Biosimilars.

Comparison between Canada, US and Europe.

Urszula Wojtyra

As more biosimilars continue to be approved across the world, it is helpful to compare the applicable regimes across major jurisdictions. We have collaborated with Brian Coggio of Fish & Richardson, and Mary Foord-Weston and Camilla Balleny of Carpmaels & Ransford to prepare the chart below comparing relevant considerations for biosimilars in Canada, the US, and Europe, including regulatory pathways, data protection and patent linkage.

	Canada	US	EU
Regulatory approval pathway for biosimilar	Same formal pathway under *Food and Drug Regulations* as for innovator biologic drugs, but see: Guidance, e.g. must establish similarity to reference product.	Distinct pathway - "Biologics Price Competition and Innovation Act (BPCIA)" Must establish "biosimilarity" and/or "interchangeability" to reference product.	Biosimilars of medicinal products authorised via the Centralised Procedure will have automatic access to the Centralised Procedure. Comparability studies with the reference biologic will test quality, safety and efficacy.
Reference product	Innovator biologic approved by Health Canada; use of non-Canadian sourced version as a proxy in comparative studies may be permitted.	Innovator biologic approved by FDA. Use of non-U.S. sourced version as proxy may be permitted provided there are comparative bridging studies.	Innovator biologic authorised in the European Economic Area (EEA). Use of a non-EEA authorised version of the reference product may be possible but this needs to be authorised by a regulatory authority with similar scientific and regulatory standards as EMA.
Extrapolation of indications possible for biosimilar?	Yes	Yes	Yes

Created: November 2019; * updated December 2019; ** updated September 2020

	Canada	US	EU
Interchangeability	No declaration of equivalence by Health Canada (unlike for most generic drugs). Designation of a drug as interchangeable is in purview of provinces/territories.	FDA can designate biosimilar as "interchangeable" (additional proof required). *See* FDA Guidance on Interchangeability (May 2019).	These decisions are outside the remit of the EMA; individual member states' national competent authorities will make these decisions. Individual states will have access to the scientific evaluation performed by the Committee for Medicinal Products for Human Use (CHMP).
Biosimilar average approval time	2019/2020, approval of biologics, including biosimilars: average of 13 months, median of 11.5 months.**	Average time is 15.5 months.	Approximately 12 months from application at the EMA.
Transparency of biosimilar filings	Submissions under review – includes sponsor name, INN and submission class of 'biosimilar'.	Until approval, no information is available.	Monthly list of medicines under evaluation – for biosimilars this only includes the INN, the therapeutic area and the total number of applications for that biosimilar in each given month.
Biosimilar naming	All biosimilars share same INN as the reference product plus a unique brand name. Both unique brand name + INN should be used throughout medication use, see: Policy.	New draft guidance (March 2019). Different standards for biosimilars and interchangeable biosimilars. With some exceptions, biologic reference products and biosimilars have a four lowercase letter suffix added to the INN.	All biosimilars share same INN as the reference product plus a unique proprietary name.

	Canada	US	EU
Patented medicine price regulation	Both innovator and biosimilar are subject to jurisdiction of Patented Medicine Prices Review Board if a "patentee".	No	No
Data protection for innovator biologic	Six years of data exclusivity, parallel eight years of marketing exclusivity (8.5 years with pediatric extension).**	Four years of data exclusivity, parallel 12 years of marketing exclusivity (12.5 years with pediatric extension).*	Eight years of data exclusivity, parallel ten year period of marketing exclusivity. The latter may be extended to max. 11 years if, during the first eight years of the marketing authorization (MA), the MA holder obtains an authorisation for one or more new indications (+ 1 year).
Pediatric exclusivity for innovator biologic	Additional 6 months of marketing exclusivity under data protection only.	Adds 6 months to all exclusivities.	6 months extension of Supplementary Protection Certificate (SPC) where a paediatric investigation plan (PIP) is carried out and results are included in the product information OR additional two years of market exclusivity for completion of the PIP where the innovator product is an orphan medicinal product (see below).
Orphan drug exclusivity for innovator biologic	None.	Possible. Seven year orphan drug exclusivity does not extend 12-year data exclusivity.	Possible. Parallel to data protection above, a ten year period of market exclusivity for orphan medicines, during which time the EMA and member states may not accept another MA application for the same therapeutic indication in respect of a similar medicinal product.

	Canada	US	EU
Patent linkage	Same as for generic drugs: *PMNOC Regulations*, like *Hatch-Waxman Act* litigation (see comparison chart here). Patents listed on Patent Register.	BPCIA controls patent litigation procedure. No resemblance to *Hatch-Waxman* procedure.	None.
Supplementary protection for innovator biologic	Certificate of supplementary protection (CSP) for up to two years may be available. Patent term adjustment due to Patent Office delays will be available under USMCA amendments.	Patent term extension (PTE) of up to two years past the expiration of the 12-year data exclusivity. Also, patent term adjustment (PTA) available to patents due to Patent and Trademark Office delay.	A Supplementary Protection Certificate (SPC) may be available to increase patent term up to a maximum of five years. An additional 6 months may be available for those products which have been submitted according to a PIP.
Number of biosimilar approvals/reference products	25 biosimilars approved for 12 innovator reference products (Health Canada does not maintain a list, but see table here).**	28 biosimilars approved for 9 innovator reference products (list here).**	58 biosimilars approved for 17 innovator reference products (list here)[1].**

[1] Currently 58 approved for use in Europe, 2 refused, 9 withdrawn**