

**REGULATION ON THE ESTABLISHMENT AND DUTIES OF THE SCIENTIFIC ADVISORY
COMMISSIONS AND BOARDS OF THE TÜRKİYE MEDICINES AND MEDICAL DEVICES AGENCY (1)**

SECTION ONE Purpose, Scope, Legal Basis and Definitions Purpose

ARTICLE 1 – (Amended: OG-9/2/2023-32099) (1) The purpose of this Regulation is to determine the procedures and principles of the scientific advisory commissions and boards that will provide scientific advisory services in the operations and transactions carried out by the Türkiye Medicines and Medical Devices Agency.

Scope

ARTICLE 2 – (Amended: OG-9/2/2023-32099) (1) This Regulation covers the scientific advisory commissions that will provide scientific advisory services in the operations and transactions carried out by the Agency, the boards to be established within the Agency, and their members.

Legal Basis

ARTICLE 3 – (1) This Regulation has been prepared on the basis of Article 796 of the Presidential Decree on the Organisation of Institutions Affiliated with, Related to and Associated with Ministries and Other Institutions and Organisations, No. 4, published in the Official Gazette No. 30479 dated 15/7/2018.

Definitions

ARTICLE 4 – (1) In this Regulation; a) Minister: means the Minister of Health, b) Ministry: means the Ministry of Health, c) Commission: means the scientific commissions that will provide advisory services, when required, in the operations and transactions carried out by the Agency, ç) Agency: means the Türkiye Medicines and Medical Devices Agency, d) (Added: OG-9/2/2023-32099) Board: means the boards established within the Agency, formed from among Agency personnel, which carry out scientific, technical or administrative assessments, e) (Added: OG-9/2/2023-32099) Board sub-working group: means the working group composed of external members or board members, which carries out scientific assessments.

SECTION TWO Establishment and Duties of the Commissions and Their Procedures and Principles of Operation Establishment of the commissions and persons to serve on the commissions

ARTICLE 5 – (Amended: OG-9/2/2023-32099) (1) Commissions are established by the Agency in the required fields. The characteristics of the commissions are determined by directives and other regulations to be issued by the Agency. Those who will serve on the commissions are selected from among persons who are experts in their field, including Agency personnel.

Appointment of commission members and their terms of office

ARTICLE 6- (Amended together with its heading: OG-9/2/2023-32099) (1) Commission members are appointed upon the proposal of the Agency and the approval of the Minister. (2) Appointments made with the approval of the Minister are renewed at least once every two years. Members whose term of office has expired may be reappointed.

Duty of the commissions

ARTICLE 7 – (1) (Amended phrase: OG-9/2/2023-32099) The commissions are responsible for providing scientific advisory services and expressing opinions in the required fields among the operations and transactions falling within the Agency's scope of duty. Commission decisions are of an advisory nature and are not binding on the Agency.

Procedures and principles of operation of commission members

ARTICLE 8 – (1) The terms of office of commission members commence on the date of their appointment. (2) Commission members may resign from commission membership of their own will, provided that they notify the Agency at least one month in advance. The membership of a member terminates as of the date the request is communicated to the Agency. (3) In the case of a valid excuse, commission members notify the Agency in writing or electronically at least three days in advance that they will be unable to attend a meeting. The membership of a member who fails to attend three consecutive meetings without a valid excuse terminates automatically. (4) The Agency determines the members who will attend commission meetings from within the list of members approved by the Minister (Repealed phrase: OG-9/2/2023-32099). The Agency may establish new commissions according to the required fields or cancel an existing commission. (5) (Amended: OG-9/2/2023-32099) A Commission Chair may be elected from among the commission members in order to coordinate the activities of the relevant commission. (6) Commissions convene with the absolute majority of the number determined by the Agency. Decisions are taken by the absolute majority of those attending the meeting. (Repealed third sentence: OG-9/2/2023-32099) Commission members may not abstain from voting. (7) (Amended: OG-9/2/2023-32099) Commission meetings may be held online in an electronic environment, physically, or in a hybrid manner. (8) Commission decisions must be written on the basis of scientific justifications. (9) The secretarial services of the commissions are carried out by the Agency.

SECTION THREE (2) Establishment and Duties of the Boards and Their Procedures and Principles of Operation Establishment and duties of the boards

ARTICLE 8/A- (Added: OG-9/2/2023-32099) (1) Boards may be established from among Agency personnel in order to carry out scientific, technical or administrative assessments in the required fields among the operations and transactions falling within the Agency's scope of duty. (2) External members may be assigned to board sub-working groups to be established where deemed necessary within the scope of the board's duty. (3) Boards are established upon the proposal of the Deputy President of the Agency and the approval of the President of the Agency.

Procedures and principles of operation of the boards

ARTICLE 8/B- (Added: OG-9/2/2023-32099) (1) The procedures and principles of operation of the boards are determined by directives and other regulations to be issued.

SECTION FOUR Miscellaneous and Final Provisions Prohibitions and confidentiality

ARTICLE 9 – (1) (Amended phrase: OG-9/2/2023-32099) Members of commissions and boards may not disclose the confidential information and documents they have obtained in the course of their duties, or the commercial, scientific and technical secrets of institutions and organisations that they have learned during their duties, even after leaving office, and may not use them for the benefit or detriment of themselves or third parties, nor have them used. Otherwise, the relevant provisions of the Turkish Penal Code No. 5237 dated 26/9/2004 shall apply. (2) (Amended: OG-9/2/2023-32099) Those who, in any manner, themselves, their spouses, or their first or second-degree relatives manufacture or import medicinal products, medical devices, cosmetics or biocidal products that come into direct contact with the human body, or who work in such organisations, or who provide consultancy services to such organisations, may not express opinions in commissions and boards on the relevant matters. Membership of the commission of a member who is found to have acted contrary to this provision shall be revoked and action shall be taken in accordance with the relevant legislative provisions. (3) (Amended: OG-9/2/2023-32099) Each commission and board member signs, upon assuming duty, a code of ethics contract and a conflict of interest declaration, the content of which is determined by the Agency.

Travel allowances and fees

ARTICLE 10 – (1) Payments are made to commission members in accordance with the procedures and principles to be determined by the Ministry and the Ministry of Treasury and Finance, within the framework of Article 377 of the Presidential Decree on the Presidential Organisation No. 1, published in the Official Gazette No. 30474 dated 10/7/2018.

Repealed regulation

ARTICLE 11 – (1) The Regulation on the Establishment and Duties of the Scientific Advisory Commissions of the Türkiye Medicines and Medical Devices Agency, published in the Official Gazette No. 29403 dated 1/7/2015, has been repealed.

Existing commissions PROVISIONAL ARTICLE 1 – (Amended: OG-9/2/2023-32099) (1) As of the date of entry into force of this Regulation, the existing commission members shall continue in office until new members are determined.

Entry into force

ARTICLE 12 – (1) This Regulation enters into force on the date of its publication.

Enforcement

ARTICLE 13 – (1) The provisions of this Regulation are enforced by the President of the Türkiye Medicines and Medical Devices Agency.

_____ (1) By the amendment published in the Official Gazette No. 32099 dated 9/2/2023, the title of this Regulation, which was "Regulation on the Establishment and Duties of the Scientific Advisory Commissions of the Türkiye Medicines and Medical Devices Agency", has been amended as incorporated herein. (2) By the amendment published in the Official Gazette No. 32099 dated 9/2/2023, a third section has been added to the Regulation to follow the second section, and the subsequent sections have been renumbered accordingly.

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