Biosimilars: Opportunities and Challenges for Health Care Professionals and Patients

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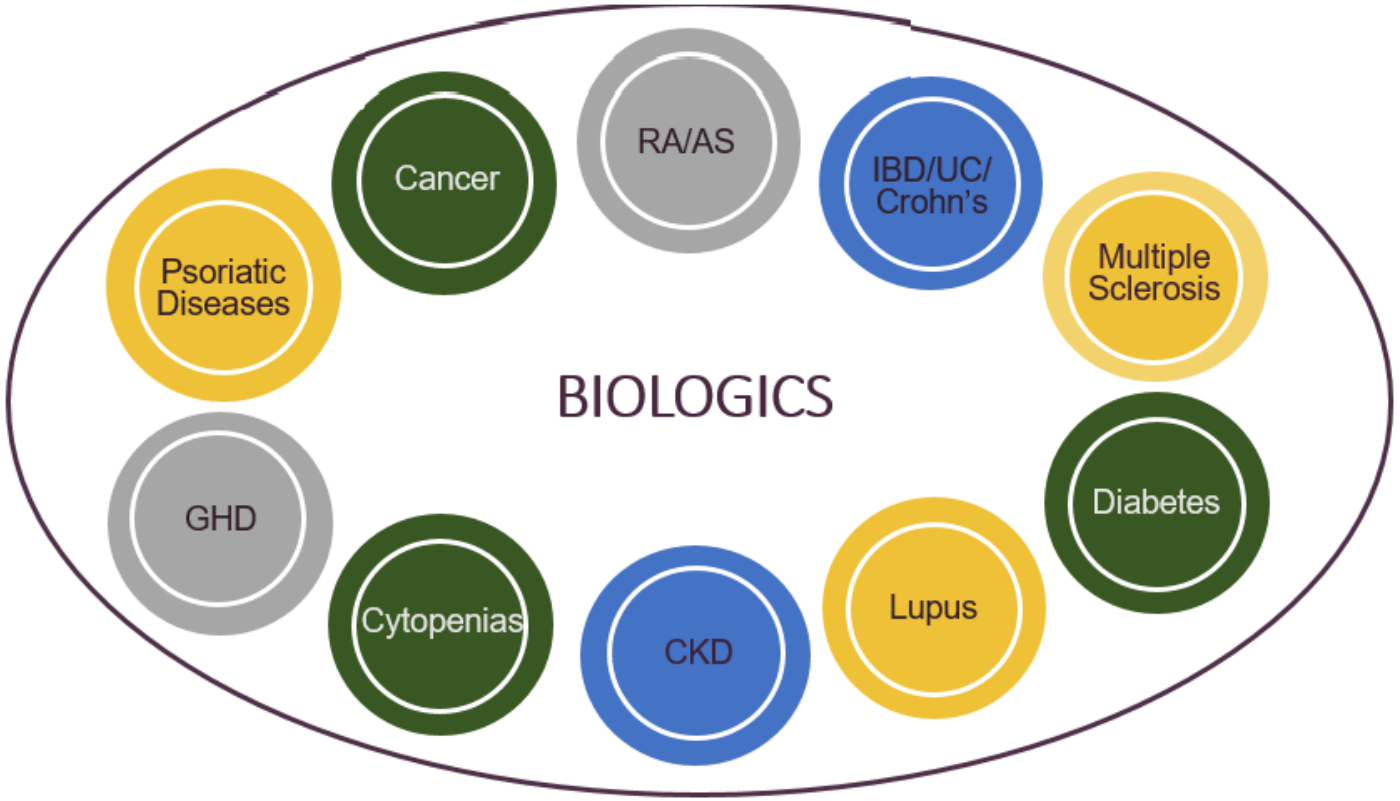
Learning Objectives

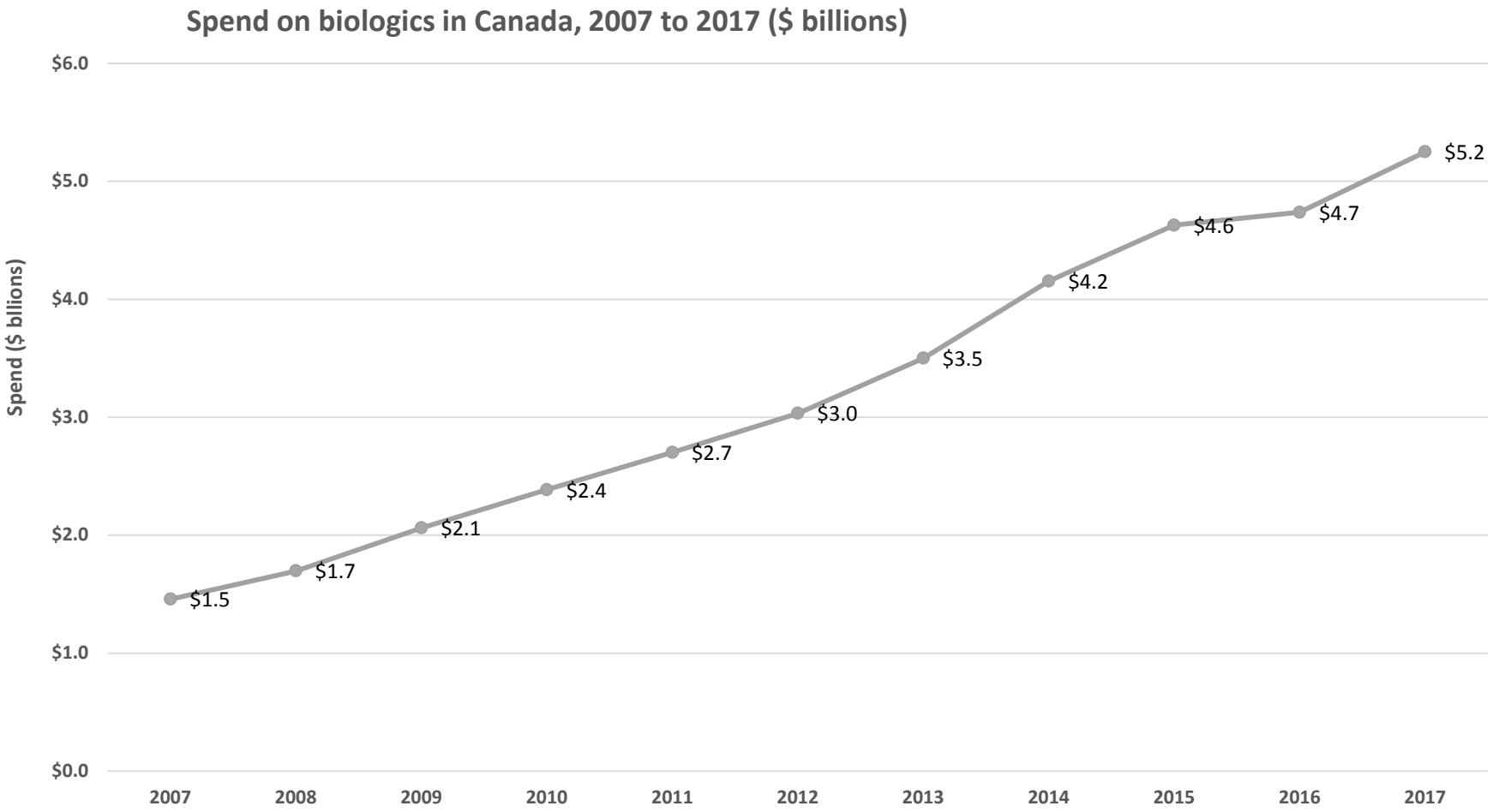
- Discuss the potential clinician and patient-specific issues relating to the implementation of biosimilars
- Review the potential impact of biosimilars on the health care system

Biologics have changed the treatment for many serious conditions



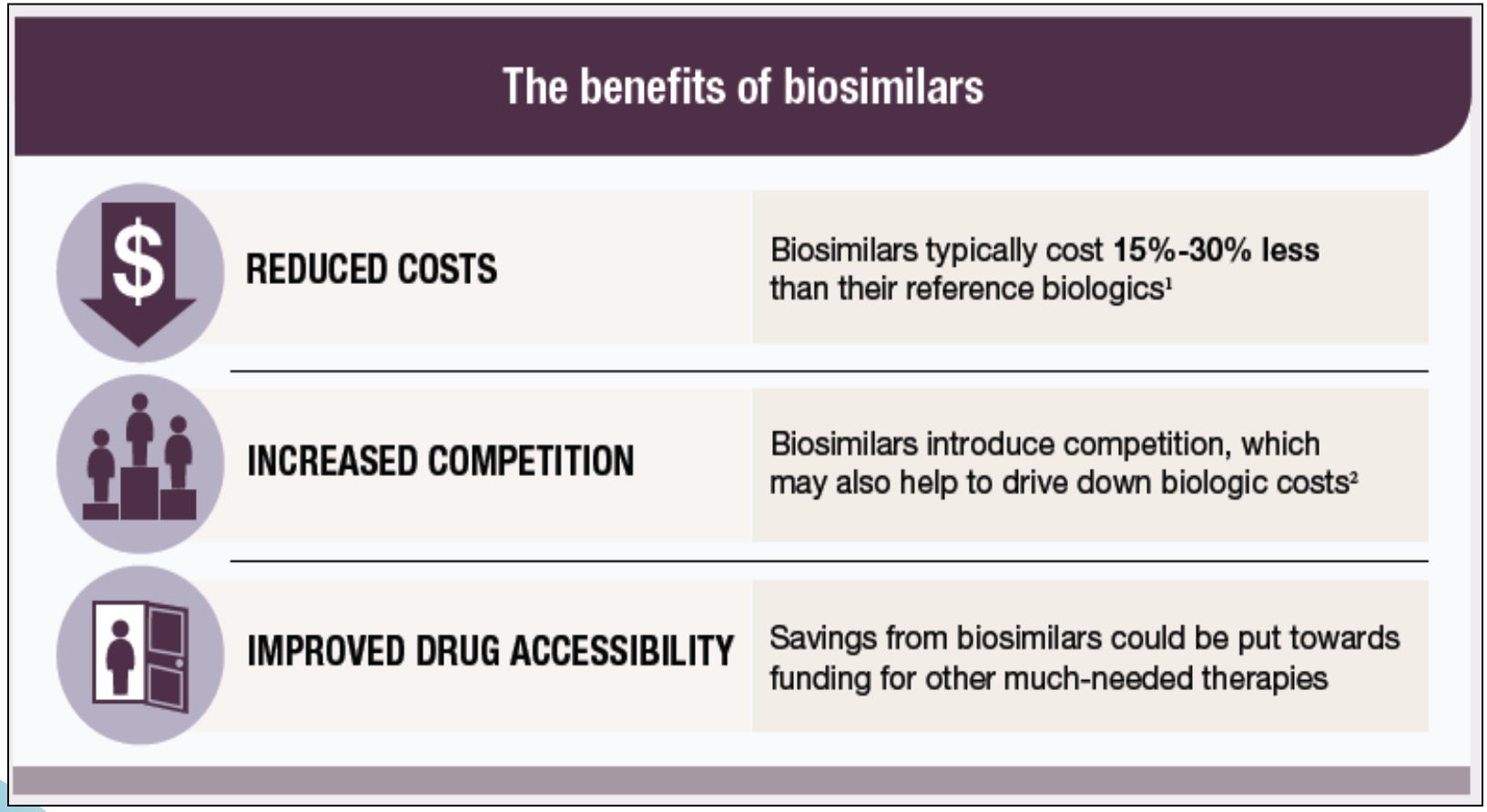
RA = rheumatoid arthritis; AS = ankylosing spondylitis; IBD = inflammatory bowel disease; UC = ulcerative colitis; CKD = chronic kidney disease. GHD = Growth hormone deficiency

Biologic Drug Spending in Canada is Rising at an Unsustainable Rate



· IMS Canada Data MAT June 2017

Promise of Biosimilars



1. Simoens S. Biosimilar medicines and cost-effectiveness. *Clinicoecon Outcomes Res.* 2011;3:29-36. 2. Buffery D. Competition from biosimilars an incentive for innovation. *Am Health Drug Benefits.* 2010;3(1):27-28

Clinician biosimilar issues

1. Pharmacovigilance
2. Naming
3. Interchangeability/Switching
4. Education

Pharmacovigilance

Pharmacovigilance

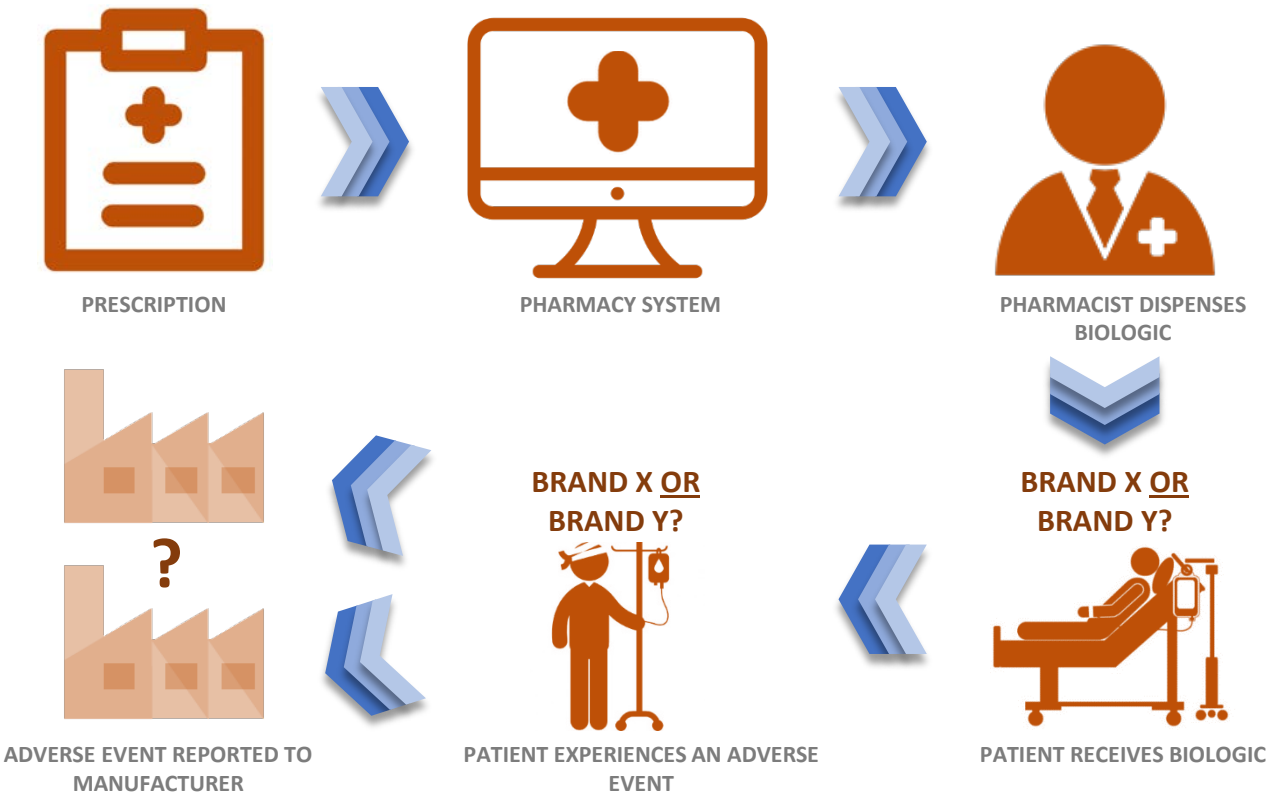
- Defined by the World Health Organization as:
  - “the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.”
- Aims of pharmacovigilance are to:
  - Enhance patient care and safety in relation to the use of medicines
  - Support public health programs by providing reliable, balanced information for the effective assessment of risk-benefit profile of medicines

http://www.who.int/medicines/areas/quality_safety/safety_efficacy/pharmvigi/en. Accessed March 13, 2017.

Practical issues…..

- Adjuvant breast cancer patient on TAC chemotherapy regimen.
- Receives biosimilar filgrastim (Grastofil) and experiences acute respiratory distress syndrome.
  - Who should/will report this adverse reaction?
  - Will this default to pharmacy?
  - Is there a potential this will not get documented?

Traceability



Reporting of Adverse Events

- Reporting of adverse events will be critical to maintaining safety and gauging effectiveness of biosimilar drugs
- Unusual adverse events (i.e. those not expected from clinical experience with the drug in question) should be reported immediately
- MedEffect™ Canada, Health Canada's reporting service for adverse reactions, allows for:
  - Reporting online
  - Reporting by telephone
  - Reporting by mail or fax
  - Information available at http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php

Improve reporting of Adverse Events

- Mandatory reporting of serious adverse drug reactions and medical device incidents by hospitals new from Health Canada
- Operational challenges and opportunities related to introducing biosimilars into the medication-use process

Naming

The issue with naming and biosimilars

- Accurate information about an adverse event
- Mechanisms to collect details of the medicine
- If batch of a medicine is implicated in an adverse event then retrieval of the batch number is important

https://www.tga.gov.au/consultation/consultation-nomenclature-biological-medicines

Nomenclature Differences

Table 1 Nomenclature differs between agencies

EMA:	FDA:
Biosimilarity is decided by EMA, interchangeability is decided by individual member states ▶ Remicade: Infliximab ▶ Remsima: Infliximab ▶ Enbrel: Etanercept ▶ Benepali: Etanercept ▶ Humira: Adalimumab ▶ Solymbic: Adalimumab Prescription by brand to distinguish actual product given to patients and allow pharmacovigilance	Interchangeability requires additional information with regard to biosimilarity: Suffix strategy to identify ▶ Remicade: Infliximab ▶ Inflectra: Infliximab dyyb ▶ Enbrel: Etanercept ▶ Erelzi: Etanercept szzs ▶ Humira: Adalimumab ▶ Amjevita: Adalimumab atto

Arguments for a suffix

- Necessity of a suffix in addition to the International Nonproprietary **Name** (**INN**) for purposes of pharmacovigilance and avoiding patient and prescriber confusion

J Clin Oncol 36:1260-1265, 2018

Arguments against a suffix

- The EU has approved the greatest number of biosimilar medicines worldwide and has acquired considerable experience around their use and safety.
- Over the last 10 years, the EU monitoring system for safety concerns has not identified any difference in the nature, severity or frequency of adverse effects between biosimilars and their reference medicine.

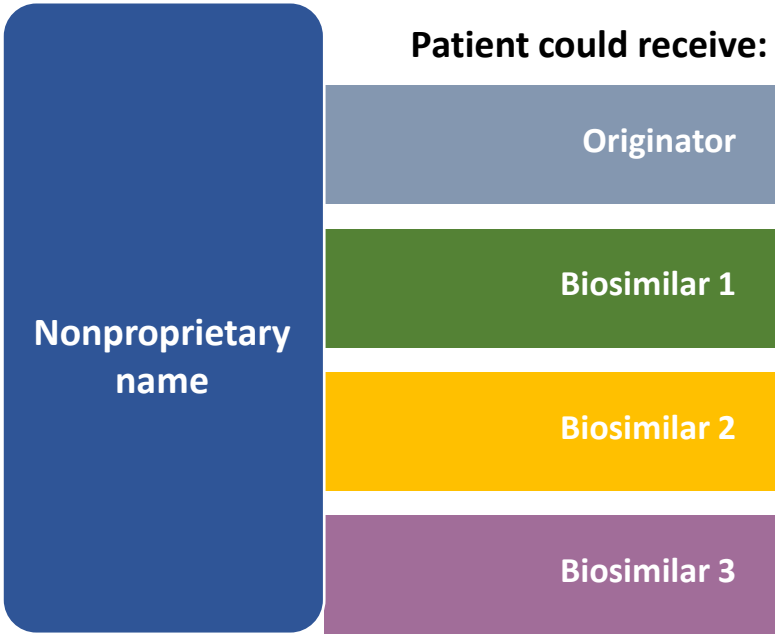
[1] Biosimilar Medicines Clinical Use: An Experience Based-EU Perspective

[2] EMA – European Commission: Biosimilars in the EU – Information guide for healthcare professionals, 2017 (link)

[3] A Clinician´s Guide to Biosimilars in Oncology: Understanding the Science of Extrapolation and

Multiple Biosimilars

- If the same nonproprietary name was assigned to all biosimilars of a reference product and a physician prescribes by the nonproprietary name:



WHO INN Working Doc. 14.342. 2014

Interchangeability/Switching

Interchangeability/Switching

- **Interchangeability**: the ability for a patient to be changed from one drug to another equivalent by a pharmacist, without the intervention of the doctor who wrote the prescription.
  - In Canada, the determination of interchangeability will be made by the province and territory.
- **Switching** - refers to a one-time change from a reference biologic drug to a biosimilar.

Interchangeability

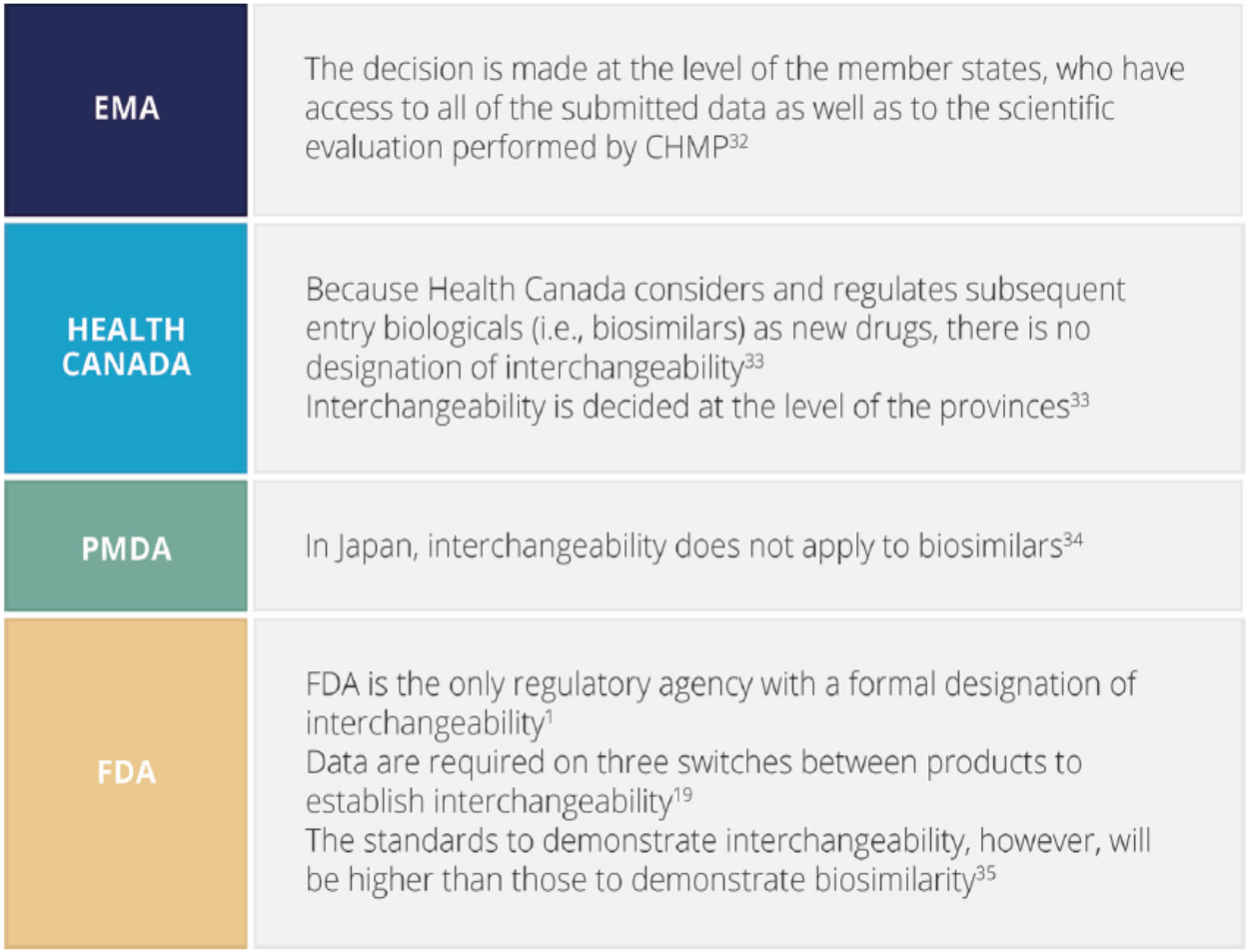


Figure 2 Interchangeability designation – heterogeneity of regulatory guidelines.

Interchangeability/Switching

- Private insurers will sometimes promote substitution with lower cost treatment options

Who should decide??

Education

Education need

- Given the novelty of biosimilar development and its reduced emphasis on clinical testing, there is greater need for education among providers regarding biosimilar products and their appropriate use

Education goals

- Education that is focused on
  - clarifying the difference between biosimilars and generic drugs
  - defining interchangeability, switching, and substitution
  - explaining naming and labeling issues
  - and emphasizing the need for postmarket safety surveillance

CARE™ Biosimilars

The CARE™ Hospital Pharmacist Faculty recently developed an **accredited** **Primer on Biosimilars**.

CARE™ Primer on Biosimilars

The Primer on Biosimilars

- Scientific Review of Biologics
- Regulatory Pathway of Biosimilars
- Overview of Recent Clinical Data
- Implications/Discussion within the Canadian Health Care System

Why is this primer needed?

- There are gaps in knowledge
- With multiple specialist groups sending pharmacists requests, need to land on common, clear Rx details.
- There is no current standard nomenclature

Thank-you

Questions?