Ares(2016)3612211

Ms. Elżbieta Bieńkowska
Commissioner for Internal Market, Industry,
Entrepreneurship and SMEs

Brussels, 17 July 2016

Dear Commissioner,

We would like to thank you for the meeting that took place 30th of June.

We particularly appreciated the opportunity to discuss some of the key issues that can significantly contribute to the development and growth of the generic and biosimilar medicines industry, the manufacturing waiver during the SPC period in Europe and the clarification of the scope of the Bolar clause, as part of 'A Single Market Strategy for Europe - Analysis and Evidence'.

In addition, we have very much appreciated the chance to highlight the important elements of the EPSCO Council Conclusions from June 2016 - "*Strengthening the balance in the pharmaceutical system in the EU and its Member States"*, related to generic, biosimilar and value added medicines, a key responsibility for DG GROW.

1. Manufacturing waiver during the SPC period in Europe

Background: The Supplementary Protection Certificate (SPC) in the EU promotes outsourcing of the European pharmaceutical industrial base, undermining Europe's industrial competitiveness. The European generic, biosimilar and value added medicines industries have extensive manufacturing capabilities throughout Europe, but cannot capitalise on the opportunities opening up worldwide.

An SPC manufacturing waiver allowing to produce generic and biosimilar medicines in Europe for the purpose of exporting to countries without SPC or where it has expired earlier would have a huge impact in terms of new investments in R&D and manufacturing, employment and economic growth. In no way will it undermine or change the existing IPR equilibrium on the EU market.

A targeted SPC Manufacturing Waiver amendment should be rapidly introduced to the SPC Regulation. This should not be linked to other legislative processes (e.g. wider IP/ SPC revision) as any delay in the process further contributes to the outsourcing of European manufacturing.

Key discussion points and agreed actions:

The European Parliament amendment to the Report on the Single Market Strategy (Comi Report – 26 May 2016) has taken a clear position in support of a quick introduction of the SPC manufacturing waiver "*Urges the Commission to introduce and implement before 2019 an SPC manufacturing waiver to boost the competitiveness of the European Generics and Biosimilar Industry in a global environment (..)"*

Medicines for Europe highly appreciates your understanding of urgency to amend the legislation as a stand-alone process. The rapid launch of the impact assessment and the public consultation would be necessary to achieve this objective.

Rue d'Arlon 50 - 1000 Brussels - Belgium
T: [redacted] F: +[redacted]
www.medicinesforeurope.com

Medicines from Europe will strongly engage in supporting advocacy at the level of European Commission and national governments to increase an understanding of this important provision for growth and jobs in the European pharmaceutical sector.

2. Clarifying the scope of the Bolar clause

Background:

There are differences among Member States on how they have implemented the Bolar exemption, with some Member States adopting a wider interpretation that covers all medicines, while others adopting a narrower interpretation (difference re API, export, third parties development, clinical studies for innovative drugs, HTA purpose etc). It creates uncertainty concerning the lawfulness of offering, manufacturing, selling and even buying patented APIs for regulatory or R&D purposes, even though the latter are supposed to be covered by the Bolar exception. This situation affects equally generic manufacturers and API suppliers.

Key discussion points:

Medicines for Europe supports the European Commission in its effort to broaden the scope of the Bolar clause and harmonise its application in EU member states as a part of the Single Market Strategy. Suggestions for clarification of the scope were proposed. The open question was raised about the process to be initiated by the EC to clarify the scope (e.g. long term- legislative change of the art 10.6 of Dir 2001/83; short term: eventual Commission Communication clarifying the scope). Commissioner Bienkowska recommended to contact a person responsible in the DG GROW to discuss possible options.

Agreed action

- Medicines for Europe to engage in technical discussion with a person responsible in the DG GROW

3. EPSCO Council Conclusions - Strengthening the balance in the pharmaceutical system in the EU and its Member States

Background:

During the recent The Hague meeting of the health ministers and industry stakeholders regarding pricing of medicines the primary focus was on the price of new compound/new indication. Medicines for Europe brought a very important dimension to the discussion on pricing indicating the significant value that generics, value added and biosimilar medicines have in balancing the healthcare spend and creating patients access to the medicines:

- Generic and biosimilar products offer better access for patients and savings for payers. In 2014, according to IMS, European healthcare systems would have paid Euro 100 bn more for medicines without generic competition. Meanwhile access to medicines has increased by 100% for seven key therapy areas thanks to generic medicine competition.
- It is therefore important to assure generic and biosimilar products can be effectively brought to market immediately after patent expiry of original product. Today, many mechanisms like patent linkage, arbitration regulations, slow pricing and reimbursement processes are causing delays of up to 18 months for effective commercial launch of generics and biosimilars

- Current pricing and reimbursement regulations in member states typically apply a reference price either to original or product. With the industry moving into more value added products, which bring important improvements to treatments for patients and healthcare professions, we need support in developing a "third pathway" for pricing and reimbursement of such products, which require substantially more investment behind pharmaceutical and clinical development – ranging from few dozen to 200 mn Euro

Action: While we appreciate the fact that our views were incorporated into the Council Conclusion paper, we would welcome the continued support of the Commissioner to help us drive this conclusions towards effective implementation. We are ready to discuss with DG GROW how to progress the Council conclusion proposals including through dialogue with the Commission and Council recognising the different EU and national competences in this area.

In conclusion, Europe has the capacity to lead in delivering economic growth and jobs in the pharmaceutical sector if the right framework is in place. We look forward to partner with you over the next years to achieve this common objective.

Yours faithfully,

Jacek Glinka
President, Medicines for Europe