Global Colon Cancer Association

BIOSIMILARS TRAINING PROGRAM

Presented in partnership with World Patients Alliance





PATIENT ADVOCACY TOOLKIT: BIOSIMILARS

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PATIENT ADVOCACY TOOLKIT:
BIOSIMILARS TRAINING PROGRAM

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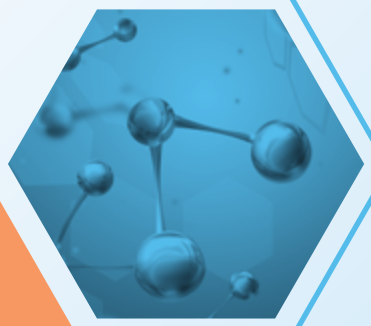
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SECTION 1:

BIOSIMILARS: KEY TERMS AND DEFINITIONS



SECTION 1:

BIOSIMILARS: KEY TERMS AND DEFINITIONS

- **A-Flagging** – Australian term for a drug which may be substituted in place of another at the pharmacy level. See: Automatic Substitution.
- **Adverse Event** – An unfavorable change in the health of a patient, either during a clinical study for a drug, or after a drug has been on the market.
- **Analytical Study** – A comparison of the structure and function of a biosimilar to its reference product to assess its similarity.
- **Automatic Substitution** – A drug which may be substituted in place of another at the pharmacy level. This is uncontroversial with generic versions of small molecule drugs, but controversial with biosimilars. This is because unlike generics, biosimilars are not identical to their reference products.
- **Batch Number** – An identifying number on a biologic medicine's packaging, showing when and where it was made.
- **Bio-Naïve Patient** – A patient who has not previously received a specific biologic medicine. Physicians are often encouraged, or required by healthcare payers or governments to start these new patients on the lowest-cost biologic medicine, which is often (but not always) a biosimilar.
- **Biologic Medicine** – A medicine made in or from living materials, in contrast to small-molecule drugs made from chemical reactions. Biologic medicines are often genetically-engineered proteins produced by living cells. These can treat many serious and chronic diseases including rheumatoid arthritis, psoriasis, and cancer.
- **Biologic Qualifier** – A pharmacovigilance tool proposed by the World Health Organization (WHO). The BQ is a four-letter random suffix that would be added to the International Nonproprietary Name (INN) shared by a biologic medicine and all biosimilars to that product, allowing each product to be clearly distinguishable for each other when tracking their safety and efficacy.
- **Biosimilar** – A copy of a biologic medicine whose patent protection has expired (its reference product). While safe and effective biologic medicines in their own right, unlike generics, biosimilars are not exact copies of their reference products. Biosimilars have an abbreviated (shortened) approval pathway to help reduce costs. Their approval process places less emphasis on clinical trials (evaluating the drug's effects in patients), and a greater emphasis on analytic trials (demonstrating similarity in structure and function to the originator/reference product).
- **Brand Name** – The name by which a medicine is marketed to the public, distinct from its scientific or non-proprietary name which describes its active ingredient. These can differ from country to country. Also known as a Trade Name.
- **Brand Substitution Not Permitted** – A physician can write this, or similar language, on a prescription and prevent a substitution they feel is medically inappropriate for that patient, including with biologic and biosimilar medicines. See also: Do Not Substitute, Dispense As Written.
- **Cell Line** – Cells of the same type and in which under certain conditions the cells proliferate indefinitely in the laboratory; these are used to manufacture a biologic medicine. Without access to the cell line, another manufacturer cannot reproduce that biological medicine.
- **Clinical Study** – A research study using human subjects to evaluate the safety and efficacy of a medicine.
- **DIN** (Drug Identification Number) – A Canada-specific identifier which describes the manufacturer; product name; active ingredient(s); strength(s) of active ingredient(s); pharmaceutical form; route of administration. Typically used in pharmacy and billing.
- **Do Not Substitute** – See Brand Substitution Not Permitted.
- **EMA** (European Medicines Agency) – The central authority responsible for approving biologic medicines, including biosimilars, in Europe.

KEY TERMS (CONTINUED)

- **FDA** – The U.S. Food and Drug Administration, the authority responsible for approving biologic medicines, including biosimilars, in the United States.
- **Forced Switching** – A controversial practice of denying coverage of the biologic medicine the physician and patient have decided on, and requiring them to switch to a different medicine. This practice is opposed by many physician societies and patient advocacy organizations.
- **Formulary** – A list of which drugs, including biologic medicines and biosimilars, will be covered by a healthcare plan, either public or private. These lists can be changed from time to time, potentially disrupting a patient's treatment if the medicine they are on is no longer covered.
- **Genetic Engineering** – Alteration of the structure of genetic material in a living organism. In a pharmaceutical context, it has been employed to create bacteria that synthesize insulin and other human proteins. These are used as biologic medicines to treat a variety of diseases.
- **Generic** – An exact copy of a small-molecule drug. These can be automatically substituted at the pharmacy level without controversy, in contrast with biosimilars, for which automatic substitution is controversial among many physicians, and banned in many countries.
- **Health Canada** – The authority responsible for approving drugs in Canada, including biologic medicines and biosimilars.
- **Immunogenicity** – An unwanted immune response to a drug in a patient. Because of their large size and complexity, biologic medicines, including biosimilars, can produce these effects.
- **Indication** – An approved use of a medicine to treat a particular disease.
- **Indication Extrapolation** – When a biosimilar is approved for an indication (to treat a particular disease) in which it has not actually been evaluated through clinical trials. With biosimilars, this is typically allowed in order to reduce time and costs associated with additional clinical trials in all the different disease states for which the biosimilar is seeking approval.
- **INN** – International Nonproprietary Name. The scientific name of a medicine. These are issued by the World Health Organization (WHO).
- **Innovator Product** – a new medicine. When this medicine's patent protection expires, if it is a small-molecule drug an exact copy called a generic can be made. If it is a large-molecule biologic drug, a highly-similar but not exact version can be made, called a biosimilar.
- **Interchangeability** – Definitions differ by country: Within the United States, this term refers to a biosimilar which has provided additional data to the U.S. FDA showing that it a patient can be switched back and forth between it and the reference product, and the same result expected without additional risks. Under U.S. state law, only interchangeable biosimilars may be automatically substituted at the pharmacy level. In Australia and Europe, the term refers to the practice of changing one medicine for another therapeutically equivalent medicine, such as a biosimilar, by the treating physician.
- **Interchangeable Biosimilar** – see Interchangeability
- **Lot Number** – see Batch Number
- **Mandated Switch** – see Forced Switching
- **Mechanism of Action (MOA)** – How a drug works; how it exerts its effects on cells or tissues. Biosimilars will use the same MOA as the originator/reference product upon which they are based. MOA is important during biosimilar approvalIf the MOA for treating two different diseases is the same or similar (see Indications), a biosimilar may be approved to treat both diseases, despite having been evaluated in only one of them. (See Indication Extraoplation).
- **Monoclonal Antibody** – A genetically-engineered protein that can bind to substances in the body in order to treat disease (see Biologic Medicine).
- **Naïve Patient** – see Bio-Naïve Patient
- **NDC** – National Drug Code. A U.S.-specific identifier describing a medicine's manufacturer, dosage, and package size. Typically used in pharmacy settings.

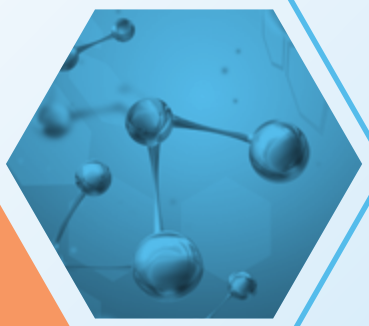
KEY TERMS (CONTINUED)

- **Non-Medical Switching** – Switching a patient from the biologic medicine the physician-prescribed biologic medicine, to a biologic medicine preferred by the health care payer; for reasons other than the patient's health. Typically this is done to reduce costs to the health system, to increase profits for a private insurer, or because of a deal with a particular manufacturer.
- **Non-Proprietary Name** – See INN.
- **Originator Product** – See Innovator Product.
- **Payer** – The entity responsible for offering health care plans and paying for health care. A payer can either be public (funded by the government through taxes) or private (funded by customers and/or employers through insurance payments). Part of the payer's coverage decisions includes determining which drugs the patient will have access to (see Formulary).
- **PBM** – Pharmacy Benefit Manager. Common in the U.S., a private, for-profit company which administers pharmaceutical benefits for a health plan. PBMs are responsible for creating and updating a health plan's formulary, the list of what drugs are covered.
- **Pharmacodynamics (PD)** – The study of what effects a drug has on the body; used in evaluating a drug's safety and efficacy prior to approval.
- **Pharmacokinetics (PK)** – The study of how the body interacts with a drug, including how a drug is absorbed, distributed, and eliminated; used in evaluating a drug's safety and efficacy prior to approval.
- **Pharmacovigilance (PV)** – Science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem. Typically handled by a national or regional health regulator such as EMA, FDA, Health Canada, PMDA, or TGA. The WHO also plays a role in PV by issuing international non-proprietary names to aid in accurate tracking of medicines (see INN).
- **Pharmacy Benefit Manager** – See PBM.
- **PMDA** – Pharmaceuticals and Medical Devices Agency; the entity responsible for ensuring the safety, efficacy and quality of pharmaceuticals and medical devices in Japan.
- **Post-Marketing Surveillance** – The practice of monitoring the safety and efficacy of a drug or biologic medicine after it has been launched onto the market.
- **Reference Product** – See Innovator Product.
- **Small-Molecule Drug** – Simpler, chemically synthesized drugs. Often taken as pills.
- **Substitution** – See Automatic Substitution.
- **TGA** – Australia's Therapeutic Goods Administration, the authority responsible for approving drugs in Australia, including biologic medicines and biosimilars.
- **Trade Name** – See Brand Name.
- **Transition** – See Non-Medical Switching.
- **WHO** – World Health Organization, the entity responsible for establishing international norms and standards for health, including assigning International Nonproprietary Names to medicines (see INN).



SECTION 2:

SEVEN LESSONS FROM PATIENT ADVOCACY EXPERTS



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SEVEN LESSONS FROM PATIENT ADVOCACY EXPERTS

The following seven lessons are adapted from the Biosimilar Training Program's panel discussion, "Lessons from the Patient Advocacy Experts" This panel featured Gail Attara, CEO of the Canada-based Gastrointestinal Society; Hussain Jafri, Executive Director of the World Patients Alliance; Zorana Maravic, CEO of Digestive Cancers Europe; and Andrew Spiegel, Executive Director of the Global Colon Cancer Association.



1. EDUCATION IS CRITICAL

Most patient advocates are regular people without special expertise in biosimilar science or policymaking. They may have great passion, but need some education in order to be effective advocates on the important biosimilar policy issues that affect patients worldwide. It's important to educate ourselves. That's why GCCA and WPA are hosting this intensive 2-day Biosimilar Training Program. The sessions presented will remain available online for repeat viewing at LearnBiosimilars.org. This toolkit also contains many resources to get you started in biosimilar policy advocacy. Many additional patient-friendly resources about are available in the Additional Resources section. We encourage you to share these resources, as well as your knowledge and training, with others in your organization and patient community.

2. WORK COLLABORATIVELY WITH OTHER PATIENT GROUPS

Work with other patient advocates and patient advocacy organizations whenever possible. This has several benefits. First, we can all learn from each other's experiences – including emerging problems in other countries or disease states. A forced-substitution policy that now only affects cancer patients can be a preview of what is coming for autoimmune patients. Second, collaboration increases the impact of patient voice in policymaking: a letter signed by multiple organizations carries more weight with a policymaker than a letter signed by a single group. An organized campaign of similar letters from multiple groups asking for the same thing is better still. Third, by presenting a united front, it makes it easier for policymakers to address patient concerns. Cooperation between multiple groups facilitates this.

3. IDENTIFY CHAMPIONS

Whenever possible, identify people within your patient community, healthcare providers, your allies in government, or other stakeholders who share your passion and your goals of patient-friendly policy. Does a particular patient have a particularly powerful story to share? Do respected healthcare leaders share your concerns? Does a prominent government official support your position? Let your members – and policymakers – know, by elevating this individual. Work with these individuals to engage on policy solutions. If they have data that supports your position, consider incorporating it into your member communications. If they are willing endorse your preferred policy solution, incorporate that into your advocacy campaigns.

SEVEN LESSONS (CONTINUED)

4. ANECDOTES & DATA: EACH HAVE THEIR PLACE

Patient testimonials can personalize an abstract or theoretical concern with a policy by citing a concrete example. Several different examples of real patients having problems can add great emotional power to policy-related communications such as letters or testimony. But they can also be easily dismissed as "anecdotal evidence". Empirical data, such as patient or physician surveys, or publicly available academic research studies supporting your policy positions, can add an intellectual rigor to your arguments. But facts and figures can come off as cold and detached from the human costs of a particular policy. Use both techniques in your efforts to educate and persuade.

5. DEVELOP SPECIFIC POLICY ASKS

Your messaging should be as simple and clear as possible – to your community, your allies, and especially to policymakers. Raise your concerns in a friendly, but firm manner. Then suggest solutions that are compatible with the policymakers' goals, but address your concerns. What do you want, ideally? Be specific. But also be realistic. Policymakers are balancing the concerns of many stakeholders, often with different concerns and conflicting goals. What would you be willing to accept realistically as a compromise position? They can't say YES if they don't understand what you want, or if it's not something that's realistically possible.

6. BUILD POSITIVE, LONG-TERM RELATIONSHIPS WITH POLICY MAKERS

An effective patient advocate is one that government (or other policy makers) will listen to and consult on policies that affect them. We achieve this by building long-term relationships built on mutual respect and constructive, positive engagement. Rather that attacking a policymaker for bad policy, respectfully point out your concerns and suggest potential solutions in a positive manner. Again, be friendly, but firm. Try to understand that they are balancing the concerns of many groups, not just yours. Be constructive and solution-focused – and be willing to compromise when it improves a policy. Express your willingness to meet and discuss future policy as it's being developed. Work to become a trusted resource to policymakers so they make less controversial, more patient-focused policies going forward- ideally, an indispensable stakeholder in these discussions.

7. ADVOCACY IS AN ONGOING PROCESS

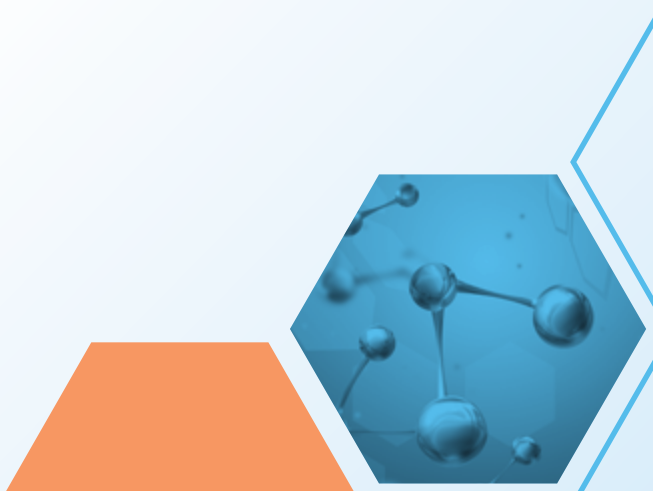
Advocacy doesn't end with issuing a position statement, sending a letter of opposition, or even declaring a policy victory. Those are the first steps in a long-term vocation. As with any area, effective advocacy in biosimilars means continual monitoring of policy developments, regular communication with allies and members, and continual engagement with policy makers. No one patient advocate, no one organization, can do this alone. Consider membership in an international patient advocacy coalition such as Global Colon Cancer Association, World Patients Alliance, or the Alliance for Safe Biologic Medicines, and be sure to join coalitions in your own country. Through their members, these organizations each gather information about emerging biosimilar policy concerns around the world, and share with their members globally through newsletters, emails, and webinars. They also develop educational materials which you can adapt for your own disease area, country, or region.

Patient testimonials can personalize an abstract or theoretical concern with a policy by citing a concrete example.



SECTION 3:

FACT SHEETS



SECTION 3:

BIOSIMILARS: THE BASICS

BIOLOGIC MEDICINES are used to treat millions of patients with serious illnesses such as Crohn's Disease, rheumatoid arthritis, psoriasis, and ulcerative colitis, and cancer. The patents for many biologic therapies are expiring over the coming years, and copies of these, called BIOSIMILARS will enter the marketplace, bringing patients new therapeutic options at reduced cost.



WHAT IS A BIOLOGIC MEDICINE?

Most people are familiar with small molecule medicines, like aspirin. These are produced via a series of chemical reactions, and their exact structure is simple and easily identified. In contrast, biologic medicines are very large, and very complex. Biologic medicines are made in living cells, grown in a laboratory.

WHAT IS A BIOSIMILAR MEDICINE?

When patents for medicines expire, other companies are free to make copies of them. For small molecule medicines, these copies are known as generics. Because it is easy to determine their exact structure and how they are made, IDENTICAL copies can be made by following a series of chemical reactions. These can be substituted at the pharmacy level without controversy.

For biologics, it's not so simple. To begin with, because of their size and complexity, it is not possible to exactly determine the structure. Second, the living cells and manufacturing processes used to make the biologic are unique and proprietary to each manufacturer, as well as being far more complex than the synthesis of chemical drugs. Thus, a different company cannot make the biologic in exactly the same way. Copies of biologics are HIGHLY SIMILAR BUT NOT IDENTICAL to the original biologic, hence the name: BIOSIMILARS.

KEY ISSUE:

AUTOMATIC SUBSTITUTION

Most physicians do not wish to switch a patient to a new medicine when they are doing well on their current therapy. Since unlike a generic, a biosimilar is not identical to the product it's trying to copy (often called the ORIGINATOR, INNOVATOR, or the REFERENCE product), most advanced countries to not permit a biosimilar to be substituted at the pharmacy level without physician involvement. This practice, called AUTOMATIC SUBSTITUTION, is banned in most of Western Europe, but common in Eastern Europe. Australia and some Canadian provinces however, have begun to permit it, often over the objections of many in the physician and patient communities.

In the U.S., the automatic substitution of biosimilars is only permitted if the U.S. FDA has approved the biosimilar as interchangeable. This means is has provided additional data to demonstrate that it a patient who is switched repeatedly between the reference product and the biosimilar can expect the same clinical result, without additional risks, relative to a patient who wasn't switched.

THE BASICS (CONTINUED)

KEY ISSUE:

WHO CONTROLS TREATMENT DECISIONS?

GCCA believes that treatment decisions, including whether to prescribe or switch to a biosimilar should remain with the patient and their healthcare professionals, rather than a third-party payer such as an insurer or government agency. In the case of a biosimilar substitution, the prescribing physican and patient must be informed when a biosimilar is substituted by a pharmacist so that a patient's response to treatment can be accurately monitored.

KEY ISSUE:

BIOLOGIC NAMING

Currently, all biosimilars share an International Nonproprietary Name (INN) with their reference product, and all other biosimilars to that product. This can make telling these medicines apart very confusing. A medicine can be identified by its BRAND NAME, but these differ from country to country, and are not always included when a physician reports that a patient is having a problem with a medicine (an ADVERSE EVENT report).

In 2020, the World Health Organization (WHO), which issues nonproprietary names, identified this as a problem: "this could potentially lead to problems with identifying products and pharmacovigilance unless careful attention is paid to the issue. This situation has caused concerns, for example, prescription mix-ups, unintentional switching, and questions on traceability."

The WHO has proposed a solution to this problem: adding a distinct four-letter suffix to each product which shares an INN. Distinguishing suffixes are in use in several countries including the U.S. and Japan. These suffixes ensure that patient records are kept accurate and any adverse events are attributed to the correct product. They reduce the chance of accidental or inappropriate substitutions, and they increase manufacturer accountability for their products. GCCA supports the WHO's attempt to extend these patient protections worldwide.

A biosimilar is not identical to the product it's trying to copy. Most advanced countries do not permit a biosimilar to be substituted at the pharmacy level without physician involvement.



SECTION 3:

BIOSIMILARS: NON-MEDICAL SWITCHING AND SUBSTITUTION

BIOLOGIC MEDICINES are used to treat millions of patients with serious illnesses such as Crohn's Disease, rheumatoid arthritis, psoriasis, and ulcerative colitis, and cancer. The patents for many biologic therapies are expiring over the coming years, and copies of these, called BIOSIMILARS will enter the marketplace, bringing patients new therapeutic options at reduced cost.

Biosimilars are copies of biologic medicines. While safe and effective, unlike generics they are not identical to their REFERENCE PRODUCT – the biologic medicine they are trying to copy.



WHAT IS NON-MEDICAL SWITCHING?

Non-medical switching is when the medicine the physician and patient have decided on is switched by a third party, for reasons other than the patient's health and safety. Typically this is done to cut costs under a public payer like a government health plan, or to increase profits for a private payer like an insurance company or pharmacy benefits manager.

CONCERNS WITH NON-MEDICAL SWITCHING

Physicians are cautious about unnecessary switching when a patient is well-treated on their current biologic – whether originator or a biosimilar. Moreover, treatment plans are not one-size-fits-all. Many times a physician and patient try several similar medicines until they find one that works best for a particular patient. Non-medical switching is done without considering the patient's previous medical history, nor the reasons the physician and patient settled on the particular course of treatment. Unnecessary switching, especially between multiple products, can lessen the control a patient has over his or her condition.

WHAT IS AUTOMATIC SUBSTITUTION?

This is the substitution of the originator biologic with the biosimilar at the pharmacy level – without the involvement of the prescribing physician. While this practice is uncontroversial with generics, but highly controversial with biosimilars due to the inherent differences they have with their reference product.

Different countries and regions handle biosimilar substitution differently:

WESTERN EUROPE

In most of Western Europe, automatic substitution of biosimilars is rare – and banned in many jurisdictions, including UK, Germany, Ireland, Spain, and Sweden. While new patients are typically encouraged to try the lowest-cost medicine, physicians and patients are free to choose between many products, including the originator and several biosimilars – all of which are reimbursed by the payer. Savings to the health system are achieved through competition between these many products. This system reduces health costs, ensures patient control of their treatment decisions and promotes, a robust and sustainable biosimilar market with multiple suppliers in a given product class.

NON-MEDICAL SWITCHING AND SUBSTITUTION (CONTINUED)

There are some exceptions: Norway has a national tender system, in which a preferred product is chosen by the government. Still, physicians retain the prescription choice among all available products. Only Denmark, following a transparent process, will solely reimburse the winning product (except in rare, substantiated circumstances.) No European country has stopped reimbursement of an originator product through an arbitrary government fiat.

EASTERN EUROPE & RUSSIA

Throughout Eastern Europe, however, financial resources are often more limited. As a result, automatic substitution is commonplace. It is permitted in Estonia, Latvia, Poland and Russia. Typically patients who do not want to switch may the pay the cost difference between the government-chosen biosimilar and the physician-prescribed medicine – OUT of their own pocket.

CANADA

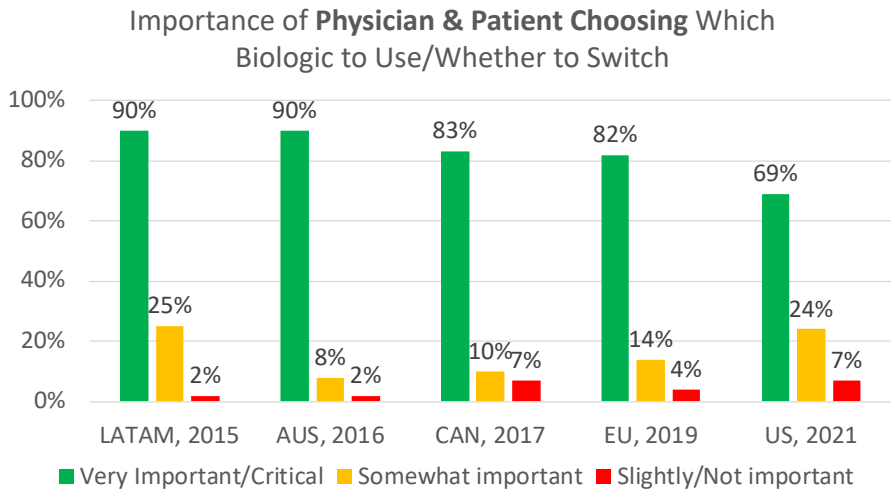
Health Canada recommends that "a decision to switch a patient being treated with a reference biologic drug to a biosimilar should be made by the treating physician in consultation with the patient". Nevertheless, substitution decisions are left to the provincial level. Several provinces, including British Columbia, Alberta, New Brunswick, and Quebec, have adopted even stricter limits on physician/patient choice: FORCED SWITCHING policies that apply to all patients. These policies were enacted over the strenuous objections of many in the physician and patient community – particularly in the case of stable patients being forced to switch. The strictness of these policies vary by province. British Columbia offers few exceptions to its policies. Quebec, by contrast, allows patients more flexibility and more exceptions in its appeal process.

AUSTRALIA

In 2015, Australia broke with the world's advanced nations by becoming the first to permit automatic substitution of biosimilars. In Australia this is referred to as "a-flagging". This was not a medical decision made by its health regulator, the Therapeutic Goods Administration (TGA), but an economic decision made by its Pharmaceutical Benefits Advisory Council (PBAC). Physician opposition to this policy was significant and sustained, but automatic substitution has now become commonplace. Physicians routinely prevent biosimilar substitutions during prescribing – if an alternative is available. But payer policies have resulted in several

Around the world, we see strong agreement: it is very important/ CRITICAL that the physician, with the patient, decides which treatment option to use – rather than a third party.

Source: www.safebiologics.org



NON-MEDICAL SWITCHING AND SUBSTITUTION (CONTINUED)

previously-approved products no longer being available. Many approved biosimilars do not launch. As choices become increasingly limited. Forced switching has now begun – including on previously-stable stage IV cancer patients.

UNITED STATES

In the U.S., only "INTERCHANGEABLE BIOSIMILARS" can be automatically substituted at the pharmacy level. Note that this is a U.S.-specific term. It means that the biosimilar's manufacturer has provided data to the U.S. Food and Drug Administration (FDA) showing that multiple switches (back and forth) between the biosimilar and the reference/originator product will provide the same result for the patient without additional risks, relative to a patient who was not switched. This higher standard is intended to allow the U.S. to enjoy the health and savings benefits of biosimilars, while also addressing physician and patient concerns about automatic substitution – and avoiding Australia-like situation where physicians routinely prevent biosimilar substitutions.

The U.S. also requires the prescribing physician to prevent a substitution, and for the physician to be informed in the event of a substitution. However, private insurers in the U.S. routinely require physicians to switch patients to their preferred product, and may frequently change which product is reimbursed by the patient's pharmacy benefits.

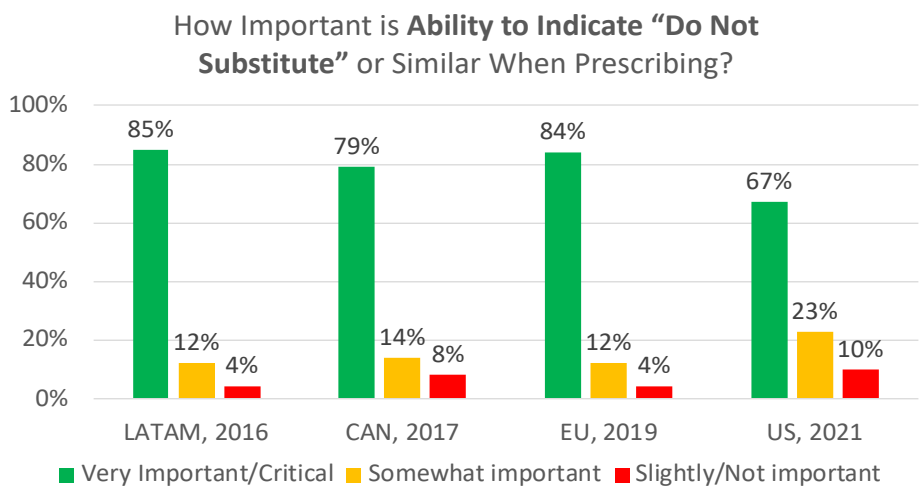
GCCA RECOMMENDATIONS FOR SUBSTITUTION POLICIES

While policies differ widely between countries, the Global Colon Cancer Association recommends that patient advocates use the following principles as a guide when developing their own positions on biosimilars:

1. New patients (sometimes called "Naïve" or "Bio-Naïve" patients) may be encouraged to start with the lowest-cost biologic, often a biosimilar. This promotes competition and cost savings, and is acceptable to the vast majority of the world's physicians.
2. Stable patients should be allowed to remain on the medicine which is working for them. The decision to switch to a biosimilar should remain with the physician and patient.
3. Payers should continue to reimburse the medicine for stable patients who do not wish to switch to the payer-preferred product.
4. Physicians should have the ability to prevent a substitution they do not feel is medically appropriate for their patient.
5. Automatic substitution of biosimilars should not be permitted without additional studies demonstrating that switching, including repeated switching, does not have negative impacts on a patient.
6. In the event of an automatic substitution, physicians should be informed of the switch, so that an accurate patient record is maintained.

The majority, about 60%, are NOT comfortable with Third Party Non-Medical Switching.

Source: www.safebiologics.org



SECTION 3:

BIOSIMILARS: NAMING AND PHARMACOVIGILANCE

BIOLOGIC MEDICINES are used to treat millions of patients with serious illnesses such as Crohn's Disease, rheumatoid arthritis, psoriasis, and ulcerative colitis, and cancer. The patents for many biologic therapies are expiring over the coming years, and copies of these, called BIOSIMILARS will enter the marketplace, bringing patients new therapeutic options at reduced cost.

Biosimilars are copies of biologic medicines. While safe and effective, unlike generics they are not identical to their REFERENCE PRODUCT – the biologic medicine they are trying to copy.



KEY ISSUE:

PHARMACOVIGILANCE

The ability to monitor a patient's response to a medicine as well as track any side effects, is an important part of clinical care. Similarly, the ability to look at how a medicine behaves in a population over time, and as more and more patients receive it, is an important part of monitoring real-world drug effectiveness. We call this post-market monitoring of a medicine PHARMACOVIGILANCE.

In order to reduce development costs and bring them to market more quickly, biosimilars are approved using a shorter process that the product they are based on, their REFERENCE PRODUCT. This abbreviated biosimilar approval process focuses less on clinical trials in patients, and more on analytic trials (showing structural and functional similarity to their reference product). Because of this, it is even more important to gather accurate, real-world evidence about how biosimilars work in patients after they are marketed. To do this effectively, regulators need to know which medicine is which.

KEY ISSUE:

CLEAR PRODUCT IDENTIFICATION

There are several ways to identify a medicine when prescribing, dispensing, and reporting an adverse event. One is by its BRAND or TRADE NAME. But these can differ from country to country, and are not always included by physicians when prescribing or reporting an adverse event. Another method of identifying a medicine is its INTERNATIONAL NONPROPRIETARY NAME (INN). This is the scientific name of the medicine, issued by the World Health Organization. Currently, a biosimilar shares an INN with its reference product, despite not being identical to that product. That INN is also shared by all other biosimilars to that reference product. For example, there are 16 different products approved in the EU which share the nonproprietary name "infliximab". This can become confusing and result in:

- Misattribution of adverse events/side effects to the wrong product
- Inadvertent or inappropriate substitution
- Inaccurate patient records
- Greater difficulty performing a targeted recall of a harmful product

NAMING AND PHARMACOVIGILANCE (CONTINUED)

THE WHO'S SOLUTION: DISTINCT SUFFIXES

Following years of studying this issue, in 2014 the WHO's INN Expert Group proposed a solution: that all biologic medicines, including biosimilars, be issued a unique four-letter suffix called a "BIOLOGIC QUALIFIER" or BQ. This suffix would be traceable to its manufacturer or marketing authorization holder, and would be appended to the INN these different products share. For example, if several products shared the INN "examplemab", they might be distinguished from one another for pharmacovigilance purposes like this: examplemab-abcd, examplemab-wxyz, examplemab-efgh, etc.

Despite broad early support from many national regulatory authorities, including the U.S. FDA, Health Canada, the Australian TGA, the Japanese PMDA, and others; the WHO has not yet made this voluntary standard available. In absence of WHO taking action to establish an international standard, regulators have developed their own systems. The U.S. uses a four-letter suffix similar to that proposed by the WHO. Japan, Thailand, and Peru also use country-specific suffix systems. Other countries, including Australia, Canada and European countries, rely on reporting of a product's brand name alongside its INN, in order to accurately identify the specific biologic medicine.

KEY ISSUE:

INCONSISTENT REPORTING OF BRAND NAME

Unfortunately, reliance on brand name is not enough to consistently identify a biologic medicine or biosimilar. When a patient has a problem with a medicine, such as an allergic reaction or harmful side effect, their physician often submits an ADVERSE EVENT report. An analysis of these reports across Canada and Europe show that between 30-40% of the time, no brand name is provided by the physician, only the nonproprietary name shared by the reference product and all its biosimilars. Surveys of physicians in 13 countries support this analysis, revealing that significant percentages of physicians (between 7%-61% depending on country) do not include a biologic medicine's brand name when reporting an adverse event.

BENEFITS OF DISTINGUISHABLE BIOLOGIC NAMING

- CLEAR PRODUCT IDENTIFICATION – Distinguish the biosimilar from its reference/originator product, and from all other approved biosimilars.
- CLEAR COMMUNICATION – between physician, patient, and pharmacist
- CLEAR PRESCRIBING & DISPENSING – Helps prevent accidental or inappropriate substitution.
- BETTER PHARMACOVIGILANCE – proper attribution of adverse events to the right product.
- INCREASED MANUFACTURER ACCOUNTABILITY – differentiating suffixes (preferably tied to manufacturer) will accomplish this.

The lack of consistency in the naming of biologics and biosimilars causes concern about prescription mix-ups, unintended switching and traceability.

Source: World Health Organization 2020 Report



NAMING AND PHARMACOVIGILANCE (CONTINUED)

PHYSICIANS WORLDWIDE SUPPORT DISTINCT NAMES

- 85% of U.S. physicians support the FDA's policy of issuing distinct non-proprietary names/suffixes for all biologics, including biosimilars.
- 68% of Canadian support Health Canada issuing distinct names for all biologics, including biosimilars.
- 76% of Australian physicians support the TGA issuing distinct names for all biologics, including biosimilars.
- 94% of Latin American physicians surveyed were supportive of the WHO's distinct naming plan as a tool to ensure their patients receive the correct medicine.

All surveys are available at www.safebiologics.org.

KEY ISSUE:

DISTINCT NAMING AND PHYSICIAN CONFIDENCE

One of the concerns with the WHO's proposal for distinguishing suffixes was that these might imply inferiority, undermine physician confidence in biosimilars, or result in lower uptake/adoption of biosimilars. The U.S. biosimilar experience, however, has now definitively shown these concerns to be unfounded. In the U.S., all new biologics – whether biosimilar or originator biologic – are issued distinct suffixes, as proposed by the WHO. A 2021 survey of 401 U.S. physicians who prescribe biologics revealed that the vast majority (73%) do not believe these suffixes imply inferiority. 92% expressed confidence in the safety and efficacy of biosimilars.

In addition, biosimilars have achieved substantial market share in the majority of therapeutic areas in which they've been launched: 80% for filgrastim biosimilars, 70% for trastuzumab and bevacizumab biosimilars, and 55% for rituximab biosimilars. Infliximab biosimilars, have had more limited adoption at 20% market share. This means that U.S. Biosimilar usage rates are now comparable to those of many European countries (20-80% range), where distinct suffixes are not in use. In other words, distinct suffixes do not imply inferiority, nor do they negatively impact physician confidence or harm biosimilar uptake.

DISTINCT NAMING BENEFITS PATIENTS WORLDWIDE

A 2020 WHO report "the lack of consistency in the [NAMING] of biologics and biosimilars causes concern about "prescription mix-ups, unintended switching and traceability."

An international system of distinct naming would help prevent accidental or unauthorized substitutions, ensure accurate attribution of adverse events to the correct product, and increase manufacturer accountability for their products. The WHO exists to establish such international standards. Their proposed system would extend the protections of distinct naming to all patients of the world. This would be especially beneficial to patients in less-developed countries who lack the resources to maintain their own robust pharmacovigilance systems.

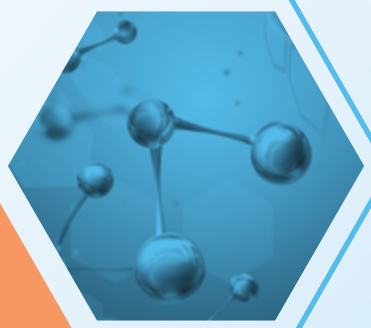
For these reasons, GCCA urges patient advocacy organizations worldwide to support a distinct biologic naming system – both in their home countries, and internationally.

94% of Latin American physicians Are supportive of the WHO's naming plan as a tool to ensure their patients receive the correct medicine.



SECTION 4:

QUESTIONS TO ASK YOUR DOCTOR ABOUT BIOSIMILARS AND SWITCHING



SECTION 4:

QUESTIONS TO ASK YOUR DOCTOR ABOUT BIOSIMILARS AND SWITCHING



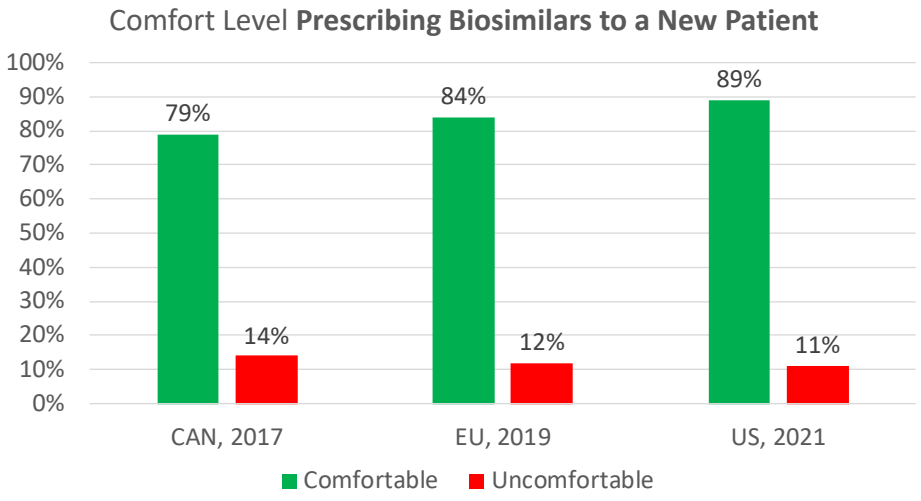
BIOLOGIC MEDICINES help treat a wide variety of serious and chronic conditions include rheumatoid arthritis, psoriasis, ankylosing spondylitis, Crohn's disease, ulcerative colitis and cancer. They are usually administered through injection or infusion.

BIOSIMILARS are copies of these drugs which offer patients new treatment choices at lower cost. While biosimilars are safe and effective, unlike generics, they are not exact copies of the originator medicines. Physicians around the world have high confidence in biosimilars:

Yet, the majority are strongly opposed to NON-MEDICAL SWITCHING – when a third party (such as a government payer or private insurance company) switches a patient's medicine for non-medical reasons such as reducing cost or increasing profit.

Physician confidence in and comfort with biosimilars is high, but the majority agree that treatment decisions should be made by physician and patient.

Source: www.safebiologics.org



QUESTIONS FOR YOUR DOCTOR:

- If I am receiving an originator biologic medicine to treat my condition, are there biosimilars available?
- If I am being switched from my prescribed originator biologic to a biosimilar, why and at whose direction?
  Or: I am receiving a biosimilar A. Why am I being switched to a different biosimilar or to the originator product?
- Has the health regulator in my country (e.g. FDA, Health Canada, EMA, PMDA, etc.) approved the use of the biosimilar for my condition?
- Will being switched to a biosimilar save me any money?
- Will the biosimilar be administered the same way?
- Will the patient assistance program be the same?
- If the biosimilar is given by infusion, will my infusion clinic change?
- If I am switched to a biosimilar, how confident are you that I can expect the same results?
- Who decides if I can be switched to a biosimilar? Can I appeal or ask for an exception? Are the decision criteria available for review so that I can see if I qualify?
- If I am changed to a biosimilar, can I be switched again to a different product? How often can I be changed?
- What is an interchangeable biosimilar? How does this differ?

SECTION 5:

POSITION STATEMENTS



SECTION 5:

SAMPLE POSITION STATEMENTS

These sample position statements are available for patient advocacy organizations and patient advocates to use as a guide for their own statements on biosimilar policy issues. You may decide to edit the language to best fit your advocacy needs based on a specific disease, health system, or a specific policy issue. The statements, as written, have been developed by the Global Colon Cancer Association and the World Patients Alliance, and reviewed by experienced patient advocates with expertise in biosimilar policy.



These are intended as tools for patient organizations to educate their patients as well and make the patient community's needs known to policymakers. Patient organizations are urged to incorporate these into their public-facing communications – including websites, newsletters, emails, social media, annual reports, and other patient education materials.

Please consult the Toolkit Section "Biosimilars: Key Terms" if any of the terms used below are unfamiliar to you. You may also email **biosimilars@globalcca.org** if you have further questions about how to use these statements in your communications.

STATEMENT ON BIOSIMILARS

[ORGANIZATION NAME] supports the approval and introduction of biosimilars as an important tool in increasing patient access to biologic therapies, offering new treatment choices to patients, and reducing health costs. [ORGANIZATION NAME] believes that biosimilars should be held to the same standards of safety, efficacy, strength, and purity as the originator or reference product upon which they are based. When decisions must be made that balance a patient's medical needs against potential economic benefits, policymakers must always prioritize the patient.

PHYSICIAN AND PATIENT CONTROL OF TREATMENT DECISIONS

[ORGANIZATION NAME] believes that ultimate control of treatment decisions, including the decision to switch between different biologic medicines (including biosimilars) should always rest with the physician and patient. While [ORGANIZATION NAME] does not oppose policies which encourage physicians to prescribe lower-cost biologic medicines to new patients, many patients must try several medicines before their condition is adequately controlled. Treatment plans are not "one size fits all". For this reason, [ORGANIZATION NAME] believes patients who are stable on their current medicines should be able to remain on the medicine which is working well for them.

SAMPLE POSITION STATEMENTS (CONTINUED)

BIOSIMILAR SUBSTITUTION

[ORGANIZATION NAME] opposes mandatory or forced substitution of biologic medicines, including biosimilars. The suitability of automatic substitution of a biosimilar at the pharmacy level should be a medical decision made solely by a country's health regulatory body responsible for the safety of medicines, not an economic decision made by a public or private payer. This determination should be made following a clinical study that evaluates the effects of switching patients repeatedly between a reference product and the biosimilar, demonstrating the same outcome can be expected without additional risk to the patient relative to a patient who was not switched.

POST-MARKET SURVEILLANCE

Due to their abbreviated approval pathway, strong post-market surveillance of biosimilars is critical to ensuring their safety and efficacy in the long term. As a medicine's brand name differs from country to country, and brand names are not consistently included by physicians in adverse event reports, [ORGANIZATION NAME] believes that this goal could best be accomplished through use of distinct non-proprietary names. Such a system would help prevent accidental or unauthorized substitutions, ensure accurate attribution of adverse events to the correct product, and increase manufacturer accountability for their products.

While several countries have adopted distinct naming systems for biologics, [ORGANIZATION NAME] believes that all patients deserve these protections, regardless of in which country they seek treatment. To that end, [ORGANIZATION NAME] supports the implementation of an international, harmonized distinct naming standard for all biologic medicines.

Effective advocacy in biosimilars means continual monitoring of policy developments, regular communication with allies and members, and continual engagement with policy makers.



SECTION 6:

SAMPLE LETTERS



SECTION 6:

SAMPLE LETTERS



A core function of a strong patient advocacy organization is communicating with policy makers to make sure the patient voice and needs of the patient community are included in policy decisions. This means opposing policies which raise concerns in your community that may harm patients, as well as supporting policies which would improve patients' health care. In order to create patient-centered policies, policy makers must hear from patient organizations like yours – and on a regular basis.

The following sample letters can be used as templates for your own advocacy on biosimilar policy issues in your country or region. This communication can take the form of written or emailed letters, social media posts, newspaper editorials, press releases, and other means.

You will most likely need to adapt these for your organization and tailor them to the disease area you represent. Your disease area may already be treatable with biologic medicines or biosimilars, or it may be in the future. Regardless, it is important for all patient advocacy organizations to work collaboratively and in solidarity with each other as these policies are being discussed and implemented.

If you are unfamiliar with any of the technical terms used in these sample letters, we strongly urge you to review the document "Biosimilars: Key Terms" located in this Patient Advocacy Toolkit. If you have additional questions or would like assistance with customizing your letter, please email **biosimilars@globalcca.org.**

TIPS FOR LETTER WRITING:

- While a letter from one patient advocacy organization is good, a letter signed by multiple groups is even more powerful. Consider asking your partners and ally organizations to sign on to your letter. If possible, have each organization write a letter based on your own. Ten letters from ten patient organizations is a much stronger statement than a single letter signed by ten groups.
- Within the first paragraph, state which policy you are writing about, and whether your organization supports or opposes it. Include this again in the final paragraph. This makes it much easier for the reader to quickly understand your position.
- Always include early in the letter the name of your organization, the disease area(s) it represents, and how many patients it represents (e.g 500,000 patients have this disease in your country or region).
- If possible, reference supporting data. For example, several of these template letters cite physician survey data and publicly available information about biosimilar market share. You may find some resources like this in the "Additional Resources" section of this Toolkit.
- Personalize your letter by including an example of a patient (either a specific patient or a type of patient) who is harmed by a current policy, and/or would benefit from your preferred policy being put in place.
- Finally, after they are sent, share your letters with your community via your website or social media accounts. Urge them to follow your lead if they share your positions. If you are a member of a patient advocacy coalition, share your letter with them, for feedback and to raise awareness of your group's advocacy efforts. Raising public awareness of your letter(s) also encourages its recipient to respond to your patients' concerns.

LETTER TO HEALTH MINISTRY: SUPPORT FOR DISTINCT BIOLOGIC/BIOSIMILAR NAMING

PLACE ON YOUR ORGANIZATION'S LETTERHEAD FEATURING YOUR GROUP'S NAME, LOGO, AND CONTACT INFORMATION.

DATE

To: Name
Title
Address

Dear Minister,

As a patient advocacy organization [or organizations] representing [XX] patients in [country/countries] suffering from [list diseases], we strongly support the use of biosimilars as a tool to expand access to biologic therapies while lowering costs. As the number of available biologic medicines, including biosimilars, increase, patients like those our organization represents deserve certainty about which among these many similar medicines they receive. As many of these medicines have been approved through an abbreviated pathway, a strong system of pharmacovigilance is especially important to ensuring their continued safety and efficacy over the long term.

Currently, the world uses a patchwork system of country – and region-specific naming systems to identify biologic medicines. Some countries rely on the WHO-issued shared international nonproprietary name (INN) in conjunction with a product's brand name, while several others including the United States, Japan, Malaysia, Peru, and Thailand have adopted their own systems, each of which append a variety of suffixes to an INN shared by the reference biologic and all biosimilars to that product.

A 2020 WHO report[1] identified this issue as one of a handful of remaining regulatory challenges for biosimilars, acknowledging that "this could potentially lead to problems with identifying products and pharmacovigilance unless careful attention is paid to the issue. This situation has caused concerns, for example, prescription mix-ups, unintentional switching, and questions on traceability." The 2020 report reminds the reader that WHO Guidelines from 2009 recommend that to avoid these problems, biosimilars "should be clearly identifiable by a unique brand name".

Yet in the thirteen years since those guidelines were issued, several analyses of adverse event reports in countries which rely on the reporting of brand name, including Canada[2], Europe[3], the UK[4], and Ireland[5], have shown this approach is not adequate. A significant percentage of ADR reports (often a third or more) do not contain a brand name – despite the recording of brand name having been required by European Union law since 2012. These findings are supported by multiple surveys of prescribers in Australia[6], Canada[7] and

LETTER TO HEALTH MINISTRY (CONTINUED)

Europe[8] which each rely on this approach. The inability to determine which out of multiple similar products is responsible for an adverse event can result in inaccurate patient records, misattribution of the adverse event to the incorrect product, and other problems for patients like those we represent.

The WHO's INN Expert Group recognized this problem and after years of study, in 2014 proposed a voluntary internationally-harmonized standard for biologic naming. Despite broad early support from many of the countries listed above, it was not made available to the countries who wanted it, leaving each to develop its own system. Objections to the proposal cited concerns that it would undermine physician confidence in biosimilars, or hurt biosimilar uptake. However, a 2021 survey[9] of biologic prescribers in United States, which in 2015 adopted a distinct suffix system like that proposed by the WHO, revealed these fears to be unfounded. 92% of U.S physicians expressed high confidence in the safety and efficacy of biosimilars. 89% were comfortable prescribing biosimilars to a new patient, a slightly higher percentage than their European counterparts (84%.) Distinct suffixes have also not hurt biosimilar uptake in the U.S., where many biosimilars have quickly achieved market shares of 50-80%.[10] These too are figures comparable to those seen in Europe, suggesting that biosimilar naming does not significantly affect confidence or uptake.

While we would be supportive of your implementing a distinct naming system, as several other countries have; we strongly urge you to consider supporting and harmonizing with the WHO's proposed international system of distinct biologic naming. Distinct naming would help prevent accidental or unauthorized substitutions, ensure accurate attribution of adverse events to the correct product, and increase manufacturer accountability for their products. The patients we represent deserve these protections.

Sincerely, the Undersigned,

1 Kang et al, Regulatory challenges with biosimilars: an update from 20 countries, Ann. N.Y. Acad. Sci. ISSN 0077-8923 2 Canada Vigilance Adverse Reaction Online Database; https://cvp-pcv.hc-sc.gc.ca/ Accessed 4/1/2021 3 EudraVigilance- European database of suspected adverse drug reaction reports. www.adrreports.eu ; accessed May 3, 2019. 4 Klein et al, The UK BIO-TRAC Study: A Cross-Sectional Study of Product and Batch Traceability for Biologics in Clinical Practice and Electronic Adverse Drug Reaction Reporting in the UK, Drug Safety (2020) 43:255–263, https://doi.org/10.1007/s40264-019-00891-6 5 O'Callaghan et al, Knowledge of Adverse Drug Reaction Reporting and the Pharmacovigilance of Biological Medicines: A Survey of Healthcare Professionals in Ireland, BioDrugs (2018) 32:267–280; https://doi.org/10.1007/s40259-018-0281-6 6 Reilly et al, A survey of Australian prescribers' views on the naming and substitution of biologicals, Generics and Biosimilars Initiative Journal (GaBI Journal). 2017;6(3):107-13., DOI: 10.5639/gabij.2017.0603.022 7 ASBM Canadian Physician Survey 2017; https://safebiologics.org/surveys/Canada2017/ 8 Feldman et al, European prescribers' attitudes and beliefs on biologicals prescribing and automatic substitution; Generics and Biosimilars Initiative Journal (GaBI Journal). 2020;9(3):116-24, DOI: 10.5639/gabij.2020.0903.020
9 McKibbin et al, Non-Medical Switching: Physician Perspectives; https://www.youtube.com/watch?v=R9ULgUQEcZ0
10 Amgen Biosimilars, 2021 Biosimilar Trends Report

LETTER TO REGULATOR OPPOSING FORCED SWITCHING

PLACE ON YOUR ORGANIZATION'S LETTERHEAD FEATURING YOUR GROUP'S NAME, LOGO, AND CONTACT INFORMATION.

DATE

To: Name
Title
Address

Dear Minister,

As an organization representing [X] patients with [disease] in [country/countries], we recognize the great value of biosimilars in offering patients new treatment choices at lower cost. We write to you today to express our strong support for those treatment choices remaining in the hands of physicians and patients; and our strong opposition to any policy which results in either automatic or forced biosimilar substitution.

Treatment plans are not one-size-fits-all. Many patients try multiple biologic medicines, including biosimilars, until they find they and their physician find the one that stabilizes their condition. Unnecessary switching of medicines can disrupt this hard-won stability.

The great successes of Europe's robust biosimilar markets have shown that the economic benefits of biosimilars can be realized without restricting physician and patient choices. In nearly every European country, physician and patient are free to choose among many biologic medicines, including the originator and several biosimilars, all of which are reimbursed. While the lowest-cost drugs are encouraged for new patients, stable patients are not forced to switch. Savings are achieved by competition between multiple products, not forced substitution.

Surveys of physicians worldwide have consistently shown a vehement opposition to a third party payer switching a patient's biologic medicine for non-medical reasons such as cost savings. This includes strong majorities in Canada, Europe, and the United States. The world's physicians are also in agreement that the physician, with the patient, should decide which treatment option to use – rather than a third party payer, whether public or private. 90% of Latin American and Australian physicians, 83% of Canadian, 82% of European physicians, and 68% of U.S. physicians consider this very important or critical.

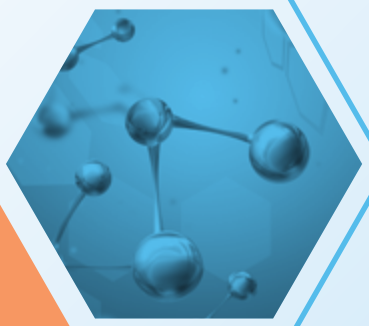
[Optional: if a forced-switching policy has been proposed, reference it here]

On behalf of the patients we represent, we strongly urge you to support biosimilar policies which maintain and expand physician and patient treatment choices, and oppose substitution policies which restrict these choices and potentially jeopardize the control stable patients have over their condition.

Sincerely,
[Name/Title/Organization]

SECTION 7:

ADDITIONAL EDUCATIONAL RESOURCES



SECTION 7:

ADDITIONAL EDUCATIONAL RESOURCES

AFRICA

FACTSHEET: BIOSIMILARS (Cancer Alliance-South Africa)

Medicines regulation in the Middle East/North Africa (MENA) region and the importance of the World H Health Organization's INN proposal of Biological Qualifier

AMERICAS – LATIN AMERICA

ABRALE (Brazilian Association of Lymphoma and Leukemia) Biosimilars Resources

Prescribing practices for biosimilars: questionnaire survey findings from physicians in Argentina, Brazil, Colombia and Mexico

AMERICAS – CANADA

Health Canada Fact Sheet on Biosimilars

Joint Statement from the Canadian Association of Gastroenterology and Crohn's and Colitis Canada

Gastrointestinal Society: Everything You Need to Know About Biosimilars

Video: Canadian Physicians Support Distinct Naming for Biologics, Oppose Third-Party Non-Medical Switching

Op-eds on Forced Switching Policies

Whitepaper: A Critical Review of Substitution Policy for Biosimilars in Canada

INESSS (Québec) Report: Safety of Switching Biologics and Their Interchangeability (ENGLISH)

INESSS (Québec) Report: Safety of Switching Biologics and Their Interchangeability (FRENCH)

AMERICAS – UNITED STATES

ALLIANCE FOR SAFE BIOLOGIC MEDICINES (ASBM)

Video: Non-Medical Switching: Physician Perspectives

Video: Understanding Non-Medical Switching

Video: Non-Medical Switching: Innovator Biologics and Biosimilars

FDA

Biosimilars Materials for Patients

5-Part Video Series on Biosimilars:

The Promise of Biosimilars

The Basics of Biosimilars

Data Requirements for Biosimilars

The Concept of Interchangeability

The Biosimilar Development Process

Biosimilars 101 Fact Sheet (Colorectal Cancer Alliance)

Biosimilars: What You Should Know (Arthritis Foundation)

Coalition of State Rheumatology Organizations (CSRO) State Legislative Map Tool



ADDITIONAL EDUCATIONAL RESOURCES (CONTINUED)

AUSTRALIA

Australian Rheumatology Association Position Statement on Biosimilars (Dec. 2021)

What if You're Forced to Substitute Biologic to Biosimilar?

Therapeutic Goods Administration (TGA): Biosimilar Medicines Regulation

Bowel Cancer Australia

EUROPE

DIGESTIVE CANCERS EUROPE BIOSIMILARS EDUCATION PROJECT

- Resources for Patients
- Biosimilar resources for Health Care Practitioners
- Biosimilar policy activities and Call to Action
- DiCE Position Paper on Biosimilars

European Medicines Agency (EMA) Biosimilars Overview

European Cancer Patient Coalition (ECPC) Biosimilars E-Module

Whitepaper: European Prescribers' Attitudes and Beliefs on Biologicals Prescribing and Automatic Substitution

Survey Highlights the Importance of Unique Names for Biosimilars

INTERNATIONAL

AMGEN

- Amgen BioEngage Site
- Amgen Fast Fact Site
- Amgen YouTube Videos

ASBM

- ASBM Physician Surveys on Biosimilars
- ASBM Video Series on Biosimilars

GLOBAL COLON CANCER ASSOCIATION

- GCCA Biosimilars Training Program
- Physician Letter: Clear Naming, Traceability of Biological Medicines Will Protect Patients
- Whitepaper: Policy Recommendations for a Sustainable Biosimilars Market: Lessons from Europe

WORLD HEALTH ORGANIZATION

- Biological Qualifier: An INN Proposal
- Biological Qualifier Frequently Asked Questions
- Guidelines on Evaluation of Biosimilars