INFARMA
Związek Pracodawców Innowacyjnych Firm Farmaceutycznych

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Warsaw, 11.04.2018 r.

Elżbieta Bieńkowska

Commissioner for Internal Market,
Industry, Entrepreneurship and SMEs
Komisja Europejska
Rue de la Loi / Wetstraat 200
1049 Bruksela
Belgium

Dear Commissioner Elżbieta Bieńkowska

On behalf of INFARMA, the trade association for the research-based pharmaceutical industry in Poland, I am writing to you regarding the European Commission's anticipated changes to patent protection of pharmaceuticals in Europe. INFARMA represents 28 leading pharmaceutical companies engaged in research and development activities and the production of innovative medicines operating in Poland.

The innovative pharmaceutical industry plays a significant role in the European Union and its Member States. The pharmaceutical industry directly employs 745,000 people in Europe, with 118,000 working in the research and development (R&D) sector specifically. The sector of innovative pharmaceutical companies is also one of the key elements of the health care system in Poland. Innovative companies operating in Poland and associated in INFARMA for years have engaged in financial resources and know-how, investing in the Polish market and significantly affecting the improvement of social well-being and public health. They are engaged, among others in the development of new drugs, clinical trials, production, distribution, marketing of new medicines, monitoring of adverse reactions and activities related to the education of healthcare professionals and patients, shared service centers. In recent years, the first investments of companies associated in INFARMA in the early stages of new drug development appear in Poland. They are based on cooperation with academic centers as well as Polish companies that develop new drug technologies.

In 2017, we prepared a report showing the impact of the role of innovative companies on the Polish economy, which I allow myself to attach to this letter.

The above-mentioned role of innovative pharmaceutical companies seems to be particularly important due to the strategic roles of the pharmaceutical industry and biolotechnology in Poland indicated in the Strategy for Responsible Development, which results in the operation of the government within the framework of the Biotechnology Development Program. An important factor determining the development of this sector is the existence of an appropriate ecosystem, as well as foreign investments. Innovative pharmaceutical companies can

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contribute to the commercialization of science and research projects and transfer of know-how, while for their activity it is important to ensure appropriate legal and economic stability.

In this context, we follow the process of discussions at the level of the European Commission regarding the review of regulations with regard to additional protective certificates in the pharmaceutical industry.

Specifically, we are highly concerned about the Commission's legislative intention to publish a proposal on a Supplementary Protection Certificate (SPC) manufacturing exemption by May 2018, and the subsequent risks that this poses to the innovative pharmaceutical industry in Europe.

We took part in public consultations conducted by the EC and we participated in discussions, during the workshop organized in the European Parliament referring to the discussion on the introduction of Manufacturing Waiver "Boosting jobs, growth, competitiveness and consumer right in Europe through the Supplementary Protection Certificate Manufacturing Waiver.

In our opinion the existing IP incentives framework is working effectively to deliver new and improved treatments to patients who need them, despite the long, complex and risky process of R&D. We therefore sincerely believe that not only is the existing framework allowing our industry to be a strong and important pillar of the European and local economy, but it is also proving to allow us to deliver upon our commitment to European society and ever-evolving patient needs.

We are highly concerned that any adjustment to Europe's existing IP incentives framework, may be to the detriment of both jobs and growth in Europe, and the health of Europe's patients. The public arguments presented to date in support of a SPC manufacturing exemption in Europe, suggests that its impact would be highly beneficial to generic or biosimilars manufacturers, yet would only have a marginal impact on the innovative pharmaceutical industry. However, we remain concerned that the different reports and studies on the exemption currently considered by the European Commission, including the Charles Rivers Associates (CRA) report, ignore at least three fundamental questions: 1) any impact of such a measure on the incentive to innovate in Europe; 2) to what degree displacement effects would arise – such as the extent to which generic products will act as substitutes for innovative ones; 3)whether this will lead to a leaner pipeline including for EU generic medicine producers in the long-run.

In the context of lack of thorough analysis of the exemption, and the above outlined risks, we believe that a legislative proposal to amend European patent protection at this point, would infringe on the principles of the Better Regulation agenda, by which the Commission has vowed to act upon in its policy making. Furthermore, we see a real risk that a recast of the SPC legislation, even with a targeted and limited scope, would have consequences going beyond its original intention and would lead to an erosion of Europe's intellectual property regime. Furthermore, other countries may relax their own IP regimes following the European decision, causing even larger losses for innovators.

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We therefore strongly recommend that the Commission undertakes a robust analysis of the full-ecosystem of the pharmaceutical sector to ensure that any decision on a SPC manufacturing exemption promotes the global competitiveness of the EU, creates jobs and growth and ultimately ensures that we continue to deliver innovative medicines to patients.

On behalf of INFARMA we would like to ask to meet with you to discuss this matter in further detail, and underline the importance of the innovative pharmaceutical industry to both Poland and Europe, and explain further the risks associated with the introduction of a SPC Manufacturing Exemption. In the meantime, we remain at the disposal of the European Commission and are looking forward to working further with you.

Yours sincerely,

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President of INFARMA

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