CATAG
Council of Australian Therapeutic Advisory Groups

CATAG submission

TGA Consultation: Nomenclature of Biological Medicines

August 2017

The Council of Australian Therapeutic Advisory Groups (CATAG) is an authoritative, expert, consensus-based collaboration of representatives from all Australian State and Territory Therapeutic Advisory Groups or their jurisdictional committee equivalents.

CATAG aims to standardise and improve medicines use primarily (but not exclusively) in the hospital sector across Australia through information sharing, advice and advocacy activities.

Contact for further information:
Jane Donnelly, National Coordinator
The Council of Australian Therapeutic Advisory Groups
Email: catag@stvincents.com.au

CONTEXT

The Council of Australian Therapeutic Advisory Groups (CATAG) believes there is a need for better visibility of biosimilars with regard to capturing accurate information.

NOMENCLATURE OF BIOLOGICAL MEDICINES - OPTIONS

Opening remarks

Biosimilar medicines have the potential to cause increased confusion for consumers, particularly with their increasing availability. It is commonly known generic medicines have caused a significant amount of confusion for consumers and a long-term education campaign has been implemented by organisations such as NPS MedicineWise to address the need for consumer clarity. The biosimilar switching concept is more complex than generic substitution and therefore requires educational support from a range of stakeholders.

Consumers are the end users of medicines and therefore any change in naming or implementation of a system should consider consumer needs and the impact it would have upon consumer utilisation of medicines. Any change to naming should have minimal or no impact upon how consumers understand, manage or utlise their medicines, therefore consumer considerations should be a component of the outcomes sought for the consultation.

1. Status quo

CATAG does not support maintaining the current system with no change.

Option one does not provide an adequate solution, the paper discusses the requirement to support the quality use of medicines (QUM) including safe prescribing and dispensing practice. This option in no way enhances QUM and pharmacovigilance activities. Dispensing and prescribing do not routinely take into account the AUST R number, which is noted as a mechanism for monitoring. Health professionals involved in the medication management cycle would rely upon the proprietary trade name for reporting purposes. This option does not address the need to capture information regarding a particular batch or batches of a biosimilar medicines, which would assist in the assessment of adverse events. The collection and notification of particular batch numbers allows for better oversight to develop an understanding of the extent of immunogenicity and if it occurs and the impact of 'biosimilar creep'. The absence of information does not confirm immune mediated reactions do not occur, there have been some studies showing these reactions are not evident, however this is a relatively new area of practice and the evidence is lacking with regard to multiple switching, which is likely to occur in real world scenarios and with the advent of multiple biosimilars for one innovator product.

2. Status quo with activities that increase public reporting

CATAG does not support this approach

Option 2 is a passive intervention, education as the sole strategy for behaviour change is ineffective when it is not combined with other approaches. Both options 1 and 2 do not meet the outcomes sought to address the required improvement in the identification of biological medicines in pharmacovigilance activities. Option 2 in no way aligns with the approaches adopted by the EMA and FDA. Australia has been adopting and adapting EMA approaches to the management of biosimilars to the Australian market and it would be prudent to continue this pathway given the EMAs experience and expertise in this area of practice.

It is notable there are benefits to maintaining the status quo as these approaches will not add unnecessary regulatory burden and would not impact upon government policy of increasing biosimilar utilisation. However they would lead to a lost opportunity for improvement in pharmacovigilance.

3. Move toward 2D barcoding, similarly adapted by the EMA

CATAG supports the implementation of a 2D barcoding system, whereby barcodes are enriched with batch and expiry information. This system would enhance current pharmacovigilance activities and the information gained from such activities would improve monitoring of biosimilars and enable real-time monitoring. The current Pharmacy Board of Australia, Guidelines for dispensing of medicines require pharmacists to use barcode scanners when dispensing medicines to reduce medication errors. Therefore the utilisation of barcode scanners would not impose additional burden onto current pharmacy practices. However, it is notable 2D barcodes differ significantly from the current 1D barcodes and would therefore require equipment upgrades including scanners and software.

Further considerations

The scope of the paper only discusses biological products, consideration should be given to 2D barcoding for all medicines to enhance pharmacovigilance and post marketing surveillance activities. A phased approach to their introduction would be appropriate, sponsors of biosimilar medicines should be the first to be required to implement a 2D barcode followed by other medicine sponsors. s

4. Introduction of suffixes to the naming of biosimilars

CATAG does not support this approach to the naming of biosimilars

CATAG is unsure how the introduction of a suffix to the name of a biosimilar product would improve pharmacovigilance. The naming of a biosimilar product would differ from all other medicines and therefore be inconsistent with other medicines and education around product recognition. The addition of a four letter suffix to a product name would increase confusion amongst healthcare professionals and particularly consumers. The FDA has introduced the four letter suffix with little support from healthcare professionals and sponsors.

SUMMARY

CATAG supports the introduction of a 2D barcoding system. The introduction of 2D barcoding would be advantageous for many stakeholders working across medicines management, in addition to enhancing pharmacovigilance. 2D barcoding would allow for sounder stock management practices such as stock rotation, expiration and recall management.