International Policies on the Appropriate Use of Biosimilar Drugs

CADTH

cadth.ca/international-policies-appropriate-use-biosimilar-drugs-0

Key Messages

- Several countries encourage the use of biosimilars in treatment-naive patients and encourage physician-led switching to a biosimilar for those already receiving treatment with a reference biologic.
- Various countries have established different pricing, procurement, and pharmacy policies for biosimilars.
- Incentives to encourage health care providers to prescribe biosimilars have been established in some countries.
- Initiatives to increase the awareness and promote the use and access of biosimilars have been implemented in many countries in various formats, at both national and organizational levels.
- No pre- or post-market policies specific to oncology biosimilars were identified.

Introduction

Biologics are large, complex drug molecules that come from the metabolism of living organisms or their cells. Biosimilars are based on a reference biologic and are highly similar but not exact copies. Biosimilars enter the market once the pre-existing biologic's patent has expired. They are considered cost-saving alternatives to high-cost biologics for the treatment of various medical conditions. For a health care system to have successful uptake of biosimilars, many factors need to be considered, such as the number and timing of entrants into the market, patient and health care providers' understanding and acceptance of biosimilars versus biologics, the cost of biosimilars, pricing policies, payer coverage and utilization policies, and policies regarding interchangeability and substitution. To help inform Canadian policy development, CADTH explored existing international post-market policies pertaining to these factors in the Environmental Scan *International Policies on the Appropriate Use of Biosimilar Drugs*.

What CADTH looked at:

- post-market policies, programs, or other strategies that have been established internationally to guide the adoption of biosimilars and to promote their appropriate and cost-effective use
- whether biosimilars used for the treatment of cancer (e.g., bevacizumab, trastuzumab, rituximab) were associated with different pre- and post-market policies internationally compared with other biosimilars.

Where CADTH looked for information:

- in published and grey literature, and through Internet searches
- in countries limited to the US, Australia, New Zealand, Finland, France, Germany, the Netherlands, Norway, and the UK.

Table 1: Policies Related to Interchangeability, Switching, and Substitution

Established Interchangeability, Switching, and Substitution Policies	Country That Established the Policy or Initiative
Automatic substitution (replacing one drug with another at the pharmacy level without consulting the prescribers) allowed for biosimilars **Note:** Some conditions may apply (e.g., automatic substitution may be prohibited by the physician)	Australia ("a-flag" designated biosimilars only),[a] France (treatment-naive patients only), Germany ("bioidentical" biosimilars only),[b] and US ("interchangeable" designated biosimilars only)[c]
Authorities recommend prescribing biosimilars for treatment-naive patients	Australia, France, Germany, the Netherlands, and Norway
(Physician-led) switching is encouraged for patients already treated with a reference biologic	Australia, Finland, France, Germany, and Norway

[a] "A-flag" biosimilars are interchangeable with the reference biologic. Biosimilars for etanercept (Brenzys), infliximab (Inflectra), and adalimumab (Amgevita and Bioepis) have received "a-flag" designation, and can be automatically substituted.

[b] Germany publishes a list of biosimilars known as "bioidenticals" that can be substituted at the pharmacy. "Bioidenticals" refer to only those biosimilars to a reference biologic that are manufactured by the same manufacturer, under the same manufacturing process, but sold under different trade names.

[c] As of September 2018, no biosimilars have been approved by the FDA as interchangeable.

Table 2: Summary of Supply-Side Policies (Policies Implemented by Payers, and Policies Related to Pricing and Procurement)

Type of Policy	Established Supply-Side Policy	Country That Established the Policy or Initiative
Pricing policy	Manufacturers are free to set the price	UK (subject to rules)[a] and US
	Price of the biosimilar cannot be more than the reference drug	Germany and Norway
	Direct price controls (e.g., mandatory discounts)	Australia, Finland, France, and Norway (stepped price discount over time and increase in number of competitors)
Procurement policy	Tendering at hospital, regional, and national levels	France, Germany, the Netherlands, Norway, and the UK
Prohibit or limit discounts offered to individual retail pharmacies	Prohibit or limit discounts offered to individual pharmacies	France (restriction on level of discount offered), Germany, and Norway
	Price markup adjustments	The Netherlands and the UK
	Clawback arrangements (take a portion of profits from the pharmacy)	Germany, the Netherlands, and the UK
Pharmacy policies	Regressive markup (offer larger percentage markups on cheaper drugs) to encourage dispensing of lower-cost drugs	France and Norway

[a] Pharmaceutical Price Regulation Scheme rules set price ceilings based on negotiations and manufacturer profit levels.

Table 3: Summary of Prescribing Incentives

Established Prescribing Incentives	Country That Established the Policy or Initiative
Monetary incentive for prescribing "best value" medicine	UK and US
Gain-sharing (splitting the cost savings from prescribing lower-cost drugs between the payer and prescriber) agreement and pharmaceutical budget limit for clinics	Germany (penalties if budget limit exceeded) and the UK
Prescribing quotas	France and Germany
Mandatory prescribing of tender-winning drugs or cheaper options	Finland and Norway

Table 4: Summary of Education Initiatives

Established Education Initiatives	Country That Established the Policy or Initiative
Initiatives established to promote the use of biosimilars and improve the understanding of biosimilars by patients and health care providers	Australia, pan-Europe,[a] France, Germany, the Netherlands, Norway, the UK, and the US

[a] European Medicines Agency.

ABOUT CADTH

CADTH is an independent, not-for-profit organization responsible for providing Canada's health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs and medical devices in our health care system.

CADTH receives funding from Canada's federal, provincial, and territorial governments, with the exception of Quebec.

September 2019

CADTH Evidence Driven.

cadth.ca