CAPA
Canadian Arthritis Patient Alliance
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To Whom it May Concern

Please find attached comments on behalf of the Canadian Arthritis Patient Alliance related to Health Canada's Consultation: Handbook for healthcare professionals on biosimilar biologic drugs. We appreciate that Health Canada is providing an opportunity for feedback on this draft handbook.

Please note that we are submitting this input on behalf of the Canadian Arthritis Patient Organization (CAPA). CAPA is a virtual, grass-roots, patient-driven, independent, national organization with members across Canada. Ours is the only Canadian volunteer arthritis patient organization that for patients and run by patients – we have no paid employees. Our operational Steering Committee is comprised of volunteers from across Canada who live with arthritis. CAPA believes in the need for Canadians with arthritis to increase: knowledge of their disease and its management (which may include many different types of therapies), patient engagement in arthritis research and policy-making, and the levels of public and political awareness of arthritis. CAPA communicates the latest news on research, technology, health policy and emerging issues relevant to members through our website, monthly newsletter, and social media outlets.

Please note that CAPA has a Medical Advisory Committee (MAC), and all of our resources and this input submission, are reviewed by at least one member of our MAC. Dr. Carter Thorne is a member of our MAC and we note has contributed to the draft handbook. Dr. Cheryl Barnabe has reviewed and contributed to this input.

We would be happy to discuss any of our input in this submission with Health Canada if you feel it is helpful to further explain our comments. We realize that our input may bring a different perspective than other submissions given that we represent patient's lived experience perspectives. We believe our input will be valuable and complementary to other input you also receive.

Sincerely

Dawn Richards

Dawn Richards, PhD
Volunteer 1st Vice President of CAPA, living with rheumatoid and osteoarthritis

…./attachment enclosed

The comments here are presented specifically to certain sections (named and numbered to correspond to the handbook's sections) of the draft handbook unless otherwise specified as being overall comments.

Overall comments:

- It is confusing as a reader that there are only two references listed overall. It appears that a number of references to Health Canada's own previous work about biosimilars, etc., throughout the handbook could be made
- All bulleted lists should have periods after the last points throughout.

1. Introduction

- One of the goals of the handbook '…is to provide objective, evidence-based information on biosimiliar development, authorization, potential use. This will enable patient care decisions, shared-decision making and counselling.' We agree that this document will indeed enable patient care decisions and counselling. However, we remain unclear about the intention to help shared-decision making (defined as "*In shared decision making, both parties share information: the clinician offers options and describes their risks and benefits, and the patient expresses his or her preferences and values. Each participant is thus armed with a better understanding of the relevant factors and shares responsibility in the decision about how to proceed*." (Michael J. Barry, M.D., and Susan Edgman-Levitan, P.A, Shared Decision Making — The Pinnacle of Patient-Centered Care, NEJM. 366;9)). Perhaps the goal of enabling shared-decision making is more aspirational with this particular handbook, while the objective to enable patient care decisions and counseling appear more realistic to us as patients.

2. Biologic Drugs

2.1 General

- Figure 1 – Would benefit from a note that the illustrations of the molecules are not to scale. Aspirin is 180 Da and IgG1 is 150,000 Da, so the latter is 833 times the size of aspirin– which is clearly not what is shown in the figure.
- It appears to be worth stating that even originator biologics change over time given that they are produced by living organisms.

3. Biosimilar drugs

3.1 Biosimilars versus generic drugs

- It is worth explaining that because biologics and biosimilars are produced by living organisms this is what gives (at least partial) rise to their inherent variability (cited as: "Due to the inherent variability of biologic drugs, biosimilars may not be identical to the reference biologic drug.")

- In Table 1: Comparison of biosimilar and generic drugs, it is worth being very specific the active ingredient in generic drugs is identical to their brand name counterparts, however because biosimilars and biologics are derived from living organisms, this is not the case.

4. The regulation of biosimilars in Canada

- The author starts to talk about Health Canada as 'we' in these paragraphs versus as Health Canada in other parts throughout (e.g., …"We need clinical studies in humans to show that there are no clinically meaningful differences in efficacy, safety and immunogenicity expected between the proposed biosimilar and its reference biologic drug.

  These studies will include those examining the levels of drug in the blood over a relevant period. We also usually require a clinical trial comparing the biosimilar directly to its reference biologic drug to confirm that no clinically meaningful differences exist. …")
- Case Study 1: Request that you use the term 'participant' in place of 'subject' as the former is more respectful and also reflects a participant's voluntary nature.

4.3 Addressing a key safety issue: immunogenicity

The acronym "ADA" is used here to denote anti-drug antibodies, however one of our Medical Advisory Committee members has commented that this may be confused by healthcare providers as meaning 'adalimumab' even though it is defined, given that this medication is also often referred to by the acronym, ADA.

5. Monitoring safety and effectiveness

- Health Canada's Canada Vigilance Program is mentioned however there is no link to it like in other areas where Health Canada links are referenced – suggest this is added - https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/canada-vigilance-program.html

5.2 Identification of biosimilars in prescribing, dispensing and Adverse Drug Reaction (ADR) reporting

- While the link to the ADR reporting is in the next section (section 5.3), it should also be added here

5.3 The role of healthcare professionals in improving pharmacovigilance for biosimilars

- This is an important section, however there should also be mention of how healthcare providers may have to work closely with patients on collecting and recording information. In the case of rheumatology patients, they may be reporting side effects to their rheumatologists, who may need to direct them to help obtain specific information about the biosimilar (e.g. lot number), etc., especially if using a self-injected device

6. Biosimilars in Canada: access and uptake

- While we appreciate that specific government-funded agencies are listed in the first paragraph, some other key stakeholders are missing such as physician associations, patient organizations, health charities, and even patients. These missing stakeholders

have often been sidelined during discussions about biosimilars to date, except through very specific calls or invitations for input. It would behoove Health Canada to recognize the importance of these stakeholders in the ecosystem of access and uptake- as much is done on this front outside the walls of government-based or -funded agencies.

7. Communicating with patients

- The statement "Outreach to patients has also been a key element of our stakeholder engagement strategy" is not supported by sufficient evidence and while it might be aspirational, feels a bit too strongly worded. For example, on the Health Canada Biosimilar biologic drugs page (https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/biosimilar-biologic-drugs.html), under stakeholder engagement, there is one formal report listed from a workshop in 2017, of whose participants included some patient organizations and health charities (including our own). Additional supporting evidence should be included here about Health Canada's outreach efforts in this space if such a statement is going to be made.

7.1 Discussions about switching

- It may be helpful to include questions here that patients may ask about switching. For example, CAPA's Steering Committee is comprised of people who live with inflammatory arthritis, many of whom have been on biologics for a number of years. We have brainstormed a number of questions that we and others have had about switching and are all listed here (https://arthritispatient.ca/questions-you-may-wish-to-ask-your-healthcare-provider-about-biosimilars/?hilite=biosimilars). We would be happy for you to use these in this document, noting that they have been reviewed by our Medical Advisory Committee, among whose membership includes Dr. Carter Thorne, who contributed to the handbook we are providing these comments on.