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From:	General Secretariat of the Council
To:	Council
Subject:	**Employment, Social Policy, Health and Consumer Affairs Council** meeting on 8 December 2016 Analysis of the impact of supplementary protection certificates and pharmaceutical incentives and rewards on innovation, availability and accessibility of medicinal products in the EU – *Information from the Commission* (Any Other Business item)

Delegations will find attached an information note from the Commission services on the above mentioned subject.

ANNEX

ANALYSIS OF THE IMPACT OF SUPPLEMENTARY PROTECTION CERTIFICATES AND PHARMACEUTICAL INCENTIVES AND REWARDS ON INNOVATION, AVAILABILITY AND ACCESSIBILITY OF MEDICINAL PRODUCTS IN THE EU

The Council conclusions on *"Strengthening the balance in the pharmaceutical systems in the European Union and its Member States"* of 17 June 2016, invited the Commission to prepare as soon as possible and with the close involvement of the Member States, an evidence-based analysis of the impact of pharmaceutical incentives and rewards, including the Supplementary Protection Certificates (SPC), data and market protection and market exclusivity on innovation, availability and accessibility of medicinal products in the European Union. To this end, the Commission was asked to present a timetable and methodology by the end of 2016[1].

This document provides an overview of the activities, estimated timetable and methodology that the Commission intends to apply in this context. Considering the scale of the analysis and the importance to take a holistic approach, taking into account also our international commitments in the areas of health and intellectual property rights, the Commission has put emphasis on the need for coordination of and coherence among ongoing and foreseen Commission initiatives, as well as on the involvement of Member States and stakeholder consultation.

[1] Paragraph 47 of the Council Conclusions on "Strengthening the balance in the pharmaceutical systems in the European Union and its Member States" of 17 June 2016.

1. Proposed timeline and methodology

Due to the importance of balanced Intellectual Property-related incentives in the pharmaceutical sector, the Commission Single Market Strategy of October 2015[2] announced an evaluation of the rules related to Supplementary Protection Certificates (SPCs) and the 'Bolar' and research patent exemptions in the EU. Since 2015, the Commission has launched several studies to collect and analyse quantitative and qualitative evidence to make an informed decision by end 2017 on the potential next steps related to SPCs (referred below as "ongoing studies on Supplementary Protection Certificates").

In order to respond to the invitation of the Council in an appropriate and timely manner, the Commission has extended the scope of an already planned economic study on SPCs (referred below as "economic study") to include the analysis of the impact of additional pharmaceutical incentives and rewards on innovation, accessibility and availability of medicinal products. This study will also take into account the outcome of a study on the economic impact of the Paediatric Regulation[3], including its rewards and incentives, as explained below.

From 2015 until end 2017: Ongoing studies on Supplementary Protection Certificates

The Commission has launched several studies to evaluate the current SPC framework for pharmaceuticals and plant protection products and 'Bolar' and research patent exemptions. A study on legal aspects of the EU SPCs framework ("legal study") was contracted in November 2016 and should be finalised by July 2017. A scoping economic study on different economic aspects surrounding SPCs in Europe ("preliminary economic study") was launched in July 2016 and should be completed by the end of 2016.

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2 Commission Communication "Upgrading the Single Market: more opportunities for people and business" of 28.10.2015, COM(2015) 550 final.

3 Regulation (EC) No 1901/2006, OJ L 378, 27.12.2006, p. 1.

An additional study ("final impact assessment study") might be launched by mid-2017, to investigate further qualitative evidence in view of a possible impact assessment. The Commission will also work with stakeholders to ensure that the patent system is fit for purpose in this area. In the coming months, it might publish an inception impact assessment and open a public consultation in order to gather stakeholders' views on possible initiatives in the SPC domain of the pharmaceutical sector.

From end 2016 until end 2017: Study on the impact of pharmaceutical incentives and rewards on innovation, availability and accessibility of medicinal products in the EU (the "economic study")

The terms of reference for the economic study on pharmaceutical incentives, including SPCs, data and market protection and market exclusivity, have been designed to cover the overall protection that pharmaceutical companies enjoy for their products, including through data and market protection, market exclusivity for orphan medicinal products, and paediatric rewards where relevant. An external consultant will carry out the study as from the beginning of 2017 for a period of 9 months.

As requested by the Council, this study will provide, *inter alia:*

* An overview of the current EU legislative instruments and related economic incentives that facilitate the investment in the development of innovative medicinal products, with particular reference to SPC-type protection, data and market protection, orphan market exclusivity and paediatric rewards.

*Economic and statistical evidence on how these incentives and rewards are used in practice by the pharmaceutical innovators, i.e. either in combination or individually, and will analyse the reasons behind these practices.

* An analysis of the overall economic effects of pharmaceutical incentives and rewards, including SPCs, data and market protection and market exclusivity, on innovation[4], availability and accessibility[5] of medicinal products for patients, 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. The study will analyse the impact of all the incentives jointly and the role of each of the incentives individually.

* An analysis to what extent incentives have an impact on pricing in general (depending on the available information).

* An analysis of whether and how these incentives relate to the launch of innovative products in the areas of unmet medical needs and to what extent they influence the market entry of generics, similar and biosimilars products. To the extent possible, the study will also gather evidence on supply shortages and deferred or missed market launches. Different commercial and public databases as well as other sources of information will be used to build relevant statistics and econometric models to provide sound economic evidence.

*** Case-studies** to get an understanding of the concrete use of SPC and pharmaceutical incentives throughout the entire product lifecycle management, and to identify on the one hand the importance of the various incentives for pharmaceutical innovators, and on the other hand their possible unintended effects on patients and national health care budgets.

First Quarter of 2017- Study on Paediatrics

The abovementioned study ("economic study") will take into account the results of the study on Paediatrics, which will be finalised at the beginning of 2017. The study on Paediatrics will provide an economic evaluation of the impact of the Paediatric Regulation with specific focus on the rewards and incentives established under it. In 2017, the Commission intends to publish a second report on the impact of the Regulation from an economic and public health perspective.

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4 Regarding the impact on innovation specifically, the study will consider, among others, whether innovation induced by exclusivity yields to therapeutic gains by new products.

5 The term “availability” is mostly understood as ensuring that innovative products are developed, authorized and placed on the market. The term “accessibility” is mostly understood as ensuring that patients can receive the products. However, there might be a need to refine the working definitions if it is deemed to be appropriate and necessary for the objectives of the study.

2018 – Potential complementary study

If relevant questions related to the requested analysis above are not covered or remain unanswered, the Commission might consider the necessity to launch another study to cover some additional aspects of the pharmaceutical legislation such as data and market protection, various aspects of innovation, shortages of medicines, or impact on the sustainability of health systems. The Commission will also take into account other relevant ongoing initiatives in this field, in order to ensure a good coordination of work and avoid duplication of efforts

2. Involvement of Member States and relevant stakeholders' consultation

The Commission would like to underline the importance of the Member States' involvement and stakeholder consultation to gather some of the data necessary to conduct an in-depth and evidence based analysis. As stated in the Council Conclusions, "*The Commission will conduct the analysis on the basis of the information that is made available or gathered, including from the Member States and other relevant sources"*[6]. This is particularly important regarding the pricing of medicinal products, where Member States collaboration will be essential.

Surveys with Member States and relevant stakeholders will be conducted. Academic and professional experts in the pharmaceutical and public health sectors, including experts from international organisations active in this area such as OECD, WHO, WIPO, will be interviewed, to obtain qualitative information on the issues to be investigated.

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6 Extract from paragraph 47 of the Council Conclusions.