



**FEDERCHIMICA  
ASCHIMFARMA**

Associazione nazionale produttori principi attivi  
e intermedi per l'industria farmaceutica

Mrs. Elzbieta Bienkowska  
European Commission Internal Market, Industry,  
Entrepreneurship and SMEs  
Rue de la Loi 200  
1049 Brussels, Belgium

Milan, 29<sup>th</sup> March 2018

**Ref.: Intellectual Property rights – Supplement Patent Certificate (SPC) waiver**

Dear Mrs. Elzbieta Bienkowska,

with this my brief letter, I want to take the opportunity to explain why Aschimfarma, of which I'm the President, is in favor of introducing into European legislation the SPC waiver.

We are waiting for reading the results of the Public Consultation on SPC ended on January 4<sup>th</sup>, 2018. As for the regulatory act, we could think of *creating a European SPC title* with a provision related to the so-called "SPC manufacturing waiver for export purposes", as written in the preliminary pages of the Consultation.

In the following let me explain what we are asking for, who is Aschimfarma, the present situation and why it's urgent and necessary a SPC waiver.

#### **What we are asking for**

Aschimfarma's request for leveling the global playing field, by means of an effective and coherent Industrial Policy for the European manufacturers of active pharmaceutical ingredients (APIs) is that:

*"APIs manufacturers are allowed to manufacture, prepare, supply and sell active pharmaceutical ingredients, covered by a Supplementary Protection Certificate before the expiry of that right, if these products are exported to countries out of the European Union where there is no patent and/or SPC or where it has expired."*

#### **Aschimfarma: an Italian leadership in the global pharmaceutical-chemical market**

Aschimfarma, a branch of the Italian Chemical Industry Federation (Federchimica), is the Association of producers of the active pharmaceutical ingredients.

Italian sector accounts for 9% of the world market.

67% of the manufacturers are small to medium-size enterprises (SMEs), according to the European definition.

The incidence of Research & Development on the total turnover of the sector may be valued at approximately 3%.

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**Present situation and why it's urgent and necessary a SPC waiver**


The different national legal situations, regarding the SPC extension, create an imbalance and put the pharmaceutical industry from countries with SPC extension (i.e. Europe) into a competitive disadvantage compared to the pharmaceutical-chemical industry from countries without an SPC extension (i.e. China, India). A SPC waiver may permit the European manufacturers to compete with the manufacturers from outside Europe. Alternatively they are obliged to consider manufacturing activities abroad.

It's important to underline that the SPC waiver will not undermine or change the existing IPR balance in the EU. It will not erode or change IPR protection in any way. The only difference is that instead of marketing from extra-EU, it would be done from Europe.

If you should need more details on the subject don't hesitate to contact us or allow us to meet you.

We look forward to reading from you.

Kind regards,



THE PRESIDENT  
Gian Mario Baccalini

