



**Canadian Rheumatology Association
Position Statement on Biosimilars and Innovator Molecules
(Biological disease modifying anti-rheumatic drugs (DMARDs))**

A rheumatologist's decision to prescribe a biologic agent (biosimilar and/or innovator molecule) must be informed by the clinical need and must adhere to the principles of a sound therapeutic alliance. It is the position of the Canadian Rheumatology Association/La Société canadienne de rhumatologie (CRA) that with the introduction of biosimilars into the Canadian marketplace, where biological DMARDs, hereafter termed innovator molecules are currently available, the following should be considered:

1. In an individual naïve to a specific molecule, choice and/or interchangeability between a biosimilar and an innovator molecule might be considered.
2. Administrative switch/interchangeability for patients on established therapy is not supported at the present time.
3. Substitutions from one biologic to another including a biosimilar or an innovator molecule, by someone other than the treating physician, must be avoided
4. There should be establishment of post-marketing surveillance for all new-entry products, including biosimilars and new innovator molecules, in order to determine uncommon side effects and durability of response. *
5. All biologic products (biosimilars and innovator molecules) should be identified by an appropriate naming system eg. molecular name - suffix, to ensure correct attribution of adverse events.
6. Biosimilars and innovator molecules (those currently available and new-entry agents) should have indications only where data is sufficient from well-conducted clinical studies and approved by Health Canada.

* The results of surveillance activities should be available for external review. Preferably, all acquired data should be collated for comparative purposes. We support the use of a research-based external groups review process, independent of the pharmaceutical industry, to ensure transparency and validity. These projects should be supported by stakeholders including patient groups, industry, private payers, and governments, and run by a third party. It is suggested that there be a defined observational period (e.g. 3-5 years).

Definitions of Interchangeability and Therapeutic substitution

“Interchangeability” in this statement generally refers to the requirement to “interchange” drugs that are similar in structure and function.

“Substitutability” or *“therapeutic substitution”* in this statement generally refers to substituting an altogether different drug as functionally equivalent to a prescribed drug for treating the same condition (a medical decision)