Scott,
These are persuasive arguments for maintaining the current approach, or at least informing patients about the choices; risks and benefits.
Can you provide your rationale for over-riding the evidence-based preference for the biologic treatment where possible?
Thankyou
David Swann MD,MLA

From: Gilchrist, Keith (JOICA) [mailto:kgilchr@ITS.JNJ.com]
Sent: Friday, November 18, 2016 5:23 PM
To: David Swann <David.Swann@assembly.ab.ca>
Subject: Our discussion on forced switching of stable patients to biosimilar medications

Dear Dr. Swann, thank you for your time on the phone this afternoon.

We discussed REMICADE (infliximab), a Janssen biologic medicine that is publicly reimbursed in Alberta for patients with rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, psoriasis, ulcerative colitis and Crohn's Disease.

REMICADE has been off patent for several years, and we now see the first alternative medicine (properly called a "biosimilar" rather than a generic) reimbursed by Alberta Health. This biosimilar is produced by Pfizer and is called Inflectra (infliximab), and its list price is approximately 55% of REMICADE's list price.

In many cases, the manufacturer of an off-patent originator product will drop out of the market when cheaper generics / biosimilars become available. In this case, Janssen is intent on staying in, being cost-competitive and continuing to provide value to patients and provincial health systems.

Alberta Health's reimbursement to biosimilars to date has deliberately preferred biosimilars over innovative reference products. Alberta Health's April 1, 2016 Drug Benefit List reimbursement criteria states clearly that REMICADE will not be reimbursed for new patients with rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis or psoriasis, only Inflectra will be approved. Alberta Health has signaled that it will take a similar preferential approach for ulcerative colitis and Crohn's Disease patients, starting December 1st.

Perhaps more troubling, Alberta Health has also notified Janssen that it intends to develop policy to require REMICADE patients currently in remission to switch to Inflectra – no timeline for implementation of this policy directive has been communicated.

Janssen has serious concerns with this approach by Alberta Health, as summarized below:

1. **There is neither a clinical nor a financial reason for Alberta Health to preferentially reimburse Inflectra over REMICADE:**

    a) as a biosimilar, no data is available that would suggest patient outcomes would be improved by Inflectra. At best, Inflectra can claim it is not inferior to REMICADE.

    b) Janssen has offered to Alberta Health and the pan-Canadian Pharmaceutical Alliance several proposals that would make the net price of REMICADE cost competitive with Inflectra. This proposal has been refused. Even without this net price reduction, Alberta Health has a Maximum Allowable Cost policy lever at its disposal to cap reimbursement at the price of the cheapest biosimilar. This would create equivalent savings without assigning patients to a particular product for non-medical reasons.

2. **Switching stable patients represents risks to patients and health care cost containment:**

It takes an auto-immune specialist time and special care to help a patient achieve remission of their symptoms while on REMICADE. Switching a stable patient to another medication risks a relapse of those symptoms, after which the patient would be ineligible to return to REMICADE. One Finnish study observed that 28% of IBD patients switched from REMICADE to Inflectra suffered a relapse, especially concerning because switched patients cannot switch back to the medication previously keeping their symptoms under control.

For patients with Crohn's and colitis, very few other therapy options exist; the next step in therapy may be surgery at significantly greater cost to Alberta Health and poorer outcomes for the patient originally in remission. For Alberta specialists treating these patients, this risk leads them to demand rigorous data showing equivalency of patient outcomes following a patient's switch from REMICADE to Inflectra, data which does not exist to date.

3. **Closure of Services to Rural and Northern Communities**

It is important to note that except for rare examples, REMICADE infusions are provided by Janssen, in a Janssen-operated clinic, at no cost to the patient, Alberta Health or any insurer. Any decision to switch patients from REMICADE to Inflectra would impact communities where only a Janssen infusion clinic currently exists. There are 25 Alberta Janssen/BioAdvance clinics that infuse REMICADE. For patients in Fort McMurray, Lloydminster, Barrhead and St. Paul, the nearest Pfizer/Innomar clinic is located in Edmonton. For the period of time it takes Pfizer to build out its network of clinics, these patients would need to drive 250 – 750+km round trip for each infusion - an inconvenience not uncommon for rural patients seeing health services in their communities erode, but absolutely not necessary for clinical or financial reasons in this case.

Of 200+ REMICADE patients in these communities, most are infused on a 6-8 week cycle. Especially for Fort McMurray patients, requiring them to travel to Edmonton would mean an overnight stay for all but the most hardy travelers. We understand that the economic realities for many patients working in the Wood Buffalo region are such that 2 days away from work might put their employment in jeopardy.

It took Janssen many months to work with autoimmune disease specialists, health region administrators, local nurses and various commercial real estate options to establish its infusion clinics in Alberta. The time it takes Pfizer / Innomar to replicate such a service may differ. Janssen argues that if switching stable patients is mandated, that policy should not be implemented before comparable biosimilar clinics open in Fort McMurray, Barrhead, St. Paul and Lloydminster.

4. **Disparity between Private and Public Reimbursement**

It is worth noting that Janssen's offer to private payers to be cost competitive with biosimilars has been enthusiastically received by firms covering 90+% of privately-insured lives in Canada, and this number grows. Should it proceed with a policy of forced switching, Alberta Health could conceivably require vulnerable Albertans receiving public drug benefits to switch from REMICADE to Inflectra, while civil servants, government employees and MLAs retain their access to REMICADE through their employer sponsored benefits. This inequity would generate risks associated with switching stable patients on public drug plans, to achieve savings that would be easily achieved through Janssen's offer or MAC pricing.

5. **Alberta Health's approach sends a strong signal that it discourages innovation.**

> Alberta Health's approach to biosimilars effectively means a government is deciding to engineer a marketplace so that an originator product can no longer participate regardless of its price point. This approach is decidedly at odds with Alberta's efforts to increase life sciences research investment. Investment competitiveness relies on a stable, predictable policy environment; having reimbursement ended for an innovative product, without clinical or financial reasons to do so, would damage Alberta's efforts to compete for research investment.

As we discussed, proponents for preferential reimbursement of biosimilars put forth the arguments below. I've included our responses.

The Need for a Preferential Environment

Alberta Health has asserted that providing a preferential reimbursement environment for biosimilars is necessary to ensure a competitive marketplace by guaranteeing biosimilar manufacturers launch products in Canada. This approach is belied by the healthy number of biosimilar products seeking regulatory approval at Health Canada. In the case of Inflectra, this product is sold by Pfizer, not a struggling Canadian startup company. Pfizer, with its huge machinery in sales, marketing and medical education, does not need special assistance from Alberta Health to compete. Cementing Pfizer's Inflectra as the preferred product does the opposite, and risks discouraging the 2nd and 3rd biosimilar from seeking market share in Canada.

Savings Potential

Proponents of biosimilars assert that savings generated by biosimilars create headroom that will help Alberta Health afford new innovative medicines that are still on patent. We completely agree: Janssen's offers to Alberta Health and PCPA are evidence that competition generates savings. These savings would also be available through Maximum Allowable Cost pricing, with a reimbursement ceiling set at the price of the lowest priced biosimilar.

Arguments regarding Transparent Pricing

Alberta Health has defended its approach by saying Janssen is not reducing its price transparently, only offering to establish a competitive net price by increasing the rebate that Alberta Health receives. Confidential rebates are an established business practice between Canadian public payers and pharmaceutical companies; they allow Canadian subsidiaries of global pharmaceutical companies to provide savings far beyond what would be available if only the published list price were adjusted. Over the last five years, Alberta Health has enthusiastically participated in dozens of product listing agreements featuring such confidential rebates. Janssen asks why such a dramatic inconsistency is necessary for this one class of medications, especially if it does not create clinical or financial benefits?

Arguments Claiming True Interchangeability and International Precedents

Proponents of biosimilars state that these products are essentially equivalent to their innovative comparators - there is no concern with using them interchangeably. Health Canada disagrees. As biologic medicines, there is no expectation that biosimilars are an exact match – their molecular structure arises partly from the unique environment in which they are grown. The data used to secure Health Canada approval for Inflectra in rheumatoid disease, psoriasis and Crohn's and colitis did not include switching data, and HC specifically instructs provinces not to consider biosimilars interchangeable with their innovative product comparators. Proponents of interchangeability refer to the NORSWITCH study, recently reported from Norway. Canadian gastroenterologists and rheumatologists have already registered their concerns regarding the small patient numbers and study design as insufficient to support a policy decision as important as forcing a stable patient off a medicine that is working effectively. Public drug plan managers who wish to rely on NORSWITCH should at least refer a request to determine clinical interchangeability to their provincial Drug Advisory expert committees – something Alberta has not committed to doing.

Proponents of biosimilars also assert that other countries use biosimilars and innovator products interchangeably. That is true in some health regions in the UK and in some countries in Europe. We are not aware of research data arising

from these regions that support such interchangeability, and argue that Alberta Health should be held to a higher bar of evidence based decision-making. Alberta conducted itself admirably in 2009, resisting calls to fund the Zamboni procedure for multiple sclerosis without rigorous clinical evidence, especially with regard to patient safety. That rigor should be applied to this decision as well. In the end, if Alberta Health is determined to switch stable patients for non-medical reasons, Janssen asserts that no financial reason exists to do so.

Our Ask

Janssen asks that Alberta Health not employ preferential reimbursement of biosimilars and forced switching of stable REMICADE patients. Janssen's financial offer to Alberta Health and pCPA would deliver the savings expected in a competitive marketplace. MAC Pricing would be a suitable alternative. Either would shield the Government of Alberta from risks associated with patient relapse and associated care costs, and from yet another closure of rural and remote health services.

Thank you for hearing me out. Please don't hesitate to contact me with any questions.

Keith

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Ministry of Health
Professional Services and Health Benefits
April 15, 2016

AR 135926

ADVICE TO MINISTER

CHIEF OF STAFF MEETING WITH JANSSEN CANADA

ISSUE:

- Keith Gilchrist from the pharmaceutical manufacturer Janssen Canada has requested a meeting with the Deputy Chief of Staff to discuss Alberta's approach to its pharmaceutical file.

DEPARTMENT REPRESENTATIVES ATTENDING MEETING:

1. Michele Evans, Professional Services and Health Benefits, 780-427-8019.

KEY BACKGROUND FACTS:

- Janssen is large, multinational pharmaceutical company with a significant range of drug products funded through the Alberta Drug Benefit List (ADBL).
  - In 2015/2016, Alberta Health spent over $60 million on Janssen's biologic Remicade (infliximab), which made it the second highest total expenditure drug funded by Alberta Health;
  - Alberta has a Product Listing Agreement for Remicade [redacted] 16(Third Party Business Interests)
- Biologics are high cost therapies used in the treatment of a variety of conditions including rheumatoid arthritis and ulcerative colitis. Significant expenditures and year over year growth in this space has created a need for cost saving.
- Subsequent Entry Biologics (SEBs) are compared to an originator or innovator biologic product similar to generic drug products.
- Alberta is a member of the pan-Canadian Pharmaceutical Alliance (pCPA) through which provincial, territorial and federal drug plans use their collective purchasing power to secure better value and consistent access for pharmaceuticals.
- The pCPA recently negotiated terms for the product Inflectra, a SEB of Janssen's Remicade.
- Inflectra is currently approved for only a subset of the Remicade's approved indications; the remaining indications are anticipated to be approved later this year.

[redacted] 16(Third Party Business Interests);21(Intergovernmental Relations)

- The pCPA negotiations provided for a transparent price reduction in addition to other confidential components. The transparent price is publically posted and known to private insurers and cash paying patients.
- Inflectra was listed on the ADBL April 1, 2016.

[redacted] 24(Advice from Officials)

[redacted] 16(Third Party Business Interests)

- Janssen has contributed $500,000 to fund real world evidence generation on existing therapies through the Johnson & Johnson Alberta Health Innovation Partnership (JAHIP) within the province of Alberta.
  - JAHIP is currently reviewing a grant proposal from the University of Alberta to research the use of long-acting injectable antipsychotic therapy for Schizophrenia;
  - Alberta currently funds two long-acting injectable antipsychotic therapies manufactured by Janssen.

ANALYSIS:

- Brand manufacturers which have historically been unwilling to negotiate substantial discounts for their high cost products are only bringing value offers forward because of pending SEBs.
- SEBs may not continue to come to market if they are not able to obtain and maintain market share.

[redacted] 21(Intergovernmental Relations)

- Consistent with its mandate that includes increasing patient access to clinically and cost-effective drug treatment options, the pCPA will encourage a competitive environment that fosters SEB market growth and is conducive to long-term cost reductions and sustainability for public drug plans across Canada.
- Research and evidence development is important to inform policy decisions; Alberta supports partnerships to invest in research opportunities.