Commission report on the Paediatric Regulation

Pharmaceutical Committee
18 October 2016, Brussels

Health and Food Safety

European Commission

The 2017 report

Article 50(3) of Regulation 1901/2006

"The Commission shall present a report to the European Parliament and the Council on the experience acquired as a result of the application of Articles 36, 37 and 38. The report shall include an analysis of the economic impact of the rewards and incentives together with an analysis of the estimated consequences for public health of this Regulation, with a view to proposing any necessary amendments."

European Commission

General context – Council conclusions

Council conclusions on strengthening the balance in the pharmaceutical system in the EU, June 2016

47. Prepare as soon as possible and with the close involvement of the Member States, while fully respecting Member States competences, the following:

a. an overview of the current EU legislative instruments and related incentives that aim to facilitate the investment in the development of medicinal products and the marketing authorization of medicinal products given to the holders of a marketing authorisation as implemented within the EU: Supplementary Protection Certificates (Regulation EC 469/2009), medicinal products for human use (Directive 2001/83/EC and Regulation EC 726/2004), orphan medicinal products (Regulation EC 141/2000) and paediatrics (Regulation EC 1901/2006);

b. an evidence based analysis of the impact of the incentives in these EU legislative instruments, as implemented, on innovation, as well as on the availability, *inter alia* supply shortages and deferred or missed market launches, and accessibility of medicinal products, including high priced essential medicinal products for conditions that pose a high burden for patients and health systems as well as availability of generic medicinal products. Among those incentives, particular attention should be given to the purpose of supplementary protection certificates as defined in the relevant EU legislative instrument and the use of the "Bolar" patent exemption[7], the data exclusivity for medicinal products and the market exclusivity for orphan medicinal products.

European Commission

General context – SPC evaluation

Call for tenders: Study on the legal aspects of the supplementary protection certificates in the EU

Published on: 09/06/2016, Last update: 02/08/2016

Deadline: 27/07/2016.

Number: 559/PP/GRO/IMA/15/15153

The European Commission's Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs plans to contract a legal study on the EU system of supplementary protection certificates (SPC).

A supplementary protection certificate (SPC) is an intellectual property right that serves as an extension of a patent right.

This study will be used by the Commission for an overall evaluation of the SPC system in the EU and to inform the decision on whether to come forward with a new SPC title at European level and whether to revise the existing SPC legislation.

The contracted study shall evaluate whether a new European SPC title, with the current or broader scope within the field of pharmaceutical and plant protection products, with improved provisions, is required to meet the requirements of current and expected innovative market developments in the EU.

With this primary purpose, the study shall evaluate the current SPC framework in terms of its legal efficiency in meeting its stated objectives given the development of directly affected and related product markets.

It shall also suggest whether the existing SPC rules need to be recalibrated given identified limitations.

The results could serve as a basis for an impact assessment for a future proposal by the Commission to recalibrate the existing EU SPC rules.

Topics

- Industry

Related news

- 13th annual plenary meeting of the EU-China consultation mechanism on industry and WTO/TBT
- Ministers use new Digital Compass to test different technologies and discuss their strategic contribution to growth
- How innovative is your country?
- Commissioner Bieńkowska to visit Ukraine on 12 July 2016
- Save the date: The European Cluster Conference 2016

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The road to 2017

- Economic analysis -> external study
- Public health impact -> EMA/PDCO report
- Views of Member States -> Pharma Committee
- EU and US system in comparison -> bilateral FDA
- Stakeholder experience -> Public consultation

=> Feed into the report

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Meeting Member States/EMA (19/9)

- Update on state of play of preparatory work for the 2nd report
- Debrief Member States on preliminary results from EMA data gathering and economic study
- Exchange of views with Member States regarding their experience with the Regulation
- Next steps including public consultation

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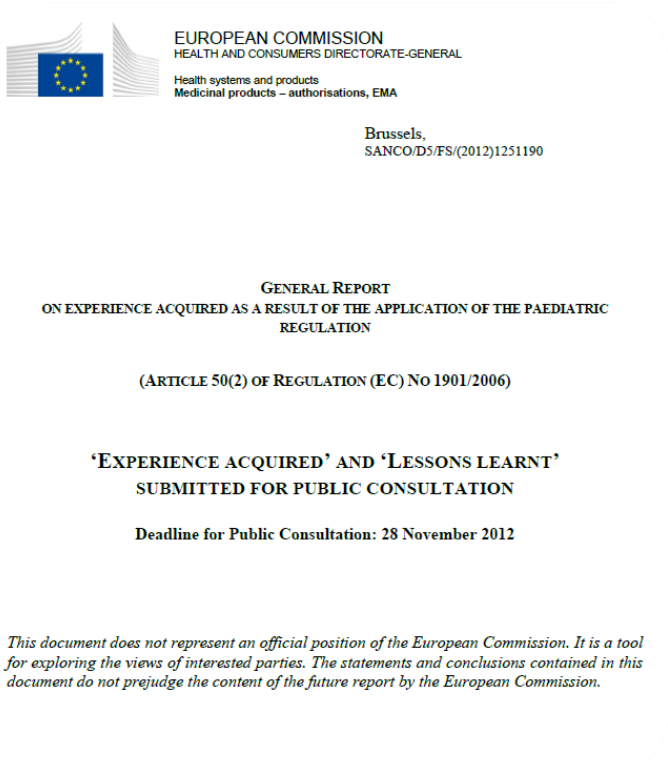
Public consultation

- Launch: November
- Based on consultation document
- 3-month period
- All answers will be analysed, published and will feed into the report



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HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
Medicinal products – authorisations, EMA

Brussels,
SANCO/D5/FS/(2012)1251190

GENERAL REPORT
ON EXPERIENCE ACQUIRED AS A RESULT OF THE APPLICATION OF THE PAEDIATRIC REGULATION

(ARTICLE 50(2) OF REGULATION (EC) NO 1901/2006)

'EXPERIENCE ACQUIRED' AND 'LESSONS LEARNT'
SUBMITTED FOR PUBLIC CONSULTATION

Deadline for Public Consultation: 28 November 2012

This document does not represent an official position of the European Commission. It is a tool for exploring the views of interested parties. The statements and conclusions contained in this document do not prejudge the content of the future report by the European Commission.

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More information:

http://ec.europa.eu/health/human-use/index_en.htm

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