Council of the European Union

Brussels, 6 May 2019
(OR. en)

8734/19
ADD 1

Interinstitutional File:
2018/0161(COD)

CODEC 989
PI 74
COMPET 358
PHARM 22
IA 139

'I/A' ITEM NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
Subject:	Draft REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products **(first reading)** - Adoption of the legislative act - Statements

Statement by Denrmark

The European Commission presented on 28 May 2018 the Proposal for a Regulation amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products.

Since the beginning of the negotiations, Denmark has focused on maintaining a balanced approach, where the interests of one industry are not emphasised at the cost of another. Unfortunately, Denmark does not believe that this has been achieved.

The purpose of the proposal is to increase the competitiveness of EU-established generic and biosimilar producers in third countries and not to lower the standards of intellectual property protection in the EU. In principle, Denmark believes that a re-balance of the competitiveness level playing field for the EU-established generic and biosimilar pharmaceutical industry versus the non EU-established generic and biosimilar pharmaceutical industry should be achieved without undermining the strong competitive position of the EU established innovative pharmaceutical industry.

While reflecting a compromise, the final text of the regulation presents wide implications that may potentially benefit one side of the pharmaceutical industry in the future but may generate significant damage today for the other. By allowing storing of medicinal products and affecting acquired rights of the SPC holders, Denmark believes that the result is disproportionate and goes far beyond what is necessary in order to achieve with the objective of the proposal.

The absence of meaningful safeguards for storing will undermine legal certainty for the generic, biosimilar and innovative industry. It will also further deteriorate market conditions for investments in research and innovation, which are, by far, higher than any benefit that the SPC waiver proposal can generate.

Therefore, Denmark cannot support the regulation.

We expect the EU Commission to monitor closely the implementation of this legislation and will encourage it to take the appropriate measures in order to ensure legal certainty and to protect Europe's attractiveness as a hub for innovation and manufacturing.

Statement by Czechia

Czechia recognizes the need to keep a balance between the imperative to ensure the attractiveness of Europe for innovative pharmaceutical companies and the urgency to allow EU based generics and biosimilars to compete on the global markets.

Nevertheless, we are concerned about the consequences of the proposed limitation of the rights of SPC holders. Any such weakening of intellectual property rights in Europe might undermine investment in research and development of new medicinal products. As a result, Europe might lose its attractiveness as a center of research and development, which might have a negative impact in particular on EU patients who are dependent on the supply of innovative medicinal products.

Against this background, we are of the view that any restriction of exclusive rights of SPC holders should only be permissible in exceptional circumstances such as humanitarian reasons addressing public health problems in developing countries. Consequently, the geographical scope of export countries should be more proportionate and limited only to those that are least developed and other developing countries.

Joint statement by Belgium, France, Ireland, Portugal, Spain and the Netherlands

The undersigned Member States can support the political compromise regarding this regulation that provides carefully crafted exceptions to the supplementary protection certificate within the remit of intellectual property. We insist that future legislative initiatives also include incentives to promote research and development and that these initiatives should aim at strengthening the necessary conditions in the European Union that allow for the enhancement of intellectual property rights and innovation by the pharmaceutical sector.