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New Regulation on Products Derived from Human Tissues and Cells and Centers Related to These Products

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I. What is the aim and scope of this Regulation?

The Regulation on Products Obtained from Human Tissues and Cells and Centers Related to These Products ("**Regulation**") was published by the Ministry of Health in the Official Gazette dated September 4, 2025 and numbered 33007[1]. The primary aim of this Regulation is to determine the quality and safety standards, ensure the protection of human health and dignity. Furthermore, the Regulation also aims to provide for the fair and equal allocation and access of human-derived tissues, cells, and products intended for diagnosis, treatment, and scientific use. It regulates the general principles for licensing, authorization, activities, facility/personnel standards, and inspection of related centers, including biobanks.

II. Competent Authorities and Commissions (Tissue and Cell Coordination Commission, Tissue and Cell Coordination Center and Scientific Advisory Commission)

The process is managed by several **competent authorities** (i) General Directorate of Health Services, (ii) the Turkish Medicines and Medical Devices Agency ("**TİTCK**"), and (iii) Türkiye Health Institutes Presidency ("**TÜSEB**").

TİTCK is responsible for planning, pre-permit applications, and the licensing/activity permits for Tissue and Cell Centers, as well as the licensing and inspection of therapeutic biobanks. The General Directorate of Health Services handles the authorization processes for Tissue and Cell Source Centers and Human Application Centers. The Ministry of Health establishes the Tissue and Cell Coordination Center to centrally register and monitor all processes (supply, distribution, application, stock levels, import/export) via a secure automation system. TÜSEB is authorized to coordinate the domestic supply and distribution of tissues, cells, and advanced therapy medicinal products, including stock tracking and control, under the planning scope.

Tissue and Cell Coordination Commissions are responsible for resolving disputes that arise in scientific advisory committees or making final decisions when necessary. These responsibilities focus particularly on issues such as ethics, strategy, classification, and the application of tissues and cells in light of new medical, scientific, and technological developments.

Additionally, Scientific Advisory Commissions are formed within the authorized bodies to provide expert opinions on matters related to tissue and cell centers.

[1] https://www.resmigazete.gov.tr/eskiler/2025/09/20250904-1.htm

The Scientific Advisory Commission provides expert advice on tissue and cell activities to ensure ethical and effective practices which include standards, national strategies, licensing, and regulatory issues.

III. Types of Centers Subject to the Regulation and their Obligations

(i) Tissue and Cell Source Centers

Tissue and Cell Source Centers procure tissue and cells for (i) autologous applications, (ii) allogeneic applications and (iii) donations. Article 13 of the Regulation constitutes the operation of these centers. For example, Tissue and Cell Source Centers are responsible for the (i) informing and consent process for donor candidates, (ii) covering mandatory expenses related to the donation, (iii) investigating whether the donor is medically suitable, (iv) taking necessary precautions to ensure the quality and safety of the tissue and cells, (v) post-operative waste collection and (vi) creating a medical follow-up plan for the donor.

Additionally, all promotional and incentive activities supporting human tissue and cell donation are subject to the permission of the competent authority. Tissue and cell procurement is forbidden from individuals serving prison sentences.

(ii) Tissue and Cell Centers

Tissue and Cell Centers operate under three licenses procurement, production, and storage/distribution. Each license correlates to different responsibilities for a different stage of handling human tissues and cells.

Tissue and Cell Centers with Procurement License:

- Collect tissues and cells from living or deceased donors.

Tissue and Cell Centers with Processing and Production License:

- Process and produce tissue and cell products.
- Manufacture advanced therapy medicinal products.

Tissue and Cell Centers with Storage and Distribution License:

- Store and distribute tissue, cell, and advanced therapy products.

(iii) Human Application Centers

Needing authorization from the competent authority to operate, Human Application Centers are hospitals and healthcare institutions that apply licensed tissue and cell products and advanced medicinal products. Hospitals that apply tissue, cell, and advanced medicinal products in experimental and therapeutic trial studies are also classified as Human Application Centers. Human application centers may also conduct experimental clinical applications within the framework of the clinical application guide.

IV. Data Storage and Confidentiality Obligations

The names of the donor candidate, donor, and recipient shall not be disclosed. Disclosure of the names of the donor and recipient may only occur in mandatory situations, such as by judicial decisions, and only to relatives. Centers must take all necessary measures to prevent the information of the recipient and donor from being disclosed to each other or their families, in compliance with relevant legislation.

Tissue and Cell Source Centers must keep a donor file for at least 30 years, including donor information, informed consent documents, transfer conditions of the collected tissues and cells, and contact details of the recipient centers.

Human Application Centers must report to the supplying tissue and cell center any adverse events or effects, clinical procedures, and post-treatment follow-up information, while ensuring the patient's identity remains anonymous for traceability purposes.

V. Administrative Sanctions

If, during inspections, it is determined that centers are operating in violation of the provisions of this Regulation, their authorization certificate, license, or some or all of their licensed activity permissions may be revoked or suspended. Those who engage in activities contrary to the Regulation shall be subject to the relevant provisions of the Turkish Criminal Code No. 5237, the Law No. 3359, the Public Health Law No. 1593, and other applicable legislation, depending on the nature of their actions.

VI. Conclusion

Overall, the Regulation establishes a comprehensive national framework for managing all stages of human tissues, cells, and derived products, all the while placing great importance to delicate ethics surrounding it. Defining the roles of specialized centers and tackling personal data issues will undoubtedly help the legislation keep track of the high paced healthcare advancements.

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