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Duplicate marketing authorisation applications :

The case of duplicates of biological medicinal products

81th Pharmaceutical Committee
23 October 2018

Health and Food Safety

European Commission

OUTLINE

- **Rationale**
- **Stakeholder consultation**
- **Next steps**

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Rationale

- **Article 82 (1) of Regulation (EC) 726/2004**

  Principle: Only one authorisation for a specific medicinal product;
  Exception: objective verifiable reasons for public health regarding the availability of medicinal products to HCPs and/or patients or co-marketing reasons (role of the COM).

- **DG SANTE 2011 note on the Handling of Duplicate Marketing Authorisation Applications – Annex I.1.**

  Public health reasons: *"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".***

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Stakeholder consultation

- **Focus:** Duplicate marketing authorisations of **biological** medicinal products authorised on the grounds that they would be a **"first generic**".

- **Issues** related to the **possible impact** of such duplicate marketing authorisations **on the biosimilar market** (including potential anticompetitive effects) **and the undermining of treatment options available to patients**.

- Targeted stakeholder consultation on DG SANTE Website : 18 May-10 September 2018

Possible clarifications of Annex I, section 1 on the first entry of generics in the case of duplicates of biologicals

Annex I - Assessment of public health and co-marketing reasons by the Commission

1. Public health reasons.

[….]

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[1]. ***Requests for duplicate marketing authorisation applications need to be properly substantiated and based on sound evidence.*** Any subsequent application of the holder of the reference medicinal product would need to be justified by further arguments, and could not be based solely on the fact that the second authorisation for the same product concerns a generic.

[1] ***On the basis of the experience gained since the publication of the notice, the first introduction of a generic product by the holder of a biological medicinal product may not improve availability. However, a case-by-case assessment of the impact on the availability of the product will be undertaken, on the basis of evidence provided by the applicant, with due consideration of the impact of the duplicate marketing authorisation on the availability of biosimilars to health care professionals and patients.***

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Next steps

- **8 contributions:** innovators, generic industry, patient organisation and hospital pharmacists.

- **Experience from Member States**: written procedure via the Phamaceutical Committee? Discussion at the next STAMP meeting?

- **Towards a clarification of the note on duplicate?**

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Thank you!