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Producers of Generic Medicines and Biosimilars even More Supported by EU

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Effective 1 July 2019, the EU adopted a regulation by introducing a supplementary protection certificate (SPC) manufacturing and stockpiling waiver. This waiver also applies for biosimilar versions of SPC-protected medicine during the term of the SPC.

SPC's are defined as IP rights extending patent protection for up to five years for medicines that are subject to lengthy clinical trials prior to their authorization to be placed on the EU market.

With this new waiver, a competitive disadvantage should not be included, i.e. the need for EU biosimilar and generic manufacturers to move out of the EU in order to take advantage of the global generic and biosimilar market. The new regulation will allow generics producers to manufacture generic medicine during the term of the SPC, either for the purpose of exporting to a non-EU market, where no protection exists, or for the purpose of creating a stock that will be placed on the EU market after the SPC expires. Such stockpiling is permitted only during the last six months of the SPC duration.

Manufacturers who would like to benefit from this waiver, will be obliged to meet specific requirements, e.g. labeling the packaging of the product with an identifiable logo indicating that it is for EU export only.

During a transitional period of three years beginning 1 July 2019, the regulation will affect only SPC's that are applied for, on or after this date.

With this adaptation of the EU regulation, the EU expects predict that, "over the next 10 years, an additional net annual export sales of approximately EUR1 billion could potentially be generated. Additionally, the result could bring up to 20,000 to 25,000 new job opportunities over that period".

Click here for the EU press release.

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