BIOSIMILARS INITIATIVE

PRESCRIBER GUIDE

RITUXIMAB

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BC PHARMACARE BIOSIMILARS INITIATIVE

PRESCRIBER GUIDE: RITUXIMAB

In This Guide

Across Canada, biologic drugs are a major contributor to healthcare costs increasing at an unsustainable rate. In 2016, Canada spent $241 million on Rituxan® alone—making it one of the top 10 highest biologic expenditures in the country. With new drugs frequently entering the market (including new biologics and innovative therapies), the cost pressures for Canada's drug plans will only continue to increase.

One solution to this challenge is already available; biosimilar versions of originator biologic drugs offer significant cost savings. In B.C., Truxima™, Riximyo™and Ruxience™ (rituximab biosimilars) offer a 30-37% cost reduction compared to Rituxan (rituximab originator), for which expenditures in B.C. were $19.8 million in 2019.

Despite these price differences, biosimilars have not yet captured much market share in Canada. Biosimilar uptake has been limited by many factors, including misconceptions about the safety and efficacy of biosimilars, and reluctance to change the status quo. With an ever-growing body of evidence and the support of many stakeholders, PharmaCare introduced the Biosimilars Initiative in May 2019. The Initiative enables the expansion of treatment options and the improvement of patient access to safe care.

The Biosimilars Initiative changes the coverage for specific biologic drugs. Patients and their prescribers have a period of six months to discuss switching treatment from an originator brand to a biosimilar brand. Coverage and Special Authority (SA) approval are provided for both originator and biosimilar brands during the switch period. Patients unable to switch or who have an adverse response to the biosimilar(s) can seek exceptional SA coverage for the originator.

Phases One and Two of the Initiative switched three biologics that were among the largest drug expenditures in B.C.: infliximab, etanercept, and insulin glargine. Biosimilar uptake in these phases was very positive, with PharmaNet data seeing 73% and 78% of total patients switched successfully in Phase One and Phase Two respectively. Those that are unaccounted for may have switched to a different biologic not included in the Initiative or may have ceased treatment entirely for various reasons.

PharmaCare's strategy to ensure a successful switch includes:

- Involving various practitioners in patient identification, education and support;
- Providing time to identify affected patients and guide them through the switch process;
- Ensuring patient supports are in place for continuous care;
- Having options for those unable to switch or experiencing challenges with switching;
- Identifying areas of concern and providing information for both patients and practitioners;
- Providing responsive contacts for healthcare practitioners;
- Facilitating changes that optimize patient care in affected therapeutic areas (e.g., adding fecal calprotectin testing for GI patients, reducing SA criteria, etc.); and
- Monitoring drug utilization, patient outcomes, and stakeholder feedback.

The role of the prescriber in the switch process is paramount. A prescriber sets the tone of the switch discussion, serves as the primary and most trusted information source, facilitates continuity of care, and empowers the patient to expect and realize the best outcomes.

Health Canada encourages patients to discuss any questions about switching from one biologic to another with their healthcare professional. PharmaCare has created this guide to provide information to support your discussions with affected patients.

(National statistics referenced in the section above are found in the Patented Medicine Prices Review Board *Meds Entry Watch 2017* report.)

What is changing?

As in the first two phases of the Biosimilars Initiative, PharmaCare continues to change the coverage of certain biologic drugs, including rituximab.

Coverage for the originator biologic drug (Rituxan) will be discontinued for PharmaCare-covered patients receiving treatment for indications including those listed below.

RITUXIMAB SWITCH PERIOD: August 20, 2020 to February 18, 2021			
Drug	**Originator**	**Biosimilars***	**Indications Include**
rituximab	Rituxan®	Truxima™ Riximyo™** Ruxience™	rheumatoid arthritis relapsing-remitting multiple sclerosis microscopic polyangiitis granulomatosis with polyangiitis

*Additional biosimilar options for rituximab may be approved and listed at www.gov.bc.ca/biosimilars/prescribers

**At this time, Riximyo is not indicated for microscopic polyangiitis or granulomatosis with polyangiitis

For patients with existing SA approval for rituximab to maintain their coverage, prescribers must write a new prescription, indicating the switch to a biosimilar option. The patient's existing SA remains in effect until the next renewal date (if applicable). New SA requests and renewals for rituximab will be granted for approved biosimilar brands only.

When do these changes take effect?

Patients with PharmaCare coverage using Rituxan and who wish to maintain PharmaCare coverage must switch to a rituximab biosimilar before February 19, 2021.

All brands of rituximab, both originator and biosimilar, will be covered during the rituximab switch period (August 20, 2020 to February 18, 2021) to provide time for patients to discuss the switch with their prescriber and get a new prescription. Rituxan will no longer be covered for affected patients as of February 19, 2021.

If you are unable to discuss the switch with a specific patient before the end of the switch period, please submit an SA request explaining the need for an extension.

Who will be affected?

Your patients will be affected by the biosimilars switch beginning August 20, 2020 if they:

- use Rituxan; and
- receive PharmaCare coverage (i.e., have existing SA for rituximab).

How many biosimilar switches will there be?

In Phase One of the Biosimilars Initiative, the focus was on switching all Lantus patients, patients using Remicade for rheumatological or dermatological indications, and those using Enbrel for rheumatological indications.

Phase Two of the Biosimilars Initiative focused on switching patients using Remicade for GI indications.

The current switch period (August 20, 2020–February 18, 2021) aims to switch over those taking Rituxan.

It is likely that further switches to biosimilars will occur for other indications and drugs. All switches will be planned in consultation with the affected prescribers and stakeholders.

Why is coverage changing?

To enable expansion of the PharmaCare formulary and B.C. health services, PharmaCare develops evidence-informed strategies like the Biosimilars Initiative to better optimize how our public resources are used. Biologic drugs represent a huge portion of the annual PharmaCare budget, and biosimilars represent a correspondingly large, but unrealized, opportunity to find value that can be applied to new treatments and services.

In B.C., the biologic drugs successfully switched by PharmaCare in 2019 (Lantus®, Enbrel®, and Remicade®) represented some of the province's largest drug expenditures. In 2018, PharmaCare spent $125 million on just these three originator drugs.

Despite being listed preferentially for new starts, the biosimilar versions of these drugs had captured only a fraction of the market before the Biosimilars Initiative. In 2018, Basaglar™ represented only 1.7% of insulin glargine PharmaCare expenditures, Brenzys® and Erelzi® only 6.8%, and Inflectra® and Renflexis® only 5.9%. As of June 1, 2020, 73% of Phase One patients and 78% of Phase Two patients have switched to the biosimilar version of their medication.

Building on the success of previous phases, PharmaCare has identified rituximab as another valuable cost-saving opportunity for the Initiative. Data shows that B.C. spent over $19.8 million on originator rituximab (Rituxan) in 2019. Now that three biosimilar options have been approved for use in Canada, the moment presents itself to effect the same opportunity to improve access to medications for patients. In B.C., rituximab biosimilar is priced at approximately 30-37% less than the originator brand.

PharmaCare is always reviewing new drugs, new indications, and existing coverage and criteria; the provincial formulary must evolve and adapt to the current market, clinical requirements, best practices, and the needs of B.C. residents and practitioners. As such, more phases may be added to the Initiative as biologic patents expire and other biosimilars are approved for safe and effective use in Canada.

What evidence supports biosimilar adoption and switching?

The safety, efficacy, immunogenicity, and therapeutic similarity of biosimilars is supported by a large body of clinical evidence, extensive post-market pharmacovigilance, as well as the results of switch programs in other jurisdictions.

Additional reading and study summaries are available online at **www.gov.bc.ca/biosimilars/prescribers.**

The Ministry will be carefully monitoring drug utilization, patient outcomes, and the response from patients and healthcare practitioners during and after biosimilar switching in B.C.

How can I identify which of my patients will be affected?

To help you identify which of your patients you may need to speak with about biosimilar switching, we can send you a list of PharmaCare-covered patients who have filled a prescription for Rituxan, written by you, in the past 9 months.

Please complete and submit the enclosed *HLTH 5842 Rituximab Patient List Request* form. Within two weeks, we will send you a list of the names of patients who may be affected by biosimilar switching.

Will patients need new Special Authority approval?

Patients with existing SA for rituximab do not require a new SA for the biosimilar version of their medication. The existing SA remains in effect until the next scheduled renewal date (if applicable).

If a patient's SA expires during the switch period, it will be renewed for rituximab biosimilars only.

Note that patients are expected to trial a biosimilar. If a trial has been attempted and halted, the rationale for halting the trial must be well documented in the request for exceptional coverage, and be unlikely to recur or intensify if the patient resumes taking the originator.

Patients with a clinical requirement that prevents switching can have their prescriber submit a new SA request for exceptional coverage of the originator biologic. Exceptional requests will be reviewed by Special Authority on a case-by-case basis.

What do I need to do to switch patients?

To switch your patients to a biosimilar:

1. Identify an affected patient.
2. Discuss switching to a biosimilar with the patient.
3. Write your patient a new prescription, clearly indicating the discontinuation of the originator and start of the biosimilar brand chosen.
4. Initiate enrolment in the patient support program for the biosimilar (if applicable).
5. Submit the Biosimilar Patient Support Fee with your MSP billing.
6. For any patients unable to switch, submit a new SA request for exceptional coverage of Rituxan.

What is the Biosimilars Patient Support Fee?

The Biosimilar Patient Support Fee is a $50 fee billable to MSP in addition to other services billed on the same date of service, using the Teleplan claims system. They are being offered in recognition of the additional effort involved in contacting patients and supporting their switch to a biosimilar. This fee can be claimed once per affected patient during the transition period, regardless of whether that patient switches to a biosimilar.

- Biosimilar Patient Support Fee: Rituxan to Biosimilar rituximab
  Fee code: 97013
  Effective: August 20, 2020 – February 18, 2021
  Limited to: Rheumatologists, neurologists, dermatologists, respirologists, hematologists and internal medicine specialists

Will the infusion protocol stay the same for switched patients?

Infusion options for Rituxan and rituximab biosimilars remain the same. It may be recommended, however, to restart a switched patient on the slower initial infusion protocol for their first treatment with a biosimilar brand of rituximab (if the patient has been receiving infusions at a rate faster than mentioned for usual initial doses).

What about patients who cannot switch to a biosimilar?

For patients with a clinical requirement that prevents switching, you can request exceptional coverage of Rituxan by submitting a new SA request using the applicable form and clearly identifying why the patient is unable to switch.

Exceptional requests will be reviewed by SA on a case-by-case basis. After an initial review by SA pharmacists, any requests requiring additional input will be submitted to the Drug Benefit and Adjudication Advisory Committee for review by a panel of specialists.

Exceptional requests should be submitted as soon as possible to allow for review, follow-up inquiries, and to ensure uninterrupted coverage.

What patient support programs are available?

Biosimilar manufacturers are committed to minimizing the impact of this Initiative for both patients and prescribers, especially regarding patient support program processes and services, as well as access to infusion centres. For more information, support, and enrolment forms and assistance, contact the patient support programs below.

TRUXIMA®
The Truxima® Teva Support Solutions® – Patient Support Program provides support services, including educational materials for patients, reimbursement services, financial assistance and medical updates to prescribers.

Phone: 1 877 714-2469 | Fax: 1 833 981-2254 | Email: tss.info@truximacanada.com
Hours: Monday to Friday, 8AM to 8PM EST

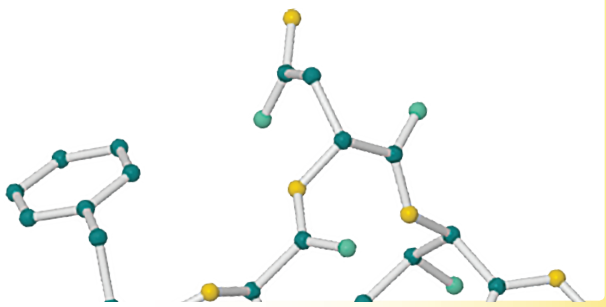
RIXIMYO®

The XPOSE® Patient Support Program by Sandoz® - an experienced full service PSP, provides support services to physicians / nurses and their patients through one point of contact; including securing coverage and providing the financial assistance patients require with their out-of-pocket expenses. The XPOSE® Patient Support Program by Sandoz® also offers infusion/education services. The Program will be working with a variety of infusions centers to provide patient accessibility.

Phone: 1 888 449-7673| Fax: 1 844 449-7673 | Email: xpose@sandozprogramsupport.ca

RUXIENCE™
Register to the PfizerFlex Patient Support Program or get more information at:

Phone: 1 855 935-3539 (FLEX) | Fax: 1 833 958-3539 (FLEX) | Email: ruxience@pfizerflex.com
Hours: Monday to Friday, 8AM to 8PM EST



Will patient access to infusion centres change?

When switching to Truxima, Riximyo or Ruxience, patients receiving their Rituxan infusions will move to an infusion centre listed below. The patient support program will coordinate this change. Infusion centres are available across the province:

TRUXIMA®

Bayshore Clinics		
City	**Address**	**Postal Code**
Abbotsford	2151 McCallum Rd, Suite 401	V2S 3N8
Burnaby	206-3825 Sunset St	V5G 1T4
Chilliwack	9181 Main St, Suite 101	V2P 4M9
Kelowna	3001 Tutt St, Suite 210	V1Y 2H4
Nanaimo	1650 Terminal Ave N, Suite 204	V9S 0A3
New Westminster	301 E Columbia St, Suite 104	V3L 3W5
North Vancouver	138 13th St E, Suite 304	V7L 4W8
Richmond	6051 Gilbert Rd, Suite 301	V7C 3V3
Surrey	13710 94A Ave, Suite 307	V3V 1N1
Vancouver	555 W 12th Ave, Suite 410	V5Z 3X7
Vernon	2306 Highway 6, Suite 225	V1T 7E3
Victoria	1900 Richmond Rd, Suite 380	V8R 4R2

Non-Bayshore Clinics		
City	**Name**	**Address**
Courtenay	PerCuro Clinical	104-1350 England Avenue
Vancouver	Mary Pack Arthritis Clinic	895 West 10 Avenue
Victoria	PerCuro Clinical	305-1120 Yates Street
Victoria	PerCuro Clinical	2349 Millstream Road

RIXIMYO®

INVIVA Clinics		
City	**Address**	**Postal Code**
Abbotsford	2031 McCallum Rd, Suite #104	V2S 3N5
Chilliwack	7491 Vedder Rd, Unit #106	V2R 6E7
Coquitlam	3000 Lougheed Highway, Unit #168	V3B 1C5
Kamloops	321 Nicola Street, Suite #401	V2C 6G6
Kelowna	305-3320 Richter Street	V1W 4V5
Nanaimo	1450 Waddington Rd, Unit #204	V9S 4V9
Penticton	437 Martin Street, Unit #115	V2A 5L1
Pitt Meadows	19070 Lougheed Highway, Suite #108B	V3Y 2M6
Richmond	6051 Gilbert Rd, Suite #317	V7C 3V3
Surrey	15966 108th Ave, Suite #106	V4N 5V6
Vancouver	943 West Broadway Ave, Suite #320	V5Z 4E1

Non-INVIVA Clinics		
City	**Name**	**Address**
Courtenay	PerCuro Clinical	104-1350 England Ave
Penticton	Penticton Infusion Clinic	577 Carmi Ave
Vancouver	Mary Pack Arthritis Centre	895 West 10th Avenue
Vancouver	Canadian Rheumatology Infusion Services	839 West Broadway
Vancouver	BioPro Biologics Pharmacy	845 West Broadway
Victoria	PerCuro Clinical	305-1120 Yates Street
Victoria	Vital Health	1825 Fort Street

RUXIENCE™

Innomar Clinics		
City	**Address**	**Postal Code**
Abbotsford	2168 McCallum Rd, Unit #2	V2S 6R6
Burnaby	7885 6th Street, Unit #208	V3N 3N4
Chilliwack	45800 Promontory Rd., Suite #203	V2R 5Z5
Courtenay	101-1350 England Avenue	V9N 8X6
Cranbrook	111 12th Ave. South	V1C 2S2
Delta	6345 120th Street, Unit #115	V4E 2A6
Kamloops	546 St. Paul Street, Suite #160	V2C 5T1
Kelowna	3001 Tutt Street, Suite #303	V1Y 2H4
Nanaimo	1450 Waddington Rd, Suite #202	V9S 4V9
North Vancouver	101-145 15th Street West	V7M 1R9
Penticton	1496 Balfour Street	V2A 4Z1
Prince George	1669 Victoria Street, Suite #306	V2L 2L5
Richmond	6091 Gilbert Rd, Suite #440	V7C 5L9
Vancouver	750 West Broadway Ave, Suite #1408	V5Z 1J4
Vernon	3210 25th. Ave., Suite #304	V1T 1P1
Victoria	1590 Cedar Hill Cross Road, Suite #330	V8P 2P5
West Vancouver	520 17th. Street, Suite #202	V7V 3S8

Non-Innomar Clinics		
City	**Name**	**Address**
Courtenay	PerCuro Clinical	104-1350 England Avenue
Penticton	Penticton Infusion Clinic	577 Carni Avenue
Vancouver	Canadian Rheumatology Infusion Services	839 West Broadway
Vancouver	Mary Pack Arthritis Clinic	895 West 10 Avenue
Victoria	PerCuro Clinical	305-1120 Yates Street
Victoria	PerCuro Clinical	2349 Millstream Road

What is the nocebo effect and how can I help prevent it?

The greatest hurdle for the successful switch to a biosimilar is the potential for the nocebo effect, where a patient's negative expectations both psychologically and physiologically affect the outcomes of and adherence to their treatment.

Patients' pre-existing beliefs, previous healthcare experiences, and mindset can have a very real effect on symptoms and their sense of wellbeing.

Many factors contribute to a patient's likelihood of experiencing the nocebo effect:

- Patient factors, such as mental health comorbidities (especially anxiety, depression, or cognitive impairment), language barriers, a history of negative interactions with the healthcare system, or the use of online media as a source of medical information (where negative responses are highly over-represented, and bias or misrepresentation go unchecked).
- Practitioner factors, such as language choices, manner, non-verbal communication, or unbalanced focus on potential adverse reactions.
- Health care setting factors, such as the physical environment, comfort, ease of access, and interactions with other staff and patients.
- Drug factors, such as an appearance or smell, administration route or routine, change in delivery device, labelling, and price.

A variety of strategies can be effective in preventing the nocebo effect:

- Empower people with information and an active role in the switch process.
- Be attentive and empathetic, so patients feel safe asking questions or expressing concerns.
- Balance the presentation of desired effects and adverse effects.
- Promote a neutral or positive outlook instead of reiterating fears.
- Acknowledge the nocebo effect itself.
- Speak face-to-face, when possible.
- Discuss a plan for follow-up, acknowledging that there are options, no matter the outcome.

In international studies, the nocebo effect was of particular note in the treatment of rheumatoid arthritis, where patient-reported outcomes were central to assessing response to a drug and fewer objective clinical measures exist.

Where can I find more resources for my patients?

A library of patient resources is available online at **www.gov.bc.ca/biosimilars**. Here they can find detailed information about:

- the Biosimilars Initiative;
- how they may be affected;
- biologic and biosimilar drugs;
- answers to frequently asked questions; and
- other resources and reading (including materials developed by patient groups).

If you require additional printed patient information sheets, please contact us at **Biosimilars.Initiative@gov.bc.ca** or **1 844 915-5005** Monday to Friday, 8:30AM-4:30PM.

How can I support patients with questions and concerns?

Patient acceptance of biosimilars is, understandably, easier to achieve among treatment-naïve patients started on a biosimilar. Treatment-experienced, stable patients using an originator biologic may require more support.

The best response to any concern your patient may have is your expertise and experience as a healthcare practitioner, as well as the provision of additional information. Patients who feel they understand the change and why it's necessary, who trust their practitioners, and who understand that there is a support plan in place are more positive and achieve better outcomes.

PharmaCare has created a brief patient information sheet for you to provide to patients to summarize the change and direct them to more detailed resources available at **www.gov.bc.ca/biosimilars** Included later in this guide is a biosimilars primer that may be useful in explaining biosimilars to your patients.

The most critical information usually required by patients is that biosimilars:

- are safe and effective;
- will work like their current medication;
- have no additional risk of adverse reactions or immunological response;
- do not require significant changes to their routines or dosing;
- are accompanied by patient support programs that will help them with benefits coordination, scheduling, access, etc.;
- are available at infusion centres near them (though it may be a different infusion centre than they currently attend); and
- are well-understood, that switching from an originator has been extensively studied, and that switch programs have been successful around the world

Other resources for you and your patients are available at **www.gov.bc.ca/biosimilars/prescribers**

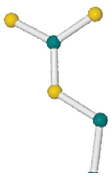
It is important to recognize this is a switch process (not a substitution policy), where patient and practitioner education, collaborative decision making, and exception options for those who need them are key. Practitioners are essential to empowering patients with information, demonstrating that there is a support system in place, and setting people up for success.

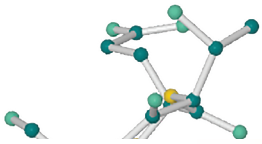
What if I have questions or need more information?

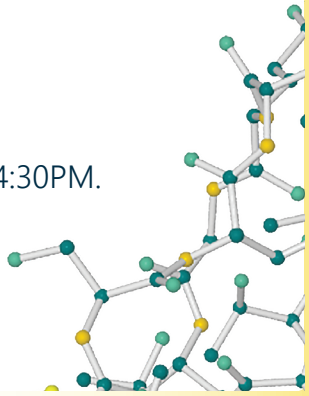
PharmaCare is committed to supporting and working with healthcare practitioners throughout the Biosimilars Initiative.

Additional information is available at **www.gov.bc.ca/biosimilars/prescribers**

For more questions and feedback, contact the PharmaCare team at **Biosimilars.Initiative@gov.bc.ca** or **1 844 915-5005** Monday to Friday, 8:30AM—4:30PM.







BIOSIMILAR BASICS

What is a biologic drug?

Most drugs (like aspirin, metformin, antibiotics, etc.) are considered synthetic drugs, where certain chemicals can be combined in a lab using a set recipe. The result is a consistent drug product composed of relatively small molecules that can be easily tested to ensure everything is identical in composition and potency across different batches and different manufacturers.

Biologic drugs were first introduced in the 1980s, as advancements allowed scientists to manipulate other organisms' cells and better identify complex compounds and feedback systems involved in human metabolism and disease processes.

Biologic drugs are produced by engineering a living cell line (like bacteria, yeast, or mammal cells, etc.) to produce a specific protein compound that is then collected and purified for human use. These protein compounds are very large and complex compared to synthetic drugs.

Biologic drugs have created new fields of research and disease treatment, providing more and better options for cancer treatment and the management of chronic diseases like rheumatoid arthritis, Crohn's disease, and diabetes.

Relative Sizes of Example Synthetic and Biologic Drug Molecules

Synthetic, $C_4H_{11}N_5$ Biologic, $C_{267}H_{404}N_{72}O_{78}S_6$ Biologic, $C_{6428}H_{9912}N_{1694}O_{1987}S_{46}$

What is a biosimilar drug?

As with synthetic drugs, when a unique biologic drug is no longer protected by patents, other manufacturers can begin to produce the protein compound under a different brand name. These new versions of a biologic drug are called biosimilars.

Biosimilars are designed to be highly similar to the biologic originator and have no difference in effect. Because biologics are so complex, both to manufacture and in structure, it is not possible to demonstrate that a biologic originator and its biosimilar are perfectly identical. (Nor is it possible to demonstrate that a batch of any biologic—originator or biosimilar—is identical to its previous batches.)

Producing biosimilars builds on the work already done for the biologic originator, and therefore requires less investment into research and development. This means the biosimilar product can be offered at a lower cost, providing patients and the healthcare system better value for the same benefit.

A PRIMER FOR PATIENT DISCUSSIONS

"Patients and health care providers can have confidence that biosimilars are effective and safe for each of their authorized indications. No differences are expected in efficacy and safety following a change in routine use between a biosimilar and its reference biologic drug in an authorized indication."

Health Canada
Fact Sheet: Biosimilars

How is a biosimilar drug proven to be as safe and effective as the originator?

Health Canada's rigorous requirements demand that a biosimilar demonstrate that there are no clinically meaningful differences in terms of physiochemical structure, quality, potency, pharmacokinetics, and immunogenicity. Clinical efficacy studies must demonstrate that the therapeutic effects of the biosimilar (both risk and benefit) are consistent.

After a drug is approved for sale, post-market analyses and studies can further demonstrate no meaningful differences in clinical efficacy between a biosimilar and the originator. These studies are common in the European Union, where biosimilars have been in use longer and have a higher adoption rate.

Are biosimilars interchangeable with their biologic originator?

As biosimilars cannot be proven to be identical to their biologic originator, they are not classified as interchangeable; that is, a pharmacist could not substitute one for the other at the pharmacy level without involvement of the prescribing physician.

Biosimilars and their originator biologics are proven to have no clinically meaningful differences in function or effect, meaning that switching from one to another is appropriate at the direction of the prescribing physician, in collaboration with the patient.

"Health Canada considers a well-controlled switch from a reference biologic drug to a biosimilar in an approved indication to be acceptable, and recommends that a decision to switch a patient being treated with a reference biologic drug to a biosimilar, or between any biologics, be made by the treating physician in consultation with the patient and take into account any policies of the relevant jurisdiction."

Health Canada's Biosimilars Workshop: Summary Report

What are the benefits of biosimilars?

Biosimilars offer major cost savings to the healthcare system, which allows for improved access to drug therapies for more people who need them. Biosimilars also contribute to a healthy and competitive drug market in Canada, supporting diversification of drug products and manufacturers, as well as driving both demand and capacity for newer, better drugs.

WHAT OFFICIALS ARE SAYING ABOUT BIOSIMILARS

"Policies and position statements on biosimilars are evolving to reflect increasing experience with and confidence in biosimilars as a treatment option."

Health Canada's Biosimilars Workshop: Summary Report

"By increasing treatment options, biosimilars can enhance competition in the market for biological products without reducing incentives to innovate."

U.S. Food and Drug Administration
Biosimilars Action Plan: Balancing Innovation and Competition

"Biosimilars have been used safely for many years. Regulators monitor the safety of medicines on the market, including biosimilars, to protect the health and safety of patients."

International Coalition of Medicines Regulatory Authorities: Biosimilars Statement

"Patients and their physicians can expect that there will be no clinically meaningful differences between taking a reference product and a biosimilar when these products are used as intended."

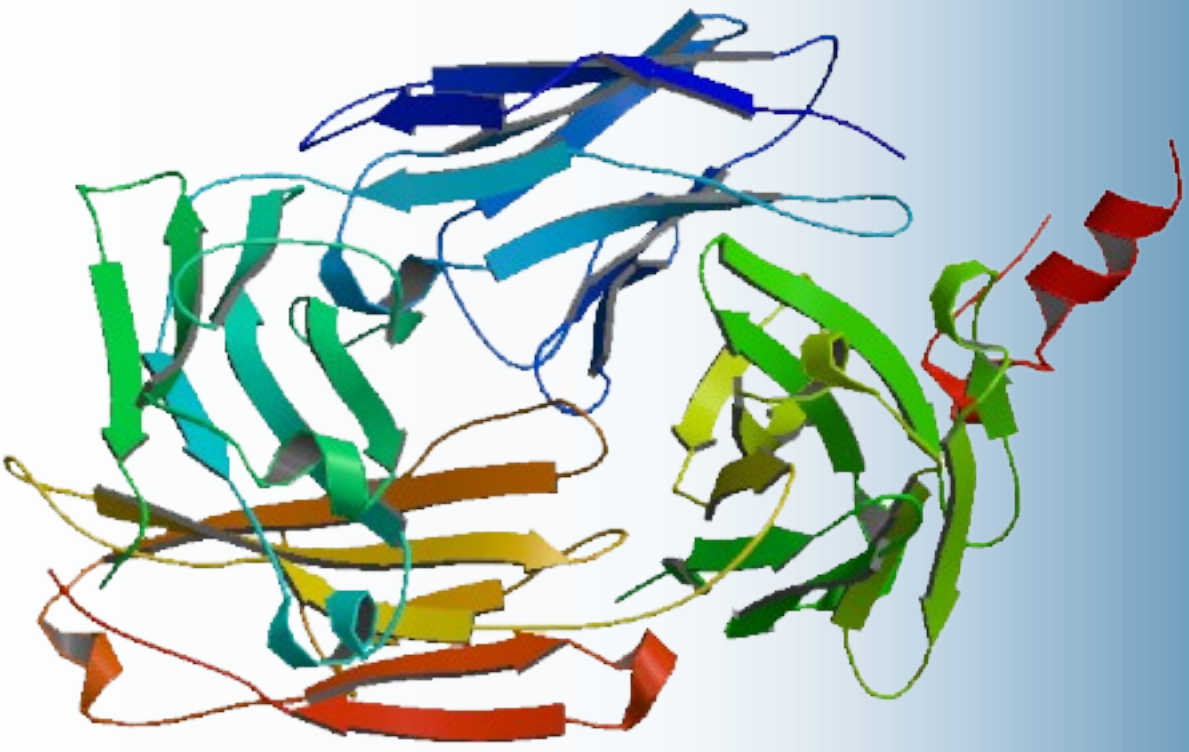
U.S. Food and Drug Administration
Prescribing Biosimilar Products

"In Europe, the availability of lower priced biosimilars has been reported to reduce the average list prices of reference products as well as prices of products within the whole therapeutic class."

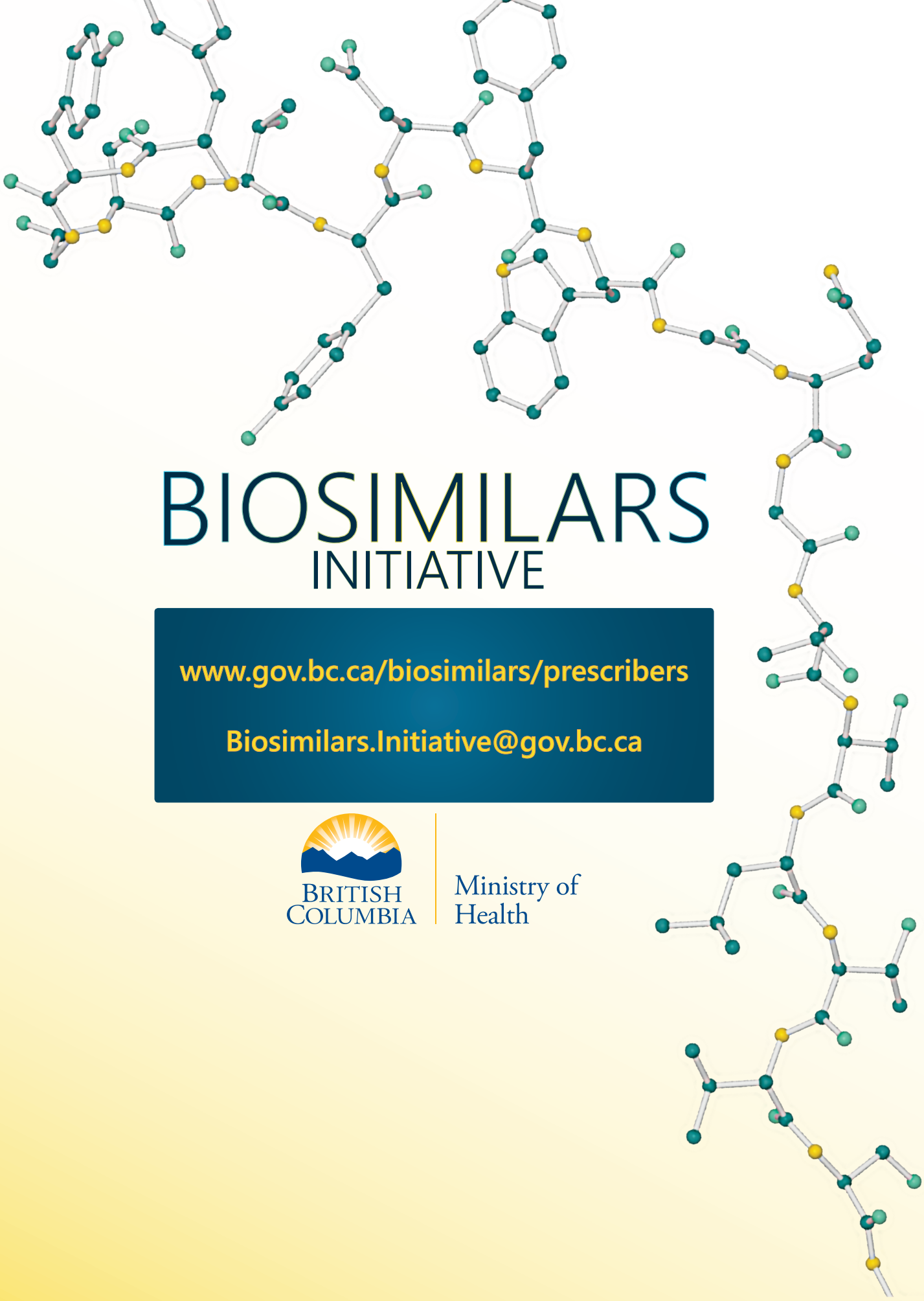
Canadian Agency for Drugs and Technology in Health
Biosimilars—Regulatory, Health Technology Assessment, Reimbursement Trends, and Market Outlook

"Over the past 10 years, the EU has approved the highest number of biosimilars worldwide, amassing considerable experience in their use and safety. The evidence acquired over 10 years of clinical experience shows that biosimilars approved through EMA can be used safely and effectively in all their approved indications as other biological medicines. Over the last 10 years, the EU monitoring system for safety concerns has not identified any relevant difference in the nature, severity or frequency of adverse effects between biosimilars and their reference medicines."

European Medicines Agency
Biosimilars in the EU: Information Guide for Healthcare Professionals



protein structure of rituximab (DrugBank.ca, 2020)



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