Press Release

Strong support for new measures to protect patient access to medicines in Northern Ireland

For Immediate Release
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Medicines for Europe welcomes the comprehensive measures package proposed by the European Commission to ensure a continuous flow of essential medicines to patient located in Northern Ireland and to small Member States that depend on United Kingdom, which we understand were also amply reviewed also by British authorities.

The Northern Ireland Protocol created regulatory and legal challenges for the supply of medicines in Northern Ireland.

Friday's package represents a positive step forward and, once approved by the EU co-legislators, it will provide both immediate and more permanent solutions for patient access to medicines in Northern Ireland by allowing the:

- Marketing authorization holders to continue to supply medicines to Northern Ireland from the UK as long as the medicines comply with EU regulations.
- Batch testing, the qualified person for batch testing and pharmacovigilance to continue to be carried out in the United Kingdom for Northern Ireland.
- Marketing authorization holders to be able to maintain one pack for Northern Ireland and the UK while applying for either national or DCP (EU-harmonised) licences – which are the most commonly used licences for off-patent medicines.
- Adjustments to the Falsified Medicines verification system to enable safety in Northern Ireland while prevent the potential diversion of UK medicines on to the rest of the EU market.

The package provides also temporary solutions to ensure supply of medicines to smaller Member States, such as Cyprus, Malta and Ireland, that rely on some supply from the UK market.

Medicines for Europe will strongly support the adoption of these vital measures for patient access to medicines in Northern Ireland in the forthcoming legislative procedure.

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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