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INFORMATIVE NOTE

HEALTHCARE, LIFE SCIENCES & PHARMACEUTICALS AND EU AND COMPETITION LAW

Initial assessment of the impact of possible legislative changes in the pharmaceutical sector

The COVID-19 pandemic has exposed the difficulties in reacting at European level to a major health crisis and the intention of the European Commission is to respond more effectively to future problems in the area of health. As a result, it is currently conducting an initial assessment of possible legislative changes in the area of medicinal products for human use.

The aim of the legislative changes is to make the European rules more adaptable to new technological developments, to achieve sustainability in production and accessibility to medicines and, above all, to simplify EU procedures relating to medicines. The industry now has the opportunity, until 27 April, to have its say and to help shape the Commission's initial proposal.

The health crisis caused by the COVID-19 pandemic and the difficulties faced in Europe in managing it have led the European Union to seek to review the existing mechanisms in the field of health, particularly in the area of medicines for human use. The new needs and challenges that the world is facing, which have a particular impact on the pharmaceutical sector, have made it necessary to reform the legislation and mechanisms for responding to health crises that may affect the European area in the future.

To this end, on 25 November 2020, the European Union published the Pharmaceutical Strategy for Europe, an ambitious long-term programme that aims to guarantee patients greater access to medicines, stimulate competition between stakeholders, and prepare Member States for future crises. This programme, designed in parallel with the European Health Union, can only be achieved with the legislative revision that is being prepared.

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Thus, the European Commission is preparing to assess the EU legislation in the area of medicinal products for human use. This assessment will essentially focus on the general pharmaceutical legislation, including (i) Directive 2001/83/EC (incorporated into Portuguese law by Decree-Law 176/2006 - Legal Framework for Medicinal Products for Human Use; and (ii) Regulation (EC) 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

The European Commission will look at the last 16 years to assess whether the objectives pursued by this legislation have been achieved. In particular, it will review the resilience of the existing rules and their ability to respond to the problems identified by the European Pharmaceutical Strategy. The aim is also to assess the consistency and complementarity of these two pieces of legislation with other legislation, and to rethink the mechanisms for adapting technical requirements to emerging technologies.

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The assessment now being carried out by the Commission has identified a set of topics that will be taken into account in this initiative:

i) Unmet and market failures that do not fall under the situations of orphan and paediatric medicines;

ii) Unequal access to affordable medicines for patients across the European Union.

iii) The possibility that the legislative framework is not fully prepared to respond quickly to innovation;

iv) Inefficiency and excessive bureaucracy in regulatory procedures.

Having identified the problems, and in order to address these difficulties, the European Commission has outlined some possible changes it considers necessary. These are general guidelines that cover a range of issues, from the development of new medicines, to a redefinition of the EMA's powers, to no less relevant issues such as the sustainability of the process associated with the distribution of medicines, among others.

Among these priorities defined by the European Commission, we would highlight the intention to:

- Reach a common understanding, either criteria based or through a definition, on the notion of 'unmet medical needs', particularly in the fields of medicines for children and rare diseases;

- Simplify existing legislation and create attractive regulatory conditions to reduce the waiting time for approval of medicines, while keeping the high standards of robust assessment of quality, safety and efficacy.

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- Revise the incentives system to promote innovation, especially in areas of greater medical need, and create adapted incentive systems, possibly with the use of rewards, to those who, for example, introduce products in all Member States, so as to guarantee access to the same products for all patients in Europe.

- Consider the creation of specific incentives to promote the development of new classes of antimicrobials in accordance with rules for their prudent use.

- Examine ways to increase support and accelerate product development and authorisation in areas of unmet need by incorporating the European Medicines Agency's Priority Medicines Scheme (PRIME) or similar mechanisms into European regulatory framework, stimulating academic research and involving SMEs.

- Improving competition rules, in particular with regard to generic/biosimilar medicines, allowing competitors to enter the market quickly. Make possible amendments to include rules on the conduct of clinical trials on patented products to facilitate the submission of marketing authorisation applications for generic medicines.

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- Provide a single assessment process between Member States for active substances used for different generic medicines (active substance master file) to facilitate their authorisation and the life-cycle management of the medicine;

- Enhance security of supply through stronger obligations for supply and transparency, earlier notification of shortages and withdrawals of medicines, enhanced transparency of stocks and stronger EU coordination and mechanisms to monitor, manage and avoid shortages;

- Improve the transparency and oversight of the supply chain, in particular, for international supply, by revising the manufacturing and distribution provisions, while defining and clarifying responsibilities to safeguard the quality of medicines.

- Address, where necessary, any structural challenges for efficient crisis management, complementing the reinforced roles of the European Medicines Agency (EMA) in times of crisis, in particular, in case of pandemics;

- Review the role of the EMA in relation to related bodies and authorities, and the governance provisions of the Agency where necessary;

- Improve mechanisms for environmental protection and sustainability associated with the production, use and disposal of medicinal products by strengthening environmental risk assessment requirements.

The European Union now intends to listen to the sector's professionals and stakeholders, and to the people of Europe, about their proposals, suggestions and comments on all the topics described, in order to prepare the appropriate legislative amendments. This initiative is currently in the initial impact assessment phase and this ends on 27 April 2021. It will then be followed by the public consultation phase, which is scheduled to end at the end of this year.

With the help of citizens and stakeholders in the sector, the European Union will seek to adapt its legislation to the intrinsically dynamic reality of the pharmaceutical world, while providing it with the arms it needs to face future crises and ensure its social, economic and environmental sustainability. ■

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