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EU Pharmaceutical Package - EU Pharmaceutical Legislative Reform and its Impact on Türkiye

On 26 April 2023, the European Commission (the "Commission") adopted a proposal for a new Directive and Regulation (the "Proposal") which revise and replace the existing general pharmaceutical legislation.

The proposal adopted by the Commission replaces the existing general pharmaceutical legislation (Regulation 726/2004 and Directive 2001/83/EC) and the legislation on pharmaceuticals for children and rare diseases (Regulation 1901/2006 and Regulation 141/2000/EC respectively).

In the Commission's press release on the Proposal, it was stated that the pharmaceuticals authorized in the EU are still not reaching patients fast enough and are not equally accessible across all Member States. The proposal aims to prevent pharmaceutical shortages and unmet medical needs due to high pricing of innovative treatments. In addition to addressing public health from a pharmaceutical access viewpoint, the proposal aims to adapt the rules to new technologies, reduce bureaucracy, and simplify marketing authorisation procedures for pharmaceutical products to ensure that the EU remains an attractive place for pharmaceutical investment and a world leader in the development of pharmaceuticals.

The revisions aim to achieve the following main objectives in particular:

- Establish a single market for pharmaceuticals to make sure all patients across the EU have timely and equitable access to safe, effective, and affordable pharmaceuticals;
- Continue to offer an attractive and innovation-friendly environment for research, development, and production of pharmaceuticals in Europe;
- Significantly reduce the administrative burden by considerably expediting procedures, and decrease the time required for pharmaceuticals' authorisation, enabling them to reach patients faster;
- Improve the availability of pharmaceuticals and ensure their availability to patients regardless of where they live in the EU through strict reporting systems on critical shortages of pharmaceuticals;
- Address antimicrobial resistance (AMR) and the presence of pharmaceuticals in the environment through a One Health approach in the world and EU;
- Make pharmaceuticals more environmentally sustainable.
- To achieve these objectives, the Proposal includes amendments regarding the entire lifecycle of pharmaceuticals. In this context, the Proposal includes the

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following amendments to incentivise pharmaceutical companies, especially regarding innovation:

- Encouraging comparative clinical research to develop pharmaceuticals to address unmet medical needs;
- Create an incentive system that rewards companies that develop pharmaceuticals that can cure irreversible diseases;
- Reconsidering market exclusivity for pharmaceuticals used to treat rare diseases and ensuring the availability of generics and biosimilars;
- Speeding up the marketing authorisation process for new pharmaceuticals, for example, by reducing the EMA's review period from 210 days to 180 days and reducing the Commission's approval period from 67 days to 46 days.

In addition, the Commission proposes reducing the current standard protection period for data exclusivity from 8 years to 6 years, with various possibilities for extension. This period may be extended by 2 years if the medicinal product is marketed in all 27 Member States, 6 months if the medicinal product fulfils an unmet medical need, 6 months if comparative clinical trials are conducted, and 1 year if the medicinal product has a new therapeutic indication. These provisions, which reduce the duration of data exclusivity, have been criticised by many institutions and organizations, notably the EFPIA (European Federation of Pharmaceutical Industries and Associations). It is argued that the Proposal reduces R&D incentives, contrary to what was announced, by stating that the criterion that the pharmaceuticals should be marketed in 27 countries is not always under the control of pharmaceutical companies and requires significant investment, in addition to the criteria on comparative clinical research and unmet medical needs failing to suffice in terms of the incentives they offer in relation to the costs and time incurred to achieve the objectives, and having narrow, unpredictable success criteria. In this light the Proposal appears to reduce R&D incentives, contrary to what has been announced. The reduction of the standard protection period for data exclusivity to 6 years is also of interest for Türkiye. Indeed, the Commission's 2023 Türkiye report states that *"Even though Türkiye has in place a regulatory data protection regime since 2005, the scope is limited and excludes biologics and combination products. The length is also limited, reducing the effective protection period in Türkiye."*

Finally, the Proposal also proposes some amendments to the Bolar Exemption provision. Under the current regulation, the scope of the Bolar Exemption includes only acts for the purposes of obtaining marketing authorisation by generic manufacturers. The proposal stipulates a broadening of the exemption to include studies and trials to generate data for Health Technology Assessments (HTA), the pricing and reimbursement process, and activities necessary for these purposes, including by third parties. This proposal has been

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criticised on the grounds that generics are not obliged to produce any data for HTA or price and reimbursement. Additionally the concept of patent linkage, akin to patent-authorisation connection in the US, does not exist in the EU, requiring patent holders to consider price and reimbursement applications as the act that initiates patent infringement in order to prevent generics from entering the market by taking risks. Indeed, both in Türkiye and in many EU countries, price, and reimbursement applications may be considered as an imminent threat of infringement or an offer for sale. Therefore, the broadening of this concept will prevent the effective and timely enforcement of patent rights.

According to the most recent European Commission report, Türkiye is still a key partner and candidate country for the European Union. Therefore, EU pharmaceutical legislation is closely monitored, and amendments are reflected in our legislation as appropriate, albeit, to a large extent. Recently, the processes of marketing authorisation and the placing on the market of medicinal products were harmonised with EU Directive 2001/83/EC, and the Regulation on Marketing Authorisation of Medicinal Products for Human Use was published in the Official Gazette on 11 December 2021 and entered into force. The amendments to EU legislation introduced by the Proposal are being negotiated by both the European Council and the European Parliament and should be closely monitored for implications for Türkiye.

1 https://www.efpia.eu/media/gy5j1nkt/efpia-recommendations-on-the-revision-of-the-pharmaceutical-package.pdf
2 https://www.ab.gov.tr/siteimages/resimler/T%C3%BCrkiye%20Report%202023.pdf