April 30, 2014

Dr. Raffaella Balocco Mattavelli
World Health Organization
1211 Geneva 27
Switzerland

Dear Dr. Balocco,

We want to thank you, the WHO INN Office and the INN Expert Committee, for your extensive efforts to maintain a globally harmonized naming system for pharmaceuticals. The importance of any system established becomes more vital in the context of biologics and the growing number of biosimilar products.

While GPhA and EGA maintain that product names (Brand/trade names) in addition to, and separate from the INN, are the best solution, we acknowledge that some countries want another level of differentiation, particularly where prescribing by INN may be endorsed. GPhA and EGA appreciate that broad consensus has been reached on the principles around an additional naming element; particularly that it would be independent from the INN, applicable to all biologic products, not solely biosimilars and applied retroactively to ensure consistency.

We understand the World Health Organization (WHO) is currently considering the addition of a biologics qualifier specific to the drug substance manufacturing site (BQXXXX). While we believe the WHO and INN Expert Committee's efforts to allow for tracing of a product back to its specific site of origin are well intended, we find the proposal difficult and problematic. Each product manufactured currently integrates technology such as barcodes on packaging and/or containers. Adding a single additional identifier will not provide any more assurance of track and trace than the current technologies of which use is not being optimized.

First, the Marketing Authorization Holder (MAH) is legally responsible for the product. All adverse event reports and quality complaints must be sent to the MAH, not the manufacturer. Many MAHs use contract manufacturers for manufacturing their drug substances, or develop a licensing agreement with another company. Connecting biologic qualifiers to these sites would divorce the product from its MAH, thus potentially diverting reports to the manufacturer, frequently a separate entity, and creating delays in the investigation timeline. As such, drug safety and legal considerations make such a proposal difficult.

A majority of companies also have multiple drug substance manufacturing sites for each product and use these sites to flexibly supply product for various jurisdictions. For example, a biologic marketed in the US could be manufactured at three different drug substance manufacturing sites, all licensed with the FDA under the same BLA, thus legally constituting the same product. The introduction of a drug substance manufacturing site-specific qualifier would lead to a situation in

which three different biologic qualifiers, and three distinct labels, are required to reflect what is legally considered a single product. This is neither legally possible, nor desirable from a drug safety perspective.

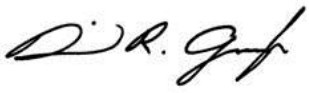
Identifying the drug substance manufacturing site falls short of providing all of the information needed in case of an adverse event. Most quality issues arise at the drug product level, which would not be covered by this system. Since most issues arise in specific drug product lots the lot number would also have to be captured, but it is not currently part of most records.

Physicians, pharmacists and patients would be confused if the same product had one biologic qualifier in one instance but another in the next (due to the current manufacturing environment in which lots of drug products are manufactured using drug substances from different manufacturing sites). In the worst case, this could lead to medication errors; the more likely result will be that physicians and pharmacists will simply not use the system.

GPhA and EGA recommends, if an additional identifier is deemed mandatory, bringing the biologic qualifier back to its original intent – to help with unambiguous prescriptions and traceability under specific circumstances of certain jurisdictions. We remain convinced that the simplest of all identifiers is also the best and most robust. GPhA and EGA kindly request the WHO INN Office and the INN Expert Committee reconsider the new proposal and closely evaluate our alternative plan to include the INN plus the company name (e.g. epoetin alfa SANDOZ).

We also kindly request the WHO INN Office and the INN Expert Committee ensure any proposal put forward for final public consultation is first systematically tested by an independent agency, with key stakeholder involvement such as physicians, patients, pharmacists, and pharmacovigilance authorities. We thank the WHO INN Office and the INN Expert Committee for your kind consideration.

Respectfully submitted,



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