HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Response Document - Public Consultation on Guide to Biosimilars for Healthcare Professionals and Patients

1 INTRODUCTION

The public consultation on the Guide to Biosimilars for Healthcare Professionals and Patients was closed on 22nd May 2015. Inputs to this consultation continued to be received and were accepted after this date. The HPRA would like to thank everybody who contributed to the process. Below is a document summarising the outcome of the consultation process.

The guide is intended to provide information on the regulation, prescribing, dispensability and traceability of biosimilar medicines in Ireland. The guide is targeted primarily at healthcare professionals but is also relevant to patients, manufacturers, distributors and those involved in hospital procurement.

The guide was open for public consultation to gather feedback from stakeholders as to whether it provided enough relevant information about biosimilars to meet their needs. The content of the guide has been amended to take account of the comments received as appropriate.

2 NUMBER OF RESPONSES

During the public consultation process, the HPRA received responses from a range of stakeholders including: a number of hospital pharmacists; a number of clinical specialists in relevant disease areas; the Pharmaceutical Society of Ireland (PSI); the Irish Pharmacy Union (IPU); the HSE's Corporate Pharmaceutical Unit; a range of marketing authorisation holder companies (including those with an interest in biological medicines); the Irish Pharmaceutical Healthcare Association (IPHA); the European Generic and Biosimilar Medicines Association; the Department of Health; the Irish Platform for Patients Organisations, Science and Industry (IPPOSI); members of the public.

The HPRA welcomes all the suggestions and contributions made and, while we are not always able to take on board the proposals, we would hope that this document provides an explanation for our approach.

2.1 Summary of responses received

The comments received were wide-reaching in nature and reflected the perspectives of individual contributor's areas of interest.

The pharmacy profession both in hospital and community settings welcomed the guidance and information provided and considered it generally met their needs well. Modifications were requested in the areas of traceability and pharmacovigilance reporting requirements, particularly relating to batch number recording. A number of areas where improvements could be made in

relation to sourcing of product and reference information were also highlighted. The pharmacy profession indicated a high interest in participating in further discussions with the HPRA on the subject of biosimilar medicines.

In general the clinicians that contributed to the consultation welcomed the guidance provided on the regulatory aspects and highlighted the importance of introduction of biosimilars in cost containment for the health sector with the caveat that patient safety is paramount. There was also considerable interest from this sector in participation in further engagement and discussion on biosimilars with the HPRA.

The most significant number of comments on the content of the guide were received from industry stakeholders. While these were broadly positive a number of recommendations were received for strengthening of the following topics contained in the guide.

- Reference to biosimilars as "similar versions" rather than "copy versions" of the medicine was recommended in line with more currently recognised international terminology.
- Requirement to include more specific content on the components of the biosimilar comparability exercise.
- Requirement to distinguish more clearly between pre-authorisation and post-authorisation requirements for the comparability exercise.
- Requirement for traceability and pharmacovigilance reporting to be based on recording of product brand names.
- Clearer distinction between pharmacy substitution of medicines and prescriber-initiated interchanging of medicines. More restrictive position on interchanging to be presented within the guidance.
- Greater clarity that a biosimilar medicine is not a generic medicine and that a different regulatory process applies to its approval.
- Strong desire to mandate brand name prescribing of biologicals.
- Clarification of the prescription writing requirements for biological medicines in the context of cross-border dispensing.
- Greater highlighting of the cost benefits that could be achieved for the health system in using biosimilars.
- Better clarification on the use of international non-propriety names for biological medicines.
- Need for additional guidance specifically for patients focussed on the use of biological medicines, including enhanced involvement in prescribing decisions.

3 HPRA RESPONSE

3.1 Updates following the consultation

In general the HPRA has on taken board the comments and suggestions received during the consultation across all areas. Throughout the document there has been strengthening with respect to sources of reference information for biosimilar medicines, taking into account the needs of relevant stakeholder groups. The terminology used to describe a biosimilar has been updated to remove references to "copies" and/or "copy versions".

The most significant updates have been made in relation to the content on the comparability exercise carried out during regulatory approval of a biosimilar medicine and in the sections dealing with interchanging and substitution. A brief summary is provided below.

Further detail has been incorporated into the content of the guidance that sets out the requirements to demonstrate quality comparability of the biosimilar medicine to the reference. This includes an overview of the quality target product profile and ranges. A clear distinction has also been made on requirements which are applicable during pre-authorisation and post-authorisation stages for the medicine. Further detail and clarity has been provided in the section dealing with the rationale for indication extrapolation and when this is considered acceptable.

Updates have also been made to the sections of the guidance dealing with interchanging and substitution. A clear distinction has now been incorporated to clarify that substitution is considered a process that takes place at pharmacy level without the involvement from the prescribing physician. In contrast, interchanging is considered a process that involves decision and involvement from the prescribing physician.

The HPRA will follow up with all stakeholders that have indicated an interest in further engaging with the HPRA on biosimilar medicines. Arrangements for this will be progressed shortly.

4 CONCLUSION

There was a broadly positive response to the HPRA Guide to Biosimilars for Healthcare Professionals and Patients. Many informative comments and suggestions were received in submissions and these have been largely considered in the finalised guide.

We would like to thank all those who contributed to the consultation process.

Human Products Authorisation and Registration Department
14th October 2015