MOROĞLU ARSEVEN

The Regulation Amending the Regulation on Drug Reimbursement of the Social Security Institution Has Been Published

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The Regulation Amending the Regulation on Drug Reimbursement of the Social Security Institution ("**Amending Regulation**") was published in the Official Gazette dated 28 November 2024 and numbered 32736, and entered into force as of its publication date.

The Amending Regulation provides certain amendments to the Regulation on Drug Reimbursement of the Social Security Institution ("**Regulation**"), that was entered into force upon its publication in the Official Gazette dated August 25, 2022, and repeating numbered 31934.

The important headings of the Amending Regulation are as follows:

- The definition of "Equivalent/Therapeutic Reference band range" was removed and the definition of "Band range" was added. Within the scope of the definition, the cheapest of the drugs in the groups formed within the scope of the internal reference pricing application will be taken into consideration in determining the band range.
- By adding the definition of group, it has been regulated that it refers to the groups that include generic groups and will be regulated within the scope of the internal reference pricing application in the Health Implementation Communiqué.
- The term therapeutic reference group in the definition of market share has been replaced with internal reference pricing group in the new text.
- The number of representatives to be appointed by the Ministry of Treasury and Finance in the Drug Reimbursement Commission was increased from 2 to 3, and the total number of members from 9 to 10.
- The number of annual meetings of the Drug Reimbursement Commission was increased from 2 to 3. The deadlines for the Commission's working periods have been set as the last working day of March, July and November of each year.
- The Drug Reimbursement Commission was assigned the task of deciding on the grouping of medicines financed and requested to be financed by the Social Security Institution ("Institution") within the scope of internal reference pricing.
- The requirement of being 30% cheaper for the first biosimilar medicinal product of the reference medicinal product that does not have a group in the Drug Reimbursement List has been removed.
- Drugs that are found to have received non-refundable prices will be inactivated with the approval of the Chairman of the Reimbursement Commission. In the event that the drug with a non-reimbursed price is included as reimbursed, upon application to the Agency for activation by the company, it may be activated with the approval of the Chairman of the Drug Reimbursement Commission, provided that the public prices do not exceed the public price on the date of inactivation.
- According to the Regulation on the Withdrawal of Human Medicinal Products and Foods for Special Medical Purposes published in the Official Gazette dated 23/10/2024 and numbered 32701 published

by the Turkish Medicines and Medical Devices Agency, no action will be taken in the payment lists since the procedures for the 1st class A level withdrawal of drugs are carried out by the said Ministry.

It is understood that the Amending Regulation removes all references to the term "Therapeutic Reference (TR)" and introduces internal referencing.

The full text of the Amending Regulation can be reached through this link. (Only Available in Turkish)

Related Attorneys

- EZGİ BAKLACI GÜLKOKAR, LL.M.
- MELİS YILMAZ TÜRKÖZ
- SELEN AKSAKAL