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Biologic medicines and biosimilars

What's in a (biosimilar) name?

Because biosimilars and their reference biologic medicine are not identical, whether compared to each other or even between biosimilars, it is important to know which product has been used. Generics may have some differences from their reference products but generally only in formulation and possibly impurity profiles. For biosimilars the differences occur at the more fundamental level of the active substance. The resulting debate is whether biosimilars should be identified by a variation of the name of the reference biologic product.

The US position

The US's Food and Drug Administration (***FDA***) has draft guidance regarding the naming of biosimilars in the US. The guidance will require biosimilars to have unique names, unlike generic products which are allowed to have the same name as their chemical reference product. A four-letter suffix will be added to the biosimilar name so as to differentiate it from its reference biologic. This is intended to minimise confusion and ensure that there is no inadvertent substitution by medical practitioners or pharmacists. Furthermore, future new biologic products will now also be required to add suffixes. This approach mirrors a solution developed by the World Health Organisation (***WHO***), which oversees the international naming system.

The European position

In contrast, in 2014 the EU member states voted against separate names for biosimilars and their reference biologic. The majority of member states considered such a policy would undermine public and professional confidence in the biosimilar products.

The current debate

Those who oppose biosimilar naming identifiers suggest that such identifiers are simply an unjustified barrier to competition. This thinking seems to underlie the EU position. However, there is some evidence from the significant differences in uptake and market penetration in different European countries that other factors, such as the use of appropriate uptake drivers, have much a greater impact effect. Australia's industry body, the Generic Medicines Industry Association (***GBMA***), which considers naming identifiers unnecessary, suggests that biosimilar success is ultimately driven by having "physicians... at the heart of the decision-making process" and where there are "uptake drivers that encourage physicians to prescribe biosimilars and incentivise patients to accept biosimilars".[1]

A contrary perspective is that not having a biosimilar identified introduces confusion and a lack of confidence because it impedes the ability to collect robust real-world data that can be used for post market pharmacovigilance to evaluate interchangeability. This is the position taken by the International Non-proprietary Name (***INN***) Committee of the WHO. Views expressed at the September 2016 Pharmaceutical and Regulatory Law Conference by hospital, pharmacist and industry representatives suggest that the lack of clarity on naming, and hence tracking which product was taken by a patient, may also impede prescriber confidence in relation to whether they should allow substitution.

Those arguing that naming identifiers are not necessary suggest that the standards for comparability between a biosimilar and the reference product mean there is no value in separate identification.[2] Comparability between a biosimilar and the reference product is assessed using the same standard as those used to evaluate if a manufacturing change to a reference product causes a relevant difference. Accordingly, it is said, there is no more variance between a biosimilar and its reference product than between one batch of the reference product and another. This implicitly assumes that the pharmacovigilance that would be facilitated by naming identifiers is unnecessary or can be achieved without being able to identify the particular biosimilar being used.

Australia's approach

Previously in Australia, biosimilar names have been composed of the reference biologic Australian Biologic Name (ABN), as well as a 'biosimilar identifier', consisting of the prefix sim(a)- and a three letter code issued by the WHO INN Committee. Accordingly, Australian biosimilars have always been separately identified from their reference biologic products.

However, as a result of these international developments, as well as WHO policy changes, Australia is currently reviewing its guidelines relating to naming conventions of biosimilars. It remains to be seen whether the TGA will follow EU or US approaches on this issue or whether it will adopt the WHO position. Recent reports suggest that Australia will adopt the WHO position.

In the interim, biosimilars are called by their ABN, but without the biosimilar identifier suffix. Australia's policy shift has implications for, and may in part be driven by, reimbursement considerations in Australia where the PBS scheme uses the drug name as part of the statutory criteria for substitutability. If the biosimilar products have different drug names, some of the statutory pricing mechanisms may not function in the same way as they do for generics. Whether the pricing scheme developed to take advantage of generic drug competition is an appropriate basis for naming policy for biologic medicines where the particular biosimilar product taken by a patient may be important, is questionable. Instead, the pricing scheme should be targeted to the different market and uptake requirements for particular biologic medicines. The naming of biologic medicines should be considered in the wider context required within a quality use of medicines framework and the particular pharmacovigilance needs that biologic medicines present.

The future

In order to best track possible interchangeability concerns, some form of identification of the particular biosimilar appears to be warranted. However, whether this requires biosimilar naming conventions shows no signs of timely resolution. WHO was advised in December 2015 by its expert group that the group's consultation (in October 2015) had recommended the use of naming identifiers. However, WHO has at this stage only resolved to pilot that naming scheme for three years, from April 2016. During this period, it will examine whether the scheme is being used and how it impacts access to biologic medicines.

Without a clear direction from WHO at this time and with competing attitudes between the FDA and the EMA, formal adoption of consistent naming of biosimilars seems at best only a long term proposition.

1 GBMA Position on Biosimilars / Awareness and Uptake www.gbma.com.au/biosimilars/healthcare-professionals/awareness-and-uptake/ accessed 7 September 2016

2 See for example GBMA Position on Biosimilars / Switching www.gbma.com.au/biosimilars/healthcare-professionals/switching/ accessed 7 September 2016

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YOUR FEEDBACK

Please contact us if you would like to discuss the challenges and opportunities presented by biologics and biosimilars.

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