



**European Biosimilars Group**  
EGA sector group

**EUROPEAN GENERIC MEDICINES ASSOCIATION**

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# WHO BQ Proposal EGA's perspective

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# Thank you!

**The EGA appreciates the WHO INN Office's efforts to counteract the proliferation of divergent naming schemes for biologics around the world.**

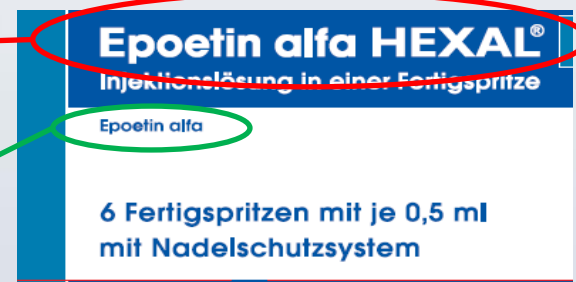
# EU naming system - reliable and proven model for the world

- **Unique product names** in addition to, and separate from, the active substance names (INNs), are the best solution
  - to clearly identify any biological product
  - for track & trace and AE reporting
  - for unambiguous prescription



Product name  
(unique)

Substance name  
= INN (shared)





# BQ should only be used where needed

- Traceability works extremely well with existing, well tested identifiers (brand name, company name, lot no.) in many jurisdictions, esp. the EU
- In such situations, additional identifiers add complexity and can lead to confusion
- The BQ scheme should **not** be introduced **where things work well**, but only where it provides a demonstrable added value



# EGA welcomes key principles of BQ proposal

- **WHO INN policy for biologicals unchanged**
- **Biologic Qualifier (BQ) will be**
  - **separate** and distinct from the INN
  - applicable to **ALL biologics**, not only to biosimilars
  - applicable **retroactively**
  - **voluntary** for regulatory agencies
  - administered and operated by the **WHO INN Office**



# EGA does not support BQ linkage to manufacturing site(s)

- Divorces product from the company which owns the marketing authorizations and is legally responsible
- Not workable in case of contract manufacturing and licensing agreements
- No globally unified BQ - different (combinations of) manufacturing sites are used for different countries
- Revives the mantra “the process is the product”

# BQ must be easy to remember and thoroughly user tested

- 4 random consonants are (a) hard to remember and (b) easy to mix up
  - This poses a risk to patients and for AE reporting
- Instead a system should be devised which provides BQs that are (a) easy to remember and (b) hard to mix up
- Different options should be generated, systematically tested with stakeholders and discussed in a workshop
  - Physicians, patients, pharmacists, payors, PV experts...
  - Company name should be considered
  - Compare e.g. qbdp vs. AMGEN



# Other items to be modified or added

- Document title “**BQ, an INN Proposal**” implies direct link to INN, which is contradictory to proposal
  - Change to “**BQ, a Proposal of the INN Expert Committee**”
- Example “**epoetin lambda bbbb**” links BQ to INN, which is contradictory to proposal
  - Remove example
- Terminology “**biosimilars**” is used for all copy biologicals, independent of the approval standards
  - State biosimilars are products which comply with WHO SBP guideline
  - Introduce separate terminology for copy biologics which do not comply with WHO SBP guideline - BQ should also apply to those
- Application procedure for **retrospective BQ** use missing
- **Commercially sensitive information** not defined
- **BQ should NOT be used for prescription purposes**
  - 4 letter random consonant code impossible to remember and easy to mix up - potential medication errors
  - Company name would be suitable

# Summary

- EGA welcomes WHO's efforts to counteract proliferation of divergent naming systems for biologics
- EGA supports independence of BQ from INN, voluntariness, applicability to all biologics, retroactivity, administration by WHO
- BQ should be used only where it adds value
- BQ must be linked to company, not manufacturing site
- BQ must be easy to remember - company name is easiest
- Different BQ options should be generated and thoroughly user tested to facilitate the final decision

**EGA is looking forward to contributing to further discussions!**

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*Making Medicines Affordable*

# Acronyms

- **AE Adverse Event**
- **BQ Biological Qualifier**
- **EBG European Biosimilars Group**
- **EGA European Generic medicines Association**
- **EU European Union**
- **INN International Nonproprietary Name**
- **PV Pharmacovigilance**
- **WHO World Health Organisation**