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Update on biosimilars in Canada - April 2021.

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To read a more recent update: Update on biosimilars in Canada – October 2021.

The following provides an overview of the many developments regarding biosimilars in Canada (approvals, pending submissions, regulatory, litigation and market access) that have taken place since our last update in August 2020.

Biosimilars approved in Canada

Since our last update in August 2020, Health Canada approved 11 biosimilars of 5 innovator products. This includes approval of 2 biosimilars of 2 innovator products in 2021.

This brings the total Health Canada approvals to 36 biosimilars of 14 innovator products. The complete list is below (*italicized products* are not yet marketed); items 37 and later are added after the initial publication of this article, and the complete table is found here):

	Biosimilar	Manufacturer (month of approval)	Review time*	Medicinal ingredient	Reference biologic (sponsor)
1	OMNITROPE	Sandoz (April 2009)	748 days	somatropin	GENOTROPIN (Pfizer)
2	INFLECTRA	Hospira (January 2014)	427 days	infliximab	REMICADE (Janssen)
3	REMSIMA (subcutaneous version marketed as REMSIMA SC)	Celltrion (January 2014)	427 days	infliximab	REMICADE (Janssen)

4	BASAGLAR	Eli Lilly (August 2015)	356 days	insulin glargine	LANTUS (Sanofi-Aventis)
5	GRASTOFIL **	Apotex (December 2015)	1039 days	filgrastim	NEUPOGEN (Amgen)
6	BRENZYS	Samsung Bioepis (May 2016)	358 days	etanercept	ENBREL (Immunex)
7	ERELZI	Sandoz (April 2017)	353 days	etanercept	ENBREL (Immunex)
8	ADMELOG	Sanofi-aventis (November 2017)	351 days	insulin lispro	HUMALOG (Eli Lilly)
9	RENFLEXIS	Samsung Bioepis (December 2017)	793 days	infliximab	REMICADE (Janssen)
10	HADLIMA, HADLIMA PUSHTOUCH	Samsung Bioepis (May 2018)	432 days	adalimumab	HUMIRA (AbbVie)
11	LAPELGA	Apotex (April 2018)	349 days	pegfilgrastim	NEULASTA (Amgen)
12	MVASI	Amgen (December 2017)	358 days	bevacizumab	AVASTIN (Hoffmann La Roche)
13	FULPHILA	Mylan (December 2018)	754 days	pegfilgrastim	NEULASTA (Amgen)
14	TRUXIMA	Celltrion (July 2018)	335 days	rituximab	RITUXAN (Hoffmann La Roche)
15	OGIVRI	BGP Pharma (March 2018)	356 days	trastuzumab	HERCEPTIN (Hoffmann La Roche)
16	ZIRABEV	Pfizer (June 2019)	336 days	bevacizumab	AVASTIN (Hoffmann La Roche)
17	TRAZIMERA	Pfizer (November 2018)	348 days	trastuzumab	HERCEPTIN (Hoffmann La Roche)
18	HERZUMA	Celltrion (September 2018)	324 days	trastuzumab	HERCEPTIN (Hoffmann La Roche)

19	OSNUVO	Avir Pharma (January 2020)	637 days	teriparatide	FORTEO (Eli Lilly)
20	KANJINTI	Amgen (February 2020)	920 days	trastuzumab	HERCEPTIN (Hoffmann La Roche)
21	AVSOLA	Amgen (March 2020)	351 days	infliximab	REMICADE (Janssen)
22	NIVESTYM	Pfizer (April 2020)	345 days	filgrastim	NEUPOGEN (Amgen)
23	ZIEXTENZO	Sandoz (April 2020)	336 days	pegfilgrastim	NEULASTA (Amgen)
24	RIXIMYO	Sandoz (April 2020)	795 days	rituximab	RITUXAN (Hoffmann La Roche)
25	RUXIENCE	Pfizer (May 2020)	344 days	rituximab	RITUXAN (Hoffmann La Roche)
26	NOROMBY, NOROMBY HP	Juno (October 2020)	349 days	enoxaparin sodium	LOVENOX, LOVENOX HP (Sanofi)
27	TRURAPI	Sanofi (October 2020)	351 days	insulin aspart	NOVORAPID (Novo Nordisk)
28	NYVEPRIA	Pfizer (October 2020)	352 days	pegfilgrastim	NEULASTA (Amgen)
29	IDACIO	Fresenius Kabi (October 2020)	346 days	adalimumab	HUMIRA (Abbvie)
30	AMGEVITA	Amgen (November 2020)	350 days	adalimumab	HUMIRA (Abbvie)
31	HYRIMOZ	Sandoz (November 2020)	348 days	adalimumab	HUMIRA (Abbvie)
32	INCLUNOX, INCLUNOX HP	Sandoz (November 2020)	345 days	enoxaparin sodium	LOVENOX, LOVENOX HP (Sanofi)
33	HULIO	BGP Pharma (November 2020)	348 days	adalimumab	HUMIRA (Abbvie)

34	REDESCA, REDESCA HP	Shenzhen Techdow (December 2020)	444 days	enoxaparin sodium	LOVENOX, LOVENOX HP (Sanofi)
35	*ABRILADA*	*Pfizer (January 2021)*	*349 days*	*adalimumab*	*HUMIRA (Abbvie)*
36	RIABNI	Amgen (March 2021)	346 days	rituximab	RITUXAN (Hoffmann La Roche)
37	*BAMBEVI*	*Apotex (September 2021)*	*363 days*	*bevacizumab*	*AVASTIN (Hoffmann La Roche)*
38	*NYPOZI*	*Tanvex Biopharma (October 2021)*	*995 days*	*filgrastim*	*NEUPOGEN (Amgen)*
39	*KIRSTY*	*BGP Pharma (October 2021)*	*n/a*	*insulin aspart*	*NOVORAPID (Novo Nordisk)*

** Calculated based on the IP hold date (May 21, 2015) in Apotex's statement of claim in Court File No. T-934-16.

***Health Canada counts ZIRABEV as two approvals, based on two NOCs approved from two separate NDSs, the latter in January 2021.

Biosimilar submissions under review

Health Canada provides a monthly update of new drug submissions under review (SUR). Since October 2018, the SUR has identified the sponsor, the filing date, and the submission class of the submission, including whether it is a biosimilar. The most recent SUR (as of April 23, 2021) identifies the following biosimilar submissions under review, which includes submissions on IP hold, with the number of submissions listed in brackets:

- Adalimumab (2)
- Bevacizumab (5)
- Etanercept (1)
- Filgrastim (1)
- Infliximab (1)
- Insulin aspart (1)
- Pegfilgrastim (1)
- Trastuzumab (1)

There are also 3 new drug submissions pending for trastuzumab, which are likely biosimilars, but are not specifically identified as such as they were filed prior to October 2018.

Biosimilar Litigation

Filgrastim and pegfilgrastim:

- In November 2020, the Federal Court of Appeal upheld the decision invalidating Amgen's patent relating to the filgrastim drug **NEUPOGEN** in an action relating to Pfizer's biosimilar **NIVESTYM** (as we reported here). Amgen has sought leave to appeal to the Supreme Court. Pfizer's action for section 8 damages remains pending.
- Amgen has three pending pegfilgrastim biosimilar actions under the amended *PMNOC Regulations* against Pfizer (**NYVEPRIA**), Purdue Pharma (**PELMEG**), and Sandoz (**ZIEXTENZO**). The trial in the action against Purdue Pharma remains scheduled for October 2021. The other two actions have been adjourned pending Amgen's appeal in the NIVESTYM proceeding, above.

Infliximab:

- In the patent infringement action between Janssen and Hospira relating to the biosimilar **INFLECTRA**, as reported here , the Federal Court of Appeal remitted issues of anticipation and obviousness for reconsideration to the trial judge. On January 12, 2021, the Federal Court issued its decision on the reconsideration, finding again that the patent is valid (see our article here). Hospira has appealed. A decision is pending in the remedies phase of the action.

Adalimumab:

- Fresenius Kabi markets **IDACIO**, a biosimilar of **HUMIRA**. In 2019, Samsung Bioepis brought an action for a declaration that its biosimilar **HADLIMA** would not infringe Fresenius Kabi's patent, and that the patent was invalid. Samsung Bioepis had received its NOC for **HADLIMA** in 2015, and began marketing in February 2021. In March 2021, Fresenius Kabi brought an infringement action against Samsung Bioepis regarding the same patent. It is believed that this is the first biosimilar vs. biosimilar patent litigation in Canada.
- In April 2021, AbbVie (sponsor of reference biologic **HUMIRA**) commenced actions under the *Patented Medicines (Notice of Compliance) Regulations* against JAMP Pharma regarding its biosimilar **SIMLANDI**. JAMP Pharma then started separate actions against AbbVie seeking declarations of non-infringement and invalidity regarding the same patents. All other patent litigation between AbbVie and other biosimilar manufacturers has been discontinued.

Regulatory

Health Canada has posted a *Regulatory roadmap for biologic (Schedule D) drugs in Canada*, a compilation of information about the regulation of biologic drugs for human use in Canada.

Market Access

As reported in our previous updates, in Ontario, the reimbursement criteria for biosimilars for infliximab, etanercept, filgrastim and rituximab are less restrictive for most indications as compared to the reference biologic. This is explicitly stated in the *Biosimilar Policy and the Reimbursement of Biologic Originators through The Exceptional Access Program Reimbursement* (at page 5 of Exceptional Access Program Reimbursement Criteria for Frequently Requested Drugs). This policy was similarly implemented for recently funded adalimumab biosimilars (Notice and FAQ) and the insulin lispro biosimilar (Notice and FAQ). Notably, Ontario does not require treatment-experienced patients to switch. However, patients who are treatment-naïve will only be funded for the biosimilar for its Health Canada approved indications.

In 2019, British Columbia PharmaCare instituted the Biosimilars Initiative to switch patients from certain reference biologics to biosimilars for certain indications. Most PharmaCare patients have been switched to biosimilars of etanercept, infliximab, insulin glargine and rituximab. Most recently, the initiative requires switching to biosimilars of adalimumab and etanercept (for an additional indication not previously included in the Initiative) by October 6, 2021.

Pursuant to Alberta's Biosimilars Initiative, patients were, and continued to be, switched from the reference biologic to a biosimilar for certain indications (most recently, for an additional indication for etanercept by May 1, 2021.)

New Brunswick has also now launched a Biosimilars Initiative. Between April 21 and November 30, 2021, patients who use six different biologic reference molecules (adalimumab, etanercept, infliximab, insulin glargine, insulin lispro, and rituximab) for various indications must switch to a biosimilar to continue their coverage.

Should you have any questions, please do not hesitate to contact a member of the Life Sciences Regulatory & Compliance group.

The preceding is intended as a timely update on Canadian intellectual property and technology law. The content is informational only and does not constitute legal or professional advice. To obtain such advice, please communicate with our offices directly.

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