Canadian Arthritis Patient Alliance
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June 3, 2014
Canadian Agency for Drugs and Technologies in Health
865 Carling Ave., Suite 600
Ottawa, Ontario
K1S 5S8

Re: CDR Consultation — Patient Input Template for Subsequent Entry Biologics

To Whom It May Concern:

The Canadian Arthritis Patient Alliance (CAPA) represents the perspectives of Canadians living with all forms of arthritis from across the country. As you are aware, Subsequent Entry Biologics (SEBs) will have an immediate impact on patients who live with inflammatory arthritis, as the SEBs come in to the marketplace in lieu of the original biologics that many of us have been on since they were first approved by Health Canada in late 2000. As patients who live daily with managing a chronic illness, a number of us have experienced how biologics absolutely transformed our abilities to function independently, participate in work and family experiences again, and simply put, to live our lives again.

As a result of anticipating how we will be impacted by the arrival of SEBs to the Canadian healthcare system, and from our unique perspective as people living with inflammatory arthritis, we thank CADTH for allowing us to comment on the Patient Input Template for Subsequent Entry Biologics. We have provided our comments below and would be happy to elaborate on these in any way you feel useful.

- Overall, the template captures the concerns that patients could have with SEBs
- The glossary is short and useful, and could potentially consider using simpler words
- In Section 3, there is contact information about the Submitting Patient Group, while Section 3.1 refers to Submitting Organization. To prevent confusion, we recommend using the same terminology throughout – either Patient Group or Organization, but not both
- As above in Section 3, in Section 4, reference is made to 'condition,' while in Section 3 this is called 'indication,' again, we suggest maintaining one of those throughout
- In the glossary, Subsequent Entry Biologic is not defined by the abbreviation SEB explicitly after the entry
- The sentence at the end of Pharmaceutical Interchangability is odd – it should just be part of the former sentence
- Why are submissions made as Word documents? Should they not be protected PDFs?
- In Section 8, we believe that CADTH should take a stronger position, as Health Canada has been very clear (and frankly, we all understand) that SEBs are not generic drugs and should not be automatically substituted for the biologic. We strongly recommend CADTH include Section 8 in its review as this section will be the primary place where patients' very real concerns are voiced about switching/therapeutic substitution. Such

concerns will be with respect to potentially being forced to take an SEB because of its price, not because of its effectiveness, and concerns about the ethics of this. Note that a number of CAPA members are on biologics and there is a real fear that being forced off a biologic on to an SEB simply because of cost will not result in the same efficacy, or therefore, quality of life. For people with inflammatory arthritis, this means potentially inducing further joint damage and loss of function, which would not happen if they remained on their current, efficacious biologic. Additionally, for patients who are switched to an SEB because of drug plans and cost, there could be further severe negative implications on their already well-managed disease such as not responding as well to the SEB, and when switched back to the original biologic, failure to respond the same way because of immune system changes, progression in their disease, etc. This could potentially result in larger healthcare system costs than the forced switch itself saved. We also feel strongly that SEBs, not being the same as the originator molecules, should require the same clinical rigour (types of trials, all indications, numbers of trial participants) as the originator molecules – it remains unclear to us why this will not be happening. We do not understand how an extrapolation to other indications can be made without proper evidence to substantiate safety, efficacy, and therapeutic value. A final point is that there already exists unawareness by trusted healthcare providers about SEBs, what they are, and how they will affect people. Within our own membership we have recent anecdotes of speaking to our pharmacists and educating them about SEBs; the same pharmacists who currently undertake generic substitutions due to cost and who will continue to do so unless educated properly on SEBs vs. biologics.

As people who live daily with a potentially devastating chronic illness, we urge CADTH to consult its patient stakeholders on all aspects of SEBs – not just those in Sections 4-7 of this draft input document. We strongly advise you to not only collect, but also take in to consideration the input from Section 8. We know a new normal living daily with a chronic illness, and we aim to participate as fully as we can in life, which includes making informed, evidence-based, healthcare decisions. Since you have generously reached out for our input, we are telling you that we want to remain in control of our health outcomes through working with our caregivers to access the best and safest therapies possible. Taking away our choice by providing SEBs that have not been tested as rigorously as medications that are currently available does not empower us any further, rather it provides more unknowns in our already unknown-filled chronic illness sphere.

Thanking you in advance for your kind consideration,

Linda Wilhelm

President
Canadian Arthritis Patient Alliance
On behalf of the Canadian Arthritis Patient Alliance Membership

Dawn Richmond

Vice-President