CANADIAN RHEUMATOLOGY ASSOCIATION | SOCIÉTÉ CANADIENNE DE RHUMATOLOGIE

Position Paper on the Establishment of a Common Drug Review (CDR) Procedure and Process for Reviewing Subsequent Entry Biologics (SEBs)

It is the position of the Canadian Rheumatology Association/La Société canadienne de rhumatologie (CRA) that while there is likely to be benefits of the approval of subsequent entry biologics (SEBs) in Canada, the following should be considered:

1. There should not be interchangeability between an SEB and an innovator molecule. There should not be substitutions from one biologic to another including SEB and innovator molecule.
2. There should be establishment of post-marketing surveillance for all SEBs in order to determine uncommon side effects, and durability of response (ie development of ADAs [anti-drug antibodies] that can cause side effects and /or lower drug efficacy). The results of surveillance activities should be available for external review. Preferably, all material should be collated for comparative purposes. We support the use of a research-based external group (eg. OBRI, Alberta Biologic Surveillance group), to ensure transparency and validity.
3. SEBs should have distinct names to ensure correct attribution of adverse events.
4. In general, subsequent entry biologics should have indications only where data are sufficient from well-conducted studies.
5. Approval and access to subsequent entry biologics must acknowledge the clinical needs of the patients and respect the context of the therapeutic interaction of patient and physician.

Dated October 4, 2013