EU to help boost exports of generic pharmaceuticals

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The EU has come a step closer to adopting new rules that will boost the export of generic medicines and biosimilar products to third countries. EU ambassadors meeting today in Coreper agreed on the Council's position on a draft regulation which introduces an exception for manufacturing for export purposes (manufacturing waiver) to the protection granted to an original medicine by a supplementary protection certificate (SPC).

Thanks to the waiver, EU-based makers of generics and biosimilars will be entitled to manufacture a generic or biosimilar version of an SPC-protected medicine during the term of the SPC if done exclusively for the purpose of exporting to a non-EU market where protection has expired or never existed.

The draft regulation is expected to remove the competitive disadvantages faced by EU-based manufacturers of generics and biosimilars vis-à-vis manufacturers established outside the EU in global markets, but also in day-1 EU markets by building up production capacity.

The exception will operate only where :

- generics or biosimilars are produced exclusively for export to third countries where protection of the original medicine does not exist or has expired;
- the maker has provided the information required by the regulation to both the authorities of the member state of production and to the holder of the SPC at least three months in advance;
- the maker has duly informed all those involved in the commercialisation of the product covered by the exception that the product can be put on the market only outside the EU;
- the maker has affixed to the packaging of the product the specific logo provided for by the regulation indicating clearly that it is only for export.

Until a set date (three years from the entry into force of the regulation), the regulation will affect only SPCs that are applied for on or after the date of entry into force of the regulation. From then on , the regulation will also affect SPCs applied for before the entry into force of the regulation, but which have become effective after the entry into force of the

regulation.

Next steps

Once the European Parliament agrees on a negotiating mandate, the Romanian presidency will start negotiations with the European Parliament with the aim of adopting the regulation at first reading.

Background

The EU harmonised SPC system was introduced in 1992. It sought to compensate for the loss of effective patent protection due to the time required in order to obtain marketing authorisation (including research and clinical trials).

Global demand for medicines has increased massively (reaching €1.1 trillion in 2017). Alongside this, there is a shift towards an ever-greater market share for generics and biosimilars. Assuming an annual growth rate of 6.9%, by 2020 generics and biosimilars will represent 80% of all medicines by volume, and about 28% by value.

With the expiry of industrial property protection, over €90 billion of the first generation of blockbuster biologics will become open to biosimilar competition by 2020.

The draft regulation should contribute to Europe’s competitiveness as a hub for pharmaceutical R&D and manufacturing. It will help new pharmaceutical companies start up and scale up in high growth areas, and is projected to generate, over the next 10 years, additional net annual export sales of well in excess of EUR 1 billion, which could translate into 20 000 to 25 000 new jobs over that period.

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