By e-submission

7 September 2017

Dear Sir/Madam,

Consultation on nomenclature of biological medicines

Dear Sir/Madam,

Novo Nordisk welcomes this opportunity to comment on TGA's consultation on the nomenclature of biological medicines. Novo Nordisk is a pioneer in biotechnology, a world leader in diabetes care, and holds a leading position within haemostasis management, growth hormone therapy, and hormone therapy for women. Novo Nordisk manufactures and markets pharmaceutical products and services that make a significant difference to our patients, the medical profession, and society.

Novo Nordisk considers that all biologics (both biosimilar and originator products) should be given a distinguishable non-proprietary name and a unique trade name so that the products are clearly distinguished for prescription, safety surveillance and adverse event reporting, and so that they are always easily traceable to source of origin. Innovative and biosimilar products should share a common root, but also include a distinguishable suffix that can be used globally and is related to the global licence holder responsible for the safety of the product. We therefore very much support TGA's option #4 of an internationally harmonised suffix for all biologicals.

Please find Novo Nordisk's specific comments on the four proposed options following.

Yours sincerely,
Novo Nordisk Pharmaceuticals Pty. Ltd.

Rowan O'Brien
Regulatory and Pharmacovigilance Manager

Novo Nordisk Pharmaceuticals Pty. Ltd.
Level 3
21 Solent Circuit
Baulkham Hills NSW 2153
Australia

Telephone:
+61 2 8858 3600
Direct dial:
+61 2 8858 3796
Telefax:
+61 2 8858 3799

E-mail:
rowo@novonordisk.com
Internet:
www.novonordisk.com.au

Novo Nordisk submission to TGA consultation on nomenclature of biological medicines, 2017

Option 1: Status quo.

As described in the TGA consultation paper, the current system does not fully support traceability as it does not promote capture of the trade name and the batch number. As the number of biological products (both related original and biosimilar products) increase, the patterns of switching are likely to become more complex. A status quo would therefore likely lead to a gradual deterioration, rather than an improvement, in the ability to monitor the incidence of adverse reactions for a specific product. While it does not add any new regulatory burden, the system will not follow the international developments and would not result in an improved ability to monitor the incidence of adverse reactions that might occur through use of the biological medicine.

Furthermore, the need for more robust pharmacovigilance goes well beyond monitoring the immunogenicity concerns of switching between products. Due to the inherent sensitivity of biologics to manufacturing adjustments, adverse events may occur as a result of manufacturing changes or updates. Being able to readily identify whether the adverse events are attributed to a single product or a biological class of products is extremely important in rapidly addressing patient safety and product supply, without unnecessarily disrupting supply of an entire class of products due to individual product manufacturing or immunological concerns (Wish, 2011; Halim *et al*, 2013).

Option 2: Status quo with activities that increase public reporting of adverse events with the inclusion of the product's trade name, AUST R and batch number.

Research from EU shows that the barriers to capturing trade name and batch number are not solely dependent on unawareness from prescribers, but also to a large extent depend on the available systems for prescribing and dispensing (Klein *et al*, 2016). Raising awareness is therefore unlikely to increase the reporting frequency to the same extent as a mandatory measure.

Option 3: Move towards adopting a barcode system similar to the EU.

The intended goals of clear distinction of products for prescription, safety surveillance and adverse event reporting, as well as traceability to source of origin, is only fully functional if all involved stakeholders have access to the information. A barcode is helpful only where equipment to read and interpret it is implemented, and experience from EU also shows that timelines for implementation are long since such systems typically have to address other needs as well. There are also aspects of interoperability between systems that could impact traceability from a pharmacovigilance perspective.

Novo Nordisk is currently in implementation phase for serialisation in several countries world-wide, and we have implemented this process for certain products in Australia. In principle, Novo Nordisk supports implementation of an EU-like bar code system in Australia, but primarily to address counterfeit medicines and supply chain management. The codes

should appear on sales carton level (secondary), but not at the primary packaging. The economic implications, for industry, of moving towards a bar-coding system depend on the distribution of cost between the different stakeholders, but overall adopting a bar code system is believed to be significantly more expensive than Option 4.

Option 4: Introduce the use of suffixes to the naming of biological medicines.

Novo Nordisk supports adopting a safe, cost-effective, and practical system for biological product prescribing, dispensing, and monitoring. A short, unique suffix would enable both health care practitioners and patients to identify a product on more than one level without the need for specific equipment. To be fully effective the system should include all biological medicines i.e. it would necessitate retrospective naming of currently registered products. Retrospective naming should be done with a timeline that enables harmonisation with other systems.

Implementing this naming for all biological medicines is important both to ensure an effective system, and to ensure that all biologics, reference products, “me too” products and biosimilars are treated equally. And whereas the products in this way may be presented as distinct entries in the prescribing lists, their relatedness will be evident from the non-proprietary name to which the suffix is attached. The distinct entries are consistent with the fundamental aspects of biosimilars, that they are similar but not the same, and they have their own independent life cycles including independent post-approval manufacturing changes.

Novo Nordisk supports international harmonisation of biological medicine distinguishing name practices, as this will facilitate global exchange of pharmacovigilance data. Coordination with the FDA naming system and, to the extent possible, also with the WHO INN biological qualifier (BQ) is of paramount importance. Harmonisation is also important from a financial perspective. Since companies are already implementing systems for the FDA suffix, the additional financial impact of adding a suffix to products in Australia is expected to be limited, so long as the suffixes are harmonised.

References

Halim LA, Brinks V, Jiskoot W *et al.* How bio-questionable are the different recombinant human erythropoietin copy products in Thailand? Pharm Res 2014; 31(5):1210-8.

Klein K, Scholl JH, Vermeer NS *et al.* Traceability of Biologics in The Netherlands: An Analysis of Information-Recording Systems in Clinical Practice and Spontaneous ADR Reports. Drug Saf 2016;39(2):185-92.

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