Multiple Sclerosis Research Australia
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Re: TGA Consultation: Nomenclature of Biological Medicines

MS Research Australia is the largest national not-for-profit organisation dedicated to funding and coordinating multiple sclerosis research in Australia, as part of the worldwide effort to solve MS. Its goal is to accelerate research into the cause, better treatments and prevention of MS, with the aim of ultimately finding a cure for MS.

MS is the result of damage to myelin– a protective sheath surrounding nerve fibres of the central nervous system. When myelin is damaged by the immune system, this interferes with messages between the brain and other parts of the body. The symptoms of MS are different for each person; sometimes they even vary within the same person. For some, MS is characterised by periods of relapse and remission, while for others it has a progressive pattern.

A range of disease modifying medications are available for people with the relapsing remitting form of MS. These medications can be very effective in controlling relapses. Many of these medications are biological medicines and it is likely that in the near future biosimilar versions of these medicines may become available.

It is very important that people with MS have access to affordable, effective and safe medications.

As such the introduction of biosimilar medications will be a welcome development, however, the long-term safety monitoring of these medications is vitally important.
that adverse events arising from switching between reference medicine and biosimilar products or immune-mediated reactions that have not been observed for the innovator medicine. However, it is important that these medications can be identified over the longer term to confirm that this is the case.

As such, a naming convention and adverse event reporting framework that mandates the capture of the active ingredient name as well as the trade name and the batch number is important. This would rule out Option 1: Status Quo.

The difficulties identified in the consultation paper for Option 4: Introduce the use of Suffixes, relating to the potential for a complex international situation in which the same product could end up with different suffixes would also be problematic for the international coordination of adverse event reporting and research.

Option 2: status quo combined with activities that increase public reporting of adverse events with the inclusion of the product's trade name, AUST R and batch number, would be a step in the right direction, but would only be effective if the adverse event reporting framework mandates the entry of the trade name and the batch number.

As such, Option 3: Move towards a barcode system similar to the EU, would provide the greatest reassurance that all the necessary information can efficiently be collected during adverse event reporting. The consultation paper notes that this system relies on healthcare facilities, prescribers and dispensers recording information by way of the bar code. This will would be facilitated by the use of appropriate electronic systems and databases, possibly incorporated into the e-health record. Whether these systems currently exist or can be easily and cost effectively implemented is outside the scope of our knowledge, but would clearly be a significant factor in the implementation of this system. Ultimately however, this would seem to be the most effective and efficient method to gather the appropriate data and would be in keeping with an integrated health system in which clinical, pharmacy and other health data can be recorded and shared.

Thank you for the opportunity to comment on this matter.
Kind regards

Dr Lisa Melton, on behalf of MS Research Australia
Head of Research