Press Release

The Supplementary Protection Certificate (SPC) manufacturing waiver becomes operational!

For Immediate Release

Brussels, 01 July 2022

Today the transitional period for the application of the Supplementary Protection Certificate (SPC) manufacturing waiver ends. The SPC manufacturing waiver will become operational and generic and biosimilar medicines companies will be able to start manufacturing in Europe for export, stockpiling, and day 1 launch in Europe.

The SPC manufacturing waiver was adopted to remove a major competitive disadvantage of EU-based generic and biosimilar medicines manufacturers compared to foreign countries and to ensure better and faster patient access in Europe and abroad.

The waiver should stimulate significant investments to seize manufacturing opportunities, create thousands of jobs in Europe and increase Europe's capacity to manufacture and supply its own medicines and boost security of supply.

The key to deliver on these key objectives depends on the implementation of the legislation in EU Member States. National courts should reject any attempt to block EU medicines manufacturing due to redundant notification requirements or strategies to access the commercially confidential information of generic and biosimilar manufacturers. The legislation should not be misused to block competition in Europe.

Adrian van den Hoven, Director General of Medicines for Europe said: "*Companies are reinvesting in Europe thanks to the SPC manufacturing waiver. We will strongly oppose attempts to block competition, better access to medicines and job creation. We call on authorities to closely monitor any potential misuse of the notification system for frivolous litigation which could delay competition from generic and biosimilar manufacturers in markets where SPCs have expired. The SPC waiver is the first step to improve access to medicines, reinvest in EU manufacturing and to build a stronger and more resilient medicines supply.*"

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.