The INN system remains a cornerstone of chemical pharmaceutical identification, and the system provides clarity for the healthcare community so that patient safety is not compromised. Appropriate conventions to provide separate names for biotech medicines would be one possibility to help avoiding inadvertent substitution by pharmacists. This in turn would help to avoid imprudent compromises in patient safety or pharmacovigilance.

At a first glance the most sensible course of action would appear to be the assignment of distinct INNs to biologicals/biosimilars. It should be realized, however, that the INN system originally has been developed to be applied to chemical, well-defined, substances and that none of the current INN rules is applicable to solve the naming problem of biologicals/biosimilars. Therefore, development of a new system, independent of the INN rules, is to be preferred for providing an unambiguous link between a unique name and a unique, process-dependent, biological product.

Considering the problems related to unambiguous naming, to substitution, to prescription based on active substance name and subsequent traceability of the actual product administered to the patient, urges the strong need for an extremely reliable pharmacovigilance and postmarketing surveillance. In this respect it is important to realize that procedures to ensure a reliable and unambiguous *traceability* should be put in place. Indeed, to correctly link an adverse event to the causative biologic, naming of the medicine, prescription practices and procedures during dispensation and administration of the medicine should be critically evaluated. (*Declerck P. PharmacoVigilance Review **3**: 15-17, 2009*)

It is clear to me that the use of (random, thus meaningless!) suffixes to the INN will not be applicable in a reliable way. Who will memorize all different suffixes (e.g if there are 5 biosimilars/biologicals with the same INN on the market)? Adequate pharmacovigilance requires a robust, reliable and implementable system that will be used in a reliable way by healthcare practitioners (at the level of prescription by the doctor, at the level of dispensing by the pharmacist and at the level of administration to the patient).The brand name is already routinely used, it's use is therefore the most logical, spontaneous starting point to ensure traceability.

Therefore, to ensure an adequate pharmacovigilance, the following is appropriate:

(a) Prescription of biologics by brand name
(b) Reporting of adverse events based on brand name, INN and batch number
(c) Routine application of e.g. barcode related systems of traceability

Thus option 2, in the long term supplemented with a barcode system (option 3) to allowing automation and reducing human errors in the reporting system, is to be preferred and is relatively easily implementable.