

Läkemedelsindustriföreningen (LIF) is highly concerned by the current approach of the Commission in the discussions around a “manufacturing waiver” for Supplementary Protection Certificates, the potential negative effects of such a waiver and the discussions within the Commission around revision of patent protection for pharmaceuticals.

Stockholm 180126

Dear Honourable Commissioner,
Dear Ms. Bieńkowska,

On behalf of *Läkemedelsindustriföreningen*, LIF (The Swedish Association of the Pharmaceutical Industry), I am writing to you regarding an issue that will have a significant impact on Swedish and European industries in general. LIF is the trade association for the research-based pharmaceutical industry in Sweden, with about 90 members and associate companies, who represent approximately 80 percent of the total sales of pharmaceuticals in Sweden. We are highly concerned about the discussions within the Commission regarding the potential revision of patent protection for pharmaceuticals, particularly the so-called supplementary protection certificates (SPCs).

We are worried about European Commission proposals being considered to limit patent extension terms (SPCs), by permitting generic and biosimilar companies to manufacture products for export – a so-called export waiver – as well as to stockpile products – a so-called stockpile waiver – whilst the duration of a SPC term is still on-going. We believe that in the current situation a legislative proposal to amend European patent protection would infringe the Better Regulation principles by which the European Commission has vowed to act in its policymaking. In addition, we believe that the introduction of such patent exemptions would not be compatible with the EU’s trade policy, as it would run counter to the provisions set out in Free Trade Agreements with the EU’s trade partners.

A study by Charles River Associates (CRA) was commissioned by the European Commission and claims that the intended revision of the patent incentives and rewards framework will result in a strengthened pharmaceutical sector. In our opinion, this study is based on unrealistic assumptions and omits important assessments that are essential for a holistic policy.

The economy of the EU and its Member States, including Sweden, is highly dependent on its innovation power. Exceptions to the SPC will give a wrong signal and certainly lead to a reduction of innovation incentives of originators and could ultimately impact patient health. As an innovation-driven country Sweden has a lot to lose if the potential long-term and secondary effects are not sufficiently evaluated or even disregarded. Our member companies have built their strategies on the condition of longstanding security, based on patent protection. The investments in the pharma and research-based industries are high-

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risk and long-term; the only way to sustain them is to offer certainty in the returns and the ability to continue the investments in the future.

This is secured by the intellectual property rights framework that currently exists in Europe, in particular due to SPCs. Picking this important framework apart puts at risk the Swedish research strategy, as the incentives that companies were previously benefiting from and that encouraged them to continue engaging in the long-winded and very costly research and development of medicines will no longer exist. In the long run this will result in lower investments into research and thus fewer medicines being made available for patients.

Our strong view is that the issues require further reflection and that the current legislation should not be changed. As a first step other less intrusive mechanisms could be considered. This was unfortunately omitted from the Commission's consultation. Successful national policies of Member States should be used as an example; such as France, where a waiver has a soft-law approach.

Any future SPC reform should in any case be done in a holistic way. Any imbalanced change of the IP framework would have profound implications and dangerous unintended consequences, such as uncontrollable spill-overs to other parts of the patent framework. Instead the Commission should focus on incentivizing and boosting innovations for Swedish and European companies and research activities in general. Policy action in this sector needs to be based on a solid assessment of all options available as well as the real implications for research into new medicines, society and patients across the EU.

Yours sincerely,

A black rectangular box redacting the signature of the Director General of LIF.

Director General, LIF
Läkemedelsindustriföreningen (LIF)

CC:
Vice-President Jyrki Katainen
Commissioner Cecilia Malmström