Medicines for Europe gears up for Ukraine's future accession to the EU

Press Release

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Medicines for Europe met today in Brussels with a high level Ukrainian government delegation led by Maryna Slobodnichenko, Deputy Minister of Health for European Integration. Medicines for Europe put forward ideas on how to plan for the future integration process which requires a lot of regulatory and market policy alignment including:

- Supporting the creation of a dynamic medicines agency with help and expertise from leading agencies in EU Member States and to encourage alignment with the regulatory standards and requirements for marketing authorisations .
- Learning from experience with other EU partners regarding Good Manufacturing Practice (GMP) recognition which is a pre-requisite for supplying medicines.
- Accelerating the alignment of digital regulatory requirements such as electronic Product Information (ePI), electronic Common Technical Document (eCTD) and access to the EudraGMDP* database all of which are needed for the modern oversight of medicines regulation.
- Ensuring Ukraine's rapid integration into EU safety systems, such as the European Medicines Verification System (EMVS) to fight against falsified medicines.
- Medicines for Europe is a committed partner with the EBA** of Ukraine to accelerate regulatory alignment and integration on medicines with Ukraine to support the country's rapid and effective accession to the EU.

Adrian van den Hoven, Director General of Medicines for Europe said: *"While we maintain our steadfast engagement to help address medicine shortages or availability problems in Ukraine***, it is time to move into the next phase of our relationship. Pharmaceutical regulation will be a complex part of the Ukrainian accession process. We need to start working now to accelerate this process with step by step integration into EU data and regulatory systems which will improve patient access to medicines in line with EU safety, quality and efficacy standards."*

Resource hub

Photos

EudraGMDP is the EU database on manufacturing, import and wholesale-distribution authorisations and good manufacturing-practice (GMP) and good-distribution-practice (GDP) certificates
** https://www.medicinesforeurope.com/wp-content/uploads/2023/06/MOU_PR.pdf
***Medicines for Europe members donated 1200 truckloads of medicine to Ukraine at the start of the war.

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.

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