



European Biosimilars Group  
EGA sector group

## EGA-EBG SUMMARY POSITION REGARDING THE WHO BIOLOGIC QUALIFIER PROPOSAL (INN WORKING DOC. 14.342)

- No additional component is needed in most jurisdictions as they manage very well with the brand name or INN accompanied company name; the BQ should NOT be implemented in these countries, including the EU since identification of biologicals is ensured and a number of legal tools and measures are in place. In any case, introducing a new identifier into the EU would require a legislative change.
- We appreciate the WHO making an attempt to prevent proliferation of different additional components or even modified nonproprietary names and making available a new identifier to those countries which do not want to use the well-established identification components described above.
- We express full support for the proposed BQ system being voluntary, applying to all biological substances and being applicable retrospectively.
- However a number of details of the proposed BQ scheme need to be addressed. We suggest the WHO INN Expert Committee generates different options for the BQ, discusses them in a public workshop, and then has the different options user-tested with all relevant stakeholders by an independent organisation. In the absence of such a study, a new system of identifiers cannot be supported and should not be made available and implemented.

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