URL :http://www.euractiv.com/
PAYS :Royaume-uni
TYPE :Web International

► 12 juin 2018 - 04:15

> Version en ligne

Andriukaitis: SPC manufacturing waiver does not damage pharma innovation

The European Commission's proposal to add an SPC manufacturing waiver on exports will not damage innovation, as the pharma industry claims, and only intends to support small and medium generic drug companies, according to EU Health Commissioner Vytenis Andriukaitis.

"I understand those messages but this is not about reality," Andriukaitis told EURACTIV.com, referring to the supplementary protection certificates (SPC), an intellectual property right that serves as an extension of a patent right in the EU.

"It's not true that it damages innovation. We have the health technology assessment to help us have innovation in our hands. It's about possibilities to allow small and medium enterprises to produce generics and sell them to the market. Of course, who likes to have more competitors?" he said.

The Commission presented on 28 May its legislative proposal to add a manufacturing waiver to SPCs as part of its upgraded Single Market Strategy in 2015.

An SPC usually extends the protection of patented medicines by up to five years to compensate for the time lost in obtaining regulatory approval of the medicine.

However, during this period, European manufacturers of generic and biosimilar medicines cannot produce their medicines in the EU.

The SPC manufacturing waiver for export purposes will allow generic and biosimilar manufacturers to start producing medicines in the EU during the SPC period and export them lawfully during this period to unprotected non-EU markets, where the SPC does not exist or has already expired.

Considering that the industry is currently import-dominated, according to the executive, an SPC manufacturing waiver for exports to countries outside the EU could allow the EU generics and biosimilars industries both to create thousands of high-tech jobs in the EU and start many new companies.

The generic industry has been pushing for this SPC manufacturing waiver so it can start manufacturing drugs even while an SPC is in place, saying this will ensure better access to generics.

On the other hand, the pharma industry does not share this view and warns of possible severe implications on innovation and investment in the EU.

In an interview with EURACTIV last October, Nathalie Moll, Director General of the European Federation of Pharmaceutical Industries and Associations (EFPIA), said that an SPC manufacturing waiver would be detrimental to innovation, research and development in Europe and the economy as a whole.

"It would be sending a concerning signal about the EU's respect for and seriousness about building a knowledge-based economy," she said.

Reacting to the Commission's proposal, EFPIA said that by reducing the IP rights, the executive jeopardises patients' access to innovative treatments.

"It also sends a global signal that Europe is weakening its commitment to IP, putting this investment, these jobs, this opportunity for economic growth and the advancement of patient care in Europe at serious risk."

The 'day 1 launch'

MedicinesforEurope, which represents the European generic industry, expressed its satisfaction

with the proposal; however, it said there were still some “anomalies” to be fixed.

Marc Alexander Mahl, president of **MedicinesforEurope,** noted that the proposal should allow companies to prepare for “day 1 launch” after expiry in Europe.

“Without this, European patients will not get timely access to European manufactured generic and biosimilar medicines,” he said.

In an emailed response, **MedicinesforEurope** told EURACTIV that EU generic and biosimilar medicines manufacturers, when they can afford to do so, currently move production outside the EU during the SPC period in order to be ready for the launch on the EU market from Day 1 after the SPC expires.

“With the Day 1 launch provision in the SPC manufacturing waiver proposal, manufacturers (in particular SMEs) will not be forced to delocalise manufacturing to be able to launch their products on the EU market on Day 1 after SPC expiry,” the association said.

Referring to the executive’s impact assessment, **MedicinesforEurope** emphasised that only a “comprehensive and usable SPC manufacturing waiver, covering export to non-EU countries and production for immediate launch in the EU after SPC expiry, will create thousands of high-skill jobs, will allow production and R&D to remain in Europe”.

Background

New Commission study fuels generic drugs industry ‘manufacturing dispute’

The European Commission launched on Thursday (12 October) a public consultation on supplementary protection certificates for pharmaceutical products and the so-called Bolar patent research exemption.