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Delegations will find in the Annex note from the Hungarian delegation on the above-mentioned subject to be raised under "Any Other Business" at the session of the Council (EPSCO) on 22 June 2018.

ANNEX

Public health aspects related to the manufacturing waiver of supplementary protection certificate for medicinal products

(Information from the Hungarian delegation)

On 28 May 2018, the European Commission presented its proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products (SPC waiver proposal).

In the long-awaited draft regulation, the Commission proposes the introduction of an exemption from SPC protection in case of manufacturing of generic and biosimilar medicinal products on condition that they are exported to third countries. The Hungarian delegation welcomes the proposal and considers it as a step in the right direction to make the world's most generous pharmaceutical incentive system more proportionate and to support the European pharmaceutical industry. We do hope that the discussions will bear fruit in a short time in order to achieve its benefits as soon as possible.

On the other hand, for the reasons below, the Hungarian delegation would like to highlight a couple of considerations that need to be taken into account when assessing the legislative proposal and that warrant an early discussion at a political level (in the form of an AOB agenda item at the EPSCO Council meeting).

1. **The draft regulation does not provide for stockpiling manufacturing allowing for actual "day1 entry"** of generic/biosimilar products on the EU market as soon as the SPC protection expires. We are aware that the export waiver already has an accelerating effect, but having seen the impact assessment accompanying the proposal, there seems to be further room for improvement. The impact assessment makes it clear that there is 4% public spending savings potential triggered by the export waiver, but further 4% in savings can be expected from a stockpiling waiver allowing for day1 entry on the European market[1], paired up with a more diversified source of supply. Timely generic entry, apart from contributing to the sustainability of national health systems, enhances patient access to new therapies as well.

2. **The SPC waiver would only be applicable in the case of certificates granted on or after the expiry of the third month after the publication of the amending regulation**. This means that in most cases, due to the fact that the SPCs expiring in the following years are mostly already granted, the earliest time when effective benefits of an SPC waiver can be reaped will be between around 10 and 15 years after the new rules are published. This transitional measure runs counter the declared objective of the proposal to give a boost to the European generic/biosimilar industry in the near future.

The Hungarian delegation would like to make it clear that it does not question the legitimacy of incentives to support innovation as they also play a very important public health role. In the same vein, we also consider SPCs as important tools to compensate for the loss of effective patent protection due to development and authorisation procedures. However, we think that these incentives could be more balanced and proportionate to meet patients' expectations.

Having regard to the above-mentioned considerations, we do hope that public health aspects will be duly taken into account in the coming discussions of the draft regulation and we also call the Austrian Presidency to organize the debate in this spirit.

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[1] SWD(2018) 240 - Impact Assessment accompanying the Proposal for a Regulation COM(2018) 317 page 47.