SUPPORT a comprehensive SPC manufacturing waiver:
for patient access, sustainable healthcare and manufacturing jobs.

Europe is a leader for pharmaceutical manufacturing and R&D. Our industry has revolutionised access to medicines through the development of complex life-saving treatments, like biosimilar medicines. The EU pharmaceutical ecosystem relies on high technology manufacturing skills that are being eroded due to forced delocalisation of our industry. But the EU is on the verge of stopping this forced delocalisation with the SPC manufacturing waiver.

We thank the EU institutions for prioritising this legislative process by adopting mandates for the final phase of the legislative procedure. The positions of the institutions are so closely aligned that an agreement is clearly possible.

As anticipated by the Council, the Parliament has introduced the possibility to use the waiver to manufacture and stockpile for EU day-1 launch albeit limited to two years. This would bring Europe in line with the stockpiling possibility that already exists in other regions of the world, like the United States.

The Parliament's position on applicability is also closely aligned with the Council wording. And both co-legislators recognise the need to protect commercially confidential information while also addressing the concerns of patent offices and competition law – as delineated in the Parliament's text.

All stakeholders and concerned parties have had the opportunity to voice their position and contribute their data throughout this legislative process – which began back in 2015 with the adoption of the Single Market Strategy. We urge the EU institutions to now adopt the SPC manufacturing waiver for patients, sustainable healthcare and manufacturing jobs.

Adrian van den Hoven

Director General Medicines for Europe

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Signatory Associations

European generic, biosimilar and value added medicines association

Asociación Española de Fabricantes de Productos de Química Fina

Hungary

Germany

Germany

Spain

Italy

Bulgaria

Croatia

Greece

Portugal

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better access. better health.
SPC waiver

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