Monday, October-07-13

CSPA Comments on CDR procedures and process for reviewing SEB's

The Canadian Skin Patient Alliance (CSPA) is a by patients, for patients organization serving the millions of Canadians who grapple with skin disease. It is also the advocacy voice for many of the smaller disease-specific organizations who are affiliate members of the CSPA. This submission represents the views of the CSPA.

The CSPA recognizes the potential benefits to patients with the entry of SEB's and hopes that their entry will drive down prices and make biological medications available to more people. We have concerns about safety, monitoring and substitution. We believe that treatment decisions must be made between the patient and the prescribing physician and have concerns that price continues to be a driver that at best influences these decisions and at worst shifts them to payers.

Also our patients have reported that their experience with similar biologic drugs, even those which target the same proteins (e.g. TNF –α) are different from drug to drug and in many cases, if they have to discontinue or interrupt their treatment, if they restart, the treatment is considerably less effective, or doesn't work at all. One can only surmise from these experiences that if SEB's get substituted, either accidentally or intentionally there will be issues of safety and efficacy for those patients whose lives are critically affected by these drugs.

CADTH has asked us to address several process issues. Here are our considered responses.

1. *Single submission for all indications versus separate submission for each approved indication*

Given that even within a disease group, no two patients respond to medications in the same way, we feel that it is critical that new SEB's be required to submit evidence of efficacy and safety for each indication. These are complex molecules and complex systemic diseases, and a one size fits all approach would seem to sidestep the need for rigour in protecting Canadians whose health is already under siege. SEB's should go through rigorous testing for every disease group – therefore clinical trials in Canada for each indication. One cannot assume an SEB will work in exactly the same way as the originator, because SEBs are not equivalent, only similar to the originator biologic. Similarly one cannot assume it to be effective for all of the same indications as the originator without proper clinical trials proving this to be the case. Quality of life data is unlikely to be the same across indications and because SEB's aren't identical to the reference drugs, that data can't be inferred from the prior reference drug submissions. Similarly uncertainties in clinical and cost-effectiveness measures would also arrive if data were to be extrapolated from one indication to another.

We support separate submission for each approved indication.

2446 Bank Street, Suite 383, Ottawa, Ontario, Canada K1V 1V8
Tel: 613. 422. 4265 • Fax 613. 422. 4267 • info@skinpatientalliance.ca • www.skinpatientalliance.ca

2. *In consideration of a tailored review for SEB's*

The concept of fast-tracking could be deemed appropriate where immediately life threatening diseases are being targeted by SEB's. Given that these drugs would be similar but not the same, the availability of additional options when time is tight, or that could be offered earlier could provide a benefit. However, these are new medicines and should be required to submit clinical and safety data in the same way any new medicine is required to do so, within the same parametres.

Where SEB's are meant to address chronic debilitating illnesses like psoriasis, given that patients would be exposed to the SEB's for a long period of time, the same rigour and consideration in process should be taken for these similar, but not identical drugs as was given to the reference drug regardless of :

- The number of indications and the similarity of different indications.
- Indications that have been approved based on extrapolation[d] of clinical data.
- Whether an existing CDR review of the reference product for the same indication(s) is available.
- Formulary listing status of the reference product for the indication(s) under consideration in the CDR review.
- The use of a reference product that is not marketed in Canada.

We believe that for chronic conditions care must be taken to provide a very thorough review. It would seem that by tailoring the review process in most cases, corners would be cut, and the potential for patient safety concerns would rise.

3. *Critical elements to be included in a CDR submission*

From an ideal perspective, in order to ensure that safety and efficacy criteria are met, we'd prefer to see the exact same elements included in a CDR submission for an SEB as are included in a submission for any other new drug. These *are* new drugs. We feel strongly that there must be SEB data specific to the indication for the submission to ensure safety and efficacy for that indication. If in the end, the process varies from that required of all other new drugs, CDR /CADTH must be transparent and disclose all assumptions made in forming its recommendations and note the uncertainties caused by making these assumptions. Also if the process deviates at all from the norm, experts (physicians who have prescribed the reference biologic for that indication) should be involved in the review process.

4. *Other issues*

Post market surveillance requirements with re-review

If, as is being contemplated, the CDR recommends the acceptance of SEB's without requiring the exact same scope of data as was required for the reference medication, then it is crucial that long term safety monitoring be mandated using post marketing registries to ensure that safety of patients is not compromised. If the rigour is not in evidence up front, then the least we can expect is that there be very close monitoring after these medications are commercialized. These medications are biochemically extremely complex and under no circumstances can it be assumed that the safety profile is identical to the reference drug. To recommend acceptance without requiring back-end safety monitoring is potentially very dangerous.

In addition to requiring post- marketing registries, we urge that a recommendation from the CDR is accompanied by a review by the CDR of the registry safety and efficacy data 2- 5 years post commercialization.

In this way, Canadians can be reassured that while shortcuts may have been taken to get these SEB's to market quickly, they have been deemed safe and effective over time.

Interchangeability

While the CDR is not taking on the issue of interchangeability or substitutability, we feel this is an area where the CDR can take a leadership role and make recommendations that will protect Canadians, which is part of the CDR mandate.

As patients, we are painfully aware that payers seek the lowest cost alternative and are not necessarily incented to put into place policies that will restrict their ability to substitute lower costs medications for higher priced reference drugs. Safety and efficacy must come first.

Unlike generics, SEB's are not bioequivalent, so substitutions cannot be made without all of the following:

- Data confirming that the new drug is exactly bioequivalent to the drug it could substitute
- The physician giving explicit instruction to the dispensing pharmacist to allow for substitution (rather than substitutions be allowed unless otherwise specified)
- Patients must be made aware that the substitution is taking place
- Either starting a course of treatment or shifting to an SEB must be a decision made based on what is in the best interest of the patient.

Distinct Names

It is of vital importance that a SEB medication has a name in Canada that is completely different from the reference drug it simulates. These are new medications – not generics, so the standard used for generics is unacceptable and breeds confusion.

The Canadian Skin Patient Alliance is hopeful that the process put in place by the CDR will support the safety of Canadians who rely on these innovative drugs to live productive lives.

Prepared by

Christine Janus
Executive Director
Canadian Skin Patient Alliance