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The European Commission strategy for the evaluation and review of the general pharmaceutical legislation

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INTRODUCTION

The COVID-19 pandemic 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-centred, efficient and resilient in the face of medical crises.

OBJECTIVES

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

The new general pharmaceutical legislation aims:

- to develop and increase patient accessibility to quality and safe medicines,
- to boost the competitiveness of the pharmaceutical sector globally
- to create an attractive regulatory environment for innovation and investment, but at the same time underpinned by harmonised international standards.

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.

RESULTS

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 favourable 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.

CONCLUSION

There are several issues that the European Commission wants to correct or improve, such as unmet medical needs and market failures in rare or paediatric diseases, unfair access to innovative medicines, aligning the legislative framework with technological progress and new knowledge in some newly explored areas, streamlining administrative procedures and processes.

KEY WORDS

pharmaceutical legislation, EC