HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Consultation Comments Form for Guide to Biosimilars for Healthcare Professionals and Patients

You can use this form to submit your comments to HPRA.

- **Please answer the questions provided and return this form to consultation@hpra.ie.**
- **Alternatively you can provide any comments in an e-mail and send to consultation@hpra.ie.**

The HPRA reserves the absolute right to edit, summarise or remove comments received during consultation on draft guidance.

What is your area of practice, or interest in this guideline?	
Doctor	☐
Pharmacist	☐
Nurse	☐
Other healthcare professional	☐
Patient	☐
Researcher	☐
Pharmaceutical industry	☐
Regulator	☒
Wholesaler	☐
Other	☐
If you would like to provide additional information you can do so here: The Pharmaceutical Society of Ireland (PSI) is an independent statutory body, established by the Pharmacy Act 2007. It is charged with, and is accountable for, the effective regulation of pharmacy services in Ireland, including responsibility for supervising compliance with the Act. It works for the public interest to protect the health and safety of the public by regulating the pharmacy profession and pharmacies.	

Do you think this guideline achieves its goal of explaining the regulatory assessment process for the authorisation of biosimilar medicines?	
Yes	☒
No	☐

This guideline clearly explains the authorisation process for biosimilar medicines.	
Disagree strongly	☐
Disagree	☐

Neither agree not disagree	☐
Agree	☒
Agree strongly	☐

Is there anything else you would like to see discussed in the section concerning authorisation of biological medicines?
Section 5, which covers the authorisation of biosimilars, is detailed and informative. Perhaps of help to the reader would be the inclusion of an appendix at the conclusion of the guide, detailing the other procedures by which products can be authorised, notwithstanding that the centralised authorisation procedure is the most common mechanism for authorsiation of such products. The use of a flow chart capturing the various strands of the authorisation procedure could be employed to provide the reader with a concise overview of the processes involved.

This guideline clearly outlines the concept of extrapolation of indications as it relates to biosimilars.

Disagree strongly	☐
Disagree	☐
Neither agree not disagree	☐
Agree	☐
Agree strongly	☒

Is there anything else you would like to see discussed in the section concerning exptrapolation of indications?
We believe that this section covers all necessary topics concerning the extrapolation of indications. For healthcare professionals and patients alike, perhaps the final sentence of the 1st paragraph of 'Section 6' could perhaps be re-formatted/included in a text box/written in boldface so that the reader fully understands the importance of referring to accompanying product literature when prescribing, dispensing and using the biosimilar medicinal products. A pharmacist generally doesn't have access to the patients medical notes and therefore when dispensing a biosimilar medicine they will not always know the exact indication that it is being used for. Therefore it may not always be 8immediately possible for the pharmacist to check whether the biosimilar prescribed is licensed for the required indication.

This guideline clearly outlines the requirements for pharmacovigilance and adverse drug reaction reporting for biosimilars.

Disagree strongly	☐
Disagree	☐
Neither agree not disagree	☐
Agree	☒
Agree strongly	☐

Is there anything else you would like to see discussed in the section concerning pharmacovigilance and adverse drug reaction reporting for biosimilars?

The European legislative framework discussed in this section provides a useful background to the area of pharmacovigilance. The HPRA website could be referenced within this section to signpost healthcare professionals and patients towards the online Adverse Event Reporting functionality available through the HPRA website. Additionally an appendix could be inserted detailing a brief step by step guide for patients and professionals on how they can report suspected Adverse Drug Reactions. Also, where patients are concerned, a reminder could be included to urge them to discuss any concerns they may have with their prescribing doctor, pharmacist or other healthcare professional as they see fit.

This guideline provides clear information about prescribing practices and interchageability between medicines.	
Disagree strongly	☐
Disagree	☐
Neither agree not disagree	☐
Agree	☒
Agree strongly	☐

Is there anything else you would like about prescribing practices and interchageability between medicines?
This section is clear and concise and plainly outlines the legislative provisions underlining the interchangeablilty between medicines in the Irish context. Perhaps the inclusion of a hyperlink to the HPRA's webpage which details the role of the HPRA under the Health (Pricing and Supply of Medical Goods) Act 2013 would be beneficial as this webpage also contains the current live lists of interchangeable medicines. Signposting this resource to healthcare professionals would prove useful. Perhaps when addressing the practices of prescribing and dispensing, the guide could separate these two tasks into two distinct points, explicitly stating what exactly is required to be written on a prescription when prescribing a biologic product and also what is obliged to be documented upon dispensing these forms of medicinal products. The inclusion of bullet points or tables may be considered to further clarify this area.

This guideline clearly explains what a biosimilar medicine is.	
Disagree strongly	☐
Disagree	☐
Neither agree not disagree	☐
Agree	☒
Agree strongly	☐

If you would like to provide further detail with your answer you can do so here.
Section 3 explains succinctly and accurately what biosimilars are. Perhaps to aid understanding, the inclusion of a graphic detailing the various structural components of both a "biologic" and a "biosimilar" would be beneficial. This may help healthcare professionals and patients alike to identify/understand the subtle differences in structure between biosimilars and biologics.

If you have any other comments or suggestions please add them here. This guide is an informative body of work, which explains fully and comprehensively what biosimilars are, the processes by which they are authorised and their use in modern medicine. However as the guide is aimed at both healthcare professionals and patients, a balance needs to be struck between the level of detail given and the scientific literacy of the reader. Perhaps two separate guides could be considred, or additional support materials or resopurces to meet the differing needs of patients and healthcare professionals.

The HPRA are planning to conduct interviews with stakeholders concerning biosimilar medicines. Would you, or colleagues in your team or members of your association be willing to participate in such an interview?	
Yes	☐
No	☐

If yes, please include the relevant contact details here.
What is your area of interest?