

**Position Paper on Subsequent Entry Biologics in Canada**

**November 2012**

1. Patients with rheumatic diseases should have access to safe, effective and affordable drugs.
2. The decision to use these specific drugs is a planned and shared decision between the Patient and their Physician taking into account many factors.
3. Subsequent Entry Biologics are designed to be “sufficiently similar to the reference product that there is no clinically meaningful difference between these in terms of safety, purity and efficacy" (Russell, 2012).
4. In order to track real world effectiveness, these drugs should have unique names from their reference products.
5. These products should NOT be considered for automatic interchangeability or substitution. See definitions below.
6. To ensure the best interests of Ontarians, the ORA supports the development of a province-wide post-marketing registry for:
   1. New-entry products such as SEB’s.
   2. Any and all new innovative biologics
   3. Should be independent of the pharmaceutical industry.
   4. Should be supported by stakeholders (patient groups, industry, private payers, and governments) and run by a third party
   5. Have a defined observational period (e.g. 3-5 years).
   6. We recommend that the ORA’s Ontario Biologic Research Initiative (OBRI) be considered for this proposal.
7. The roles of SEBs should be evaluated in the context of long-term management of chronic rheumatic disease. The ORA suggests the development of a Chronic Disease Management Model of Care to optimize patient outcomes.
8. There should be ongoing reassessment of SEB’s. This position paper will be reviewed in three years.

*References*

*Tony Russell et al (2012): Subsequent entry biologics/biosimilars: A viewpoint from Canada. Clin Rheumatol Published online: 26 August 2012*

*Ontario College of Pharmacists website www.* *http://www.ocpinfo.com*

**Definitions of Interchangeability, Therapeutic substitution and Extrapolation**

* *•* ***“Interchangeability”*** *generally refers to the requirement to “interchange” a lower cost generic version of a name brand drug (a ‘financial’ decision).*
* *In Ontario, interchangeability is regulated by the provincial government through legislation (Drug Interchangeability and Dispensing Fee Act).*
* *Under the provisions of the legislation, a pharmacist may select and dispense a lower cost interchangeable drug without contacting the prescribing physician. (reference: Ontario College of Pharmacy)*
* *•* ***“Substitutability****” or “therapeutic substitution” generally refers to substituting an altogether different drug as functionally equivalent to a prescribed drug for treating the same condition (a medical decision).*
* *Substitution of a drug in Ontario (whether it is a generic or therapeutic equivalent) requires the authorization of the prescribing physician*
* *·* ***Extrapolation*** *refers to the evaluation by Health Canada of a proposal to grant additional indications held by the reference biologic drug to the SEB, in the absence of such clinical data.*

Health Canada has stated, "SEBs are not "generic" biologics and authorization of an SEB is not a declaration of pharmaceutical or therapeutic equivalence to the reference biologic drug." Health Canada "does not support automatic substitution of a SEB for its reference biologic drug."