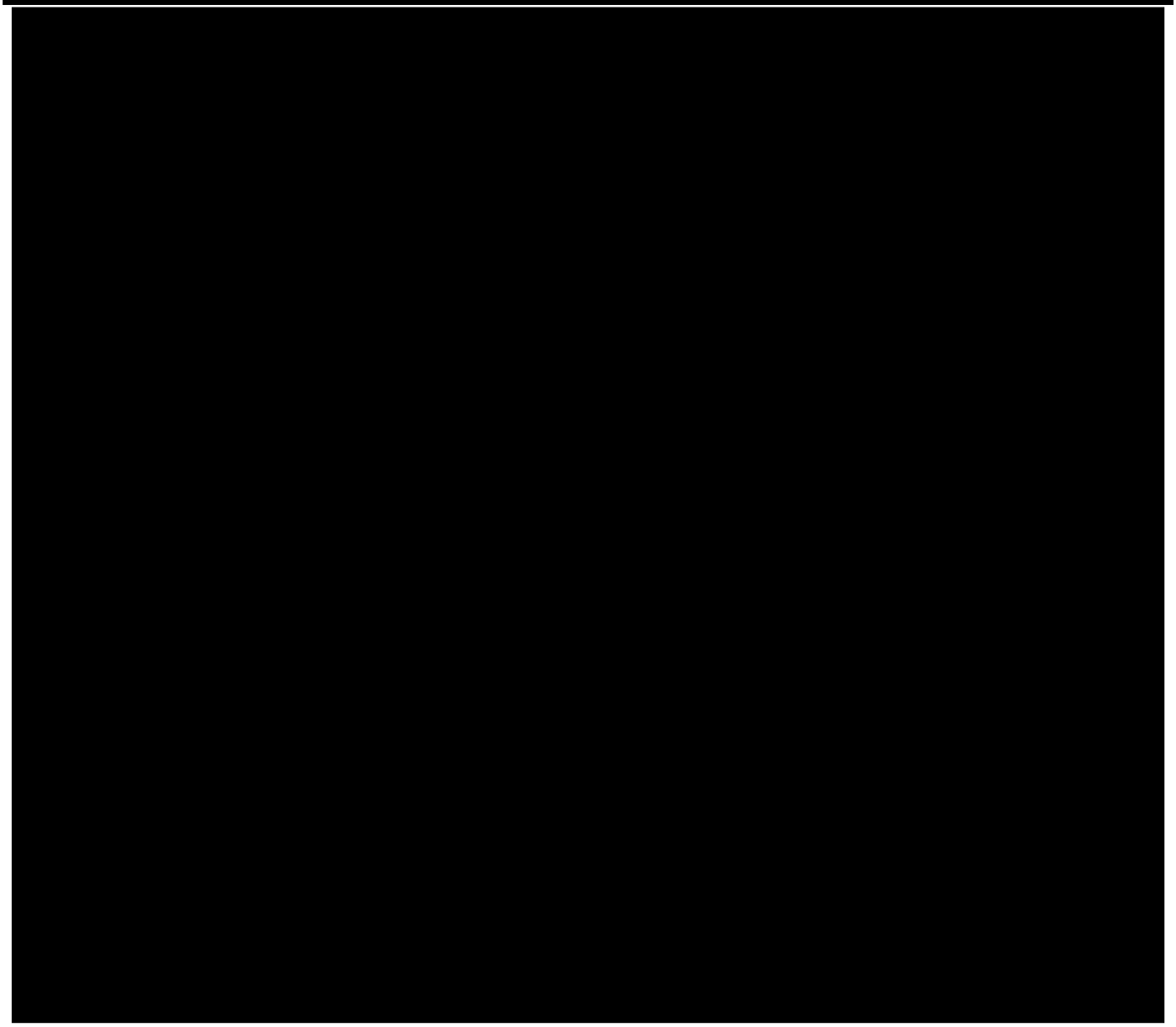

**Pfizer Australia**
38 - 42 Wharf Road
West Ryde NSW 2114

8 September 2017

Biological Science Section
Therapeutic Goods Association
PO Box 100
Woden ACT 2606

To whom it may concern,

**RE: NOMENCLATURE OF BIOLOGICAL MEDICINES**

Thank you for providing Pfizer Australia with the opportunity to make a submission to the above consultation. Pfizer Australia is one of Australia's leading providers of prescription medicines and consumer health products. We manufacture medicines and vaccines that millions of Australians use every day to live longer, healthier and more productive lives. We are proud of the active role we play in Australia's health system and the wider contribution we make as an innovator, employer and manufacturer.

For the past 30 years, Pfizer has dedicated significant resources to providing high-quality biological medicines with a development program supported by robust clinical and analytical data. We believe that biosimilar medicines are part of the future of biological treatment, and Pfizer is committed to working at every level to make the full potential of biosimilar medicines a reality across the communities we serve. We are proud to be the number one biosimilars manufacturer globally, and one of only a handful of pharmaceutical companies in Australia whose portfolio includes both biological and biosimilar medicines.[1] This provides us with a unique perspective on the current debate on the nomenclature of biological medicines in the Australian context.

Pfizer Australia's firm position is that biological medicines should be given distinguishable names to facilitate pharmacovigilance, support physician and patient choice, and help build confidence in the use of biosimilars. Our response to the consultation paper (Attachment 1) addresses each of the four options for biological medicine nomenclature proposed by the Therapeutic Goods Administration (TGA) in turn.

Pfizer Australia is a member of Medicines Australia, the peak body representing innovative pharmaceutical companies in Australia. Medicines Australia's submission is informed by three key principles:

- Decisions regarding all medicines should be based on appropriate and well understood standards of scientific and clinical evidence
- Prescribing physicians should retain the right to choose what brand of medicine to prescribe for their patient, in consultation with their patient, and what is dispensed
- Post-market quality safety and efficacy should be assured through robust pharmacovigilance and traceability mechanisms.

We support Medicines Australia's submission and encourage the TGA to carefully consider the analysis and recommendations provided within.

Thank you again for the opportunity to contribute to this consultation. Pfizer Australia is available at any time to provide further information to the TGA, as required.

[redacted]

[1] Pfizer Australia's first biosimilar medicine filgrastim (Nivestim) was launched in Australia in 2011, followed by biosimilar infliximab (Inflectra) in 2015.

ATTACHMENT 1

## Submission to the Therapeutic Goods Administration's Consultation on the Nomenclature of Biological Medicines

### Option 1 – Maintain status quo

*Do you support maintaining the current system with no change? Please provide reasons to support this view, or not.*

Pfizer Australia does not support maintaining the current system with no change.

Pfizer Australia acknowledges and supports the work the Therapeutic Goods Administration (TGA) is already undertaking to enhance post market monitoring and surveillance as part of implementing the recommendations of the Review of Medicines and Medical Devices Regulation.[b] However, we believe more can and should be done to improve pharmacovigilance systems, particularly in the context of biological medicines.

By definition, biosimilars are not generic medicine products. There may be subtle differences between biosimilars from different manufacturers or compared with the reference biological product. This means, for example, that adverse events that have not been observed for one biological medicine may occur with use of another or may arise from switching between products. Such differences may not be fully apparent until greater experience in their use has been established. Correctly attributing an adverse event is therefore particularly important.

Under the current system, healthcare providers are guided to provide a medicine's international non-proprietary name (INN), as well as its trade name and Australian registration number when reporting an adverse event. Nevertheless, the reported information can vary significantly and is often missing key fields which would definitively identify the biological product.

When adverse events are reported using the INN only, Pfizer's practice for global safety reporting is to take a conservative approach and interpret that report as relating to our own product, unless it can be categorically established the report does not relate to a Pfizer product. This has two important implications:

- New, early safety signals not relating to Pfizer products could be inadvertently captured in the Pfizer database. This data would then be diluted by other safety data, meaning an early signal relating to another biological medicine could be lost.
- An inability to trace individual medicines would make it difficult for biosimilar manufacturers to provide unequivocal post-approval safety data. This risks undermining confidence in biosimilars, which could adversely impact uptake.

The use of distinguishable names for biological medicines, including biosimilars, is therefore essential for pharmacovigilance reasons.

### Option 2 – Maintain 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*

Pfizer Australia supports in principle any efforts to increase public reporting of adverse events, including the activities proposed in Option 2. However, though we agree that increasing education on the importance of reporting adverse events could certainly help improve pharmacovigilance, we would argue that such efforts alone would not be sufficient (as per our commentary under Option 1

[b] TGA. (2017). *Consultation: Strengthening monitoring of medicines in Australia, Enhanced medicine vigilance*. Retrieved from: www.tga.gov.au/sites/default/files/consultation-strengthening-monitoring-of-medicines-in-australia.pdf

above); distinguishable names are still required.

Moreover, mandating the inclusion of the trade name, AUST R and/or batch number in the online reporting form would be impractical to enforce when adverse event reporting itself is not mandatory. An unintended consequence of mandating additional adverse event reporting fields could be that consumer and healthcare practitioners may not report the adverse event at all if some of the mandatory information is not available at the time.

Pfizer Australia therefore does not support moving forward with this option alone.

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

*Do you support use of a similar barcode system in Australia? Please provide reasons to support this view, or not.*

*What system and level of serialization should a barcode use?*

*What is the impact (including financial impact) of this option on you?*

Pfizer Australia does not support Option 3.

The barcode system in the European Union (EU) is not designed for pharmacovigilance – it is designed to maintain the integrity of the supply chain and guard against counterfeits (i.e. to facilitate track-and-trace under the Falsified Medicines Directive). The 2D bar code system only guarantees traceability of your own product and does not deal with the situation where you have multiple biological medicines from different companies that share the same INN. It is unclear, therefore, how this option would enhance pharmacovigilance outcomes in the broad sense of the term. The US, for example, is also introducing a track-and-trace system via bar coding and yet is still requiring a biological qualifier.

In addition, given the EU system is designed to verify medicines at the point of dispensing, it is also unclear how the system would work in practice, for example:

- How would a patient know that they were dispensed the correct product by just looking at the barcode on the packaging?
- How would a patient or healthcare provider report an adverse event using the barcode? Would special scanning technology be needed?

### Option 4 – Introduce the use of suffixes to the naming of biological medicines

*Do you support maintaining the current system with no change? Please provide reasons to support this view, or not.*

*What is the impact (including financial impact) of this option on you?*

*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.*

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

In line with Medicines Australia's position, Pfizer Australia strongly supports the introduction of suffixes to the naming of biological medicines. Distinguishable names improve pharmacovigilance and facilitate patient and prescriber choice (as outlined in the commentary provided under Option 1 above). Having a biological qualifier provides an additional level of redundancy and capability to assign adverse drug reactions correctly.

Global Harmonisation

Pfizer Australia supports global harmonisation of nomenclature for biological medicines. Global

harmonisation would be optimal from a pharmacovigilance perspective by enabling timely signal detection if safety issues were to arise for a particular product or product class. To this end, we have supported the World Health Organisation's (WHO) efforts to establish a global biological qualifier scheme and encouraged national regulators, including the TGA, US Food and Drug Administration (FDA), European Medicines Agency and others to work with the WHO to find common ground on suffixes and naming conventions.

However, inability to fully harmonise systems should not prevent implementation of a distinguishable biological product naming convention system within Australia. We understand that, at this point in time, the WHO's proposal to establish a global identifier for biological medicines seems unlikely to go ahead.[c] Meanwhile, the FDA has introduced a scheme to apply random suffixes to biological and biosimilar medicines. Pfizer has applied for these suffixes to be assigned for our biosimilar products. In this context, Pfizer Australia recommends the TGA recognise the suffixes applied by the FDA scheme.

Retrospective Application

There is no doubt that retrospective application of a new naming system for biological medicines would be complex. There may be unintended consequences of adding the suffix during the lifecycle of the product. For example:

- There could potentially be adverse event reports for a product with different names
- A name change could lead to the misconception that the product has changed.

Matters of practical application would need to be carefully thought out; this includes impact to prescribing, the need to update supply chain and pharmacovigilance systems, timing of implementation, etc.

Nevertheless, Pfizer Australia is of the view that the long term benefits of transparency in prescribing and improved pharmacovigilance outweigh the need to manage potential short term issues associated with implementation of a new naming system.

Miscellaneous Comments

The consultation paper acknowledges the Government's commitment to supporting a viable and competitive market for biological medicines, including mechanisms to drive uptake of biosimilars. The consultation paper, however, lacks any detail on how the four proposed options would work in practice to enhance pharmacovigilance within this context.

For example, if a medicine is a-flagged and the 'no substitution' box on the prescription is not ticked, the medicine can be substituted at pharmacy level with patient consent. It could be reasonably assumed that this system would remain in place even with the introduction of a barcode (Option 3) and/or biological qualifiers (Option 4), as the substitution could be made on the basis of the root name, i.e. the name that precedes the hyphen. It is unclear then how pharmacovigilance could be improved in these scenarios without the introduction of a feedback mechanism to alert the treating physician to what was actually dispensed. Though we understand Government has indicated it intends to pursue software changes to support this feedback mechanism, the details and timeline remain unclear.

[c] WHO. (2017, April). 64th Consultation on International Nonproprietary Names for Pharmaceutical Substances (Executive Summary). Geneva. Retrieved from: http://www.who.int/medicines/services/inn/64th_Executive_Summary.pdf?ua=1