Recent developments in named patient pharmaceutical supply programme

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Introduction

The Pharmaceutical and Medical Device Institution – established under the Ministry of Health – published new Guidelines on the Supply from Abroad and the Use of Pharmaceuticals in April 2014, which were amended in December 2014. The amendments – as well as developments at the Social Security Institution – introduce important changes to the named patient programme in Turkey.

The purpose of the guidelines is to determine the procedures and principles regarding the supply of pharmaceutical products from abroad that have no marketing authorisation in Turkey under their import permit or that have marketing authorisation but are not available on the Turkish market for various reasons. Although this type of import without marketing authorisation is an exception, it has increased considerably in recent years. The reasons for the increase in named patient programme imports are the lengthy regulatory approval process caused by the Pharmaceutical and Medical Device Institution's onsite good manufacturing practice inspection requirements and pressure from the Pharmaceutical and Medical Device Institution and the Social Security Institution regarding the price of pharmaceuticals.

The Ministry of Health is implementing a reference pricing system in which the maximum sales price of pharmaceutical products is determined by taking into account the lowest price among reference EU countries. The ministry also applies a fixed exchange rate that is approximately 30% lower than the current rate. Further, these prices – which are considerably lower than those in other European countries – may be used as reference by other countries. The Social Security Institution also requires public discounts for the reimbursed pharmaceutical products which range between 28% and 41%. These factors are important for a pharmaceutical company to consider when deciding whether to introduce a product to the Turkish market.

Legal framework

The new guidelines explicitly state that pharmaceuticals whose safety and efficacy have been proven in a sufficient number of scientific and clinical studies within the scope of relevant treatment guides, and which are granted market authorisation by the Pharmaceutical and Medical Device Institution, will be supplied by pharmacies. However, the institution must also determine and approve which active substances and pharmaceuticals not authorised in Turkey – or authorised but not available on the market – can be used and imported by suppliers from abroad.

In order for a pharmaceutical to be imported by such means, it must be added to the Foreign Pharmaceutical List, which is published on the Pharmaceutical and Medical Device Institution's official website. To include an active ingredient on the Foreign Pharmaceutical List, the application to the institution must be made by a physician and must include:

- a completed application form;
- a health committee report or medical use report sample;
- a patient consent form;
- literature showing a high degree of evidence that the product is effective and reliable; and
- background medical information regarding the patient's treatment.

If the application is accepted, it is published on the Pharmaceutical and Medical Device Institution's website, which is updated every Friday. Acceptance of an application is at the institution's discretion. The list also includes pharmaceuticals that must be stocked in Turkey and that are provided to the patient within one business day. The delivery period for these products may be set differently, taking into consideration the details of the product, when they are added to the list.

Supplier

The previous guidelines and practice allowed only the Pharmacists Association to import pharmaceuticals by such means. Together with the changes to the guidelines, the Pharmaceutical and Medical Device Institution has authorised 20 pharmaceutical warehouses to import pharmaceuticals from abroad on a named patient basis.

According to the new guidelines, pharmaceuticals will be provided by these suppliers from a warehouse authorised by the health authority in their country of origin or directly from the manufacturer in accordance with the regulations of the country from which the product is imported. To prevent the import of counterfeit products or illegal imports, suppliers must submit documents as part of the import application which confirm that the manufacturer is aware of the different phases that the product has gone through from manufacture to when it reached Turkey.

An agreement was first signed between the Social Security Institution and the Pharmacists Association in April 2007, which stipulates the reimbursement conditions for imported pharmaceuticals. So far, the Social Security Institution has included no such agreement with another supplier. Consequently, it is questionable whether and how products provided by suppliers other than the Pharmacists Association will be reimbursed by the Social Security Institution.

According to the agreement between the Pharmacists Association and the Social Security Institution, in principle, pharmaceuticals will be purchased from the manufacturer at an appropriate price. The Pharmacists Association is obliged to monitor the price of products and their equivalents and should give priority to the cheapest prices available.

The December 2014 amendments introduced provisions on liability. Accordingly, as most of the pharmaceuticals supplied by such means have not been granted marketing authorisation, the responsibility for compliance control lies with:

- the physician who prescribes the product;
- the suppliers that import the product; and
- the reimbursement institutions that decide to purchase the product by selecting from alternatives determined by suppliers.

Comment

The guidelines appear to provide new opportunities through which pharmaceutical companies can import pharmaceuticals without market authorisation. Although the products supplied through the Pharmacists Association are the only ones that can be reimbursed according to its agreement with the Social Security Institution, the opening up of the market to other distributors is a sign that this practice will continue. Nevertheless, from the perspective of public spending and promotion, companies should be prudent, as this practice will not be used as a means of introducing and promoting a product on the Turkish market. Companies that consider supplying products through the named patient programme need to consider that the Ministry of Health and the Social Security Institution are determined to reduce the number of foreign pharmaceutical imports according to the guidelines. One way to limit such practice is the Social Security Institution's initiative to invite pharmaceutical companies to sign a direct agreement in which the price and reimbursement conditions – as well as the timeframe for companies to apply for marketing authorisation – are mutually decided. However, for this initiative to succeed, the authorities need to find a way to accelerate the regulatory approval process and improve pricing conditions, or the supply of and access to pharmaceuticals will always be a problem for Turkey.

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