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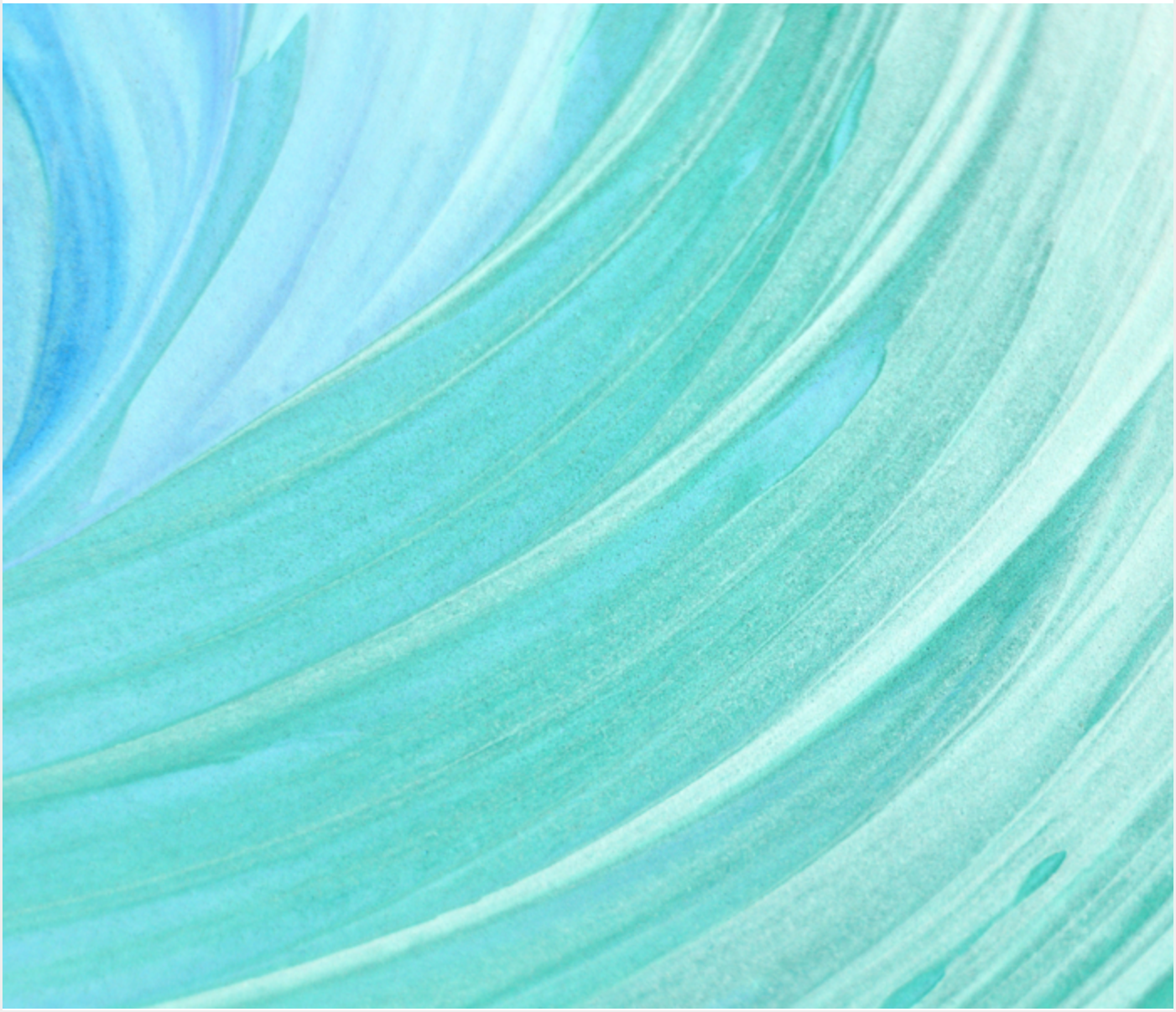
Recent Developments in **Healthcare Legislation**

2024 Summer Edition

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



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Medicinal Products for Human Use

Draft Regulation on the Promotional Activities of Medicinal Products for Human Use and Foods for Special Medical Purposes

The Draft Regulation on the Promotional Activities of Medicinal Products for Human Use and Foods for Special Medical Purposes concerning the proposed amendments to be made over the Regulation on the Promotional Activities of Medicinal Products for Human Use regarding promotional activities for medicinal products for human use and foods for special medical purposes has been shared with public for stakeholders' feedback. The proposed changes are as follows:

- Promotion of foods for special medical purposes are included within the scope of the regulation.
- In addition to promotions directed at dentists and pharmacists, promotions targeting dieticians -exclusively for foods for special medical purposes- are also permitted.
- Promotional activities for products procured from abroad are permitted only if they are for pharmacovigilance purposes and conducted by the licence holder or its representative.
- In addition to the responsibilities of the marketing authorisation or licence holder and product promotion representatives, details on the responsibilities and related sanctions concerning the healthcare institutions, organisations, healthcare professionals ("**HCPs**") and product promotion representatives have been provided. In this regard, it is prohibited to offer food/beverages or similar refreshments to healthcare institutions and organisations or HCPs during product promotion activities.
- Licence holders are permitted to provide support to HCPs and healthcare institutions for scientific meeting expenses, provided that the charged cost items are in the currency of Turkish Lira.
- For product promotions within the scope of a satellite symposium at scientific meetings, the products must not only be licensed or authorized according to the legislation, but also must be available on the Turkish market.
- The threshold for notifying the Turkish Medicines and Medical Devices Agency ("**Agency**") of value transfers to HCPs, universities or healthcare institutions is suggested to be reduced from 10% to 5% of the monthly gross minimum wage. Any value transfers exceeding this threshold must be notified to the Agency.

Amendment to the Guideline on Conditions Requiring Re-licensing for Licensed Medicinal Products for Human Use

As part of the amendment to the guideline dated 1 July 2024, change of the production location from abroad to inland or vice versa has been added as a condition requiring re-issuance of the licence. In this regard:

* For applications to the Licensed Medicinal Products Technological Evaluation Unit, all mandatory documents required to be submitted have been are specified, including (i) the original of the licence/ certificate previously issued for the product; (ii) the current SmPC/PI (*Summary of Product Characteristics/ product information*) information; (iii) inner and outer packaging drafts prepared for the packaging dimensions of the product; (iv) in case the product is produced under a licence, the document issued by the licensor company certifying that it is the authorised representative for the licensing, production and sale of the product in Türkiye.

* In case of loss of the original licence, an application for lost licence must be made before applying for a licence transfer, and the original licence must initially be obtained by the current licence holder.

* For human medicinal products whose licence validity period has expired, neither the transition to a certified licence nor the procedures for a lost licence can be conducted until the licence renewal procedures are completed.

Amendment to the Guideline on Packaging Information and Instructions for Use of Medicinal Products for Human Use

With the amendment to the guideline dated 10 June 2024, the importance of selecting name for every medicinal product for human use for which a licence application has been filed or which has been licensed, in a manner that does not lead to confusion with any other medicinal product name has been emphasized. In this context, when the indications of certain products are the same but their compositions are different, even if the trademark owner consents, it will not be possible for a different applicant/licence holder to use the same product name.

Amendment to the Guideline on the Working Procedures and Principles of the Priority Evaluation Board for Medicinal Products for Human Use

According to the amendments to the guideline dated 29 July 2024 and 7 June 2024, certain revisions have been introduced regarding the evaluation of prioritisation applications.

In this context:

- Application for an assessment for Good Clinical Practices (GCP) inspections and application for prioritisation of inspections for imported or licensed products that will be licensed for the first time in Türkiye through a hybrid application and for medicinal products produced in Türkiye have been introduced.

- It has been clarified that advanced therapy medicinal products, traditional herbal medicinal products and homeopathic medicinal products are outside the scope of the guideline.

- Pursuant to the amendments to the guideline, in applications for special importation or sales licence, if there is no alternative to the said product or if the existing products on the market do not meet the need, following the review by the Drug Supply Management Commission, a commission decision may allow for the evaluation of special importation and marketing authorisation.

- The importation period for products approved for special importation has been restricted with one year.

- As per the amendments to the guideline, the Priority Assessment Board of Medicinal Products for Human Use may, in addition to its regular quarterly meetings, also hold extraordinary meetings as needed and based on the workload of the agenda, upon the decision of the Chairman of the Priority Assessment Board of Medicinal Products for Human Use.

Announcement on Readability Test for Medicinal Products for Human Use

Pursuant to the Regulation on Packaging Information, Instructions for Use and Tracking of Medicinal Products for Human Use, to ensure the traceability of the products, the QR code and visually readable information regarding the content of the QR code must be made available either on the external packaging of the product or on the internal packaging if there is no external packaging. According to the announcement published on the official website of the Agency dated 14 June 2024, a local readability test must be conducted on the QR code and its contents in Türkiye and submitted to the Agency during the marketing authorisation application

process. For purposes of marketing authorization applications to be filed after 31 December 2024, readability tests conducted abroad will no longer be acceptable. Previously conducted foreign readability tests for any medicinal product for which an application has been made but not yet licensed by 31 December 2024 (even if a Turkish translation has been submitted) must be repeated in Türkiye and submitted to the Agency.

Amendment to the Guideline on Co-Marketed Medicinal Products for Human Use

It has been stipulated under the amendment to the guideline dated 7 June 2024 that variations which have not yet been approved for the main product shall not be included in the marketing authorization applications for co-marketed medicinal products for human use. Accordingly, in co-marketing licence applications, the applicant is required to provide an undertaking that the abovementioned condition has been fulfilled.

Amendment to the Common Technical Document (CTD) Guideline

The amendment to the guideline dated 5 June 2024 has aligned the principles of the Common Technical Document (CTD), which must be considered when submitting information and documents for licensing applications of medicinal products for human use, with the European Pharmacopoeia. Consequently, the annexes prepared for the use of applicants of CTD submissions for medicinal products have been updated to, among others, include declaration annexes providing information on the requirements for *primary myelofibrosis* (PMF) for products containing blood products as excipients.

Amendment to the Guideline on Applications for GMP Inspections of Production Facilities Abroad

With the amendments to the guideline dated 7 June 2024, several novelties have been introduced regarding GMP inspections. Primarily, diversity of items subject to GMP inspection has been expanded to include semi-finished and homeopathic stock production facilities under the principles of "split production". It is required to file a GMP inspection application (i) for semi-finished products facilities, depending on whether they hold a GMP Certificate or CEP certificate, and (ii) for homeopathic stock production sites, if they fall within the scope of *nosodes* and *sarcodes*. Furthermore, general principles on GMP inspections have been updated and details on the inspection procedures for newly added buildings or activities at production facilities have been provided. Lastly, details regarding post-inspection processes have been included, and it has been provided that the validity period of an on-site inspection can be maximum nine years from the date of the inspection.

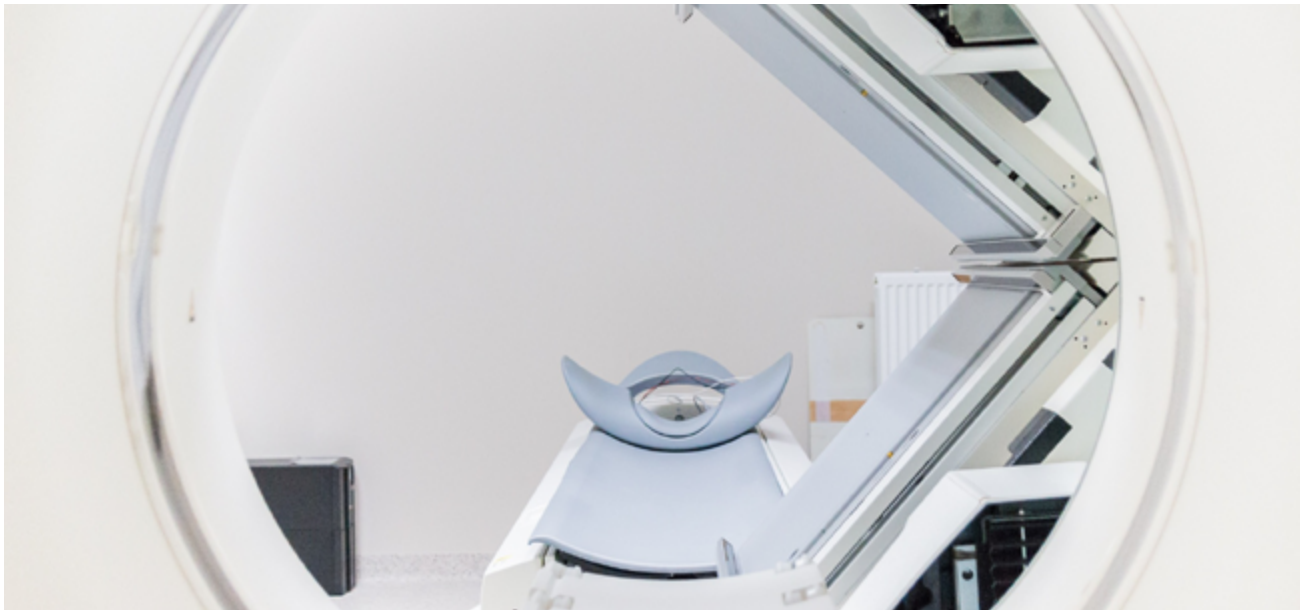
Amendment to the Guideline on Safety Practices in Clinical Trial Applications

The revisions on the guideline dated 5 June 2024 aim to ensure compliance with and implementation of the requirements under the Regulation on Clinical Trials of Medicinal Products for Human Use. In this context:

- Investigational product file and use of auxiliary medicinal products for human use have been added to the evaluation process within the scope of safety practices.
- Further details have been provided on the principles for the Agency's assessment on the good clinical practices inspection report and the good manufacturing practices certificate/production site authorization certificate.
- It has been set forth that if the investigational product is not licensed in Türkiye but is licensed by foreign authorities identified by the Agency, and there are no changes to the information on which such licence is based, the applicant will be exempt from submitting the investigational product file.

Amendment to the Guideline on Supply of Medicines from Abroad

Details have been provided under the amendment to the guideline dated 29 August 2024 on the documents to be submitted for initial product applications that contain active substances listed in the Foreign Active Substance List, and the necessity to submit benefit/risk reports has been emphasized. In this context, if the required documents cannot be submitted, applicants with a valid reason for not being able to provide these documents are now allowed to submit alternative scientific documents.



Amendment to the Guideline on Clinical Trial Applications to the Clinical Trials Department of the Turkish Medicines and Medical Devices Agency

Through the amendment to the guideline dated 7 June 2024, the annexes of the guideline were revised and the research plan table regarding the information and documents to be submitted in pediatric research plan applications and the plan regarding the benefit-risk assessment were published.

Medical Devices

Amendments to the Medical Device Regulation and In-Vitro Diagnostic Medical Device Regulation

As part of the efforts to align with the European Union legislation, certain amendments were made on 17 August 2024 to both the Medical Device Regulation and the In-vitro Diagnostic Medical Device Regulation. These amendments reflect into local legislation the measures introduced by the European Commission to mitigate supply issues of medical devices as follows:

- Following the announcement that the EUDAMED modules have become operational, their phased use will be mandatory starting from the last quarter of 2025.
- The amendments aim to reduce the risk of market unavailability of high-risk in-vitro diagnostic medical devices, provided specific conditions are met.
- Manufacturers are now obliged to provide advance notice of any potential disruptions in the supply of medical devices and in-vitro diagnostic medical devices that are deemed to pose a serious threat to patient safety or public health.

Regulation on the Reclassification of Certain Active Non-Medical Product Groups

In compliance with the European Union regulations, the regulation concerning the reclassification of certain active non-medical product groups such as contact lenses, lasers for skin applications, liposuction equipment listed in Annex XVI of the Medical Device Regulation was published in the Official Gazette and has come into force on 17 August 2024. It is required thereunder that before the relevant products are placed on the market, a conformity assessment be conducted consistent with the structural risks.

Communiqué on Determination of Common Specifications for Certain Class D In-Vitro Diagnostic Medical Devices

The communiqué issued by the Agency on 25 July 2024 introduces provisions on determining common specifications for class D in-vitro diagnostic medical devices. Generally, the provisions on in-vitro diagnostic medical devices are updated in line with the European Union legislation. Alongside this communiqué, the common specifications determined under the Medical Devices Regulation (EU) No. 2017/746, which was last updated on 4 July 2022 have been incorporated into the local legislation.

Guideline on the Implementation of the Regulation on the Technical Service Provisions of Medical Devices Used in the Scope of Health Service Provision

The guideline dated 21 August 2024 has been prepared to determine the procedures and principles on the implementation of the provisions of the Regulation dated 26 May 2023 on Technical Services of Medical Devices Used in the Scope of Health Service Provision. The guideline provides for the conditions that must be met by individuals and legal persons seeking to obtain a medical device technical service activity certificate, how to submit applications, evaluation criteria and the details of technical service activities.

Cosmetics

Guideline on the Use of Product Tracking System for Cosmetic Products and Applications

Through the amendment dated 12 July 2024, the guideline with the title Guideline on Electronic Transaction Processes for Cosmetic Activities has been renamed as the "Guideline on the Use of Product Tracking System and Applications for Cosmetic Products" and reissued. With this amendment, the guideline has been aligned with the updates related to company registration processes within the Product Tracking System (*Ürün Takip Sistemi (ÜTS)*). Additionally, the details of the technical steps that must be followed within the ÜTS for cosmetic product applications has been provided.

Amendment to the Guideline on Cosmetic Products and Bordering Products

The amendment, which came into effect on 14 June 2024, has brought the guideline into closer alignment with European Union legislation. In this context, the list of products considered as cosmetic products and within the scope of cosmetic regulations has been expanded. Additionally, with a view to preventing confusion between cosmetic products, medicinal products for human use, and medical devices, it is emphasized that cosmetic products must (i) not be intended for the treatment, prevention, diagnosis, or correction, regulation, or modification of any disease or physiological function, (ii) not claim or imply that they restore, correct, or modify physiological functions as a result of pharmacological, immunological, or metabolic effects, (iii) not refer to the effects of medicinal products for human use, and (iv) not contain health claims.

Amendment to the Guideline on Cosmetic Product Safety Assessors, Training and Certification

The amendment, which took effect on 14 June 2024, has aligned the guideline with the European Union legislation. In this context, changes have been made to the training topics and durations for product safety assessors, reducing the duration of theoretical training from 48 hours to 32 hours. Additionally, the details of the exams related to theoretical training, including the number of questions and the grading scale have been updated.

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