Professor Iqbal Ramzan
Dean of Pharmacy

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Consultation on Nomenclature of Biological Medicines

Associate Professor Veysel Kayser and Professor Iqbal Ramzan

Faculty of Pharmacy, The University of Sydney

The following comments are related to additional naming requirements for biological medicines as a way of strengthening traceability and pharmacovigilance.

Traceability and pharmacovigilance are particularly important for biological medicines due to their inherent complexities. Therefore, in our view, developing a robust method to identify each particular medicine, each lot, and if possible each container/box, and if necessary to link a specific product to an individual consumer and to a particular side effect is of utmost importance. This will be especially critical in the near future because of the current landscape where more biological medicines – including new biological entities as well as biosimilars, are entering the market.

Inherent inhomogeneity of biological medicines may arise from different sources: different sources of raw materials (e.g., heparins), differences in cell lines and processing differences, posttranslational modifications of proteins (e.g., glycosylation), storage conditions, different dosage forms etc. For example, the presence of different glycoforms arising from posttranslational modifications of proteins, which is something we cannot control for many products such as in monoclonal antibodies, already causes a concern. It is extremely difficult, if not impossible, to ensure presence of identical glycoforms in biosimilars to originator product owing to different manufacturing settings, that is in turn instigating further inhomogeneity. Even smaller biological medicines such as heparins, including low molecular weight heparins, suffer from such complexity that may arise from raw material and differences between production procedures each manufacturer employs. The final product may look the same overall; however, observed adverse effects may be considerably different. This is probably one of the reasons why switching or substituting of most biological medicines and biosimilars amongst them are not recommended at the moment by many regulatory agencies.

Due to abovementioned reasons and considering the recent changes recommended by EU's EMA and the USA's FDA on the topic, the TGA should also consider changing the nomenclature to include additional information for biological medicines. In our view, this is essential for proper identification of the medicine in use and more critically it is necessary in order to distinguish between originator products and their biosimilars. In addition, under the current regulations, it is not recommended to switch or substitute the biological products by a physician or pharmacist; however, this may change in the future. Therefore, proper identification of the medicine is quite important. Another reason why a change in the nomenclature of biological medicines is necessary and important is that we should be able to identify easily and rapidly which product was used if an undesired effect is observed. For instance, if a consumer or a healthcare worker would like to report a side effect, they should be able to correctly and easily identify which product is involved including whether it is the originator or biosimilar, and the lot number and perhaps even the particular package/box or individual medicine that was used. This requires changing the current nomenclature of biological medicines. This may involve adding an extra abbreviated

Faculty of Pharmacy
S323, A15
2 Science Road
The University of Sydney
NSW 2006 Australia

T +61 2 9351 2831
F +61 2 9351 6950
E pharmacy.dean@sydney.edu.au
sydney.edu.au

ABN 15 211 513 464
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name/code similar to that of the FDA's or the EMA's method, adding another barcode, a QR code that has all the aforementioned information about a particular medicine. For biosimilars, adding the name of the active ingredient and/or the originator drug name should also be considered for easy identification similar to that of small molecule generics.

Yours sincerely,

Iqbal Ramzan
Dean