
Guidelines on the quality, safety and efficacy of biotherapeutic protein products prepared by recombinant DNA technology

APPENDIX 7. REGULATORY ASSESSMENT OF APPROVED rDNA-DERIVED BIOOTHERAPEUTICS

NOTE:

This document has been prepared for the purpose of inviting comments and suggestions on the proposals contained therein, which will then be considered by the Expert Committee on Biological Standardization (ECBS). Publication of this draft is to provide information about the proposed WHO document on *Regulatory Assessment of Approved rDNA-derived Biotherapeutics* to a broad audience and to improve transparency of the consultation process.

The text in its present form does not necessarily represent an agreed formulation of the Expert Committee. Written comments proposing modifications to this text MUST be received by 14 September 2015 in the Comment Form available separately and should be addressed to the World Health Organization, 1211 Geneva 27, Switzerland, attention: Department of Essential Medicines and Health Products (EMP). Comments may also be submitted electronically to the Responsible Officer: Dr Hye-Na Kang at email: kangh@who.int.

The outcome of the deliberations of the Expert Committee will be published in the WHO Technical Report Series. The final agreed formulation of the document will be edited to be in conformity with the "WHO style guide" (WHO/IMD/PUB/04.1).

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This guidance document published by WHO is intended to be scientific and advisory in nature. Each of the following sections constitutes guidance for national regulatory authorities (NRAs) and for manufacturers of biological products. If an NRA so desires, this document may be adopted as definitive national requirements, or modifications may be justified and made by the NRA. It is recommended that modifications to this document be made only on condition that the modifications ensure that the product is at least as safe and efficacious as that prepared in accordance with the principles set out below.
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This appendix considers the regulatory assessment needed for dealing with situations where, for various reasons, rDNA-derived biotherapeutic products were licensed with data packages that do not follow current international regulatory standards for these biologicals – for instance, biotherapeutic products licensed by a generic pathway or with limited analytical, nonclinical and/or clinical data (1, 2). The International Conference of Drug Regulatory Authorities (ICDRA) discussed such situations at its meeting in Singapore in 2010 (3) and requested WHO to assist in developing approaches for evaluating these already-licensed products according to current WHO guidelines. In 2014 the Sixty-seventh World Health Assembly adopted two relevant resolutions: one on critical needs in the biotherapeutics area, aiming to promote access to these products as well as to ensure their quality, safety and efficacy (4), and the other on strengthening of regulatory systems, whereby WHO is requested to provide guidance on strengthening regulatory systems, and especially those dealing with increasingly complex biological products (5).

Although this appendix deals primarily with rDNA-derived biotherapeutic protein products, some aspects may also be relevant to other biotherapeutics.

1. Regulatory expectations for rDNA-derived biotherapeutics, including similar biotherapeutic products

Regulatory expectations for rDNA-derived biotherapeutic protein products are found in the main text of these guidelines which were adopted by the WHO Expert Committee on Biological Standardization (ECBS) at its meeting in October 2013 (6). Following considerable international consultation at the global level since 2004, the Guidelines on evaluation of similar biotherapeutic products were adopted by the ECBS in 2009 (7). These guidelines emphasize the need for a head-to-head demonstration of the “similarity” to biotherapeutic products of assured quality, safety and efficacy that have been licensed on the basis of a full licensing dossier. A head-to-head comparability exercise of a candidate similar biotherapeutic product (SBP) with a reference biotherapeutic product (RBP) is essential to justify a reduced nonclinical and clinical package for licensing (7). Studies should be designed to detect any potential difference in quality, nonclinical and clinical attributes between the SBP and RBP rather than simply to confirm safety and efficacy of the two products. It should be ensured that any detected differences have no clinically meaningful impact on product performance.
If a head-to-head comparison of the SBP with the RBP is not performed throughout the
development process as outlined in WHO’s guidelines for SBPs (7), the final product should not
be referred to as an SBP (8, 9). SBPs are not “generic medicines” and the approval process used
for small molecule generic drugs is not applicable.

2. Review of products on the market

Problems have been identified in some countries where, for various reasons, biotherapeutic
products were licensed using data which do not now meet current WHO regulatory expectations
– such as biotherapeutics licensed as simple generics or as small molecule drugs. Often little is
known about the safety and efficacy of the individual products since, in many cases,
pharmacovigilance in the countries concerned is weak and sometimes nonexistent. In addition,
the nomenclature of these products is confusing and traceability is poor (10, 11). In some
countries, the coexistence on the market of these products and SBPs, as well as rDNA-derived
biotherapeutics licensed with full data packages, is a matter of concern. This was the situation for
erthropoietin (12) and similarly for heparin (13). Some updating of national regulations has
occurred to take account of recognized difficulties and there have also been changes in
international regulatory expectations (14–17). Special considerations apply to the production and
control of biological medicines, including biotherapeutics, which do not apply to chemical drugs.
This is because of the biological nature of the starting materials, the manufacturing processes and
the test methods needed to characterize batches of the product. Nonclinical and clinical
evaluations are key components of the regulatory assessment of all biotherapeutics. Products
already approved under the pre-existing regulations will need to be reassessed to ensure that they
meet the new requirements.

National regulatory authorities (NRAs) should undertake a stepwise regulatory review of
biotherapeutic products already on the market, as follows:

• First, NRAs should identify products that have been licensed with data which do not meet
current international regulatory standards.
• Second, an assessment of identified products and gaps, based on the product-specific
  considerations listed in section 3, should be carried out in order to decide the appropriate
  action to remedy the situation and the timelines for implementing this action. This will
  inevitably involve a risk–benefit assessment of the situation.
• Third, manufacturers should submit to the NRA within a defined – but short – period of
time a plan of action for dealing with the problem. The plan of action should consist of an
analysis of available and missing data in accordance with WHO guidelines (6, 7), as well
as a description of measures, which may include interim assessments, and proposed
timelines needed to address the identified gaps.
• Fourth, NRAs should evaluate the plan of action proposed by the manufacturer and agree
  with the manufacturer on the next steps for generating missing data and their (possibly
  stepwise) submission to the NRA.
• Fifth, NRAs should assess in a stepwise approach the data (e.g. quality/manufacturing
data) that have been submitted – possibly in several separate packages at different times –
and on the basis of the outcome should decide on appropriate regulatory action.

The timeline for completing the overall review exercise will depend on the time needed to
generate and provide the missing information, taking into consideration the product-specific
points outlined in section 3. For example, in 2009 Health Canada clarified the “appropriate
regulatory pathway” for dealing with changes in the regulatory oversight of heparins to reflect
the fact that in future they would be regulated in Canada as biologicals (biologics) and not as
pharmaceutical drugs. In addition, Health Canada announced that any biosimilar heparin
submissions should follow Health Canada’s regulatory framework for subsequent entry biologics
and not the generic pathway used for small molecule drugs. Health Canada set a transition period
to allow manufacturers to update their files to reflect the data required for biological drugs (e.g.
12 months in the case of heparin). Manufacturers were also required to identify immediately
after the official date of transfer of regulatory authority how much of their licensed product was
sold in Canada per year (16). Similar transitional provisions have been made by other NRAs
when updating regulations. In Peru, for instance, draft regulations for the registration of
biotherapeutics and SBPs using complete dossiers include transitional provisions for products
licensed prior to the effective date of the proposed new regulations (17). Mexico recently
finalized a regulation covering requirements for biotherapeutics and SBPs. The regulation
includes a transitional article covering biotherapeutics licensed prior to introduction of the updated regulation. A period of approximately 2 years from the effective date of new regulation is normally anticipated for the entire assessment process. In the first 8 months, existing dossiers and comparative analytical characterization data will be reviewed. After this initial period, the manufacturer may be requested to provide additional nonclinical and clinical data according to a specified timeline. On the basis of the outcome of the assessment, the manufacturer will be recommended a renewal of the licence, risk mitigation or withdrawal of the licence (15).

3. Points to consider in a stepwise regulatory assessment

A particular licensed product should be allowed to remain on the market during the review process. Consideration should be given to the following in deciding appropriate regulatory actions:

a) It should be considered that the number of products on the market which have been licensed without adequate quality, nonclinical and/or clinical data and whether there are any therapeutic alternatives on the market which have been either licensed locally with an adequate data package and/or also licensed by an experienced NRA and that meet the standards of the relevant WHO guidelines (see b, below).

b) It is important to find out if the product in question is manufactured and licensed in a country with a jurisdiction which has, and follows, well-established regulatory frameworks, including all the principles set out in these guidelines for biotherapeutic products (6) and, where appropriate, in WHO’s guidelines for SBPs (7). Account should also be taken of whether the jurisdiction concerned has considerable experience in the evaluation of biotherapeutic products, SBPs and post-marketing surveillance activities. If a product is manufactured and licensed in a country with considerable experience in these areas, then this provides confidence regarding quality, safety and efficacy. However, it would be important to ascertain whether the actual product on the market in the country with limited regulatory experience is comparable – with respect to manufacturing process and controls, recent good manufacturing practices inspection and labelling – to the product licensed, supplied and used in the manufacturing country with the more
experienced jurisdiction. It would also be important to see whether registration of the
product in question has been rejected, cancelled or suspended by other stringent NRAs.

c) It is also important to know the extent to which the registration dossier of the
biotherapeutic product meets the recommendations of WHO’s *Guidelines on the quality,
safety and efficacy of biotherapeutic protein products prepared by recombinant DNA
technology* and *Guidelines on evaluation of similar biotherapeutic products* (6, 7).
Attention should be paid to key differences between national requirements and WHO
guidelines – such as the lack of a head-to-head comparability exercise for an SBP. The
NRA should recommend a critical dataset for re-registration of such products. Changes in
regulatory requirements may be needed, as well as amendments to the legal framework of
the country concerned, to enable such new requirements to be implemented.

d) The level of actual use of the biotherapeutic product (market share or number of patients
impacted) should be ascertained. This includes whether the product is essential for
treating certain patients and what the clinical outcomes would be if the product were
taken off the market. This assessment should cover: the disease that is being treated,
whether the condition is life-threatening, the consequences of treating or not treating or
stopping treatment in patients already using the product, the risk of switching between
therapeutic alternatives, the likelihood (and potential consequences, if any) of supply
problems on clinical outcomes should the product be taken off the market, and the type of
patient population (paediatric, adult, older persons).

e) The seriousness of a potential lack of efficacy should be considered, as should possible
safety issues (including higher efficacy) that may result from the continued use of the
product under review. This should include an assessment of the severity of the potential
impact on a patient of an immunogenic effect arising from the use of the product and an
assessment of any adverse effects (e.g. biotherapeutic products that may cause cross-
reactivity with native proteins, as in the case of pure red cell aplasia caused by
erthropoietin (1)).

f) The ability of the pharmacovigilance system in the country should be considered to
monitor and determine adverse reactions and/or efficacy problems (such as reduced
clinical effectiveness) associated with the biotherapeutic product, should they exist.
Criteria for the evaluation of functional pharmacovigilance systems can be found in
WHO’s document *The safety of medicines in public health programs: pharmacovigilance an essential tool* (18). With poor pharmacovigilance systems in many countries, as well as nomenclature difficulties, it may be impossible to obtain sufficient data to demonstrate that a particular product was the cause of an adverse reaction or that patients may be at risk from the use of products that are clinically untested or are tested with inadequately designed studies. Traceability is a key element in monitoring the safety and efficacy of biologicals as it enables pharmacovigilance measures to be put in place.

g) The expertise and capacity of regulators responsible for licensing biotherapeutic products is critically important for the appropriate evaluation of these products. Collaboration between NRAs, including work-sharing agreements and joint reviews with other NRAs, should also be explored (for example, see 2, 19, 20).

h) Consideration should be given to transparency with respect to informing health-care professionals, pharmacists and patients of the review process and its timelines. This could be done through website posting, as in Canada (16), or via a symbol and some text in the product information, referring to the need to align the licensing process with current international expectations.

### 4. Regulatory actions

On the basis of the outcomes of the regulatory assessment, the NRA should make decisions on appropriate actions to be taken. The decisions and actions of NRAs may differ depending on the assessments made according the points listed in section 3, which will be jurisdiction-specific. In a stepwise approach, product supply would not be compromised and authorization might be regularized after the defined time period during which the product would undergo further regulatory evaluation and so long as it is shown to be efficacious and safe. Capacity-building will be needed where resources and expertise are considered inadequate. Where the number and experience of persons available to undertake an overall review is limited, consideration could be given to the possible mentoring, through WHO, of the NRA needing support by an experienced authority that has established processes which follow relevant WHO guidelines. The sharing of information between NRAs regarding the basis for regulatory decisions on biotherapeutic
products, including SBPs, is considered an important support for regulatory authorities that are less experienced in dealing with these highly complex products and may accelerate the assessment of the products. Communicating details of what information was reviewed and how it was incorporated into decision-making is also important for prescribers, patients and other stakeholders and can help them gain confidence in biotherapeutic products. The summary basis of decision documents of Health Canada, the European Medicines Agency and the United States Food and Drug Administration are examples of informative documents. The stepwise regulatory assessment approach outlined in this addendum is flexible and is designed to support the accessibility of biotherapeutic products of assured quality, safety and efficacy, as requested in the two resolutions of the Sixty-seventh World Health Assembly in 2014 (4, 5).
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