Biosimilars

Roche Australia (Pharmaceuticals) policy position

Summary

- Biosimilars are non-identical but "similar" versions of biological medicines that compete in the market after patent expiry.
- Roche supports the use of savings from the off-patent market to reinvest in innovative medicines. Patient safety, however, must always be the highest priority.
- Given the complexity of biological medicines, appropriate clinical studies are required to evaluate quality, efficacy and safety of biosimilars.
- Biosimilars should only be subject to automatic substitution by pharmacists where sufficient evidence has been evaluated by the health authorities, including studies of multiple switches.
- Roche considers that for patient safety, biosimilars must be identifiable by a unique name and prescribers must be aware of the exact brand that has been dispensed.

Background

Globally, innovative biological medicines are losing patent protection, and new versions of these products, called biosimilars, are being developed and commercialised. Biosimilars are not identical copies, but are "similar" to innovative products[1]. While it is relatively easy to make generic copies of small molecules produced by chemical synthesis, it is more challenging to copy complex biological medicines. In particular, monoclonal antibodies (i.e. therapeutic proteins which specifically recognise and bind to other unique proteins in the body) have complex molecular structures and are obtained from living systems through complicated development processes, which are difficult to reproduce[2].

Roche position

As a research-based healthcare company, Roche believes strongly that sustainable healthcare systems are those that can deliver continuous advances in treatment through innovative products. It is also our strong belief that regulations relating to biosimilars should promote, rather than impede, innovative research towards new medicines.

Roche recognises the important role of biosimilars and acknowledges that they may help improve access to medicines for patients and ensure the continued sustainability of the Pharmaceutical Benefits Scheme (PBS). Roche supports the use of competition in the off-patent market to drive savings that can be reinvested in innovative medicines. To ensure the continued value of medicines and the viability of the Australian pharmaceutical industry, it is critical that these savings are not lost to non-medicine-related activities. Patient safety, however, must always be the highest priority.

Due to the complex nature of these diverse products, a well-defined and transparent regulatory framework, covering development, approval and post-authorisation procedures, must be in place for biosimilars.

Biological medicines range in complexity from relatively small and simple proteins (such as insulin or growth hormone) to very large and complex antibodies where different parts of the molecule have different functions. Accordingly, the scope of the clinical evidence required to support the approval of biosimilar medicines should be defined on a case-by-case basis.

The physical process of making biological medicines determines their characteristics. A change in any part of the process can significantly alter the product and/or its composition and subsequent processing by the cell[3], and so change the nature of the medicine and its effects in patients.

Regulatory authorities such as the TGA agree that non-clinical and clinical data, including the assessment of the risk of immune-system reactions to the medicine, are needed in order to demonstrate similar safety and efficacy profiles of a biosimilar compared to the reference (originator) product[4]. This risk must be assessed before approval in comparative clinical studies of appropriate size and duration that include homogeneous and sensitive patient populations.

Additionally, post-authorisation safety monitoring and relevant epidemiology data must be an essential part of a risk management programme, enabling clear identification of the product used. Furthermore, similarity should always be demonstrated for each of the claimed uses (indications) unless there is a solid scientific rationale to extrapolate the clinical safety and efficacy data from one indication to another.

Compromising on safety or efficacy would present an unacceptable risk to the doctors who prescribe and the patients who rely on these medicines. That is why Roche considers that biosimilars should only be subject to automatic substitution by pharmacists where sufficient evidence has been evaluated by the health authorities, including studies of multiple switches. Roche supports a key role for the TGA is evaluating this evidence and informing decisions by the Pharmaceutical Benefits Advisory Committee (PBAC).

Roche supports the use of mechanisms to ensure accurate dispensing and traceability such as:

- A unique identifier for all biological molecules;
- A 'no substitution' box on prescriptions to afford prescribers the right to ensure the prescribed brand is dispensed; and
- Where substitution has been permitted, notification of the brand dispensed to the prescriber.

Roche also supports the application of the existing brand price premium policy to biosimilars, allowing the manufacturer of the originator product to charge an optional premium once a biosimilar is reimbursed.

Roche supports the establishment of an ongoing forum involving the Government and medicines industry to consider and agree on appropriate policy levers for biosimilars. Policy best practice would include broad stakeholder consultation on all new policies. Clearly defined and agreed biosimilar policy is needed to provide certainty and facilitate future planning for all stakeholders.

As noted above, innovation is critical for continued improvement in healthcare. Roche supports the provision of appropriate intellectual property protection for medicines that is in line with comparable countries.

Further reference

Roche Position on Similar Biological Medicinal Products (Global policy)

This position paper was adopted by the Roche Australia (Pharmaceuticals) Leadership Team on 5 December 2016 and entered into force the same day.

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[1] Council of Australian Therapeutic Advisory Groups (CATAG). 2015. "Guiding principles for the governance of biological and biosimilar medicines in Australian hospitals". May 2015, Sydney

[2] Australian Rheumatology Association. 2015. "Joint letter to Minister for Health", accessed from http://rheumatology.org.au/downloads/20150908%20Final%20Joint%20letter%20to%20Minister_PBACre%20a%20flagging%20biosimilars.pdf, 27 September 2016

[3] BIO. "BIO Principles on the Substitution of Biologic Products", accessed from https://www.bio.org/sites/default/files/files/BIO-Principles-on-Substitution.pdf, 27 September 2016

[4] TGA. "Regulation of biosimilar medicines", December 2015, accessed from https://www.tga.gov.au/publication/evaluation-biosimilars, 27 September 2016