are indicated to be among the duties and powers of our Agency: (a) “To designate the

rules and standards of the regarding the registration, production, storage, sales, import, export, market supply, distribution, putting into service, collection and utilization of the products included into its sphere of duty, to authorize, grant registration to, inspect and apply sanctions, where necessary, and conduct or commission the conduct of laboratory analyses of public and private and legal entities and real persons that will carry out these activities”; (d) “To adopt relevant measures for ensuring continuous availability on the market of medicines, medical devices and products of vital importance”. Thus, the production, import, market supply, quality, content, promotion and similar matters related with medicinal products for human use in our Country are essentially regulated by Law No. 1262 on Pharmaceutical and Medicinal Preparations; the individual provisions in this Law clearly foresee that during the production, export of medicinal preparations, their provision to and utilization by the patients, medicines are duly produced, are not open to degradation, avail of the therapeutic qualifications reported in line with their formulation as detected by analyses and tests and do not give rise to any health issues when used and authorize and thus keep liable our Agency for ensuring that preparations are freely sold with or without the need for a physician’s prescription and designating and specifying how the medicine will be used as well as other matters. As per abovementioned provisions, our Agency is assigned with and authorized to execute the registration transactions of manufactured and import medicines and adopt any kind of measure for ensuring market availability of medicinal products for human use which have a vital importance and are indispensable.

Within this framework, the production, import, export and market availability of medicinal products for human use, prepared for the purpose of treating and/or preventing a disease, making a diagnosis or correcting, restoring or modifying a physiological function, is important in terms of public health. Hence, prior to the market introduction of medicinal products for human use in our Country, the demand for such medicines is identified upon making a market research and medicines are produced and placed on the market accordingly. Prior to the market supply of these products, the manufacturing site comprising all production phases of the products are inspected by our Agency as per the provisions of the Regulation on the Registration of Medicinal Products for Human Use, a GMP Certificate is issued to the manufacturing sites identified and certified to carry out production within the framework of Good Manufacturing Practices and import is allowed only for products fulfilling these conditions. Essentially, as medicinal products for human use are directly related with human health unlike many products and are thus associated with public health, our Agency is actually responsible for and authorized to regulate and inspect the procedures and principles of this field and, hence, considering the fact that the procedures required before the market placement of the referred products in accordance with the relevant legislation are very costly and time-consuming and the importance of their market placement and availability in terms of public health, it is necessary and mandatory for our Agency to adopt relevant measures in this field. Thus, the State intervenes directly or indirectly in medicine prices and thus prices in the pharmaceutical sector are not composed under free market conditions. Therefore, considering that the pharmaceutical sector is a sector with significant price difference between countries, it is also obvious that price variability between countries will make importation between these countries profitable which is an important topic for the pharmaceutical sector. Under these conditions, the exportation of the medicinal products for human use, permitted to be manufactured and imported for our Country, to other countries after their market placement prevents the market availability of these products thus giving rise to major problems in the procurement of medicines at a sufficient amount to our patients and causing a significant threat for public health. As such, in order to ensure market availability of medicinal products for human use permitted to be imported on the basis of the need in our Country and considering the public health and service requirements, it is not suitable for the referred import products to be sent to the markets of other countries by taking them out of the country, and all relevant measures, including barriers via the system, will be adopted. I hereby submit for your information and kindly request for the conduct of relevant action. Dr. Saim KERMAN President of the Agency