Press release

2018 – A year of unprecedented challenges and opportunities for pharmaceutical regulatory systems

For Immediate Release

London, 25 January 2018

- Regulators and industry experts are meeting in London this week to improve the regulatory framework of the generic, biosimilar and value added medicines industry
- Future challenges posed by Brexit and the implementation of the Falsified Medicines Directive (FMD) require close cooperation between regulators and industry to handle these unprecedented challenges
- Regulatory convergence and optimisation will support patient needs and enable the industry to deliver increased access to safe, quality medicines.

This week in London, **Medicines for Europe** gathers regulators and industry leaders to discuss future opportunities and challenges in the regulatory environment of the generic, biosimilar and value added medicines industry. Future changes in the regulatory landscape as a result of Brexit and the implementation of the Falsified Medicines Directive (FMD) will be discussed over the course of a two day conference in London. The opportunities for regulatory optimisation and international convergence will also be advanced as positive trends for the future.

The optimisation of regulatory operations, reflected in the HMA/EMA and CMDh 2020 workplans, are an important milestone for regulators and industry. In particular the 'Regulatory Optimisation Group' (ROG) offers a promising platform to find practical solutions for regulatory efficiency and operational excellence. **Medicines for Europe** will support this optimisation process for the benefit of patients and partners involved in or impacted by regulatory activities.

Marc-Alexander Mahl, **Medicines for Europe** President commented: "This conference provides an invaluable platform for stakeholders to adapt to the challenges posed by Brexit and FMD implementation while seizing opportunities to progress on regulatory optimisation and convergence for a more efficient system. Efficient regulatory systems will play a key role for patient access to medicines across Europe."

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, 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.

Medicines for Europe Communications:

Andrea Bedorin abedorin@medicinesforeurope.com

Kate O Regan koregan@medicinesforeurope.com