Press Release

Window of opportunity to enhance EU regulatory systems wide open as EU pharma strategy prioritises stronger EU networks

Brussels, 19 January 2021

The recently published EU pharmaceutical strategy is a welcome tool to address public health challenges in Europe, including equitable access to medicines, reducing medicines shortages, and supporting secure supply chains. At the foundation of addressing these issues is a robust and agile regulatory system. The EU regulatory network, the European Medicines Agency (EMA) and national counterparts, is among the most advanced system worldwide, but still has room for greater efficiency.

The EMA has great inroads to make to embrace the digital era and leave behind burdensome paperwork and processes. Practical digital infrastructures like an electronic patient information (ePI) leaflet can be easily implemented and benefit the entire health community: patients can access readable and up to date information on their medicines, as can the healthcare professionals who manage their treatment pathways. A more digitalised network can also be more responsive to tackling medicines shortages, by collating harmonised data on medicines availability, in real time. For this, a inter-connected EU-national digital portal must be developed for the system to be efficient.

The outbreak of COVID-19 exposed the scope for improvements in the regulatory system, as unprecedented flexibilities allowed countries and industry to allocate urgent supplies of medicines to hospitals across Europe. While these flexibilities proved invaluable during a crisis, we should not overlook the benefits of a more agile regulatory system.

Commenting at the **Medicines for Europe** Regulatory Affairs webinar series, association President Christoph Stoller (Teva) said *"the outbreak of COVID-19 was among the most severe challenges ever to face the EU health industry and regulatory networks. We cannot miss the opportunity to implement the hard-learned lessons of the pandemic and make our systems more resilient and responsive in the future. The EU pharma strategy paves the way to improve the regulatory network, making it more digital, connected, and agile. Practical tools like an e-leaflet for medicines or a common digital shortage reporting system have benefits in times of crisis but also well beyond. We count on our partners in the European Medicines Agency and the health policy network to work together with us to find workable solutions, that not only give more competence to the agencies, but also enhance the way of operating."*

Medicines for Europe

Medicines for Europe represents the generic, biosimilar and value-added medicines industries across Europe. Its vision is to provide sustainable access to high quality medicines, based on 5 important pillars: patients, quality, value, sustainability and partnership. Its members directly employ 190,000 people at over 400 manufacturing and 126 R&D sites in Europe and invest up to 17% of their turnover in R&D investment. Medicines for Europe member companies across Europe are both increasing access to medicines and driving improved health outcomes. They play a key role in creating sustainable European healthcare systems by continuing to provide high quality, effective generic medicines, whilst also innovating to create new biosimilar medicines and bringing to market value added medicines, which deliver better health outcomes, greater efficiency and/or improved safety in the hospital setting for patients. For more information please follow us at www.medicinesforeurope.com and on Twitter @medicinesforEU.