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THE EUROPEAN COMMISSION STRATEGY FOR THE EVALUATION AND REVIEW OF THE GENERAL PHARMACEUTICAL LEGISLATION

Marinela CHIRILĂ[1], Daniel CORD[2], Mirela RÎMBU[2], Roxana COLETTE SANDULOVICI[1]

[1]Departamentul Farmacie, Facultatea de Farmacie, Universitatea Titu Maiorescu, București, România
[2]IOSUD, Doctoral School – Medicine

Correspondent author*: marinella_pantazi@yahoo.com

Rezumat

STRATEGIA COMISIEI EUROPENE PENTRU EVALUAREA ȘI REVIZUIREA LEGISLATIEI FARMACEUTICE GENERALE

Pandemia de COVID-19 a reprezentat o mare provocare pentru profesioniștii din domeniul sănătății și a subliniat importanța accesului pacienților la medicamente sigure și eficiente în timp util. În acest context și pentru a îmbunătăți nivelul sănătății publice în Uniunea Europeană, în noiembrie 2020, Comisia Europeană a publicat noua Strategie farmaceutică pentru Europa. Scopul Comisiei Europene este de a evalua și revizui legislația farmaceutică generală și de a realiza un sistem farmaceutic european care să fie centrat pe pacient, eficient și rezistent în fața crizelor medicale. Aceasta va avea ca scop dezvoltarea și creșterea accesibilității pacienților la medicamente de calitate și sigure, stimularea competitivității sectorului farmaceutic la nivel global și crearea unui mediu de reglementare atractiv pentru inovare și investiții, dar în același timp susținut de standarde internaționale armonizate.

Cuvinte cheie: legislație farmaceutică, Comisia Europeană

Abstract

The COVID-19 pandemic has posed a great challenge to healthcare professionals and highlighted the importance of patient access to safe

and effective medicines in a timely manner. In this context and in order to improve the level of public health across the European Union, in November 2020, the European Commission published the new Pharmaceutical Strategy for Europe. The aim of the European Commission is to evaluate and review the overall pharmaceutical legislation and to achieve a European pharmaceutical system that is patient-centered, efficient and resilient in the face of medical crises. This will aim to develop and increase patient accessibility to quality and safe medicines, boost the competitiveness of the pharmaceutical sector globally and create an attractive regulatory environment for innovation and investment, but at the same time underpinned by harmonized international standards.

Keywords: pharmaceutical legislation, European Commission

INTRODUCTION

In November 2020, the European Commission published the new Pharmaceutical Strategy for Europe. The strategy covers the evaluation of the existing legislation, as well as the development of new regulations where necessary.

The revision of general pharmaceutical legislation is part of a series of ongoing initiatives such as the European Health Data Space (EHDS), the European Green Deal, and the European Industrial Strategy.

The European Health Data Space (EHDS) aim to improve healthcare by utilizing digital resources and the work of the EU Health Emergency Preparedness and Response Authority (HERA), allowing individuals in the EU to exercise their health data rights.

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The new Pharmaceutical Strategy will promote the European Environmental Pact's goals by implementing regulations to address the environmental impact of pharmaceutical substances.

Moreover, the strategy is consistent with the European Industrial Strategy's objectives, albeit with a specific focus on the pharmaceutical industry. Its aim to foster a favorable environment for research and innovation investment, establish strategic industrial ecosystems, and support the industry.

AIM OF THE STUDY

The aim of this paper is to present the strategy of European Commission for the evaluation and review of the general pharmaceutical legislation.

MATERIAL AND METHOD

The information related to the new strategy of European Commission for the evaluation of the general pharmaceutical legislation and its review is collected from the official website of the European Commission: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12963-Revision-of-the-EU-general-pharmaceuticals-legislation_en

RESULTS

According to the information posted by the European Commission for the evaluation and review of the general pharmaceutical legislation, the Commission has identified multiple areas that require attention and enhancement, including addressing unmet medical needs and market failures in rare diseases or pediatric diseases, improving access to innovative medicines, updating the legislative framework to keep pace with technological advancements and new discoveries in emerging fields, and simplifying administrative procedures and processes.

Thus, the new pharmaceutical strategy, complementary to the objectives of the EU's industrial, environmental, and digital strategies, has the following objectives:

- ensuring access to affordable medicines for patients and addressing unmet medical needs;
- facilitating an environment that enables the innovation and

development of high quality, effective and safe medicines, benefiting from advances in science and technology, while reducing environmental impact;

- ensuring the supply of medicines and preventing shortages in the supply of medicines;
- reducing administrative burden by simplifying legislation and ensuring a flexible legislative framework.

The new pharmaceutical strategy is expected to have a positive economic and social impact, but also on the environment and fundamental human rights.

The positive impact on the economy is expected to come from the flexibility and simplification of the legislative framework to make it attractive for investment and marketing of innovative medicines, stimulating competition in generic and biosimilar medicines.

The positive social impact is expected to result from the introduction of public service obligations (which currently exist in Romania) and the increased availability and affordability of medicines for patients across the EU. These measures together with the stimulation of competition lead to lower costs of medicines, thus having a positive impact on health expenditure directly benefiting patients and their families or carers.

The positive impact on the environment is expected to be the result of regulations that will target both the production and use of environmentally safer medicines and the monitoring and assessment of environmental risks. These measures aim to decrease the amount of pharmaceutical residues disposed of in nature with the protection of the environment and biodiversity, and ultimately to protect human health through a healthier environment. These measures support the objective of the European Green Pact and the European Industrial Strategy.

The new pharmaceutical strategy seeks to enhance patient access to medicines while also safeguarding the environment. As a result, it is anticipated that this initiative will have a favorable effect on patient

access to medical treatment and contribute to the protection of public health and the environment, both of which are rights outlined in Articles 35 and 37 of the Charter of Fundamental Rights of the European Union (2012/C 326/02).

The development of new pharmaceutical policies involves an extensive consultation process with various stakeholders, including the European Medicines Agency, national competent authorities, the pharmaceutical industry, civil society representatives, and others. This process incorporates both public and targeted consultations to ensure that all perspectives are considered.

CONCLUSION

The European Commission's strategy for the evaluation and review of the general pharmaceutical legislation aim at ensuring that the regulatory framework governing pharmaceutical products in the European Union (EU) remains up-to-date and fit for purpose. The strategy covers the evaluation of the existing legislation, as well as the development of new regulations where necessary.

The Commission's evaluation process is based on several criteria, including the effectiveness, efficiency, relevance, coherence, and EU added value of the existing legislation. The evaluation considers the latest scientific and technological developments, as well as the needs and expectations of patients and healthcare professionals.

BIBLIOGRAPHY

1. https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12963-Revision-of-the-EU-general-pharmaceuticals-legislation_en