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Biological Science Section
Scientific Evaluation Branch
Therapeutic Goods Authority (TGA)
PO BOX 100
Woden ACT 2606

Submission via: www.tga.gov.au/consultation/consultation-nomenclature-biological-medicines

Re: Consultation – Nomenclature of Biological Medicines

The Gastroenterological Society of Australia (GESA) wishes to submit an opinion on the naming conventions being considered for biosimilar medications in Australia.

Biosimilar medications represent an important source of potential savings for the Australian health care system. These potential savings, however, must be balanced against ensuring the safety of biosimilars, and in particular the safety and durability of response in patients who are switched from originator medications to biosimilars.

As these medications have been A-flagged, it is up to the clinician to indicate a specific brand name and whether substitution is permitted at the level of the pharmacy if they want their patient to be maintained on the same version of a biologic medication.

Although trial data has been reassuring with respect to switching from originator to biosimilar, these studies are limited in terms of subject numbers and duration of follow-up as well as number of switches (i.e. only one switch from originator to biologic).

This is a particularly important limitation when considering low frequency serious adverse events. To accomplish these goals of pharmacovigilance requires unambiguous identification of biosimilars and would be aided by tracking individual lot numbers of all biologic drugs.

With respect to the options proposed:

Option 1:

We do not believe that the status quo is acceptable due to the impediment that this poses to broad and accurate pharmacovigilance. While this has not appeared to be an issue to date, the voluntary reporting regimen likely leads to underreporting of drug reactions and adverse events, and an under appreciation of potential harms.

Option 2:

Increased education around pharmacovigilance to report adverse events and mandated brand name reporting using a medication's registered name would represent an improvement on the status quo. In this option, mandated brand name recording should be implemented for all biologics at time of dispensing. It would also be important in the case of biosimilars to have fields capturing whether the patient had previously been exposed to another branded medication (i.e. originator or a different biosimilar) and to capture information on concomitant medication use, since other immunomodulatory medications have been implicated in reducing rates of adverse reactions.

Option 3:

Barcoding of individual medication vials with information on batch number allows for data collection, which would be critical for tracing potential issues from an individual batch. An outstanding question with this approach is where barcode embedded information is recorded. Given that biologic and biosimilar medications are being dispensed in both public and private pharmacies and that some are self-administered by the patient, barcode information is best recorded at the point of dispensing medications. In this case any adverse event should be reported to the pharmacy and then reported back to the regulatory agencies so that it can be matched to batch number.

Option 4:

Unique naming of Biosimilar medications would allow practitioners to easily identify exactly which version of a biologic medication (Biosimilar or originator) a patient was previously taking, and also specify which version they wish a patient to be dispensed. This would also limit the possibility of unintentional switching between versions. This would be the most preferred option of options 2-4. However, this approach adds little to pharmacovigilance assuming options 2 and 3 are pursued.

Should you require further clarification on this consultation, please do not hesitate to contact GESA via email: president@gesa.org.au or phone 1300 766 176.

Kind regards,

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