INTERNATIONAL GENERIC AND
BIOSIMILAR MEDICINES ASSOCIATION

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IGBA CALLS FOR FULL TRANSPARENCY AND NEW TIMELINES FOR IMPACT ASSESSMENT WITH REGARD TO THE VOLUNTARY WHO BIOLOGICAL QUALIFIER (BQ) PROPOSAL

The International Generic and Biosimilar medicines Association (IGBA) welcomes the WHO's continuous interest in the development of a global identification system for biological substances, as well as the decision to perform an impact study assessment of the voluntary Biological Qualifier (BQ) proposal. However, IGBA does not support the BQ proposal since successful product identification and tracking using multiple identification components are already in force, such as the brand name or the INN combined with the company name, the lot number and various national codes.

Furthermore IGBA is concerned:

- about the immature proposal which consists of random 4 consonant letters and a two-digit checksum which is meaningless, unmemorable, confusing, unnecessarily complicated and not in line with the ISO IDMP (Identification of Medicinal Products) standards;
- about the uncertain retrospective application of the BQ to already licensed biological products which may lead, where implemented, to a discriminatory and anticompetitive situation between existing reference biologics and new and future biosimilar medicines and hampered access;
- about the extremely short timelines for the production of the final report which can hardly allow for a comprehensive and meaningful impact assessment on all the various international stakeholders and areas potentially affected by the proposed identifier;
- about the lack of transparency regarding the few national drug authorities which have requested the development of a global identification system.

IGBA therefore calls on the World Health Organization:

1. to make fully transparent all the positions on the BQ during the consultation periods, in particular those of the drug regulatory authorities requesting action by the WHO;
2. to urgently extend the timelines for the final report by a minimum of 6 months to allow a proper international impact assessment "*on the possible implementation of the scheme, both in terms of access to biological medicines as well as reviewing the quality and safety issues*" and "*the implications of implementing the BQ scheme in conjunction with the respective INNs (as the BQ is not part of the INN) – for patients, regulators, healthcare providers, healthcare funders and health technology assessment authorities".*

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- Biological Qualifier An INN Proposal (Final 2015)
  pdf, 123kb
- Biological Qualifier Frequently Asked Questions (December 2015)
  pdf, 164kb
- Biological Qualifier Request for proposal on Impact assessment study (Short)
  pdf, 95kb

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. Its membership includes the EGA (Europe), the CGPA (Canada), the GPhA (USA), the JAPM (Jordan), the NAPM (South Africa), the TGPA (Taiwan) and the JGA (Japan) while the associations from Australia (GBMA), Brazil (ProGenericos) and Mexico (AMEGI) are Associate Members. The IGBA is at the forefront of stimulating competitiveness and innovation in the pharmaceutical sector by providing high quality pro-competitive medicines to millions of patients around the world. Through its constituent member associations, the IGBA maintains constant dialogue with government authorities (including the European Commission for Europe) as well as with international institutions such as WTO, WIPO and WHO. More information: www.igbamedicines.com