Biosimilars

Roche Australia (Pharmaceuticals) Policy Position

Summary

- 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.
- Roche considers that for patient safety, biosimilars should not be subject to automatic substitution by pharmacists and that each biosimilar must be identifiable by a unique name.
- Roche supports the application of price savings measures on the Pharmaceutical Benefits Scheme (PBS) when a biosimilar is listed, including movement of the originator and the biosimilar brands out of the F1 (single brand) formulary and an appropriate statutory price reduction.

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. 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.

To date, the Therapeutic Goods Administration (TGA) has only registered a handful of biosimilars in the classes of erythropoetin, colony-stimulating growth factor, human growth hormone[1] and long-acting insulin[2]. Roche refers to this first wave of biosimilar products as "non-antibody biosimilars". Now with more complex biological medicines reaching patent expiry, issues around biosimilars need to be addressed in the interests of all stakeholders.

Roche position

As a research-based healthcare company, Roche believes strongly that advances in healthcare are driven by innovation. 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, and so change the nature of the medicine and its effects in patients. The TGA has recognised that "the principles relevant to the evaluation and use of generic medicines cannot be simply extrapolated to biosimilars"[3].

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. 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 supports the TGA decision that biosimilars are not subject to automatic substitution and that each biosimilar must be traceable for patient safety.

Regarding listing of biosimilars on the PBS, Roche supports the use of mechanisms to appropriately deliver savings to the taxpayer from competition in the off-patent market, while recognising the

unique features of biological medicines. Along with the industry body, Medicines Australia, Roche supports movement of the originator and the biosimilar brands out of the F1 (single brand) formulary, an appropriate statutory price reduction, appropriate market competition and application of other suitable policy levers.

The *National Health Act 1953* triggers a move from the F1 formulary when a new brand is bioequivalent/biosimilar to the originator brand. For reimbursement purposes, Roche supports a definition of biosimilar that is aligned with the TGA's decision-making rules. PBS listing arrangements should not permit substitution of biosimilar medicines at the pharmacy level without the prior consent of the treating physician. Roche supports the use of mechanisms to ensure accurate dispensing of the prescribed brand such as the "no substitution box". 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 does not support using a new biosimilar entry to apply reference price reductions across existing or newly-defined therapeutic groups, as this can act as a disincentive to innovation for on-patent medicines.

In line with Medicines Australia, Roche supports the establishment of a biannual forum involving both the Government and 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 24 September 2015 and entered into force the same day

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[1] Generics and Biosimilars Initiative. 2014. 'Biosimilars approved in Australia', accessed from http://www.gabionline.net/Biosimilars/General/Biosimilars-approved-in-Australia, 18/03/15

[2] PharmaDispatch. 2015. 'Confusion over biosimilars', published 19/01/15, retrieved from https://pharmadispatch.com/news/confusion-over-biosimilars, 21/04/15

[3] TGA. 'Evaluation of biosimilars', accessed from http://www.tga.gov.au/industry/pm-argpm-biosimilars-01.htm#.VB-qNvmSx1Z, 10/03/15