Statement

Subject: Medicines for Europe reaction to European Council negotiating mandate on the proposal for an EU Supplementary Protection Certificate (SPC) manufacturing waiver

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Medicines for Europe appreciates the agreement reached today in the Council on the SPC manufacturing waiver, which shows the political will to move the negotiations forward.

There is positive momentum in the Council and in the European Parliament on the SPC manufacturing waiver.

Both institutions seem committed to reaching a successful conclusion under this legislature and are addressing the key issues point by point.

- **On Day-1** there are clear expectation from the European Parliament to follow the opinions of the ENVI and the INTA Committees. We stress the importance of Day-1 launch to actually achieve the jobs and the public health benefits of the manufacturing waiver as demonstrated by the Commission studies and impact assessment. The absence of the Day-1 launch would be detrimental to EU SMEs and European patients.
- **On notification**, the protection of commercially confidential information is now well understood by all parties, but it is important that this is clearly reflected in the actual wording of the manufacturing waiver.
- **On the date of applicability**, while it is fundamental to keep the ambitions very high in the next weeks in order to actually achieve the benefits of the waiver as soon as possible, the progress achieved in the Council goes in the right direction.

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 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.