TAKEAWAYS
CLEAN ENERGY SUMMIT
8 June 2023

KEYNOTE SPEECH BY DG SANTE DIRECTOR GENERAL SANDRA GALLINA ON THE EUROPEAN PHARMA STRATEGY

Doing things in the "European way" was one of the most remarkable insights that Ms Sandra Gallina, Director-General at DG Sante, highlighted from her overview on the recently released Pharmaceutical Legislation. In a geopolitical context in which the European Union is striving for strategic autonomy from the rest of its competitors, European healthcare systems will equally benefit from having a more innovative and competitive single market in medicines. Special emphasis was placed on the affordability and accessibility of innovative medicines and therapies to all patients across Europe, as well as on the importance of the industry in working towards the same goal.

Furthermore, it is essential to note that the Commission does not expect this piece of legislation to solve all the problems concerning European healthcare systems.
Nevertheless, it is understood that it is the beginning of a positive change. Finally, there is a strong belief that a digital boost in the sector and a European use of data are crucial for increasing the efficiency of the system, reducing costs and, ultimately, delivering sustainable, better-quality, and safer drugs for its patients.

"We cannot have 27 Member States that still don't benefit from a single market with regard to access to medicine."
- Sandra Gallina, Director General, DG Sante

EUROPE'S REVISION OF THE PHARMACEUTICAL PACKAGE LEGISLATION DELIVERING FOR THE NEXT 20 YEARS

All the cross-sectoral stakeholders participating in this debate agreed on the urgency to cooperate to reach the goal they all have in common: having an effective, innovative, and competitive European healthcare system in which all patients, regardless of their geographical location or socioeconomic condition, can receive the most innovative medicine and/or therapy. However, it is their expectations of how it happens that were a point of discussion.

The patient perspective is that they are not being involved enough in the definition of unmet needs, which, in the end, has an impact on the entire cycle of the pharmaceutical product, on the prioritisation of research, and on the identification of new treatments, pricing, and reimbursement.

On the other hand, industry puts more emphasis on the issue of not having enough clinical trials in Europe, as well as on the need to incentivise continued research and having a predictable and stable IP system.

Finally, the policymaking side stated that several instruments will be proposed during the discussion at the European Parliament, such as the Open Medicine Fund or the Platform of Innovation and Fund. Moreover, issues of digitalisation, strategic autonomy, and competitiveness will also be stressed, as well as the need for minimum quality standards across Europe.

"All critical substances should be produced in the EU, starting from paracetamol to cancer medicine. In case of a crisis, that would grant us a degree of autonomy."
- Sirpa Pietikäinen, Member of the European Parliament

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The discussion on the opportunities and challenges posed by the new Pharmaceutical Legislation in Europe was driven by contrasting views between the private and public sectors, particularly on Intellectual Property protection and the promotion of accessibility and affordability for innovative medicines to meet unmet medical needs.

The European Commission's strategy of maintaining regulatory protection and offering incentives for research and medicine production hasn't convinced the industry, which argues that development costs are high. Following discussions on clinical trials, investment, incentives, ATMPs (Advanced Therapy Medicinal Products), innovation, and IP protection, stakeholders agreed on the need for closer cooperation.

The goal is to facilitate negotiations between industry and Member States to ensure innovative drugs reach all European patients effectively.

"The purpose is not to reduce regulatory protection, but to incentivise companies to produce the medicine that patients need the most."
- Lilia Luchianov, Policy Officer, DG SANTE

EUROPEAN HEALTH SUMMIT
SUMMER EDITION

TAKEAWAYS
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8 June 2023

RESILIENT EU HEALTH SYSTEMS - HOW TO SECURE PATIENT ACCESS TO SUPPLY CRITICAL MEDICINES?

Doing things in the "European way" was one of the most remarkable insights that Ms Sandra Gallina, Director-General at DG Sante, highlighted from her overview on the recently released Pharmaceutical Legislation. In a geopolitical context in which the European Union is striving for strategic autonomy from the rest of its competitors, European healthcare systems will equally benefit from having a more innovative and competitive single market in meWhen discussing resilience in the healthcare sector, it cannot be done without analysing all aspects affecting it, as it is key not only to the health community but also to economic stability.

This panel discussion highlighted the importance of learning from the past to build a future resilient system. In this case, the Covid-19 pandemic serves as the perfect reference to analyse the strengths and weaknesses of the overall apparatus.
This crisis revealed a structure in which basic technology systems did not meet the demand, patient access was undermined, drug supplies were unavailable, and professional staff were vulnerable and overwhelmed. Underinvestment in public health led to a lack of preparedness.
In the case of plasma, where the European Union heavily relies on external actors, this resulted in poor accessibility for patients.

The Pharmaceutical Legislation, as well as the SoHo file and the Critical Medicines Act, are seen as good opportunities to build the resilient EU Health System desired by all stakeholders involved. However, to reach that goal, an improved public debate based on scientific evidence, supply chain viewed as a value chain, successful public-private partnerships, harmonisation of regulatory mechanisms within a situation of strategic autonomy, and an increase in the number of internal plasma collectors through attractive compensation packages are needed.

Overall, the creation of an enticing system is of utmost importance as a way to achieve a resilient EU Health System.

"One of the main issues for us is:
how can we ensure the resources to make our healthcare systems more resilient?"
- Csaba Kontor, Health Attaché, Permanent Representation of Hungary to the European Union

QUESTIONS OR REMARKS? CONTACT US!

EUROPEAN BUSINESS SUMMITS

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