EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Health systems, medical products and innovation
Medicines: policy, authorisation and monitoring

PHARM 759

PHARMACEUTICAL COMMITTEE
23 October 2018

Subject: **Duplicate marketing authorisation applications of biological medicinal products**

Agenda item 4iv

Following the last Pharmaceutical Committee meeting held on 23 October 2018, the purpose of this document is to provide additional background information regarding the duplicate marketing authorisation applications under the centralised procedure and to clarify the objective of the consultation on this issue.

- **Background**

In the framework of the centralised procedure, only one marketing authorisation may be granted to an applicant for a specific medicinal product[1]. In view of the unique nature and EU dimension of marketing authorisations granted under the centralised procedure, Regulation (EC) 726/2004 limits the ability of applicants/holders to obtain more than one marketing authorisation per medicinal product ("duplicate marketing authorisations").

In particular, Article 82(1) 2nd subparagraph of Regulation (EC) 726/2004 provides that:

> *"the Commission shall authorise the same applicant to submit more than one application to the Agency for that medicinal product when there are objective verifiable reasons relating to public health regarding the availability of medicinal products to health-care professionals and/or patients, or for co-marketing reasons."*

In such cases, the Commission assesses whether the conditions of Article 82(1) are met on a case-by-case, taking into account the overall objectives of preserving public health and the harmonisation of centrally authorised products[2]. In cases where the Commission agrees to the submission of an application for a duplicate marketing authorisation, the choice of the legal basis remains the sole responsibility of the applicant.

To be noted: Article 82 (1) concerns marketing authorisation applications submitted by an applicant regarding a medicinal product in respect of which a marketing authorisation has already been granted under the centralised procedure. There are no corresponding

[1] Article 82 (1) first subparagraph of Regulation (EC) 726/2004.
[2] For further details, see the Commission services note on the handling of Duplicate Marketing Authorisation Application, http://ec.europa.eu/health/files/latest_news/2011_09_upd.pdf

provisions in Directive 2001/83/EC that apply to the mutual recognition and decentralised procedures.

- **The specific case of duplicate marketing authorisation applications of biological medicinal products**

Under Article 82(1), the Commission shall agree to the application for a duplicate if there are objective verifiable reasons relating to public health regarding the availability of medicinal products to health-care professionals and/or patients. According to Annex I.1 of the 2011 Commission note on the Handling of Duplicate Marketing Authorisation Applications, "*The first introduction of a generic product by the holder of the reference medicinal product can also improve the availability of a medicinal product. This is because the first entry of a generic to the market has an impact on availability as it usually increases accessibility*".

On this basis, several duplicate marketing authorisations of already authorised chemical medicinal product have been granted as generics to originator companies. In one case, an originator company was granted a duplicate of its own biological medicinal product as a generic.

The granting of duplicate marketing authorisations as generics in the case of biological medicinal products has raised concerns from the generic industry. They underlined the impact this may have on the biosimilar market at national level, as only originator companies can request a duplicate of their own biological medicinal product as a generic. As national pricing, reimbursement and substitution rules in the European Union are generally linked to the regulatory status of the medicinal product, they consider that this would affect choice and competition, and also undermine the EU concept of biosimilar medicines, and ultimately may limit the range of options available to patients.

- **Objectives of the consultation**

We would welcome Member States' comments on attached consultation paper, which was prepared for the recent targeted stakeholder consultation (lasting from 18 May to 10 September 2018). We would in particular be interested in the following issues:

- What are your views on the impact of duplicate marketing authorisations of biological medicinal products on the availability of biosimilars to healthcare professionals and patients?
- What is your experience in the case of first introduction of a generic product by the holder of the reference medicinal product (chemicals and biologicals, if any) in terms of improving the availability of the medicinal product to patients?
- Do you share the generic industry's concerns described above? What is your experience in terms of duplicates of biological medicinal products authorised as generics? Can they be considered as increasing the availability of medicinal products to patients, or do you believe that they could hamper the biosimilar market and patients access to biosimilars?
- Is there a need to reflect the specificities of biosimilars in the note on duplicate marketing authorisation applications?

Action to be taken: For comments **by 30 November 2018.** Please note that we do not seek for comments on legal considerations related to Article 82 (1) of Regulation (EC) 726/2004 or to the granting of duplicate marketing authorisations at national level.