Notice to Stakeholders - Policy Statement on the Naming of Biologic Drugs

Health Canada thanks those who responded to the 2018 Consultation on the Naming of Biologic Drugs. A "What We Heard" Report summarizing the results of this consultation has been published on the Health Canada website. All responses were reviewed and considered to inform the development of a naming convention for biologic drugs.

Following internal and external stakeholder consultations and analysis of related issues, Health Canada has decided that biologic drugs, including biosimilars, will be identified by their unique brand name and non-proprietary (common) name, without the addition of a product-specific suffix. Both the brand name and non-proprietary name should be used throughout the medication use process so that biologics that share the same non-proprietary name can be distinguished by their unique brand names.

All biologics, including biosimilars, will continue to have a unique Drug Identification Number (DIN). The DIN distinguishes key characteristics of a drug product, including the brand name, manufacturer name, medicinal ingredient(s), strength(s), dosage form, and route of administration.

Health Canada's naming convention, which is consistent with Option 2 in the 2018 Consultation on the Naming of Biologic Drugs:

- Will serve to achieve the objective of distinguishing among biologics in prescribing, dispensing and pharmacovigilance in the Canadian context
- Was the most favoured option among respondents to the stakeholder consultation
- Does not impose unnecessary regulatory burden, and
- Avoids the complexity associated with implementation of a suffix-based naming convention with retroactive application to previously authorized biologics

In coming to this decision, Health Canada also took into consideration the following:

- Brand names are consistent with current biologics naming practice and are already recognized and in use
- All biologics authorized in the last 20 years that are within scope of the biosimilars guidance document have a unique brand name
- The DIN is used to specifically identify products in Canadian healthcare system databases
- There is no internationally adopted naming scheme to distinguish among biologics that, based on active ingredient, will be assigned the same International Nonproprietary Name (INN) by the World Health Organization
- An analysis of how biologic drugs, including biosimilars, are identified in Adverse Drug Reaction (ADR) reports in Health Canada's Canada Vigilance database shows that reporting by brand name is largely successful in achieving accurate product-level attribution of spontaneously reported adverse events for suspected biologics. The traceability of biologics primarily used in hospital settings was identified as an area for improvement

- Activities are underway to implement mandatory reporting of serious adverse drug reactions and medical device Incidents by health care institutions
- Encouraging ADR reporting by brand name and/or DIN would have program-wide pharmacovigilance benefits for both biologic and pharmaceutical drugs
- This option avoids any potential perception that different suffixes indicate clinically meaningful differences between a biosimilar and its reference biologic drug

To implement this naming convention, Health Canada will:

- Update related guidance documents and proceed with a regulatory amendment to ensure that the current practice of sponsors submitting unique brand names for biologics is adequately supported
- Provide stakeholder communications on the importance of recording both brand and non-proprietary names throughout the medication use process (as well as other product-specific-identifiers, such as DIN and lot numbers where appropriate) to help ensure product-specific identification and traceability of biologics
- Undertake activities to assist pharmacovigilance:
    - Update ADR reporting forms and associated instructions to support reporting of brand and non-proprietary names as well as other product-specific identifiers
    - Leverage current outreach activities being conducted in preparation for mandatory reporting of serious adverse drug reactions and medical device incidents by health care institutions; activities include providing education to improve ADR reporting practices with communications reflecting key messages about the importance of providing product-specific identifiers in ADR reports

Health Canada will continue to conduct analyses of the Canada Vigilance database to monitor ongoing traceability of ADRs for biologics to the product level.

Unique brand names play a critical role in distinguishing among biologics. Biologics generally consist of large, complex molecules and raise unique safety concerns related to immunogenicity. In addition, all biologics, including biosimilars, are considered to be stand-alone drugs after authorization. Since a biosimilar and its reference biologic drug are not identical and are manufactured by independent processes, newly identified safety issues that affect the reference biologic drug may or may not also affect the biosimilar and vice-versa. In their responses to the Consultation on the Naming of Biologic Drugs, numerous healthcare system stakeholders, including prescribers, pharmacists, patients, and drug information systems providers, indicated that unique brand names are a key component for readily distinguishing among biologic drugs.

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