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# Recent Developments in **Healthcare Legislation**

*2023-2024 Winter Issue*

**A summary of the recent changes and developments in the healthcare legislation**

# Contents

## MEDICINAL PRODUCTS FOR HUMAN USE

### Draft Guideline on the Definition of Investigational Products and the Use of Ancillary Medicinal Products for Human Use

The draft guideline, which was submitted to the relevant parties' review on 23 November 2023, emphasizes the necessity of a common understanding in relation to the definitions of "investigational product" and "ancillary medicinal product for human use" in order to facilitate the conduct of clinical trials. The draft aims to clarify the definitions of these medicinal products in accordance with the national and international standards and to provide information on the use of foreign medicinal products. Additionally, the draft provides for the labelling requirements, documents to be submitted in the application file as well as matters relating to the form of filing safety reportings. The deadline for clinical research parties to submit their opinions on the draft to the Turkish Medicines and Medical Devices Agency's ("**Agency**") Clinical Trials Department has elapsed on 14 December 2023. The guideline is expected to be finalised taking into consideration the opinions that may have been submitted and to be subsequently published and put into effect.

### Amendment to the Regulation on the Licensing of Medicinal Products for Human Use

With the amendment dated 26 December 2023, certain changes were made in relation to the licensing application procedures under the Regulation on the Licensing of Medicinal Products for Human Use. Previously, with the amendment dated 27 May 2023, failure to submit to the Agency the requested information and documents or an explanation for failure to submit (as well as the proposed submission date) within thirty days was added as a procedural rejection ground, except for applications in the preliminary review stage. The latest amendment dated 26 December 2023 defines the same situation also as a ground for substantive rejection. Further, the licence suspension period is extended from six months to 30 months to be applicable in case of failure to place at least one commercial batch of the medicinal product on the market within the first 30 months from the licensing date or failure to submit the official documents confirming the market placement to the Agency.

### Amendment to the Regulation on Variations in Licensed Medicinal Products for Human Use

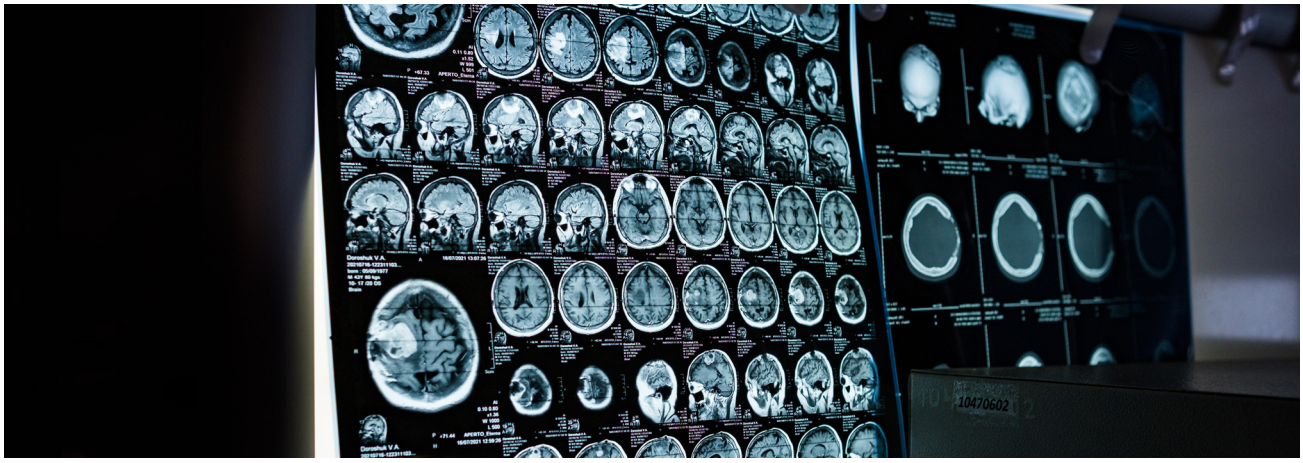
The amendment, which entered into force on 26 December 2023, defines the term "manufacture site" of medicinal products as the place where the pharmaceutical form of the product (*bulk product*) is produced prior to internal packaging. As per the amendment, a new licence must be issued if the manufacture site of the respective medicinal product changes from abroad to inland or *vice versa*. In addition, the regulation introduces new provisions concerning variation applications. Accordingly, in case a new licence is issued for a product that is subject to variation application, the products that were manufactured based on the previous licence can continue to be produced and marketed under their existing barcode, for a period of six months upon the issuance of new licence. Such products can also remain on the market until their expiry date.

## Guideline on the Export Conditions Except for Pharmaceutical Warehouses

The guideline, which entered into force on 29 December 2023 regulates the procedures and principles for transportation and exportation of medicinal products for human use in accordance with the good distribution practices and national and international standards with a view to ensuring the uninterrupted provision of healthcare services and protection of public health. The guideline prohibits the exportation of products without a valid export authorisation issued by the Agency. However, manufacturers located in Türkiye or entities with medicinal products licensed in Türkiye or abroad are permitted to authorise another entity to export their products. In case of such an authorisation, the exporter entity shall liable as the responsible manager.

## Draft Guideline on Digitalisation in Clinical Trials

The Regulation on Clinical Trials of Medicinal Products for Human Use ("**Regulation on Clinical Trials**"), which entered into force on 27 May 2023 provides that digitalisation practices can be implemented in the performance and organisation of clinical trials with a view to keeping up with the developing technology and information infrastructures. In this context, on 2 January 2024, the Agency shared a draft guideline outlining the details of applications which involves digital technologies such as electronic information tools and electronic data collection tools for the clinical trials.



## Amendment to the Guideline on Applications for Human Medicinal Products Facilities

According to the amendment published on 22 January 2024, when applying to obtain a permit for facilities where medicinal products and their active ingredients, including clinical research products and dietary foods for special medical purposes are manufactured, the application fee for the year 2024 specified in the price tariff published by the Agency must be paid starting from the publication date of the guideline. Another significant change introduced by the amendment is that in addition to address change which requires updating the permit, change in the trade name of the permit holder shall also require updating the permit.

## Guideline on Chemical and Pharmaceutical Quality Requirements for Medicinal Products Used in Clinical Trials

The guideline has entered into force on 22 January 2024 in line with the Regulation on Clinical Trials and the relevant European Union ("**EU**") legislation. The guideline has been drafted taking into account the EU guideline on the similar subject-matter, and determines the chemical and pharmaceutical quality requirements for the medicinal products to be used in clinical trials in accordance with national and international standards, with the intent of protecting volunteers.

## Guideline on the Quality Requirements for Biological Medicinal Products Used in Clinical Trials

The guideline was published in accordance with the Regulation on Clinical Trials and the EU legislation, and entered into force on 22 January 2024. Similar to the Guideline on Chemical and Pharmaceutical Quality

Requirements for Medicinal Products Used in Clinical Trials, this guideline also determines the quality requirements for biological/biotechnological medicinal products to be used in clinical trials in accordance with the national and international standards, with the objective of protecting volunteers.

## Amendment to the Guideline on the Principles and Procedures of Pharmacovigilance Studies Held by Contracted Pharmacovigilance Service Providers and Marketing Authorisation Holders

The guideline sets out the responsibilities, working principles and procedures of contracted pharmacovigilance service providers and licence holders with a view to ensuring compliance of pharmacovigilance activities with the legislation. The amendment dated 24 January 2024 has postponed the effective date of the requirement to have one-year experience which was previously set forth for pharmacovigilance officers, until 1July 2025.

## Amendment to the Guideline on Good Clinical Practices

With this amendment, which came into force on 1 February 2024 a number of definitions set out in the relevant guideline have been updated, and further details regarding these definitions have been provided. Among others, the amendment has introduced the concept of computerised system verification to ensure accuracy and reliability throughout the process from system design to decommissioning. The amendment has also introduced quality management standards for all parties involved in the research team. The standards aim to minimize the risks by identifying critical processes in order to protect volunteers and ensure reliability of research outcomes.

## Amendment to the Guideline on Procurement of Medicinal Products from Abroad

As per the amendment which entered into force on 13 February 2024, the Agency may request licence holders to initiate an "Early Access to Medicines for Humanitarian Purposes Program" during their primary medicinal product application assessments. Additionally, if deemed necessary as part of the conformity applications concerning the medicinal products, the Agency can also request up-to-date documents regarding the products that can be procured from abroad.

## Amendment to the Guideline on the Procedures for Scheduling of Licensing Applications of Medicinal Products for Human Use

According to the amendment that entered into force on 27 February 2024, in case a medicinal product is granted a priority decision during the inspection processes, and if the preliminary review results positive, the application will be included in the scheduling list without requiring a GMP certificate. In addition, it is provided that in conditional or exceptional licence applications, if the preliminary review results positive based on a priority assessment board decision, licensing procedures will be initiated with high-priority and without being included in the scheduling list.

## Medical Devices

### Amendment to the Guideline on the Scientific Meetings and Educational Activities to be Held Within the Scope of the Regulation on the Sale, Advertisement and Promotion of Medical Devices

According to the amendment published on 3 January 2024, applications to the Agency for scientific meetings or educational activities will be subject to a fee. If the scientific meeting or educational activity is cancelled later, the payment made to the Agency will not be refunded.

### Amendment to the Guideline on the Implementation of the Regulation on the Sale, Advertising and Promotion of Medical Devices

The guideline which entered into force on 9 January 2024 abolished the previous guideline dated 11 February 2021. The new guideline includes new rules regarding training, examination and qualification certificates of individuals working in medical device sales centres. Accordingly, in line with the amendment to the Regulation on the Sale, Advertisement and Promotion of Medical Devices, starting from 1 January 2025, individuals who do not hold medical device registration officer qualification certificate will not be allowed to register medical devices in the Product Tracking System (namely "*Ürün Takip Sistemi*" or "***ÜTS***"). However, this requirement will not apply to those who have completed trainings for responsible managers, sales promotion personnel or clinical support personnel. The guideline also brings the requirement for manufacturers and importers to pay a "Medical Device Market Launch Announcement Permit Application" fee to the Agency in order to make a market announcement and apply to the Agency for such permission.

### Amendment to the Guideline on Testing, Inspection and Calibration Activities to be Conducted under the Regulation on Testing, Inspection and Calibration of Medical Devices

The amendment dated 20 February 2024 sets out the procedural steps for institutions seeking authorisation to perform testing, inspection and calibration services, in respect of their applications for personnel dismissal, addition, removal, update of reference equipment, and for expansion and reduction of scope. Also, types of branches of authorisation groups relating to the medical devices have been updated, the test, inspection and calibration procedures have been included, and the timing for entering reports related to such procedures into the Product Tracking System (namely *Ürün Takip Sistemi – UTS*) has been specified under this guideline.

## Cosmetics

### *Information Guideline on Cosmetic Product Responsible Persons and End Users*

The guideline, which entered into force on 7 December 2023 aims to prevent potential hazards that may arise from the misuse of cosmetic products, and to provide guidance on placing and safe use of cosmetic products in the market in accordance with the legislation. In this respect, the guideline brings requirements to prove the statements such as "natural", "organic", "halal", "vegan", "gluten-free", "cosmototextile" and other statements which may be used on the cosmetic products and requirements for their certification by relevant organisations. Additionally, the guideline also includes requirements for the packaging of cosmetic products.

### Guideline Consolidating the Guideline on Cosmetic Product Information File, Responsible Technical Personnel, Product Safety Assessors and Trainings

The Guideline on Cosmetic Product Information File, Responsible Technical Personnel, Product Safety Assessors and Training, which came into force on 12 December 2023 consolidates the Guideline Contents of the Cosmetic Product Information File, the Guideline on Safety Assessment of Cosmetic Products and Safety Assessors and the Guideline on Responsible Technical Personnel Working in Entities Engaged in Cosmetics. The new guideline primarily regulates the obligations of individuals acting as responsible persons under the Cosmetic Products Regulation and the procedures and principles regarding the content of product information file. According to the guideline, the responsible technical personnel in charge of ensuring the professional competence can be chemists, biochemists, chemical engineers, biomedical engineers, biologists, microbiologists and pharmacists. The guideline also sets out the procedures and principles regarding trainings to be provided for the safety assessment of cosmetic products.

## Healthcare Services

### Amendment to the Regulation on Private Healthcare Facilities Engaged in Outpatient Diagnosis and Treatment

The amendment, which entered into force on 16 January 2024 provides that the polyclinics shall be licensed under two different groups, namely Type A and Type B clinics. The amendment further provides that the polyclinics with two or more personnel shall not be granted additional personnel. The amendment enables private healthcare facilities to issue in favour of patients they treat sick leave and incapacity reports, medical reports for use of medicines or medical devices used in treatments, and medical reports for driver licence applicants. It is noted that the physician issuing such reports must be full-time employer at the relevant private healthcare facility.

## Amendment to the Regulation on Private Hospitals

In the previous version, the number of personnel working as specialist physicians that may be transferred between private hospitals was limited to 20% of the total number of the staff working as specialist physicians in the transferor institution. With the recent amendment entered into force on 16 January 2024, this limit has been revised as one-third of the total number of specialist physicians working at the transferor institution, which rule will be applicable both to intra-city and inter-city transitions. Additionally, similar to the Amendment to the Regulation on Private Healthcare Facilities Engaged in Outpatient Diagnosis and Treatment, private hospitals may also issue medical reports in line with the conditions specified under the Regulation on Private Hospitals.

## Amendment to the Fundamental Law on Healthcare Services

On 1 March 2024, the Law No. 7496 on Amendments to Certain Health Related Laws and Decree Law No. 663 was published in the Official Gazette and entered into force, and brought certain changes to the Law No. 3359 on Healthcare Services. According to the amendment, studies on medicinal products for human use, medical devices and certain treatment methods shall be initiated after notifying the Ministry of Health ("**Ministry**") upon obtaining the approval of the ethics committee. If the studies do not comply with the legislation and ethical principles, the studies may be temporarily suspended. Additionally, in order to obtain approval of the Ministry for cosmetic product trials on humans, a prior approval should be obtained from the ethics committee. The amendment also made it mandatory to hold a compulsory financial liability insurance in order to protect volunteers against potential damages that may arise from clinical researches. Further, it is provided that research sponsors may delegate their duties and authorities to third parties. It is expected that the Ministry may issue a regulation which will determine the responsibilities of parties in case of delegation of duties and authorities of sponsors to third parties.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