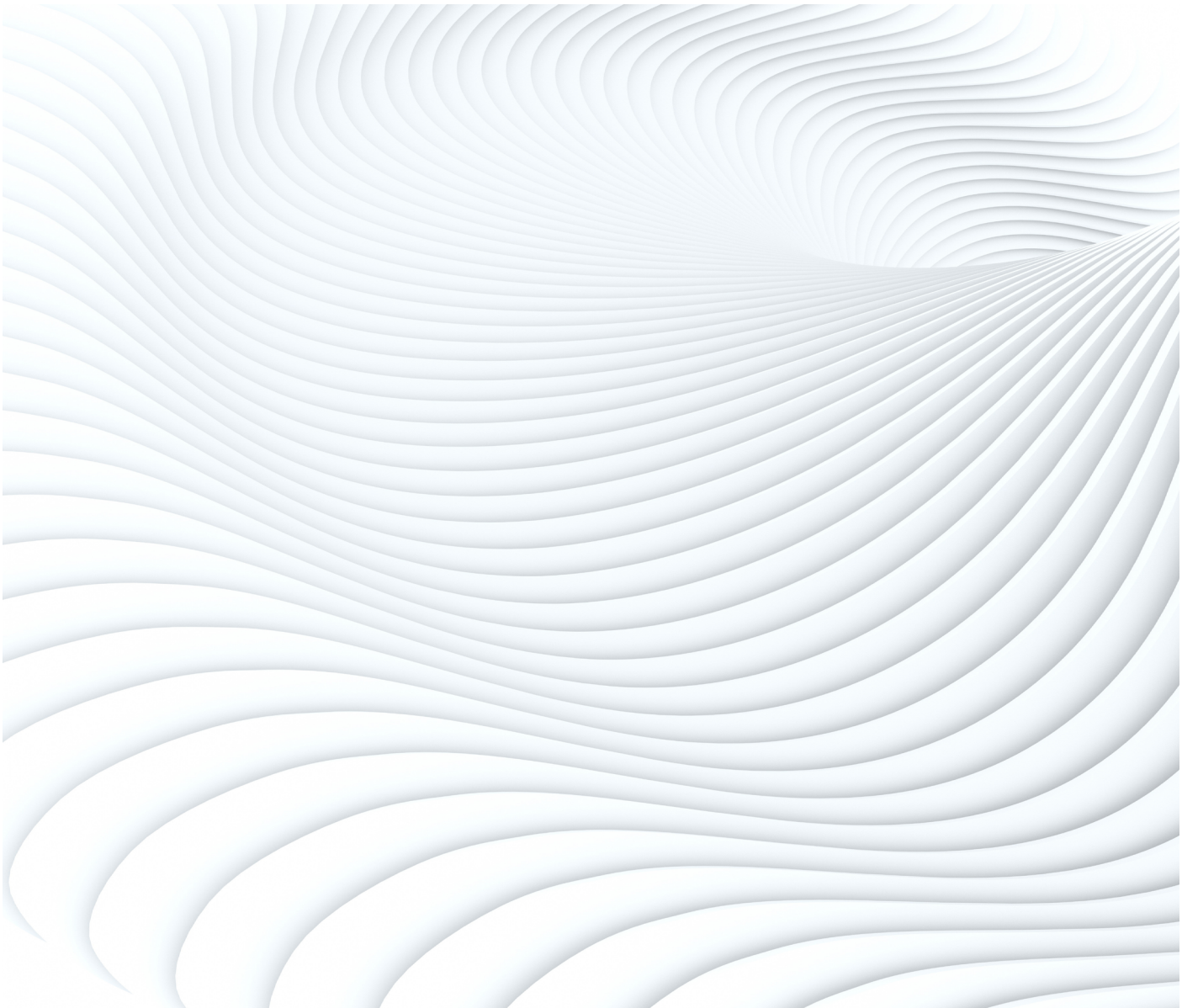
Paksoy

Recent Developments in **Healthcare Legislation**

2023 Summer/Fall Issue

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



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MEDICINAL PRODUCTS FOR HUMAN USE

Amendment to the guideline on renewal of licenses for medicinal products for human use

The Guideline on Renewal of Licenses for Medicinal Products for Human Use entered into force on 24 January 2023, and was amended on 3 February 2023. A third amendment has been made to the guideline on 17 May 2023, which requires the renewal applications to be made to the Turkish Medicines and Medical Devices Agency ("**Agency**") nine months prior to the expiration of the five-year term of the license. The updated version of the guideline also determines the application procedures, the relevant departments of the Agency, which will assess the applications and the time periods within which these departments will complete their reviews.

Amendment to the regulation on licensing of medicinal products for human use

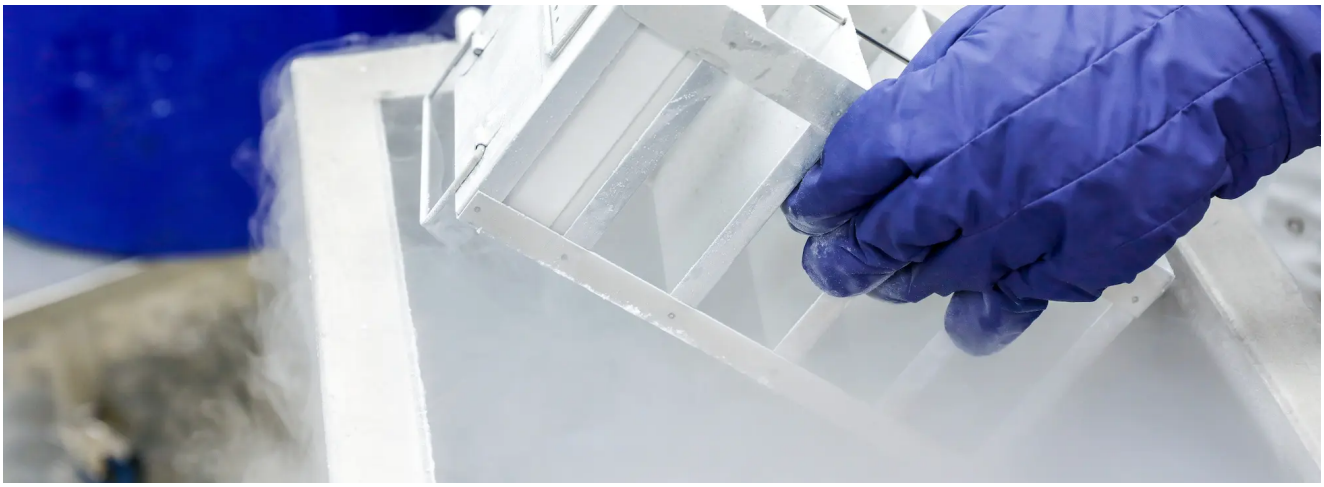
The Regulation Amending the Regulation on Licensing of Medicinal Products for Human Use published in the Official Gazette dated 27 May 2023 and numbered 32203 introduces significant changes regarding the licensing application procedures. Accordingly, if the information and documents requested by the Agency are not provided within 30 days at the latest, and an explanation as to why they are not provided together with a date at which these will be submitted are not provided to the Agency within the same period, the license application will be rejected on the procedural grounds, except for applications that are at the stage of preliminary review. Additionally, it is provided that if the conditional license of a product is decided to be cancelled in its annual review, the cancellation will be effected without going through a pre-suspension process. Further, it is stated that in license transfer applications, the license will be suspended in the event that the license holder fails to submit the certificate confirming that the relevant production sites are in compliance with the good manufacturing practice guidelines (and the production site permit certificate in case the active substance is manufactured in Türkiye).

Regulation on licensing of medicinal products for advanced treatment

The Regulation on Licensing of Medicinal Products for Advanced Treatment entered into force upon publication in the Official Gazette dated 27 May 2023 and numbered 32203. The regulation introduces licensing and pharmacovigilance obligations for medicinal products for advanced treatment with a view to ensuring their effectiveness, safety and quality. In this context, a license and a sales permit should be obtained from the Agency in order for a medicinal product for advanced treatment to be placed on the market. The regulation also includes the information and documents to be submitted in the licensing application, rejection of the application on procedural and substantial grounds, suspension or cancellation of the license, the responsibilities and the post-licensing obligations of the license holder.

Amendment to the guideline on conditional licensing (Emergency Use Approval) application and analysis

Details of the conditional licensing procedures have been determined under the revised guideline published by the Agency and entered into force on 6 June 2023. It has also been set forth that analyses of the reference regulatory authorities will be taken into account in conditional licensing applications. Accordingly, if available, assessment reports of the national pharmaceutical authority of the manufacturing country, the World Health Organization (WHO), the competent authorities who are founding or permanent members of International Committee for Harmonization (ICH), the Australian Therapeutic Goods Administration (TGA) or the UK Medicines and Healthcare Products Regulatory Agency (MHRA) must be submitted to the Agency.



Amendment to the guideline on inspections on Good Distribution Practices (GDP)

With the revision dated 20 June 2023, the definition of "transfer centres" was added to the guideline. Accordingly, transfer centres refer to temporary storage centres where all necessary precautions are taken to comply with the storage conditions of the products and active substances, and where such products can be stored for a maximum of 72 hours. The guideline also includes the details regarding the applications to be made to the Provincial Health Directorates by those that will operate as transfer centres. Further, it has been elaborated on the application procedures as well as applications to be made and permits to be obtained for the transportation, modification and closure of transfer centres.

Amendment to the guideline on reliance practices regarding the licensing process of medicinal products for human use

The amendment dated 24 August 2023 clarifies the fast-track licensing application to be made to the Agency within the scope of cooperation with the World Health Organization. In this context, necessary documents to be submitted for recognition of a medicinal product for pre-qualification / emergency use by the World Health Organization or grant of conditional licensing / emergency use approval by the reference regulatory authorities have been specified. In addition, templates of documents, forms and declarations that should be submitted in fast-track licensing applications are provided under the guideline.

Amendment to the guideline on applications for inspections on Good Manufacturing Practices (GMP) of overseas production facilities

This guideline has gone through several revisions on 7 July 2023, 18 September 2023 and 5 October 2023 respectively. The revision dated 7 July 2023, requires the party subject to the inspection to ensure that the

related documents are prepared in full in order to facilitate the proper conduct of inspection activities. The version dated 18 September 2023 introduces a fast-track licensing procedure within the scope of cooperation with the World Health Organization. It also allows, reserving the Agency's right to further inspect, the GMP inspections within the scope of fast-track licensing procedures to be held over the file. The latest version dated 5 October 2023 removes the ability to apply for on-file inspection, which was introduced due to pandemic-related restrictions in favour of certain facilities (i.e., those manufacturing products other than biological and biotechnical products) that were previously subject to on-site inspection.

Guideline on scientific advice for medicinal products for human use

This guideline published on 15 September 2023 explains the requirements and procedures related to requests that can be addressed to the Agency for scientific advice in connection with a licensing application for a medicinal product. Obtaining a scientific advice is expressly urged by the Agency. According to the guideline, obtaining scientific advice can expedite the assessment of the licensing application and increase the likelihood of a positive outcome.

Guideline on cases requiring reissuance of license for medicinal products for human use

The guideline, which entered into force on 9 October 2023 determines the procedures and principles for the transfer, loss and issuance of licenses for licensed medicinal products as well as transition to certified licenses for such products. The guideline also clarifies the required information and documents to be submitted in license transfer, loss and transition applications depending on the type of the application as well as key points to be observed in these applications.

MEDICAL DEVICES

Guideline on common specifications for non-medical product groups

The Agency announced on 16 December 2022 that the Commission Implementing Regulation (EU) No. 2022/2346 setting out the common specifications for non-medical product groups, which was published on 1 December 2022 in the EU, will be applicable in Türkiye as of 23 June 2023. In this context, the guideline which entered into force on 23 May 2023 and has been updated on 6 October 2023 provides further details on the common specifications (such as specific risk control measures, instructions for use, and labelling rules) applicable to each non-medical product group listed under Annex XVI of the Medical Device Regulation such as contact lenses, tattoo products, liposuction products.

Amendment to the regulation on sale, advertisement and promotion of medical devices

With the amendment published in the Official Gazette dated 26 May 2023 and numbered 32202, sales centres will be required to issue a warranty certificate for devices they sell as of 1 January 2025. The amendment also provides for the details regarding the applicable period and content of the warranty certificates.

Another important change, which will be effective as of 26 August 2023 is the removal of the requirement to apply and obtain the approval of the Agency at least 15 days prior to the meeting date for scientific and educational activities. The notification procedures for scientific and educational activities are regulated under the Guideline on Scientific Meetings and Educational Activities To Be Held Within the Scope of the Regulation on Sale, Advertisement and Promotion of Medical Devices dated 22 August 2023, the details of which are provided below.

Regulation on technical services for medical devices used within the scope of healthcare services

The regulation published in the Official Gazette dated 26 May 2023 and numbered 32202 provides for the procedures and principles of technical service activities to be performed for eliminating the risks associated with medical devices used in rendering healthcare services and ensuring their proper and safe use. Those that will operate within this scope are required to obtain from the Agency (i) a technical service activity certificate, (ii) a technical director work certificate, and (iii) a technical personnel work certificate. The regulation elaborates on the application procedure, and also provides for the required documents and responsibilities of technical services providers

Guideline on consultation procedures specified in the medical device regulation

According to the Regulation on Licensing of Medicinal Products for Human Use, medical device components in the medicinal products shall comply with the general safety and performance requirements specified under Annex 1 of the Medical Device Regulation. In this context, the guideline which entered into force on 2 June 2023 provides guidance to manufacturers and accredited organizations regarding the regulations to which such products are subject as well as related consultation procedures.

Amendment to the guideline on withdrawal and recall of medical devices and In Vitro diagnostic devices

The revised version of the guideline published on 19 July 2023 addresses matters concerning withdrawal and recall of devices used by healthcare professionals and those placed on the market for direct consumer use. The previous version of the guideline envisaged that the measures taken by the Agency such as withdrawals

and recalls would be announced on the website of the Agency. The revised version of the guideline makes a distinction in this regard. Accordingly, in case of withdrawal or recall of a medical device placed on the market for direct consumer use, this will be announced on the Agency's website or through other methods deemed appropriate by the Agency, whereas withdrawal and recall of a medical device used by healthcare professionals will be announced on the product tracking system (Ürün Takip Sistemi) or through other methods deemed appropriate by the Agency.

Guideline on implementation of Article 59 of the medical device regulation and Article 56 of the In Vitro diagnostic medical device regulation

This guideline, which entered into force on 12 August 2023 regulates the conformity assessment applications and their assessment procedures as part of harmonization with the EU legislation. As known, manufacturers, authorized representatives, importers and distributors in Türkiye can apply for a conformity assessment to determine whether the legal requirements for the relevant medical device are met. The guideline sets out the required documents for such application as well as the application format.

Amendment to the guideline on scientific meetings and educational activitie carried out within the scope of the regulation on the sale, advertisement and promotion of medical devices

With the amendment published on 22 August 2023, pre/post-meeting notifications are re-determined in line with the amendment dated 26 May 2023 to the Regulation on the Sale, Advertisement and Promotion of Medical Devices. Accordingly, an "initial notification" should be made for scientific meetings or educational activities via the Electronic Application System (Elektronik Başvuru Sistemi – EBS) until the end of the last day of the relevant meeting/activity. Similar to the previous practice, a post-meeting "feedback notification" should be made within 30 days after the end of the meeting. The pre/post-meeting notification requirements for trainings held in simulation and cadaver centres have been completely removed with the aforementioned amendment.

Announcement on the reciprocal recognition of authorized representatives and notified bodies in the field of medical devices between the EU and Türkiye

With this announcement dated 19 September 2023 on the website of the Agency, as part of the efforts for harmonization with the EU medical device legislation, some uncertainties regarding the free movement of medical devices between the EU and Türkiye were clarified. Accordingly, EU manufacturers are not required to appoint an authorized representative resident in Türkiye in order to place their medical devices in the Turkish market. Likewise, manufacturers residing in Türkiye are not required to appoint an EU resident authorized representative in order to offer their medical devices in the EU market.

In addition, it was noted that an accredited organization authorized to issue medical device certificates in Türkiye is subject to the same rights and obligations as an accredited organization in EU. Therefore, if a medical device is certified by an accredited organization in Türkiye, the respective medical device can be placed on the EU market without need to obtain a new certificate. Likewise, a medical device certified by an accredited organization in the EU can be placed on the Turkish market based on such certificate.

COSMETICS

Cosmetic products regulation

Cosmetic Products Regulation published in the Official Gazette dated 8 May 2023 and numbered 32184 will enter into force on 8 November 2023, and will abolish the Cosmetic Products Regulation dated 23 May 2005 that is currently in force. The new regulation which aims to achieve full compliance with the European Union (EU) legislation, introduces definitions of responsible person and commercial operator, and determines the responsibilities of responsible persons and distributors. Classification of product ingredients, safety assessment reports required for placing cosmetic products on the market, product notifications to be made through the National Electronic Database and transparency vis-à-vis the public are also regulated thereunder.

Guideline on declarations on cosmetic products

The guideline published on 9 June 2023 which will come into force on the effective date of the Cosmetic Products Regulation (i.e., on 8 November 2023) sets out the basic rules, common criteria and practices regarding declarations on the features, effectiveness and/or safety of cosmetic products which should be disclosed on the labels, packaging or promotions of such products. For instance, declarations such as "Provides 48 hours of moisturization" cannot be used for a product proven to have a short-term moisturizing effect. Another example is that declarations such as "Does not contain substance X" cannot be used for a cosmetic product which, by nature, cannot contain such substance. On the other hand, the guideline requires declarations on whether the product is hypoallergenic to take place

FOODS

Guideline on packaging information of foods for special medical purposes and their legibility

The guideline, which was published and entered into force on 23 June 2023, brings disclosure and legibility requirements for packaging of foods for special medical purposes. The guideline provides for key points to be observed by license holders when disclosing the ingredients on the packaging of products, includes sample tables indicating energy and nutrient details, and gives examples on the information to be disclosed on the packaging, such as intended use and preparation instructions.

Guideline on license application for foods for special medical purposes

The licensing requirements regulated under the Regulation on Licensing of Foods for Special Medical Purposes were elaborated in this guideline which was published on 3 July 2023. The guideline includes practical information and indicates the required format and order of documents to be submitted in license applications. The guideline also includes a template application form to be prepared in license applications.

Amendment to the regulation on use of health declarations in food and food supplements

According to the amendment published in the Official Gazette dated 23 August 2023 and numbered 32288, only the health declarations, the examples of which are provided in the Guideline on Use of Health Declarations in Food and Food Supplements and its annexes can be used in labelling, promotion and advertisement of foods and food supplements that are placed on the market. On the other hand, products manufactured before the publication of the regulation but has not yet been placed on the market, or products for which a manufacturing contract has been made but which do not conform to the new legal requirements can be supplied to the market for a one year term upon the publication date of the amendment. New contracts and related productions will need to comply with the provisions of the regulation.

HOMEOPATHIC MEDICINAL PRODUCTS

Regulation on licensing of homeopathic medicinal products

With this regulation published on 8 July 2023, the Regulation on Licensing of Homeopathic Medicinal Products published in the Official Gazette dated 24 December 2021 and numbered 31699 was abolished. The new regulation, which has come into force within the context of harmonization with the EU legislation introduces a fast-track application process for homeopathic medicinal products that satisfy certain conditions and elaborates on the co-marketing procedures.

VACCINES AND IMMUNE SERUMS

National batch release regulation

The National Batch Release Regulation entered into force upon publication in the Official Gazette dated 1 June 2023 and numbered 32208, and abolished the Regulation on Batch Release of Vaccines and Immune Serums

dated 30 September 2022. According to the new regulation, a batch release application should be made to the Agency in order to obtain a permit for placement to the market of each batch, final bulk or finished product (final lot) of all vaccines, immune serums and blood products which are filled and/or manufactured in Türkiye. The respective vaccines, immune serums and blood products can be placed on the market after obtaining the batch release permit.

HEALTHCARE SERVICES

Regulation on promotional and informative activities in healthcare services

The regulation published and entered into force on 29 July 2023 concerns promotional and informative activities carried out by all health institutions and organizations, international health tourism intermediaries, including those authorised or holding a license to provide healthcare services. The regulation does not abolish the promotion legislation that is currently in force, but introduces additional restrictions to promotion and advertising activities. According to the regulation, posts on social media platforms and websites will also be subject to the relevant restrictions, and before-and-after images should not lead to comparison on the treatment effects.

Please do not hesitate to contact us for any further information on this briefing.

Nihan Bacanak
Partner
nbacanak@paksoy.av.tr

Zeynep Toma
Senior Associate
ztoma@paksoy.av.tr

Selen Toma
Associate
stoma@paksoy.av.tr

İrem Deyneli
Associate
ideyneli@paksoy.av.tr

Melis Pekmezci
Associate
mpekmezci@paksoy.av.tr