WHAT CAN CANADA LEARN FROM THE EUROPEAN BIOSIMILAR EXPERIENCE?

The undisputed leader in biosimilars with more than 60 products approved and the largest biosimilar market in the world, Europe has achieved impressive biosimilar uptake rates. These can be as high as 91% for older products (before the approval of the first monoclonal antibody biosimilar in 2013) and up to 43% for newer products (approved post-2013)[1]. **How did they do it?**

BUILDING PHYSICIAN CONFIDENCE

After 13 years of experience using biosimilars, Europe's physicians are the most experienced and familiar with biosimilars in the world. The percentage of European physicians who rate themselves as being "familiar" or "very familiar" with biosimilars has increased from 76% in a 2013 survey[2] to 90% in 2019. The 2019 survey[3], of 579 prescribers in six Western European countries, also revealed:

- **84% are comfortable prescribing a biosimilar to a treatment-naïve patient.**
- Yet, while only 17% are uncomfortable in prescribing a biosimilar to a naïve patient; **more than twice as many (40%) are uncomfortable with switching a stable patient to a biosimilar.**

PRESERVING PHYSICIAN CHOICE

In the vast majority of Europe, **which biologic to prescribe remains a decision made by the physician**, in consultation with the patient. Notably, as physician familiarity with biosimilars has increased, so has the importance to physicians of maintaining control of treatment decisions:

- **82% feel that it is either "Very Important" or "Critical" for them to decide which biologic medicine is dispensed to their patients, an increase (from 72%) in the 2013 survey.**
- 84% consider authority to prevent a substitution either "Very Important" or "Critical", an increase (from 74%) in the 2013 survey.

REJECTING AUTOMATIC SUBSTITUTION

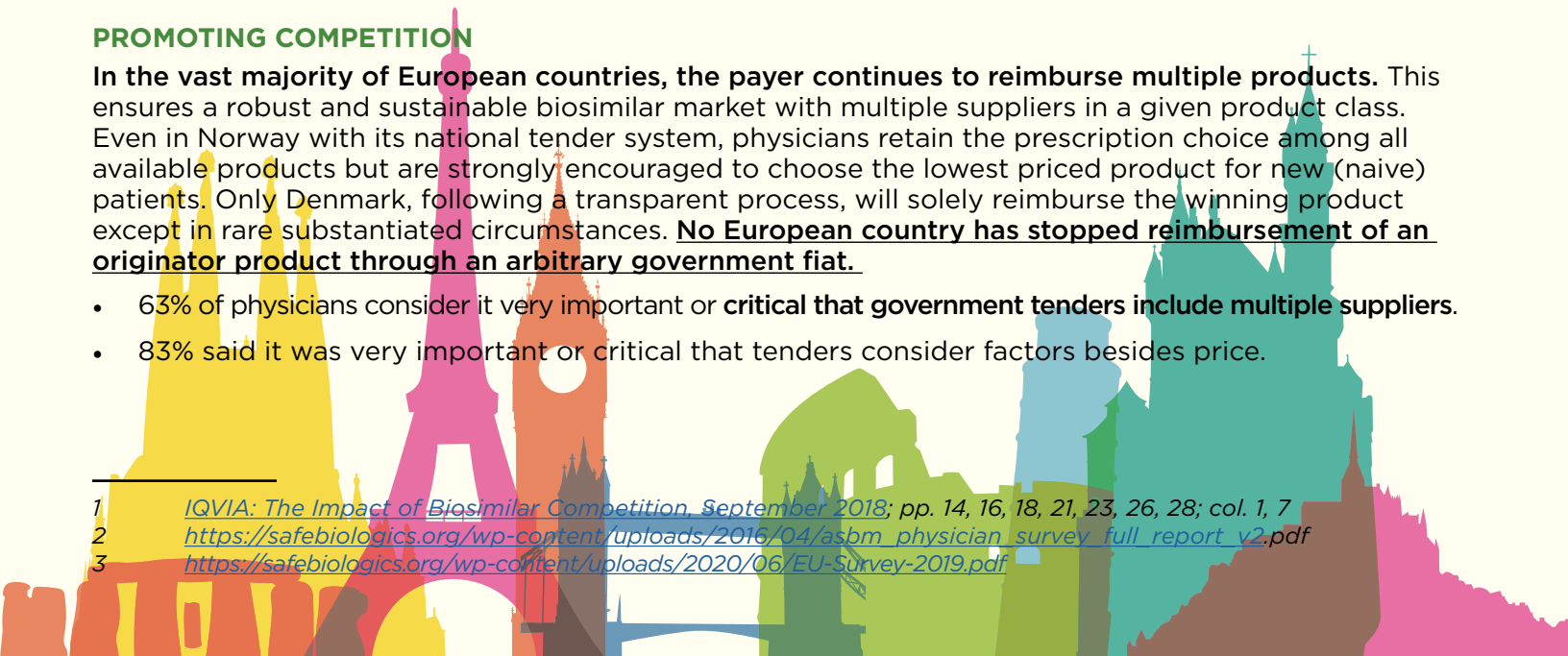
Unlike generics, which are identical to their reference products, biosimilars will always have inherent differences from the originator product and from other biosimilars in their product class. While safe and effective products in their own right, due to these differences, **most European countries do not allow "automatic substitution" with biosimilars**. In addition:

- 58% of physicians are uncomfortable switching their patients to a biosimilar for non-medical reasons (e.g., cost)
- 73% are uncomfortable with a third party initiating a non-medical switch.

PROMOTING COMPETITION

In the vast majority of European countries, the payer continues to reimburse multiple products. This ensures a robust and sustainable biosimilar market with multiple suppliers in a given product class. Even in Norway with its national tender system, physicians retain the prescription choice among all available products but are strongly encouraged to choose the lowest priced product for new (naive) patients. 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.**

- 63% of physicians consider it very important or **critical that government tenders include multiple suppliers**.
- 83% said it was very important or critical that tenders consider factors besides price.



1 *IQVIA: The Impact of Biosimilar Competition, September 2018; pp. 14, 16, 18, 21, 23, 26, 28; col. 1, 7*
2 *https://safebiologics.org/wp-content/uploads/2016/04/asbm_physician_survey_full_report_v2.pdf*
3 *https://safebiologics.org/wp-content/uploads/2020/06/EU-Survey-2019.pdf*

IS CANADA ON THE WRONG PATH?

In May 2019, British Columbia announced that it would be forcibly switching more than 20,000 of its arthritis, psoriasis, and diabetes patients from their originator biologic medicines to the government's choice of preferred biosimilar products. In September it was announced that an additional 1,700 patients with Inflammatory Bowel Disease would be switched.

Europe's success can't be replicated if it's misunderstood.

B.C. Health Minister Adrian Dix cited Europe's high biosimilar uptake rates as a justification for the policy, but disregards the path and principles that led to this success.

It was not accomplished through a reimbursement ban on originator biologics, i.e., the limitation of medicine choice and resulting forced switching mandates, but through preserving choice for physicians and patient and promoting ongoing competition between all products approved by Health Canada based on many factors including cost, clinical evidence, delivery mechanism, patient history, and other factors.

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CANADA'S PHYSICIANS, PATIENTS OPPOSE FORCED SWITCHING

In a 2017 survey[5] of 403 Canadian physicians:

- 83% considered it "very important" or "critical" **that prescribing physicians decide** the most suitable biologic for their patients.
- 64% were **uncomfortable with a third party switching a patient's biologic medicine** for non-medical (e.g. cost) reasons.

"**We do not recommend automatic substitution of biologic with a biosimilar** in IBD patients **given the paucity of evidence for the efficacy and safety** of this approach."

- Canadian Association of Gastroenterology and Crohn's and Colitis Canada[6]

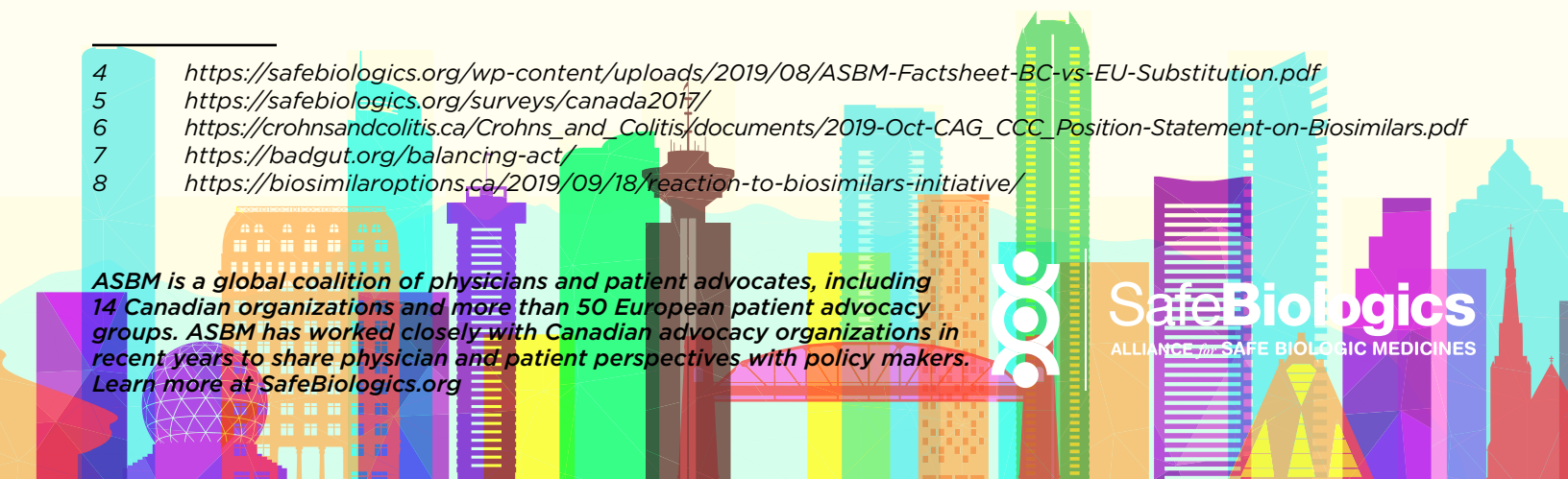
"Reimbursement policies must **recognize and respect the physician's right to prescribe** based on clinical evidence **and a patient's right to choose** the therapy that is best for them."

- Gastrointestinal Society [7]

"The cost-driven objective of [B.C.'s] forced-switch policy is **worrisome** as it fails to put **physician wisdom, patient choice**, appropriateness of care, accessibility, and affordability at the forefront of health policy."

- Biosimilars Working Group [8]

4 *https://safebiologics.org/wp-content/uploads/2019/08/ASBM-Factsheet-BC-vs-EU-Substitution.pdf*
5 *https://safebiologics.org/surveys/canada2017/*
6 *https://crohnsandcolitis.ca/Crohns_and_Colitis/documents/2019-Oct-CAG_CCC_Position-Statement-on-Biosimilars.pdf*
7 *https://badgut.org/balancing-act/*
8 *https://biosimilaroptions.ca/2019/09/18/reaction-to-biosimilars-initiative/*



ASBM is a global coalition of physicians and patient advocates, including 14 Canadian organizations and more than 50 European patient advocacy groups. ASBM has worked closely with Canadian advocacy organizations in recent years to share physician and patient perspectives with policy makers. Learn more at SafeBiologics.org

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