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Biologics and their similars: *Patients First*

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Agenda

- Biologics – the fight for right proves to be right
- Regulation of SEBs in Canada
- Consumer/patient input to date on SEBs
- Questions (still) unanswered
- At the end of the day……(commentary)

The impact of biologic therapy

- What it's like to be Cinderella – from fireplace ashes to The Westin Grand Edmonton
- Fighting for equity since 2000
- Inflammation is a tumour – research, policy and models of care must treat it as such

Spending money to reach the "promised land"

- Before biologics, no drugs developed for RA – NONE
- RA the largest driver of indirect health care costs and work disability in Canada
- German study (Jan 2014) found increase in treatment costs for RA over the last decade associated with:
  - lower hospitalisation rates
  - better functional status and a lower incidence of work disability
- Offset a large proportion of rise in drug costs
- Drug costs have plateaued from 2009, no relevant further increase in total costs for patients with RA is expected

*Huscher D et al. Ann Rheum Dis. 2014 Jan 9. doi: 10.1136/annrheumdis-2013-204311.
Evolution of cost structures in rheumatoid arthritis over the past decade.

Regulation of SEBs in Canada

- The entry of SEBs into the Canadian market place affects a huge number of patients
- Auto-immune arthritis is on the front line of this discussion
- Policy "Testing" in 350,000 Canadians (RA, PsA, AS)
- Potential for doing harm is a reality, and possibly significant

Strength in numbers in regulatory / HTA review

- Do we belief in data?
- Is the allure of *imagined savings* so seductive we are *choosing* to sacrifice on process/safety?
- Infliximab (which one?) “Remsima” reviewed in approximately 12 months
- Tofacitinib (JAK-3 inhibitor, small molecule, 5,000 patient years of data, new treatment pathway) stuck at Health Canada – 790 days give or take – same as etanercept 15 years ago!
- Imagined savings trumps innovation

Consumer / Patient input on SEBs to date

- ACE held the first SEB Roundtable in Canada in BC – March 2011
- ACE, other patient orgs affected/interested, BIOTEC Canada, Life Sciences BC, CDRD, BC College of Pharmacy
- Shared evidence-based information on issues from different perspectives
- Stimulated broad-based discussion on SEBs
- Output: a consensus report on patient views regards SEBs and their future regulation/review

Consumer / Patient input on SEBs to date

- Since then, patient surveys conducted and scientific review and opinion papers published
- Dozens of multi-stakeholder regional and national meetings/gatherings to discuss SEBs and their regulatory/HTA review
- To what end? Is anyone out there? Is anyone listening?

Consumer/Patient input to date

Health Canada (Guidance documents and presentations)	Input from real people living with real diseases
SEBs are similar, not identical to their originator biologic	Patients' overriding concern is safety, safety, safety – originator and SEBs alike Patients want SEBs to undergo the same rigorous review as their originator
Does not support automatic substitution	Patients want to discuss and decide what meds to take in consultation with their physician
Each biologic: 1) interacts with a patient differently; 2) has a unique safety profile and may behave differently in clinical care Small changes in mfg-ing can have major implications for patient care	Patients want Health Canada's assurance (not hypothesis) that approved meds are safe and effective
Switching back and forth btwn similar biologics may cause different immune system reactions in patients, with negative health consequences	Patients want Health Canada's assurance (not a hypothesis) that approved meds are safe and effective

Consumer/Patient input to date

CADTH (Framework Report Fall 2013)	Input from real people living with real diseases
SEBs will be subject to tailored reviews	Patients want SEBs to undergo the same HTA rigour as their originator given they are not the same
SEBs may be recommended for indications w/ varying levels of supporting evidence, maybe none for extrapolated indications	Patients want Health Canada's assurance (not hypothesis) that approved meds safe and effective
SEBs only required to provide simple cost-comparison, not full pharmacoeconomic model and with no reference to current standards of care, as recommended for innovative products.	Patients want Health Canada's assurance (not a hypothesis) that approved meds are safe and effective
May 15, 2014 - patient input template for subsequent entry biologics issued for consultation	Patient groups collecting member/patient feedback for June 6, 2014

Consumer/Patient input to date

Rumour Mongers	Real people with real diseases
SEB as a mandatory first line therapy -adding another “fail” step to SA processes; “New starts”	Scientifically or clinically unsubstantiated Patients want to discuss and decide what meds to take in consultation w/ their physician
Pharmacists should be allowed to make “at the counter” substitutions between SEBs and their originators	Unacceptable
Coverage for SEBs for IBD and Crohn’s “off-label”	Unacceptable

Consumer/Patient input to date left by the road side

- Distinct brand and generic names
- Canadian reference product in all SEB reviews
- Mandatory post-marketing surveillance program(s) (like their originators)
- Disease specialists consultation and guidance for SEB placement on public formularies

Who can tell me…….

- Will the rates of infusion and/or injection site reactions be similar?
- What about the rates and types of serious infections?
- If a SEB is substituted for the prescribed drug, will this have any adverse impact?
- How will the pricing of SEB products affect the overall price of the RA biologic class?
- Where will the therapy be administered and will they require similar co-medications to the reference drug?

At the end of the day…..

What do patients need?

- Timely access to evidence-based (safe and effective) medicines
- Timely and fair reimbursement access on public and private drug formularies
- The right to choose with their health care team the therapy best suited to their unique health needs, beliefs, preferred route of administration, and have that choice respected by patient-centred policy
- To learn from historical knowledge to best decide to put something in their body, or not