September 2018

EFCG views on Commission proposal amending Regulation (EC 469/2009) concerning the supplementary protection certificate for medicinal products SPC manufacturing waiver

Innovation and Quality of Active Pharmaceutical Ingredients

save patients' lives.

The value of Active Pharmaceutical Ingredients and innovation

APIs are the **essential building blocks** of pharmaceutical products; they are the chemically **active substances** that are designed to produce the **desired therapeutic effect** in the body.

The European API and fine chemicals industry, represented by EFCG, is a high technology sector, that should be supported and promoted. **Its mission is to provide patients and healthcare professionals with top quality pharmaceutical ingredients for their medicines,** thus ensuring the **availability**, **affordability** and **adequate choice of pharmaceuticals** that help to promote **quality of life**.

This mission can only be achieved by means of an effective and coherent Industrial Policy for this sector, which helps to uphold its **high quality standards** and improve the global competitiveness of the entire EU pharmaceutical value chain, thus ensuring its future in Europe**.** In order to achieve its mission, our industry needs the necessary support to innovate.

EFCG member companies include companies that manufacture Generic APIs as well as companies that provide development and manufacturing services to the innovative pharmaceutical industry. As such, EFCG understands and supports efforts to keep a balanced regulatory framework that ensures strong IP rights whilst allowing for a competitively strong global generic industry to be based in Europe.

EFCG has consistently strived for a level playing field, where European Manufacturers of Active Pharmaceutical Ingredients and medicinal products are at no advantage over manufacturers located outside European countries – but are also not at a regulatory disadvantage versus these countries.

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The EU Commission proposal contributes to ensuring a level playing field and EFCG welcomes and fully supports it. At the same time, EFCG has always advocated for strict compliance with Intellectual Property Rights - wherever such rights exist and have not yet expired. Therefore we support any measure that prevents the re-importation and resale of medicinal products manufactured under the SPC Manufacturing Waiver regulation into the European space.

Our proposal

EFCG believes that the Commission's proposal will be strengthened in the final legislative text if additional clarity and certainty on terms and implementation of the waiver are provided without leaving room for any abusive interpretation of the spirit of the proposal, thus weakening the IP framework in the EU and putting EU producers at a disadvantage globally.

For instance, it should leave **no room for interpretation** that the waiver should solely apply for export to countries where there is no IP protection or where it has expired. This is essential to ensure the integrity of EU producers' intellectual property rights.

The text should also ensure the coherent and harmonised implementation of the SPC waiver across the EU.

Finally, special precautions must be taken in order to avoid that APIs produced for export under the updated terms of the SPC waiver cannot be re-imported into the EU or placed on the EU market before the expiry of their SPC. These precautions could include special markings and identifiers for these medicinal products intended for export.

EFCG supports

- **Commission's proposal for SPC manufacturing waiver for export to countries where such protection does not exist or has expired.**
- **Upholding the concept and principles of Intellectual Property Rights protection for innovative medicinal products.**
- **Any measure that ensures APIs produced for export under the updated terms of the SPC waiver are not re-imported into EU countries where their SPC has not yet expired.**
- **A reasonable timeframe for application of the SPC waiver, that allows the generics industry a swift launch whilst preserving the best interest of the innovators and the future of innovative medicines in Europe.**

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Background

On 28th May 2018, the European Commission published a proposal to amend the existing SPC Regulation (469/2009) with the objective of introducing a Supplementary Protection Certificate ("SPC") manufacturing waiver.

This waiver would allow companies to manufacture, prepare, supply and sell active pharmaceutical ingredients (APIs) covered by a Supplementary Protection Certificate before the expiry of that right, provided that the API is exported or used to manufacture medicines that will be solely exported to non EU countries where there is no patent and/or SPC or where such Intellectual Property rights have already expired.

About EFCG

EFCG was formed in 2004 to be the focus, the forum and the voice of the European fine chemicals and Active Pharmaceutical Ingredients manufacturers. We are a non-profit international sector group within Cefic - the Brussels-based European Chemical Industry Council.

EFCG represents over 100 organisations with over 200 manufacturing sites.

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About Cefic
Cefic, the European Chemical Industry Council, founded in 1972, is the voice of large, medium and small chemical companies in Europe, which provide 1.1 million jobs and account for 15% of world chemicals production