



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

TARGETED STAKEHOLDER CONSULTATION ON DUPLICATE MARKETING AUTHORISATIONS FOR BIOLOGICAL MEDICINAL PRODUCTS

CONSULTATION DOCUMENT

Deadline for replies: 10 September 2018

This document does not represent the European Commission's official position. It is a tool for exploring the views of interested parties. The proposed changes to the existing note contained in this document do not prejudice any decision with regard to possible clarifications of Annex I, Section 1 of the note on the handling of duplicate marketing authorisation applications.

Stakeholders are invited to comment on this consultation paper by 10 September 2018 at the latest. Responses should preferably be sent to sante-pharmaceuticals-B5@ec.europa.eu. They can also be sent by post to Directorate-General for Health and Food Safety, Unit SANTE B/5, BE-1049 Brussels. The subject line of the email or letter should include the reference: **"Targeted stakeholder consultation on duplicate marketing authorisations for biological medicinal products"**.

1. ABOUT THE CONSULTATION

1.1. Objective of the consultation

Since the publication of the note on the handling of duplicate marketing authorisations in 2011¹, the Commission Services have identified potential issues related to the granting of duplicate marketing authorisations for biological medicinal products on the grounds that they would be a "first generic". These issues relate 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.

It needs to be noted that requests for duplicate marketing authorisation applications for public health grounds must be justified by objective verifiable reasons regarding the availability of medicinal products to healthcare professionals and/or patients, as required by Article 82 (1) of Regulation (EC) 726/2004.

The objective of the targeted stakeholder consultation is to seek the views of interested parties on the specific issue of the impact of duplicate marketing authorisations of biological medicinal products on the availability of biosimilars to healthcare professionals and patients.

1.2. How can you contribute?

Stakeholders are invited to share their views, experience and data on the proposal outlined in Section 2 of this paper, by 10 September 2018 at the latest. Possible clarifications to the existing wording of Annex I, Section 1 of the note on duplicates regarding the first entry of generics are outlined in *bold italics*.

Please note, the consultation is not intended to seek editorial comments on the wording itself, but to receive feedback on the general principles that underly these possible clarifications, in particular with regard to the impact of the duplicate marketing authorisation of biologicals on the availability of biosimilars to healthcare professionals and patients.

Responses should preferably be sent to sante-pharmaceuticals-B5@ec.europa.eu. They can also be sent by post to Directorate-General for Health and Food Safety, Unit SANTE B/5, BE-1049 Brussels. The subject line of the letter or email should include the reference "Targeted stakeholder consultation on duplicate marketing authorisations for biological medicinal products".

When submitting your response, please include your name and e-mail address and specify if you are responding as an individual or as a representative of an organisation. If you represent an organisation, please indicate its name and category (company/business; public authority (local, regional, national, international); academic, patient organisation; healthcare professional organisation; NGO; other).

¹ https://ec.europa.eu/health/sites/health/files/files/latest_news/2011_09_duplicates_note_upd_01.pdf

If you represent a company, please state whether it falls within the EU definition of a small and medium-sized enterprise (i.e. less than €50 million annual turnover and fewer than 250 employees).

If your organisation is registered in the Transparency Register, please indicate your **Register ID number** at the beginning of your contribution.

Received contributions and/or a summary report will be published online. In view of this, please indicate whether your contribution (choose one option):

- (a) Can be published with your personal/organisation information (I consent to publication of all information in my contribution in whole or in part including my name/the name of my organisation, and I declare that nothing within my response is unlawful or would infringe the rights of any third party in a manner that would prevent publication).
- (b) Can be published if you/your organisation remains not identified (I consent to publication of any information in my contribution in whole or in part (which may include quotes or opinions I express) provided that this is done anonymously. I declare that nothing within my response is unlawful or would infringe the rights of any third party in a manner that would prevent publication).
- (c) Cannot be published but may be included in aggregated statistical data (I understand that my contribution will not be published. No personal data may be included in published statistical data, for example, to show general trends in the response to this consultation).

If you choose option (c), note that your contribution is still subject to requests for public access to documents under Regulation (EC) No 1049/2001.

1.3. What will happen after the consultation?

All contributions will be carefully analysed and inform the Commission as to the need to clarify the current wording of annex I, section 1 of the note on the handling of duplicate marketing authorisations applications regarding the issue of first entry of generics in the case of duplicate of biologicals.

In the interim, requests for duplicate marketing authorisation applications in this specific case will be assessed on a case-by-case on the basis of the evidence provided by the applicant.

2. PROPOSED POSSIBLE CLARIFICATIONS OF ANNEX I, SECTION 1 OF THE NOTE ON THE HANDLING OF DUPLICATE MARKETING AUTHORISATION APPLICATIONS

The wording provided in **bold italics** constitutes a basis for reflection and feedback from stakeholders.

For ease of the reference, the existing wording of Annex I, Section 1 on the first entry of generics is included in the left column.

<p>Existing wording on the first entry of generics (Extract from Annex I, Section 1 of the note on duplicates)</p>	<p>Possible clarifications of Annex I, section 1 on the first entry of generics in the case of duplicates of biologicals</p>
<p>Annex I -Assessment of public health and co-marketing reasons by the Commission</p> <p>1. Public health reasons.</p> <p>[....]</p> <p>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. 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.</p>	<p>Annex I - Assessment of public health and co-marketing reasons by the Commission</p> <p>1. Public health reasons.</p> <p>[....]</p> <p>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 accessibility¹. <i>Requests for duplicate marketing authorisation applications need to be properly substantiated and based on sound evidence.</i> 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.</p> <p>¹ <i>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.</i></p>