INTERNATIONAL GENERIC AND
BIOSIMILAR MEDICINES ASSOCIATION

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IGBA CONGRATULATES THE AUSTRALIAN GOVERNMENT FOR MAINTAINING THEIR BIOLOGICS NAMING CONVENTION AND FOR STRENGTHENING PHARMACOVIGILANCE

The International Generic and Biosimilar medicines Association (IGBA) welcomes the Australian Government's decision to maintain the existing naming convention for biological, including biosimilar, medicines, that is to continue using the Australian biological name (without a specific identifier suffix) and to strengthen the adverse event reporting. This includes making the product's trade name, as well as the non-proprietary name, a mandatory field when reporting an adverse event to the Therapeutic Goods Administration (TGA).

This Government's decision aligns with the EU, which has approved the highest number of biosimilar medicines worldwide, and has acquired considerable experience of their use and safety.[1] Indeed, "*over the last 10 years, the EU monitoring system for safety concerns has not identified any difference in the nature, severity or frequency of adverse effects between biosimilars and their reference medicine*" [2]. Furthermore, the preliminary results of an ongoing European Medicines Agency's (EMA) pharmacovigilance study showed that 95,5% overall product identification has been achieved for classes of biologicals for which biosimilar medicines have been approved.[3]

The Australian Government's decision also aligns with the World Health Organization's (WHO) approach for nomenclature of Biological Medicines.

IGBA also applauds this decision as it supports quality use of medicines, including safe prescribing and dispensing practice, by avoiding the complexity and potential confusion that would be associated with the introduction of a non-memorable suffix-based system.

- [1] Biosimilar Medicines Clinical Use: An Experience Based-EU Perspective
- [2] EMA – European Commission: Biosimilars in the EU – Information guide for healthcare professionals, 2017 (link)
- [3] A Clinician´s Guide to Biosimilars in Oncology: Understanding the Science of Extrapolation and Interchangeability – Dr. Elena Wolff-Holz

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About IGBA

The International Generic and Biosimilar Medicines Association (IGBA) was founded as IGPA (International Generic Pharmaceutical Alliance) in March 1997 to strengthen cooperation between associations representing manufacturers of generic medicines from around the world. Its membership includes AAM (USA), CGPA (Canada), GBM – Southern Africa (South Africa), IPA (India), JAPM (Jordan), JGA (Japan), Medicines for Europe (Europe), and TGPA (Taiwan), while the associations from Australia (GBMA), Brazil (ProGenericos), Mexico (AMEGI), and Malaysia (MOPI) are Associate Members. The IGBA is at the forefront of preserving sustainable competition within our industry, by stimulating competitiveness and innovation in the pharmaceutical sector; thereby, ensuring millions of patients around the world have access to high quality, pro-competitive medicines. Through its constituent member associations, the IGBA maintains constant dialogue with government authorities around the world, as well as with international institutions such as WTO, WIPO and WHO. More information: www.igbamedicines.org