#HEALTHSUMMITEU2023

8 June 2023, Residence Palace

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 thriving for getting 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 put on the affordability and accessibility of innovative medicines and therapies to all patients across Europe, as well as in 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 believe that a digital boost in the sector and a European use of data is crucial for increasing the efficiency of the system, reducing costs and, at the end, releasing 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 regards to access to medicine."-DG SANTE Director General Sandra Gallina at #HealthSummitEU2023

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

All the cross-sectorial 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 their geographical location or socioeconomic condition, can receive the most innovative medicine and/or therapy. However, it is their expectations in how it happens that was 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 prioritization of research, and on the identification of new treatments on 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 of incentivizing continued research and having a predictable and stable IP system. Finally, the policy-making 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 digitalization, strategic autonomy and competitiveness will also be stressed, as well as the need of having 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." MEP Sirpa Pietikäinen on Europe's revision of the pharmaceutical package

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WILL EUROPE MISS OUT ON THE NEXT WAVE OF INNOVATION?

The discussion on the opportunities and challenges to innovation that the new Pharmaceutical Legislation brings to the healthcare sector in Europe was driven by the contrasting position between the private and the public sectors regarding, mainly the treatment on Intellectual Property protection and the way to promote accessibility and affordability of innovative medicines and therapies when addressing unmet medical needs. The European Commission's strategy of not reducing the regulatory protection of the products, give incentives to companies to conduct their research and produce medicines needed by patients does not convince the industry. The second group points out that development is expensive and cutting back on IP protection while creating incentives that, from their standpoint, are too hard to get, is not the proper solution. After an insightful exchange of points of view regarding clinical trials, investment, incentives, the value of ATMPs, innovation, and IP protection, all involved stakeholders agreed on the need of a closer cooperation with the objective of facilitating the process for negotiation between industry and Member States in order to get the most innovative drugs to all the patients across Europe.

"The purpose is not to reduce regulatory protection, but to incentivize companies to produce the medicine that patients need the most." - Lilia Luchianov,- Policy Officer,DG SANTE at #HealthSummitEU2023

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

When discussing about resilience in the healthcare sector, it cannot be done without analyzing all aspects affecting it, as it is key not only to the health community but for economic stability as well. This panel discussion highlighted the importance of learning from the past in order to build a future resilient system. In this case, the Covid-19 pandemic serves as the perfect reference to analyze the strengths and weaknesses of the overall apparatus. This crisis revealed a structure in which the basic systems of technology did not meet up the demand, where the patient access was undermined, the drug supplies were not available, and in which professional staff was vulnerable and therefore hammered. The underinvestment in public health led to a lack of preparedness which, in the case of plasma, where the European Union heavily relies on external actors, has had a poorly result in a poor in terms of 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, which is viewed as a value chain, successful public-private partnership, harmonization of the regulatory mechanisms within a situation of strategic autonomy, and an increase in number of internal plasma collectors through attractive compensation packages is needed. Overall, the creation of an enticing system is of outmost importance as way to have 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 at Permanent Representation of Hungary to the European Union