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SANOFI CONSULTATION RESPONSE

Nomenclature of Biological Medicines

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INTRODUCTION

Sanofi welcomes the opportunity to comment on the consultation document *Nomenclature of Biological Medicines.*

As a diversified health care company Sanofi supplies a broad range of medicines and devices in Australia across the spectrum of complementary, OTC and prescription products including pharmaceuticals and vaccines. Globally the company portfolio includes innovator as well as generic and biosimilar medicines.

To support a robust pharmacovigilance system Sanofi considers it critical to be able to accurately identify the medicine subject of any adverse event reports, regardless of whether the medicine is an innovator product, generic or biosimilar. Sanofi also considers that the choice of medicine for an individual patient should be determined by the prescriber who has the necessary knowledge and understanding to address any patient specific needs. This is especially important when considering many biological medicines are administered by injection and are often presented with unique delivery devices to facilitate ease of use. Prescriber choice should thus ensure quality use of medicines to deliver optimum clinical outcomes for an individual patient.

Sanofi acknowledges the submission by the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), of which Medicines Australia is a member company, that recommends a globally harmonized approach aligned with the Biological Qualifier (BQ)scheme proposal of WHO and is against any unique approach by the TGA.

In response to the consultation, feedback on the four different options outlined in the consultation document is provided below:

Option 1 Status quo

Do you support this option? Please provide reasons to support this view, or not.
Maintaining the status quo will not address deficiencies in identifying the medicine subject of adverse event reporting and is therefore not supported. Consumers have poor recognition and understanding of Approved Biological Name and AUST R and in the absence of any ongoing education program this is unlikely to change.

Option 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.

Do you support this option? Please provide reasons to support this view, or not.
Sanofi considers that trade names are better understood by most stakeholders including prescribers and consumers than AUST R and batch number. The trade name should therefore be included as a mandatory field by default for all adverse event reports regardless of whether the medicine is an innovator, biosimilar or generic product. Any education initiatives that enhance understanding of the importance of reporting of adverse events is also supported for all medicines.

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

Do you support this option? Please provide reasons to support this view, or not.
In the absence of a fully established e-health system with the necessary connectivity to ensure patients have a single consolidated record of all medicines prescribed and dispensed, this option does not offer a robust solution for meeting pharmacovigilance needs. Recognising ongoing technology developments make electronic management of information desirable, this would be an area to be revisited in the future when a fully established e-health system is in place.

What system and level of serialisation should a barcode use?
Adoption of any system should align with approaches used overseas such as in the EU to ensure a common standard.

What is the impact (including financial impact) of this option on you?
For new products addition of a unique identifier in the form of a specific barcode, would not add extra burden or cost to the development of labelling and packaging materials. However, any option to introduce a bar-coding solution retrospectively would require an adequate transition period so that the change is introduced at the time of other updates to the product packaging. This will minimise associated workload and costs. A detailed cost impact could only be prepared based on an understanding of the requirements for implementation.

Option 4

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

Do you support this option? Please provide reasons to support this view, or not.
To enable a robust pharmacovigilance approach to ensure that a biological medicine can be uniquely identified, Sanofi supports the adoption of a suffix as outlined in Option 4. As proposed by IFPMA any suffix adopted should align with international approaches to avoid a unique Australian system.

What is the impact (including financial impact) of this option on you?
For new products adoption of the suffix would not add extra burden or cost to the development of labelling and packaging materials. However, any option to introduce a suffix retrospectively would require an adequate transition period so that the new naming convention is introduced at the time of other updates to the product packaging to minimise associated workload and costs.

If this option was to be implemented should Australia adopt the outcomes of the FDA scheme or develop its own scheme for adding a suffix? Please provide reasons to support your view.

With a globally mobile population harmonization of approach is important to ensure a common understanding for both health care professionals and patients. Sanofi therefore concurs with the submission of IFPMA that the TGA should avoid developing a unique scheme that applies only in Australia.

If this option was to be implemented should it apply retrospectively? Please provide reasons to support this view, or not.

Sanofi considers that the ability to differentiate biological medicines is important for pharmacovigilance reporting regardless of whether a product is new or well established on the market. A scheme that is applied retrospectively would thus be optimal but should align with any approaches adopted internationally to avoid unique Australian requirements.