Changes in landscape of foreign supply of non-approved products

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In May 2016 the Pharmaceutical and Medical Device Agency – established under the Ministry of Health – amended the Guidelines on the Supply from Abroad and the Use of Pharmaceuticals, which changed the practice of the Named Patient Programme (NPP) in Turkey. Supplying non-approved or unavailable pharmaceutical products from abroad is an exceptional route under the NPP. However, increased regulatory and price pressures in recent years have resulted in more products becoming unavailable on the Turkish market, which has led to changes to the supply rules.

NPP practice

In Turkey, the law explicitly states that pharmaceuticals whose safety and efficacy are proven through sufficient scientific and clinical studies within the direction of existing treatment guides, and which are granted market authorisation by the Pharmaceutical and Medical Device Agency must be supplied only by pharmacies. However, the agency is also competent to determine the procedures and principles applicable to the supply from abroad of pharmaceutical products without marketing authorisation in Turkey or with marketing authorisation but which are unavailable on the Turkish market for various reasons.

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 Agency's official website and updated every Friday. To include an active ingredient on the Foreign Pharmaceutical List, a physician must file an application to the agency. Acceptance of an application is at the agency's discretion.

The recent amendments to the guidelines were intended to return to the previous practice, under which only the Pharmacists Association could import pharmaceuticals from abroad within the scope of the NPP. The former guidelines allowed 20 pharmaceutical warehouses authorised by the Pharmaceutical and Medical Device Agency to import pharmaceuticals from abroad on a named patient basis, as well as the Pharmacists Association.

According to the guidelines, the Pharmacists Association is expected to import these drugs within the scope of the NPP in accordance with the priority order.

The Pharmacists Association shall import only in the order defined below:

- products that have an authorisation from the US Food and Drug Administration or the European Medicines Agency and are put on the market; or
- products manufactured, authorised and put on the market in a country that is a member of the Pharmaceutical Inspection Convention and the Pharmaceutical Inspection Cooperation Scheme.

If the relevant product cannot be found in or supplied from these countries, the commercial name of the product manufactured and used in another country can be added to the Foreign Pharmaceutical List following an opinion from the Scientific Commission and approval of the president of the Pharmaceutical and Medical Device Agency.

Legal and administrative actions

There is no doubt that the guidelines were issued for the sole purpose of importing products that patients need. However, the increase in supplies also increased the commercial stakes, which created conflicts between the Pharmacist Association and the authorised warehouses.

First, the 2015 amendment to the guidelines introduced some warehouses as new suppliers that were competitors to the NPP system. However, the changes to the guidelines had no legal basis. To overcome this hurdle, the provisions in the Warehouses Regulation regulating the sales conditions of warehouses were amended by the Pharmaceutical and Medical Device Agency in order to allow the retail sale of pharmaceuticals by warehouses. However, the Law on the Warehouses, which prohibits retail sales by warehouses, remained unchanged, thus leading to criticism and debate as to the enforceability of the guidelines and the Warehouse Regulation.

Several pharmacist chambers filed an administrative action against the Pharmaceutical and Medical Device Agency and requested the cancellation and the stay of the Warehouses Regulation's provisions enabling warehouses to perform retail sales. Although the action has not yet been finalised, the Council of State has ordered a stay of execution on the grounds that the amendments were unlawful.

As the Warehouse Regulation's relevant provisions were unenforceable, the guidelines continued to lack legal grounds until the publication of amendments in May 2016. The new version of the guidelines explicitly states that only the Pharmacists Association may import products under the NPP. Consequently, the agency has removed the authorisations granted to 20 warehouses to import products.

Reimbursement issues and competition scrutiny

The legal basis for warehouses to carry out retail sales through supply from abroad was not the only problem. The Social Security Institution, which covers 90% of Turkish patient health spending, is the biggest purchaser of pharmaceutical products, so the reimbursement of products supplied by the warehouses was another hurdle.

The Social Security Institution and the Pharmacists Association first signed a protocol in April 2007, which covered the reimbursement conditions for NPP pharmaceuticals imported by the Pharmacists Association. Following the authorisation of 20 warehouses in 2015, the industry expected similar protocols between the Social Security Institution and each supplier. However, such protocols were not negotiated and the Pharmacists Association remained the sole entity importing reimbursable products.

One of the authorised warehouses filed a complaint with the Competition Authority claiming that the Social Security Institution's practice of reimbursing only products imported by the Pharmacists Association violated the Competition Law.

The Competition Authority decided to investigate the matter and sent letters to the local affiliates of global pharmaceutical companies requesting information regarding the NPP practice, particularly regarding the content of any alternative reimbursement agreements signed by the global company with the Social Security Institution. During its examination, the main goal of the Competition Authority is to establish whether the Pharmacist Association has monopolised this practice by being the only party to a protocol with the Social Security Institution. The outcome of the investigation remains to be announced.

Comment

Although supplying non-approved or unavailable pharmaceutical products from abroad is exceptional, the practice has become more widespread in recent years, causing the Ministry of Health to amend the guidelines regularly. The increase in NPP imports is due to, among other issues:

- the lengthy regulatory approval process under the Pharmaceutical and Medical Device Agency's onsite good manufacturing practices inspection requirement; and

- increased pressures from the Pharmaceutical and Medical Device Agency and the Social Security Institution on pharmaceuticals prices.

Indeed, expenses from pharmaceuticals imported from abroad in 2015 made up 7% of Turkey's total budget of pharmaceuticals (TRY1.4 million).

Although the recent amendments to the guidelines have clarified the sale purchaser of such products from abroad, recent media reports have indicated that further changes may be on the horizon. The vice president of the Social Security Institution recently stated that in the new term, the Social Security Institution will start to import pharmaceuticals from abroad and intends partially to take over this practice from the Pharmacists Association. The Economic Coordination Committee has already held that the Social Security Institution should commence work to establish a social security health centre in Ankara and an agency in Istanbul to deliver these imported pharmaceuticals to Turkish patients. The various legal amendments required for such imports have not yet been drafted.

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