Australian Government
Australian Digital Health Agency

Consultation: Nomenclature of Biological Medicines - TGA Submission from the Clinical Terminology Team

30 October 2017
Approved for external information

Submission

The Clinical Terminology team within the Australian Digital Health Agency provides this submission for consideration by the TGA

In summary we support Option 2, to increase public reporting of adverse events with the inclusion of a products Trade name, AUST R and batch number. Additionally, Option 3 could further support the automation of this change.

The below sections provide feedback statements regarding the four options:

1. **Status quo**
    - Maintaining the status quo without any changes to the 'system' does not support the objectives for 'improvements in the identification of biological medicines in the reporting of adverse events'; nor does it support improvement of the quality use of medicines. If these objectives are to be met, some measure of change is required.
    - Maintaining the status quo would have no impact on Clinical Terminologies
    - Maintaining the status quo will continue to support the uptake of biosimilars and minimise prescriber/patient confusion

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.**
    - We support maintaining the current system with activities that increase public reporting of adverse events
    - This improvement would have no impact on Clinical Terminologies
    - This improvement will continue to support the uptake of biosimilars and minimise prescriber/patient confusion
    - We believe that the differentiation of biosimilars is a proprietary/brand issue, therefore, it is logical to mandate the recording of the trade name
    - This option would also improve reporting for non-biosimilars as the differentiation within generics is a proprietary/brand issue e.g. excipients used. Just as excipients are not considered when looking at generic products, the same can be said for manufacturing processes

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

- We support a move towards adopting a barcode system, however, we believe that it should only be done in conjunction with Option 2, as a method to support the automation of information collection, and may also find utility in other/broader use cases.
- Cost benefit of implementing barcodes may be a factor for this option
- Move towards adopting a barcode would have no impact on Clinical Terminologies as it is out of our scope and additionally, we do not (at this point in time) have an opinion on what system or level of barcode should be used
- We believe that the differentiation of biosimilars is a proprietary/brand issue, therefore, using additional identifiers such as barcodes would be useful

4. **Introduce the use of suffixes to the naming of biological medicines.**

- We do not support the use of suffixes
- The introduction of suffixes (regardless of format) would change the way biosimilars are represented within the Australian Medicines Terminology (AMT) and result in a completely unique medicinal side which removes the ability to link (and group) the biosimilars generically which would impact:
    - Prescribing from the Medicinal side of the AMT
    - The querying of data for secondary use in areas such as cohort identification, research, epidemiological studies, etc
    - Decision support systems leveraging on a single distinct entry as there would now be multiple entries
- The financial impact of this change would be significant for the Australian Medicines Terminology in that changes to the concept model design would be required, in addition to the re-modelling of all biosimilar products. Education and implementation advice and potential new tools would also be required to support AMT users
- There would also be financial impact for AMT implementers/users in relation to the impact points noted above
- We agree with statement that developing a suffix-based naming scheme specific to Australia may add to prescriber and patient confusion
- If this option was implemented it would be advised to be applied retrospectively in order to fulfil the objective of 'identification of biological medicines in the reporting adverse events' and to support the quality use of medicines. In fact if only applied prospectively it would further complicate the required changes for the AMT
- Naming conventions for products in Australia vary greatly and the use of suffixes will add to the variability across all medicines, yet add a small measure of standardisation for biosimilars

For questions, or requests for further information, please contact:

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