Drug Reimbursement Practices

We come across constantly on the street, on the Internet, in the cafés when we go to buy coffee with donation campaigns carried out to cover the costs of patient treatments. Although it is essential for the state to cover the health costs in accordance with the constitutional principle of the social state, we encounter with more news of uncovered treatment costs.

For example, Spinal Muscular Atrophy, the disease known colloquially as SMA, results from the inability of patients' bodies to produce enough motor neuron protein. When this protein cannot be produced, the motor neurons gradually become smaller and eventually disappear. This causes fatal muscle weakness. However, the disease can be cured by treating the mutated gene that produces this protein. This definitive treatment, on the other hand, is very expensive and can be applied to patients who met certain criteria (age/weight). The state does not always cover the costs of this treatment.

So, how does the state decide which treatment costs and how much of them will be covered?

The Drug Reimbursement Regulation of the Social Security Institution determines the types, amounts, duration of use and the payment procedures and principles of the drugs financed by the Social Security Institution ("SSI") and the drugs requested to be financed. In other words, the provisions regarding which and how much of the drug costs used in a treatment are reimbursed are set in this regulation. The Drug Reimbursement Commission, established in accordance with this regulation, determines the drugs to be reimbursed and the payment procedures and principles for these drugs. These drugs are published in the lists annexed to the Social Security Institution Communiqué on Health Implementation ("CHI"). The drugs that are not licensed in Turkey, prescribed on a patient basis, and therefore obtained on prescription basis from abroad are also included to these lists.

Therefore, the reimbursement system is based on the rates clearly announced in the CHI, which were determined as a result of a unilateral evaluation by the SSI. However, even though drugs which do not have a marketing authorization in Turkey create a financial burden to the state, the state is expected to pay the costs for the drug purchased abroad.

In recent years, there has been a need for a reimbursement model that allows the reimbursement conditions to be determined by joint negotiation between the pharmaceutical company and the SSI, especially in order to ensure that innovative drugs are included in the reimbursement system.

Alternative reimbursement models have become an important agenda in the health sector in Turkey, with the amendment made on the Social Security and General Health Insurance Law in September 2014. With the Alternative Reimbursement Regulation ("Regulation") published in February 2016, it is aimed to encourage the production of product groups procured from abroad, which cannot be manufactured or not available in our country, to switch imported products to domestic production and to ensure their availability in the market.

With the Regulation, it is aimed to establish an alternative reimbursement model in which the SSI enters into direct contractual relationship with drug companies, and to ensure rapid access of the patients to especially innovative drugs in Turkey. In the alternative reimbursement model, the information regarding the price of the drug to be reimbursed is kept confidential. In these alternative models, the most important point that distinguishes them from the usual reimbursement system is that negotiations and the price of the drug is kept confidential. However, the secrecy of prices in the alternative reimbursement model has created various concerns in the eyes of other stakeholders in the sector.

The role of pharmacies, which take an active role in the ordinary drug supply chain, can be minimized in alternative reimbursement models. That is why, when the Regulation was published, the Turkish Pharmacists' Association (TEB) and the Union of All Pharmacist Employers (TEIS)

filed separate lawsuits against various provisions of the Regulation. It was claimed that especially the confidentiality provisions of the Regulation were against the public interest and the law.

However, the Council of State did not find that the provisions of the Regulation subject to the lawsuits were against the public interest or the law. The Council of State emphasized that alternative reimbursement models aim to ensure the sustainability of the financing of health services. Regarding confidentiality, it is stated that preventing the disclosure of the company's trade secrets are in no violation of the law.

Decisions in both actions were appealed. However, as a result of the evaluation made by the Board of Administrative Litigation Chambers (“IDDK”) of the Council of State, which examined the appeal, the legality of the provisions subject to the actions was not discussed. It has been confirmed that the SSI is the authorized administration in determining the payment methods and principles regarding the health services to be financed. However, as per legislation, the SSI is obliged to obtain the opinion of the Ministry of Health, before publishing a regulation on the financing of health services. Since the SSI failed to obtain such opinion before publishing the Regulation, the provisions subject to the action were annulled due to this formal deficiency.

In both cases, the entirety of the Regulation and alternative reimbursement models were not subject to the case and therefore are still in force. Only some provisions of the Regulation have been brought into the action. At this stage, it can be expected that this formal deficiency will be corrected by the SSI, and the relevant provisions will be republished exactly or slightly revised. In this context, alternative reimbursement models can be applied to include more drugs in the scope of the reimbursement. However, the failure of this important payment mechanism may pose the risk of stopping the reimbursement of various treatments, particularly as there are still patients which need to have access to these variety of treatments.