Canadian Biosimilars Landscape

Jody Cox
Vice President, Biosimilars Canada

CAPRA Biologics and Biosimilars Symposium
March 28, 2025

Biosimilars Canada
The Voice of Biosimilar Medicines in Canada

AGENDA

Biosimilars Canada
The Voice of Biosimilar Medicines in Canada

- Biosimilars Canada Overview
- Canadian Biosimilars Market
- Regulatory Priorities for a Robust and Sustainable Biosimilars Market for Canadian Patients

WHO WE ARE

- A national association representing the biosimilar medicines industry established in January 2015
- A division of the Canadian Generic Pharmaceutical Association (CGPA)
- Actively engaged in the International Generic and Biosimilar Medicines Association (IGBA)

OVERVIEW - CANADIAN BIOSIMILARS MARKET

>3.28m Rx in retail

>$2.19b In sales

12.6% of retail Rx fill

69 Biosimilars Approved By HC

11.7% of Biologics sales

26 Biosimilar Submissions in Review

* IQVIA, 12 months ending December 2024

BIOSIMILAR TRANSITION POLICIES

- All 10 provinces and 2 territories have implemented biosimilar transition policies, as have NIHB and Corrections Canada
- Ontario and Quebec published predictable go-forward transition policies
- Some public payers are also removing red tape and expanding reimbursement criteria beyond what was covered for originator

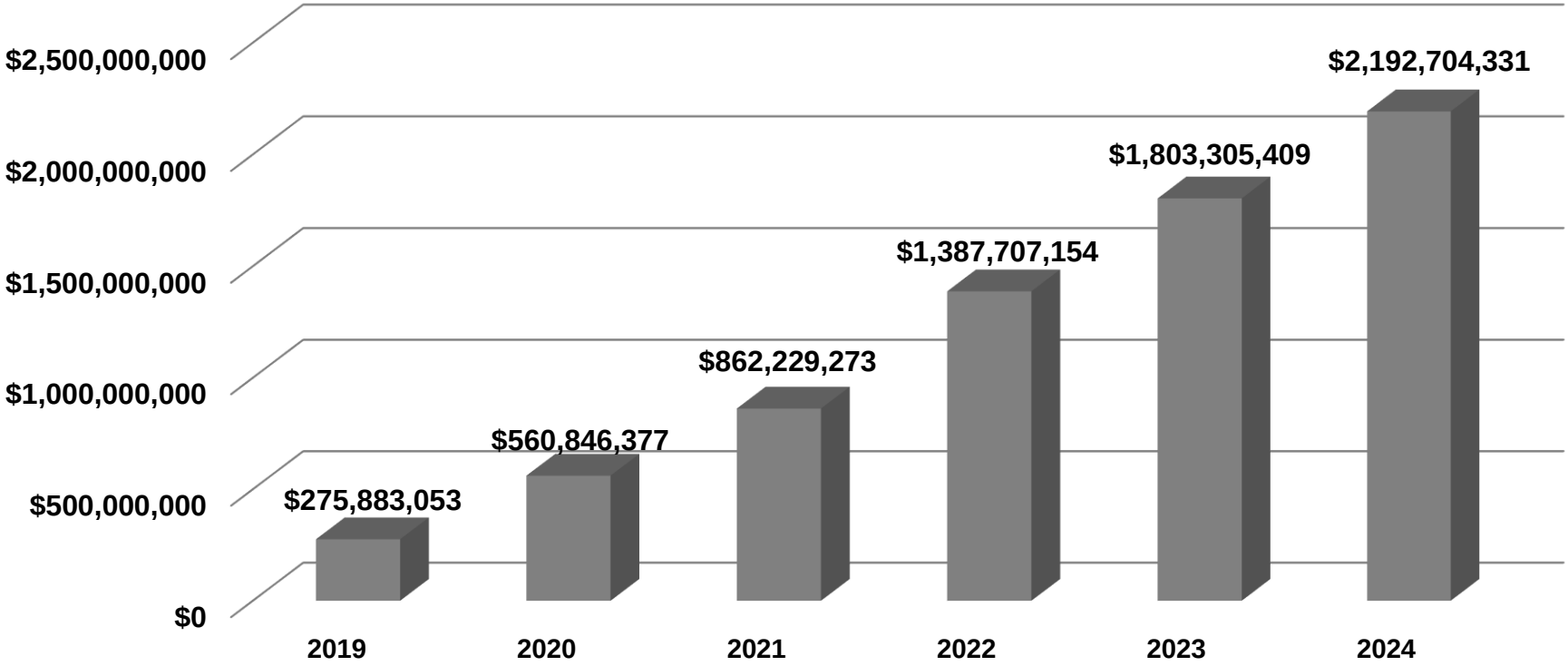
69 BIOSIMILARS APPROVED BY HEALTH CANADA TO DATE

- ✓ 11 biosimilar approvals in 2024
- ✓ Health Canada has approved biosimilars for 22 different reference biologic drugs
- ✓ 26 submissions currently under review, including 2 additional reference biologic drugs

Active Substance	Approved	Submissions Under Review
adalimumab	8	
aflibercept		5
bevacizumab	6	
denosumab (2 ref products)	2	11
eculizumab		3
enoxaparin sodium	5	
etanercept	3	
filgrastim	4	1
human insulin (recombinant)	1	
infliximab	7	
insulin aspart	2	
insulin glargine	2	
insulin lispro	1	
natalizumab	1	
omalizumab	1	
pegfilgrastim	6	1
ranibizumab	2	
rituximab	4	1
somatropin	1	
teriparatide	1	
tocilizumab	1	2
trastuzumab	6	
ustekinumab	5	2
Total	69	25

* Health Canada website, accessed March 20, 2025

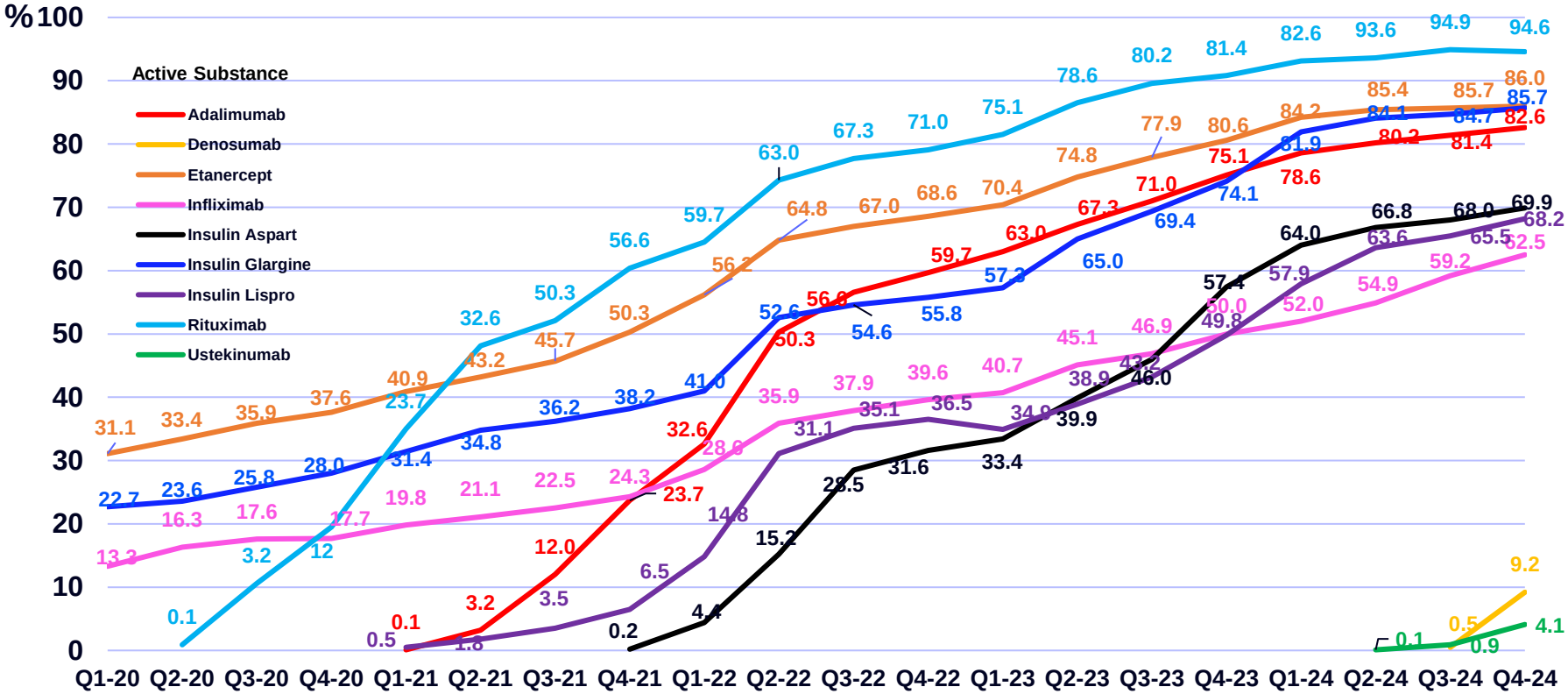
BIOSIMILARS MARKET DRUGSTORE AND HOSPITAL DOLLARS



Source: IQVIA Drugstore & Hospital Dollars

BIOSIMILARS FOR CHRONIC CONDITIONS
SHARE OF PRESCRIPTIONS BY ACTIVE SUBSTANCE

Biosimilars Canada
The Voice of Biosimilar Medicines in Canada



PRIORITY: HEALTH CANADA REVIEW PERFORMANCE

- Impact of BRDD's inadequate resourcing is being experienced throughout the review process.
  - Submissions are being picked up late
  - Inconsistency and lack of responsiveness in communication from review
  - Biosimilars Canada members do not have confidence that their submissions will be approved within performance targets
- More education needed to ensure Health Canada understands how the off-patent industry is different for the
  - e.g., IP regime and the importance of same-day issuance of NOC to prevent unjust originator monopoly extensions

PRIORITY: RELABELLED BIOLOGICS

- These products are a second name for an existing originator biologic drug
- No objective verifiable reasons why companies would seek approval of a second name for their originator biologic, other than to:
  - Entrench dominant positions in the private market
  - Maintains current international pricing for originator biologics
- The Competition Bureau is monitoring developments closely and raised public concerns about potential for anti-competitive conduct with respect to these products in a preliminary investigation
- Allowing the approval and marketing of such products represents poor health policy

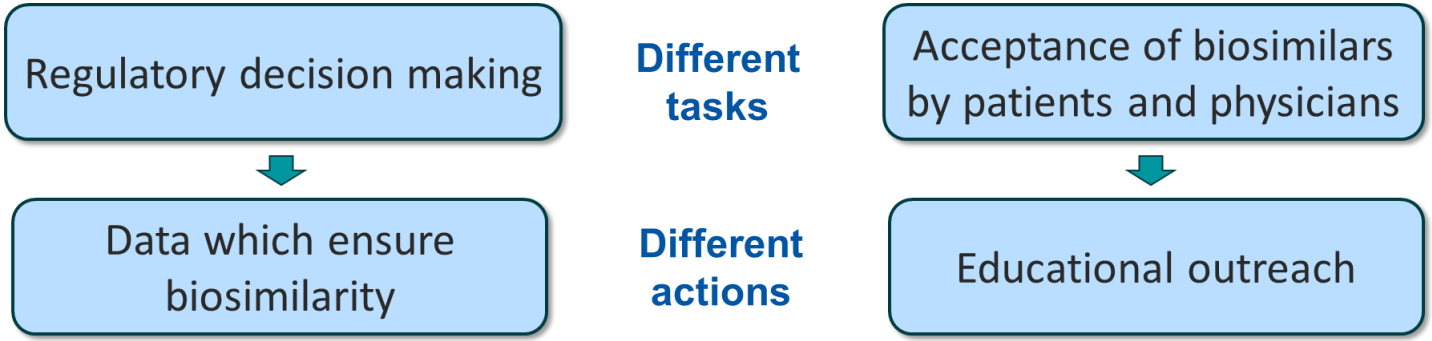
PRIORITY: STREAMLINED GLOBAL DEVELOPMENT

- Streamlining global biosimilar development is the next step in the evolution of the biosimilar regulatory pathway
- There is currently a lack of biosimilar development programs for many originator biologic drugs – biosimilars cannot be taken for granted
- This is primarily due to the high cost of comparative efficacy studies
- There is a growing international regulatory science consensus that comparative efficacy studies are usually unnecessary for biosimilars
- While Health Canada has approved some biosimilars without requiring comparative efficacy studies, this approach has only been applied to non-complex products to date

PRIORITY: STREAMLINED GLOBAL DEVELOPMENT, CONT'D

Regulatory decision making and acceptance of biosimilars require different information

- Regulatory decision-making requires data to address scientific questions
- Acceptance of biosimilars require educational outreach
- Preapproval data should not be required with the sole purpose to address non-scientific concerns of external stakeholders



PRIORITY: STREAMLINED GLOBAL DEVELOPMENT, CONT'D

Studies

- Recent studies show that demonstrating clinical comparative efficacy via a comparative efficacy study or PD study was never predictive for the marketing authorization of biosimilars in the EU

Do the Outcomes of Clinical Efficacy Trials Matter in Regulatory Decision-Making for Biosimilars?
Kirsch-Stefan et al. BioDrugs 37, 855–871 (2023) | https://doi.org/10.1007/s40259-023-00631-4

A Data Driven Approach to Support Tailored Clinical Programs for Biosimilar Monoclonal Antibodies
Guillen et al. Clin Pharmacol Ther, 2023;113, 108-123 | https://doi.org/10.1002/cpt.2785

Streamlined approval of biosimilars: moving on from the confirmatory efficacy trial
Bielsky et al. Drug Discov. 2020;25, 1910-1918 | https://doi.org/10.1016/j.drudis.2020.09.006

The Path Towards a Tailored Clinical Biosimilar Development
Schiestl et al. BioDrugs 2020;34, 97–306 | https://doi.org/10.1007/s40259-020-00422-1

- These studies support the claim that comparable efficacy can be ensured by comparative analytical (physicochemical and functional) and clinical PK data alone

PRIORITY: STREAMLINED GLOBAL DEVELOPMENT, CONT'D

IPRP Workshop

- The Biosimilars Working Group of the International Pharmaceutical Regulators Program (IPRP) hosted a major virtual workshop on "Reevaluating the Need for Comparative Clinical Efficacy Studies in biosimilar development" in September 2023

- Workshop Report Conclusions[1]
  - "Both regulators and industry experts […] broadly agreed that CES [Comparative Efficacy Studies] are not sensitive enough to detect anything but very large analytical differences between proposed biosimilars and RPs, [...].

  - Therefore, CES are not likely to be additionally informative with respect to the small differences typically observed in analytical comparisons, particularly if comparative PK show similar profiles between a proposed biosimilar and its RP."

1. IPRP Final Workshop Summary Report: Increasing the Efficiency of Biosimilar Development Programs — Reevaluating the Need for Comparative Clinical Efficacy Studies, May 6, 2024

EMERGING ISSUES

- Tariffs and trade barriers
- National pharmacare

QUESTIONS?