Press Release

EU digital strategy requires investments in the digitalisation of Europe's medicines regulatory agencies to succeed

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EU digital health and pharmaceutical strategies will miss the mark unless they address the clearly defined need to digitalise and to interconnect EU and national medicine agencies. Medicine manufacturers and healthcare practitioners submit a wealth of data to medicine agencies every year which could be used to improve healthcare delivery, reduce the risk of supply disruptions, increase information to patients and improve the efficiency of regulatory procedures – thus increasing the availability of medicines across Europe. Unfortunately, this data is siloed in medicines agencies and difficult to access for these important public health purposes. This can be easily and rapidly changed by digitalising and interconnecting all of Europe's medicines agencies. In future, a digital, interconnected medicines regulatory system could serve as the foundation for other critical digital health initiatives to connect healthcare organisations.

The COVID-19 pandemic highlighted the need to digitalise the regulatory network. When EU and national agencies are linked, medicines supplies can be monitored and relocated to where they are needed more efficiently, thus reducing the risk of medicines shortages. This benefits patients who rely on secure supply of their medicines, as well as doctors, nurses and pharmacists who manage treatment. Furthermore, the introduction of digital tools, such as the electronic product information (ePI) leaflets would provide patients and healthcare professionals with the latest information on medicines, in a more accessible online format, in their own language thus improving their ability to manage their illness and facilitating the flow of medicines across Europe to where they are needed.

Commenting at the **Medicines for Europe** Digital Webinar, Executive Committee member Markus Sieger (CEO, Polpharma) said *"Our industry supplies the majority of prescription medicines to patients and submits important data to regulatory agencies every day. Digitalised systems would allow us to share information with regulators in real time, reduce administrative paperwork, and improve patient information and access to medicines. The EU digital strategy can help medicines agencies in all European countries progress into the digital era. We call on the EU to address this missing link and to build an interconnected digital regulatory infrastructure by 2022."*

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.