

Emerging Safety Issues: Biosimilars

Stakeholder Consultation on the Naming of Biologic Drugs

Systemic Treatment Quality and Safety Symposium

Sylvia Hyland

Institute for Safe Medication Practices Canada

March 2, 2018

Stakeholder Consultation on the Naming of Biologic Drugs

Issue:

- Increasing number of biologic drugs sharing the same non-proprietary name
- Complexity and variability of biologics - important to be able to distinguish
- No global approach to naming (The WHO suffix-based approach is not proceeding)

Consultation Questionnaire:

- January 18 - February 9, 2018
- 3 options for a naming convention; 5 questions
- Responses will inform Health Canada policy decision

OPTION 1 - Continue the current Canadian drug identification and naming approach [status quo]	OPTION 2 - Use of the brand name with the non-proprietary name to distinguish among biologics	OPTION 3 - Implement a 4-letter suffix appended to the non-proprietary name																								
Biosimilars, reference biologics, and innovator biologics that share the same non-proprietary name can be distinguished by their unique brand names or DINs, however, in some settings only the non-proprietary name is used.	<p>Both brand and non-proprietary names would be used, so biosimilars, reference biologics, and innovator biologics that share the same non-proprietary name would be distinguished by their unique brand names.</p> <p>New guidelines would be provided on the importance of using both the brand name and non-proprietary name in prescribing, dispensing, administration, and documentation, including adverse reaction reporting.</p>	<p>All biologic drugs, including biosimilars, reference biologics, and innovator biologics, would receive a unique, meaningless 4-letter suffix appended to the non-proprietary name. Products sharing the same non-proprietary name would be distinguished by the suffix.</p> <p>Guidelines would be provided to support this option and would be developed to align with the United States Food and Drug Administration (FDA)'s suffix-based naming convention as much as possible. A resolution would be found to match suffixes where biologics or biosimilars are submitted for authorization to Health Canada before the FDA.</p> <p>The FDA intends to apply their naming convention to both newly licensed and previously licensed biological products.</p>																								
Examples (in alphabetical order by brand name):																										
<table><tr><th>Brand Name</th><th>AND/OR Non-proprietary Name</th></tr><tr><td>INFLECTRA®</td><td>infliximab</td></tr><tr><td>REMICADE®</td><td>infliximab</td></tr><tr><td>RENFLEXIS™</td><td>infliximab</td></tr></table>	Brand Name	AND/OR Non-proprietary Name	INFLECTRA®	infliximab	REMICADE®	infliximab	RENFLEXIS™	infliximab	<table><tr><th>Brand Name</th><th>AND Non-proprietary Name</th></tr><tr><td>INFLECTRA®</td><td>infliximab</td></tr><tr><td>REMICADE®</td><td>infliximab</td></tr><tr><td>RENFLEXIS™</td><td>infliximab</td></tr></table>	Brand Name	AND Non-proprietary Name	INFLECTRA®	infliximab	REMICADE®	infliximab	RENFLEXIS™	infliximab	<table><tr><th>Brand Name</th><th>Non-proprietary Name-suffix*</th></tr><tr><td>INFLECTRA®</td><td>infliximab-dyyb</td></tr><tr><td>REMICADE®</td><td>infliximab</td></tr><tr><td>RENFLEXIS™</td><td>infliximab-abda</td></tr></table> <p>* Examples provided are US examples, approved by the US FDA. See Food and Drug Administration, Nonproprietary Naming of Biological Products Guidance for Industry and Drugs@FDA</p>	Brand Name	Non-proprietary Name-suffix*	INFLECTRA®	infliximab-dyyb	REMICADE®	infliximab	RENFLEXIS™	infliximab-abda
Brand Name	AND/OR Non-proprietary Name																									
INFLECTRA®	infliximab																									
REMICADE®	infliximab																									
RENFLEXIS™	infliximab																									
Brand Name	AND Non-proprietary Name																									
INFLECTRA®	infliximab																									
REMICADE®	infliximab																									
RENFLEXIS™	infliximab																									
Brand Name	Non-proprietary Name-suffix*																									
INFLECTRA®	infliximab-dyyb																									
REMICADE®	infliximab																									
RENFLEXIS™	infliximab-abda																									