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Türkiye's Update: Key Changes in Named Patient Program

Pharmaceuticals that are not authorized in Türkiye or authorized but not available on the market shall be procured from abroad as per a special authorization and on a case by case basis (Named Patient Program-NPP). This supply can be conducted by public institutions approved by the Ministry of Health that are defined as Foreign Pharmaceutical Suppliers (Suppliers) and currently constitute of the Social Security Institution and the Turkish Pharmacists Association. The Suppliers can procure the product from a foreign entity defined as the Pharmaceutical Drug Source, which shall have a Representative based in Türkiye.

On April 17, 2024, the Guidelines on Supply of Pharmaceuticals from Abroad (Guidelines), which contains the guiding provisions regarding the implementation of the Regulation on Supply of Pharmaceuticals from Abroad (Regulation) is amended.

The applications for first-time use of a pharmaceutical are made by the treating physician before the Medicines and Medical Devices Agency (Agency), based on the reasoned decision of a council consisting of at least three specialist physicians related to the patient's illness. Pursuant to the new amendments, in the first-time use applications, the Commission for the Evaluation of the Use of Medicinal Products in Personal Treatment (Commission) shall further evaluate the authorities by which the pharmaceutical is authorized, its availability in the market, and its compliance with regulatory requirements. The first-time use applications approved by the Commission shall be submitted to the Foreign Medicines Evaluation Board (Board) of the Agency. After the Board's approval, the pharmaceutical containing the relevant active ingredient and form may be supplied by Suppliers.

Another change stipulates that in cases where the authorized product is included in the reimbursement list of the Social Security Institution but is not available on the market or is not available in sufficient quantity, the procurement of the pharmaceutical containing the relevant active ingredient can be supplied through NPP upon the decision of the Pharmaceutical Supply Planning Commission of the Agency and the Board. Therefore, in the event that the pharmaceuticals that are currently supplied to patients through the NPP obtains a marketing authorization in Türkiye, their supply from abroad may be continued the product becomes accessible on the market.

Given Türkiye’s current economic situation, it is more difficult for products to reach or be available on the market. The Social Security Institution faces financial difficulties when it supplies goods from overseas through NPP; as a result, innovative ideas are developed

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and put into practice to establish a different kind of procurement where the goods are provided free of charge.