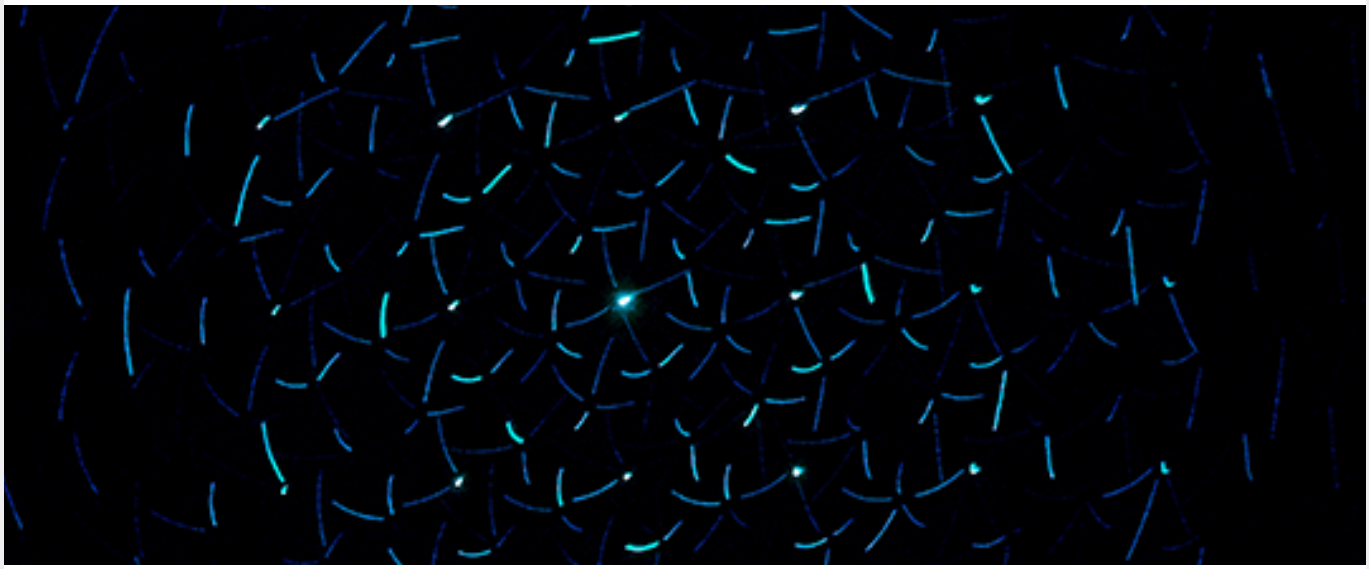
Latest Developments in the Turkish Pharmaceuticals and Healthcare Sector

September 2022



Dear Clients, Colleagues and Friends,

The summer of 2022 has witnessed a number of significant developments in the pharmaceuticals and healthcare sector in Turkey. The Turkish Medicine and Medical Devices Authority ("**Authority**") has issued guidelines and announcements with a view to aligning with the international standards and addressing the commonly encountered procedural issues. Below is a summary of the recent developments in the sector:

Guideline on GPP - Module X. The Good Pharmacovigilance Practices - Module X - Pre-marketing Benefit/ Risk Assessment has been issued by the Authority, and entered into force on 20 June 2022. The purpose of the module is to guide licence holders on how to handle basic findings and uncertainties in the benefit/risk assessment of human medicinal products. The guideline also includes a benefit/risk scheme for those who apply for obtaining a manufacturing licence for human medicinal products.

Guideline on GPP - Module XI. The Good Pharmacovigilance Practices - Module XI - Post-marketing Benefit/ Risk Assessment has been issued by the Authority to assist licence holders in conducting their post-marketing risk/benefit assessments. The module entered into force on 20 June 2022.

Amendments to the Medical Device Legislation. On 1 August 2022, the Authority announced a number of amendments to the Medical Device Regulation and the In Vitro Diagnostic Medical Device Regulation. The amendments mainly aim to extend the transition periods under the In Vitro Diagnostic Medical Device Regulation in line with the amendment to the EU Regulation 2022/112 adopted as a result of the COVID-19 pandemic and the public health crisis which came along with it. Upon the extensions, manufacturers, authorised representatives, importers and distributors will be able to continue to supply in vitro diagnostic medical devices, which have already been certified or approved under the abolished regulation, until the end of the respective transition periods.

Guideline on Risk-Based Inspections for Good Clinical Practice (GCP). The Guideline on Risk-Based GCP Inspections, which entered into force on 8 August 2022 sets out the risk based inspection procedures for clinic researches. The guideline mainly applies to clinical researches submitted during the licensing application,

including bioavailability/bioequivalence studies and ongoing clinical researches. It specifically addresses (i) cases where GCP inspections can be carried out, (ii) cases that may trigger inspections, and (iii) routine inspections.

Guideline on Good Distribution Practices (GDP). The Guideline on GDP for Medicinal Products for Human Use has entered into force on 8 August 2022. The purpose of the guideline is to provide for the supervision of the entire supply chain and to ensure the quality and integrity of medicinal products for human use in accordance with the national and international standards. The guideline is mostly relevant to pharmaceutical businesses with supply, storage, sale, distribution and export activities, including those based in customs areas such as free trade zones. The respective parties are obliged to become compliant with the guideline within a year of its issuance.

Reliance Guideline on GMP. The Reliance Guideline on the Assessment of Good Manufacturing Practices was issued by the Authority and entered into force on 9 August 2022. The guideline sets out the principles as per which the manufacturing sites located outside Turkey shall be assessed for their compliance with the GMP standards as part of applications regarding licensing of imported products. The guideline includes, among others, the conditions under which GMP related documents issued by other countries' competent authorities shall be accepted and relied upon. According to the guideline, the Authority will focus on uninterrupted and timely access to medicinal products and prevention of supply issues, particularly in case of force majeure.

Guideline on Good Pharmacovigilance Practices (GPP) - Module VI. The Authority issued an updated Guideline on GPP - Module VI - Risk Management Systems, which entered into force on 11 August 2022. The main purpose of this module is to set out the process for adopting a risk management plan whereby significant risks of medicinal products shall be identified and minimized through a documented risk management system by the applicants or licence holders of human medicinal products.

Guideline on Batch Release. The new Guideline on Batch Release was issued by the Authority, and entered into force on 11 August 2022. The objective is to determine the principles regarding examination, quality control and testing processes for sample products (i.e. vaccines and immune serums). The quality control process to be carried out by the Authority is now based on the batch release guideline of the World Health Organization and European Union Official Control Authority.

Guideline on Scientific and Product Promotional Meetings. The Guideline Regarding Scientific Meeting and Product Promotional Meetings was issued by the Authority and has entered into force on 11 August 2022. The guideline has abolished the previous one and has brought new rules regarding scientific and product promotional meetings. The new guideline, which should be observed by all licence/marketing authorisation holders sets forth limitations for support to be provided for scientific meetings and times to be allocated to satellites symposiums.

Guideline on Pharmacovigilance Indicators. The new Guideline on Pharmacovigilance Indicators entered into force on 23 August 2022 based on the World Health Organization's "WHO Pharmacovigilance Indicators: A Practical Manual for the Assessment of Pharmacovigilance Systems" with an aim to align the local practices with global standards. Certain objective indicators as per which success of pharmacovigilance programs shall be measured are provided under the guideline.

New Requirements for Medical Device Manufacturers on Exports to the United Kingdom. The Authority has announced on 24 August 2022 the steps to be taken for release of medical devices to the UK market, which is no longer a part of the European Union upon Brexit. Accordingly, as of 1 July 2023, (i) only UKCA *(UK Conformity Assessed)* marked medical devices may be placed on this market, (ii) medical device manufacturers shall register their products with the Medicines and Healthcare Products Regulatory Agency in the UK, and (iii) a "UK Responsible Person" must be appointed by manufactures based outside the UK to fulfil certain responsibilities.

Amendments to Module III – Periodic Benefits / Risk Assessment Report. The Authority has updated the Guideline on Good Pharmacovigilance Practices Module III – Periodic Benefits / Risk Assessment Report, which is effective as of 25 August 2022. The updated module provides for rules regarding preparation and

submission of "Periodic Benefits/Risk Assessment Report" ("**PBRAR**"), which must be submitted to the Authority by the licence holders on a regular basis. A quality and records management system must be established by licence holders to prepare the PBRARs, and PBRARs must be submitted by observing the timelines specified in the Regulation on the Licencing of Human Medicinal Products.

New Guideline on Import Applications and Market Release Permit. On 29 August 2022, the Authority has issued the Guideline on Import Applications and Market Release Permit. The guideline sets forth requirements for import applications as well as procedures and principles to be observed in the application process. The requirements introduced by the guideline will be applicable to, among others, human medicinal products containing blood products, immunological human medicinal products, and traditional herbal medicinal products.

Reliance Guideline on Clinical Research Applications. The Reliance Guideline on Clinical Research Applications has entered into force on 1 September 2022. The guideline sets forth reliance procedures applicable to (i) Good Manufacturing Practices (GMP) Certificate and Production Site Licence, (ii) Good Laboratory Practice (GLP) Certificate, and (iii) Good Clinical Practices (GCP) Certificate, which may be required by the Authority during clinical research applications.

New Guideline on Crisis and Emergency Management for Human Medicinal Products Where Routine Regulatory Operations Cannot Be Followed. The Guideline on Crisis and Emergency Management has been issued by the Authority on 7 September 2022. Pursuant to the guideline, the Authority can take the necessary actions at its discretion at times of emergency with a view to ensuring access to safe medicine and to preventing any potential public health problems. Simplified procedures that may be implemented during emergencies in licencing of human medicinal products, inspection of good manufacturing practices of human medicinal products, analysis and control activities and clinical researches have been provided under the guideline.

New Reliance Practices Guide on Pharmacovigilance Activities. The Authority has announced the Reliance Practices Guide on Pharmacovigilance Activities, which entered into force on 8 September 2022. According to the guide, the Authority can rely on the opinions of founding or permanent members of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, Medicines and Healthcare products Regulatory Agency (MHRA) and World Health Organization Uppsala Monitoring Centre, in the assessment of safety of human medicinal products.

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