Stakeholder consultation on the EU proposal for a Regulation of the European Parliament and of the Council amending Regulation No 469/2009 concerning the supplementary protection certificate for medicinal products

The Department of Business, Enterprise and Innovation is seeking views from stakeholders and interested parties on a proposed Regulation intended to amend Regulation No. 469/2009 (the SPC Regulation) by introducing an export manufacturing waiver.

A supplementary protection certificate (SPC) is an intellectual property right that constitutes an extension (of up to 5 years) to the term of a patent right (of 20 years). SPCs apply to innovative pharmaceutical products that have been authorised by regulatory authorities. They aim to offset the loss of effective patent protection that occurs due to the compulsory and lengthy testing and clinical trials that products require prior to obtaining regulatory marketing approval.

The Commission's proposed waiver will permit EU based companies to manufacture a generic or biosimilar version of a SPC protected medicine during the term of the certificate if done exclusively for the purpose of exporting to an non-EU market where the patent and SPC protection has expired or never existed.

The Commission's proposal adds an exception to Article 4 of Regulation No. 469/2009 allowing manufacture for export to non-EU countries where the patent and SPC protection have expired or never existed. The scope of the proposal is specific, limited and subject to a number of safeguards; prior notification by the generic/biosimilar manufacturer, labelling and due diligence requirements on the generic/biosimilar manufacturer.

The Commission's proposal, impact analysis, studies and public consultations are available on http://ec.europa.eu/growth/industry/intellectual-property/patents/supplementary-protection-certificates_en

Background

The Single Market Strategy (2015) announced a targeted recalibration of certain aspects of patent and SPC protection to boost the competitiveness of regulated industries such as the pharmaceutical industry. The aim was to tackle a number of problems including loss of export markets, lack of timely entry onto Member State markets following expiry of the SPC, for EU-based manufacturers of generics and biosimilars, due to unintended effects stemming from the current

EU SPC regime adopted almost three decades ago, and in view of changes in the pharmaceutical sector (e.g. the emergence of biosimilars).

The European Parliament's Resolution on the Single Market Strategy endorsed the need for actions on the EU SPC regime and urged the Commission to introduce and implement before 2019 an SPC manufacturing waiver to boost the competitiveness of the generics and biosimilars sector, but without undermining the market exclusivity granted under the SPC regime in protected markets.

To scope out the market and to evaluate the possible impact of various options the Commission contracted a number of independent studies, two of which were published in early October 2017. From mid-October to 4 January 2018 the Commission held an online public consultation.

Responses to call for views
Views from stakeholders and interested parties on the draft proposal are requested no later than close of business on 27th July 2018. Submissions should be marked "EU Proposal on SPC Regulation" and can either be emailed to ipu@dbei.gov.ie or sent in hard copy to the Intellectual Property Unit, Department of Business, Enterprise and Innovation, Kildare Street, Dublin 2, D02 TD30.

Further queries can also be made to ipu@dbei.gov.ie or to julia.omalley@dbei.gov.ie

Responses may be made available on the website of the Department of Business Enterprise and Innovation. Any material contained in responses which respondents do not wish to be made public in this way should be clearly identified as confidential in the submission.

Respondents should also be aware that responses may be disclosed by the Department following a request under the Freedom of Information Act 2014. Any information that is regarded as commercially sensitive should be clearly identified and the reason for its sensitivity stated. In the event of a request under the Freedom of Information Act, the Department will consult with respondents about information identified as commercially sensitive before deciding on such a request.

Any personal information which you volunteer to the Department will be treated with the highest standards of security and confidentiality strictly in accordance with the Data Protection Act 1988 to 2018.