



6 September 2017

Biological Science Section
Scientific Evaluation Branch
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606
Australia

Re: Consultation - Nomenclature of Biological Medicines

IFPMA welcomes the opportunity to respond to the Therapeutic Goods Administration (TGA) consultation on nomenclature of biological medicines. Noting that TGA has included an option to consider a suffix, IFPMA believes this is a good opportunity for the TGA to request the WHO formally implement their published Biological Qualifier (BQ) scheme. The BQ can be used as an adjunct to a robust pharmacovigilance (PV) system, will serve to provide a direct link to a patient's medical records and the actual biological medicine received while also providing a manner of facilitating communication between different global pharmacovigilance systems. Furthermore, given that Australia operates in a global environment for pharmaceuticals, IFPMA recognizes the benefits of a globally harmonized approach to a naming convention for biological medicines and thus recommends against the adoption of a unique approach by TGA. IFPMA would like to express its continued and strong support for the adoption of a suffix-based nomenclature system that aligns with the BQ proposal of WHO.

Best regards,

Thomas B. Cueni
Director General