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Obligation to Apply for and Obtain Marketing Authorization is regulated for the Drugs Supplied from Abroad on a Named Patient Basis

The Omnibus Bill Amending Some Laws and Decree-Laws related to Health ("the Bill") is published on the Official Gazette dated 5 December 2018 and numbered 30616.

Article 1, 2, 3 and 4 of the Bill amended the Law on Commercial Pharmaceutical Warehouses and Shops that Sell Poisonous Chemical Substances Used in Arts and Agriculture ("Law on Warehouses") numbered 984, Article 8 of the Bill amended the Pharmaceuticals and Medical Preparations Law numbered 1262 and Article numbered 31 and 33 amended the Veterinary Services, Plant Health, Food and Feed Law numbered 5996. In this context, the law introduces new regulations, especially for drugs, pharmaceutics and dietary foods for special medical purposes.

The Outstanding Amendments Brought by the Bill

- Supply from abroad of the medicinal products for human use which do not have marketing authorization or have marketing authorization but is not available in the market for various reasons shall be made by the Social Security Institution and the Turkish Pharmacists' Union as well as by institutions / organizations deemed appropriate by the Ministry of Health.

- For products supplied from abroad, it is mandatory to apply for marketing authorization within three years from the date of entry into the Foreign Drug List and it is also mandatory to obtain marketing authorization within two years from the date of application for marketing authorization. However no sanction has been determined in case this rule is breached. After the completion of the given durations, the President of the Republic is authorized to decide on the continuation of the supply of drugs which did not obtain a marketing authorization or for which no marketing authorization application is filed. For the products which were supplied from abroad prior to the entry into force of the Bill which is 5 December 2018, the application period for marketing authorization and for the products that were previously applied for marketing authorization the period to obtain a marketing authorization begins from 5 December 2018.

- In case of non-compliance of the provisions of the Law on Warehouses, it is regulated that the sanctions to be applied shall be imposed by the Turkish Medicines and Medical Devices Agency ("Agency") as well as the local health administration.

- It is set forth that the examinations and analyzes to be carried out for the drugs shall be carried out in the laboratories authorized by the Ministry of Health as well as the Ministry of Health itself.

- The authority to impose administrative fines and sanctions mentioned in the Veterinary Services, Plant Health, Food and Feed Law is no longer in the Provincial Agriculture Directorate, but it is given to the Agency and the local health authority. Additionally, when an administrative fine and/or administrative sanction are issued by the Agency, the Agency shall inform the relevant local health authority.

Assessments

Among the legislative amendments made by the Bill, the amendments concerning medicines that are being supplied to our country from abroad based on the Named Patient Program ("NPP") procedure bring significant rules which raises question marks.

The Bill rules that the supply from abroad of pharmaceutical products without marketing authorization in Turkey or with marketing authorization but which are unavailable on the Turkish market for various reasons shall be made the Social Security Institution and the Turkish Pharmacists' Union as well as by institutions / organizations deemed appropriate by the Ministry of Health. However, it is noteworthy that for institutions and organizations deemed appropriate to supply drugs from abroad by the Ministry of Health, the selection criteria, features and with which regulation they shall be assigned is not stated in the Bill. Previously, the Ministry of Health had granted permission to supply from abroad to some warehouses, but the execution of the permission has been suspended by the decision of Council of State. It will become significant whether or not the institutions / organizations which will receive these new authorizations will be legally authorized to supply drugs from abroad.

In addition, in our opinion, it is not correct that without making any change in the regulation on the marketing authorization or NPP and by only amending the legislation on pharmacies, the obligation to obtain marketing authorization within 3 years after being listed in the Foreign Drug List and to obtain marketing authorization within 2 years after the application for the marketing authorization is set for the drugs that are included in the Foreign Drug List. The supply of drugs from abroad starts with the prescription of the product by the physician

and the request of the product from its manufacturer located abroad, by the Turkish Pharmacists' Union or the Social Security Institution, since the Ministry of Health is unable to meet this demand with licensed products which are available on the market in Turkey. The obligation to apply for marketing authorization in a certain period of time for the drugs supplied by such means, creates hesitations on the applicability of this obligation by the manufacturer located abroad, considering that there are no contractual obligations. In addition, the applicability of the obligation to obtain a marketing authorization within a certain period of time also creates hesitation, since the authorization process and its duration is not under the control of the marketing authorization applicant. For the drug which is prescribed for a patient by a physician, but for which no application for a marketing authorization has been filed or which did not obtain marketing authorization within the specified periods, the decision to continue the supply from abroad is left to the President of Republic's discretion.

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