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New Regulation on Drug Reimbursement has been Published

The Social Security Institution's ("SSI") Regulation on Drug Reimbursement ("Regulation") was published in the Official Gazette no. 31934, dated 25.08.2022. With this new Regulation, the Social Security Institution Drug Reimbursement Regulation dated 10.02.2016 was abolished.

The most important amendments that came into force with the Regulation are the introduction of new definitions, new provisions regarding the prioritization of the applications for the reimbursement of some drugs and working principles of the Drug Reimbursement Commission.

1. New Definitions

New definitions are included in the Regulation. One of the most significant is the definition of Therapeutic Reference (TR) group which has been defined as a group consisting of more than one drug formed on the basis of price comparison between similar dosage forms of products containing active substance(s) that can be used for the same or similar indication, in a limited therapeutic equivalence.

In addition, biosimilar medicinal product, equivalent (generic) medicinal product and reference (original) medicinal product are defined in accordance with other legislation.

2. New Prioritization Rules

The Chairman of the Pharmaceutical Reimbursement Commission ("Commission") is authorized to prioritize reimbursement applications for various product groups:

The chairman of the Commission can approve the prioritization applications of the below groups to be handled in the ordinary/extraordinary meeting of the Commission, by evaluating the opinions created by Medical Economic Evaluations Commission ("TEDK"):

- Drugs that are difficult to supply and are of vital importance, issues that are closely related to public health and require urgent measures, drugs that are licensed and requested to be added to the Drug Reimbursement List from the drugs listed in the Foreign Drug Price List published by the SSI, and drugs in the same or similar pharmaceutical form containing the same active substance in the same amount as these drugs and other matters including the reasoned recommendations of the chairman of the TEDK; or
- For the first biosimilar medicinal product that has applied for inclusion in the Drug Reimbursement List and is found to have a unit price of at least 30% below the unit price of the reference drug listed in the drug price list.

3. New Regulations on Working Principles of the Drug Reimbursement Commission

In the old regulation, there was no provision regarding the deadlines for reimbursement applications, but with the Regulation the deadlines for the Commission working periods were determined as the last working day of March and August of each year. In addition, it has been regulated that, apart from company applications, applications made by institutions, organizations and individuals will be included in the agenda according to the working period.

It has been regulated that the Commission can evaluate the requests to hide the public institution discount rates (including private discounts) determined in the relevant article of the Communiqué on Health Implementation for the drugs on its agenda. Therefore, discount rates may be kept confidential in reimbursements applied according to this Regulation as well, as it was possible according to the alternative reimbursement model.

Evaluation

Upon the cancellation of some provisions in the Social Security Institution Alternative Reimbursement Regulation due to formal deficiencies with the decision of the Council of State, the SSI expected to update the Alternative Reimbursement Regulation by duly republishing the canceled provisions. Instead, the SSI revised the Regulation including these articles to be updated. With the innovations brought by the new Regulation, the confidentiality of the discount rates, which is important for alternative reimbursement models, will be ensured again.