Biosimilars Canada
The Voice of Biosimilar Medicines in Canada

Biosimilars Canada Statement on Revised Canadian Guidance for Sponsors of Biosimilars

Toronto, January 9, 2017 – Jim Keon, President of Biosimilars Canada, issued the following statement regarding the release of the revised Guidance Document, Information and Submission Requirements for Biosimilar Biologic Drugs:

"The convergence of regulatory requirements is a top priority for sponsors of biosimilar medicines as single global development programs are typical given the high R&D costs for these complex products.

Canadian-specific requirements add to the cost associated with domestic submissions, and are difficult to justify from a global business perspective due to the small size of the Canadian market. Different requirements also create unnecessary business uncertainty and risk for sponsors, and may result in patients being denied access to safe, effective biosimilar medicines

With the release of this revised Guidance Document, Health Canada has significantly improved its approach and requirements, and is now much more aligned with leading regulatory partners such as the European Medicines Agency and the US Food and Drug Administration. We believe that sponsors can now have greater confidence in the Health Canada approval pathway for biosimilar medicines.

Biosimilars Canada congratulates the staff in the Biologic and Genetic Therapies Directorate at Health Canada for their considerable efforts in working to improve the Canadian approval pathway for biosimilar medicines and increasing the alignment of its requirements with key regulatory partners.

The full revised Guidance Document, Information and Submission Requirements for Biosimilar Biologic Drugs is available on the Health Canada website at http://www.hc-sc.gc.ca/dhp-mps/brgtherap/activit/announce-annonce/notice-avis_biosimilars-biosimilaires-eng.php."

About Biosimilars Canada
Biosimilars Canada represents companies that are at the forefront of the global development and marketing of biosimilar medicines. Biosimilar medicines are federally-approved alternative equivalents to reference biopharmaceutical products. They are as safe and effective as their reference biopharmaceutical products, and are developed to the same quality standards. Biosimilar medicines present a significant opportunity to embrace cutting-edge therapies while addressing the cost-effectiveness demands on healthcare systems in Canada.

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