Press release

Vigilance saves lives! More focus needed on sustainability and patient engagement

For Immediate Release

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- Pharmacovigilance is crucial to promoting and protecting public health and ensuring patient access to safe medicines.
- Greater use of IT systems can improve pharmacovigilance needs and should be optimised to ensure the most effective use of regulatory and industry resources.
- A clear roadmap will enable a better use of processes and tools to target risk and to reduce large volumes of non-essential data to be treated by industry and regulators.

National authorities, regulators, industry leaders and key stakeholders gathered in London this week to discuss how to improve patient access to safe medicines with an effective pharmacovigilance framework. This 11th edition of the **Medicines for Europe** pharmacovigilance conference highlighted the need to engage effectively with patients and making sure the information is communicated in a clear and real-time matter. As modern technology advances, industry and regulators have an unprecedented opportunity to include patients in pharmacovigilance activities, a key element of patient involvement.

When ensuring pharmacovigilance systems remain effective, it is crucial to think not only of the operational aspects but also that every effort should be made to ensure that systems are sustainable. The 11th Pharmacovigilance conference dedicated sessions to the future of our current systems, in addressing issues such as enhancement of the Eudravigilance database, audits and inspection practices that need rethinking and how to maximise the use of electronic reporting, and minimise waste and overlap in the system.

Adrian van den Hoven, **Medicines for Europe** Director General commented: "Efficient pharmacovigilance is paramount to ensuring the safe use of medicines. Industry and regulators have a shared responsibility to ensure that this system remains effective and efficient. Together, we can reduce waste in the system, improve operational efficiency, prioritise and focus on processes which bring the highest benefits to patients. We commend the regulatory community on the close cooperation in the implementation the enhanced Eudravigilance and look forward to developing a clear roadmap to focus on the highest risks for patients while reducing the overload of non-essential data that the system currently generates."

About 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,

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value, sustainability and partnership. Its members employ 160,000 people at over 350 manufacturing and R&D sites in Europe, and invest up to 17% of their turnover in medical innovation. **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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