MEETING MATERIAL

Cliff #:1049709

PREPARED FOR: Honourable Terry Lake, Minister of Health

TITLE: April 11, 2016, Meeting between Minister Terry Lake and Ms. Mina Mawani, President and CEO, Crohn's and Colitis Canada

MEETING REQUEST/ISSUE: Ms. Mina Mawani of Crohn's and Colitis Canada, requested the meeting to discuss: GoHere washroom access program; drugs in the review process (Simponi and Entyvio); development of the provincial guidelines on subsequent entry biologics.

SHOULD MINISTRY STAFF ATTEND THIS MEETING: Barbara Walman, ADM, MBPSD or Eric Lun, Executive Director, Drug Intelligence & Optimization, or Tijana Fazlagic, Director, Formulary Management (Both Barbara Walman and Eric Lun may be out of town on April 11, 2016).

BACKGROUND:

- Crohn's and Colitis Canada was founded in 1974 as a national, volunteer-based registered charity focused on finding the cures for Crohn's disease and ulcerative colitis and improving the lives of children and adults affected by these diseases.
- Crohn's and Colitis Canada raises funds to invest in Crohn's and colitis research to
    - foster advances in prevention, treatments, cures and health policy;
    - educate patients, families, industry and governments about Crohn's and colitis;
    - increase public awareness of these chronic diseases and our organization; and
    - advocate to governments and stakeholders on behalf of those affected by Crohn's and Colitis.
- It is a registered charity. According to its 2015 filing, 85 percent of its funds are spent on research (scientific, medical, environmental) and 15 percent are spent on public education and other study programs. Its total revenue in 2015 was $14,234,152 and its total expenditure was $14,806,830 (the largest expenditure was $5,587,894 for research grants).[1]
- Government Partnerships include collaborations with the Canadian Institutes of Health Research (CIHR) and Genome Canada.
- Major industry supporters include AbbVie Corporation, manufacturer of adalimumab (Humira®); Janssen Inc., manufacturer of infliximab (Remicade®) and golimumab (Simponi®), Takeda Canada Inc., manufacturer of vedolizumab (Entyvio™); and Vertex Pharmaceuticals (Canada) Inc.

[1] See http://www.cra-arc.gc.ca/ebci/haip/srch/t3010form23-eng.action?b=118831486RR0001&fpe=2015-06-30&n=CROHN%27S+AND+COLITIS+FOUNDATION+OF+CANADA+FONDATION+CANADIENNE+DES+MALADIES+INFLAMMATOIRES&r=http%3A%2F%2Fwww.cra-arc.gc.ca%3A80%2Febci%2Fhaip%2Fsrch%2Fbasicsearchresult-eng.action%3Fk%3DCrohn%2527s%2520and%2520Colitis%2520Foundation%2520of%2520Canada%26amp%3Bs%3Dregistered%26amp%3B%3DSearch%26amp%3Bp%3D1%26amp%3Bb%3Dtrue%26amp%3B.

Go-Here Washroom Access Program

- One in every 150 Canadians lives with Crohn's or Colitis; one of the highest rates in the world.
- For individuals with Crohn's and Colitis, it is normal to use the washroom over 20 times each day.
- In addition to the physical symptoms of Crohn's and Colitis, there is often isolation and a debilitating social stigma that lowers the quality of life for many Canadians.
- Launched in Calgary on June 25, 2015, GoHere is an initiative led by Crohn's and Colitis Canada to increase access to washrooms, hoping to lead towards a national washroom access program. It is the first of its kind in Canada and a model for other national-level Crohn's and Colitis organizations to replicate.
- The initiative currently receives support from organizations in Ontario and Calgary.
- There are three major components to the initiative: GoHere Decal; GoHere Washroom Finder App; and GoHere Washroom Access Card.
    - GoHere Decal: participating businesses opt into the GoHere program, at no cost, and display a GoHere decal on their front window. The decal indicates to program users that the business allows their washrooms to be used by those needing the service.
    - GoHere Washroom Finder App: a mobile phone application (for iOS, Android and Blackberry) that helps users locate the closest available washroom in any city in Canada. The app indicates which businesses have opted into the initiative, and works with mapping software to show locations.
    - GoHere Washroom Access Card: the app includes a "personalized virtual washroom access card" outlining the user's proof of medical need, making access to washrooms an easier process. It also ensures that businesses are opening their washrooms up to legitimate users.
- There is an absence of legislation on washroom access for people living with chronic incontinence issues in Canada. The GoHere initiative is working towards establishing a favourable environment to start dialogue and eventual development of legislation and/or by-laws in municipalities and provinces, with the goal of securing access to washrooms usually available only to employees or customers for those living with medical conditions.
- British Columbia and P.E.I. are the only provinces to have no participating businesses at this point. There has been discussion regarding cooperation with municipal buildings in Burnaby and Vancouver.
- Crohn's and Colitis Canada is calling on municipalities, and the provincial and federal governments, to participate in the GoHere decal project by opening up and identifying public washrooms with the GoHere decal sticker on all government service buildings.

Drugs in the review process

- **Vedolizumab (Entyvio™):** On October 28, 2015, the Canadian Drug Expert Committee (CDEC) recommended that vedolizumab (Entyvio™) be listed for the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, loss of response to, or were intolerant to either conventional therapy or infliximab, a tumour necrosis factor (TNF) alpha antagonist, if specified clinical criteria were met and on the condition of a reduction in price to improve the cost-effectiveness to a level acceptable to drug plans.
- The Ministry is currently reviewing Entyvio™.

- The CDR is currently waiting for the manufacturer of Entyvio™ to send a submission for the Crohn's disease indication, after which it will be able to review the drug for this indication
- **Golimumab (Simponi®)**: On March 19, 2014, the Canadian Drug Expert Committee (CDEC) recommended that golimumab not be listed at the submitted price for the treatment of ulcerative colitis (UC).
- As of March 2016, the pan-Canadian Pharmaceutical Alliance (pCPA) is negotiating with the manufacturer.
- **Adalimumab (Humira):** On September 25, 2015, the CDR received a submission for Humira for treatment of Ulcerative Colitis. The CDR is currently reviewing the drug for this indication. The expected completion date is later in 2016.

Plans for managing Subsequent Entry Biologics (SEBs)

- Public payers fund the majority of biologics in Canada.
- Since their introduction more than 15 years ago, biologics have also represented the largest cost growth drivers for all payors. New generation biologics for rare or specialized diseases, some with extremely high prices, will continue to drive growth.
- The objective of funding SEBs should be: (1) provide access to safe and effective biologics which are clinically the same as the reference product, (2) decrease pharmaceutical spending by supporting the use of SEB's. Any achieved savings can then be used to fund other health priorities, which may or may not include other new medications.
- Health Canada's reviews of SEBs are thorough and without compromise to patient safety. The pCPA and the provincial and territorial drug coverage programs are working on a strategic framework for future negotiations with manufacturers of SEBs.
- **Infliximab (Inflectra™):** Inflectra™ is a SEB similar to its reference product Remicade®.
- **Remicade®** is indicated for several uses and BC as a province spent about $110M on 4,000 patients last FY, making Remicade® the most costly drug in BC. BC PharmaCare covers the majority (62%) or $68M of infliximab as Remicade® for about 2,850 patients.
- BC and Ontario led PCPA negotiation to lower the transparent price for Inflectra™ to 47 percent less than Remicade. If switching were supported, then the province could save more than $30M each year. If all payers took advantage of the lower cost, then the total provincial savings would be about $50M per year.
- Currently, BC PharmaCare funds Inflectra™ only for arthritic conditions and psoriasis for new infliximab patients and continues to cover Remicade® for those already on coverage. Health Canada has not yet approved Inflectra™ for Crohn's disease or ulcerative colitis, despite it being approved for these indications in other countries. Health Canada is expected to complete its review by June 2016.
- Efficacy, safety and cost-effectiveness of SEBs is also reviewed by the Common Drug Review (CDR) and a coverage recommendation issued to the participating drug plans.
- The Ministry reviews SEBs through its drug review process including the Drug Benefit Council and participated in pCPA, if applicable.

s.21

ADVICE:

- Biologics represent a group of useful but expensive group of drugs to treat a broad range of health conditions. These products are also major costs drivers threatening BC PharmaCare's sustainability.
- BC PharmaCare provides coverage for several biologics for various gastrointestinal conditions but has several patented medications under review, include: vedolizumab (Entyvio™), golimumab (Simponi®), and adalimumab (Humira).
- Subsequent entry biologics (SEB) are drugs that safe and effective, near identical copies of a reference biologic but may be priced significantly less. The first SEB covered by BC PharmaCare is Inflectra™ and PCPA negotiated a 47% transparent price reduction compared to the reference product.
- SEB's represent a significant opportunity for the health system to provide an equivalent product at must lower costs, so any savings achieved may be used for other health priorities, including possibly other new medicines.
- s.21

JOINT MINISTER MEETING: N
IF SO, CAN THIS MATERIAL BE SHARED: N

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Withheld pursuant to/removed as

s.21

INFORMATION BULLETS

Cliff# 1069336 – Honourable Shirley Bond, MLA Prince George-Valemount, re: s.22 and Crohn's disease and ulcerative colitis PharmaCare coverage.

REQUEST:

- On October 8, 2016, Honourable Shirley Bond received a form email from s.22 requesting she support "No Forced Switch for patients who have found a successful treatment" for Crohn's disease and colitis.
- The email did not mention a drug name but it can be assumed that s.22 is referring to infliximab (Inflectra™).

BACKGROUND:

- Crohn's and Colitis Canada is a registered charity that provides funds for research, patient programs, advocacy, and awareness in the area of Crohn's disease and colitis.
- Major corporate supporters of Crohn's and Colitis Canada include Abbvie Corporation (manufacturer of Humira®), Janssen Inc. (manufacturer of Remicade®), Takeda Canada Inc. (manufacturer of Entyvio®), and Vertex Pharmaceuticals (Canada) Inc. (no products approved yet but currently developing several Crohn's and colitis drugs).
- Crohn's and Colitis Canada has a form on its website (http://action.crohnsandcolitis.ca/) that sends form letters to MPPs and MLAs.

FINDINGS:

- Health Canada approved infliximab (Inflectra™), a biosimilar of infliximab (Remicade®), for the treatment of Crohn's disease and ulcerative colitis in June 2016.
- The price of Inflectra™ is approximately 50 percent of the reference product, Remicade®.
- Inflectra™ is currently under review by the Common Drug Review (CDR) for this indication. A final CDR recommendation is expected later in October 2016.
- British Columbia is co-leading the pan-Canadian Pharmaceutical Alliance (pCPA) negotiations with Pfizer Canada and is engaging physicians, both provincially and nationally, to educate physicians about biosimilars, implement coverage for treatment-naïve infliximab patients and work together towards switching from reference products to biosimilars.
- Janssen Inc. and other manufacturers of biologic medicines now facing marketplace challenges from biosimilar versions of their medications and have tried to raise fears in patients about the safety and efficacy of biosimilars like Inflectra™.

SUGGESTED MLA RESPONSE:

- While your letter does not mention a specific drug, I believe the drug to which you are referring is infliximab (Inflectra™), a drug which has been approved by Health Canada as a biosimilar of the drug infliximab (Remicade®) and which has been recently approved for treatment of Crohn's disease and ulcerative colitis.

- PharmaCare is the provincial program responsible for providing financial assistance for eligible prescription drugs and designated medical supplies. To ensure our services are sustainable, fair and effective, the Ministry of Health (the Ministry) requires all drugs undergo a rigorous, scientific review process. If the review process determines a drug has therapeutic advantages and cost-effectiveness advantages over established treatments, the Ministry considers adding the drug to the PharmaCare program formulary (a list of drugs eligible for coverage).
- The Ministry makes PharmaCare coverage decisions by considering existing PharmaCare policies, programs, priorities and resources, and the evidence-informed recommendations of an independent advisory body called the Drug Benefit Council (the DBC). The DBC's advice to the Ministry is based upon a review of many considerations, including: available clinical and pharmacoeconomic evidence (pharmacoeconomics is the branch of economics which compares the value of drugs); clinical practice and ethical considerations; input from patients, caregivers and patient groups provided through the Ministry's *Your Voice* web page; and the recommendations of the national CDR. The Ministry may also participate in the pCPA negotiations with the manufacturer if applicable and consider the outcomes of the pCPA's negotiation when making a listing decision for the drug.
- Inflectra™ is a biosimilar version of infliximab based upon the reference product Remicade®. It was approved by Health Canada for the treatment of Crohn's disease, fistulising Crohn's disease and ulcerative colitis based upon the established similarity between Inflectra™ and Remicade® in patients with rheumatoid arthritis and ankylosing spondylitis, as well as newly submitted physiochemical and biological data pertinent to the review of the drug for Crohn's disease and ulcerative colitis. Health Canada will only approve a biosimilar if there are no clinically meaningful difference between the biosimilar and the reference product.
- PharmaCare provides coverage for infliximab (Remicade®) and adalimumab (Humira®) for the treatment of Crohn's disease. For ulcerative colitis, BC PharmaCare currently does not have any biologic product listed for this use. As of October 12, 2016, the CDR is currently reviewing the manufacturer submission for Inflectra™. When this review is complete, the pCPA and PharmaCare will be making decisions regarding next steps for the coverage of this drug.
- Inflectra™ is also approved for the treatment of rheumatoid arthritis, ankylosing spondylitis, plaque psoriasis and psoriatic arthritis and since February 2016, is an eligible PharmaCare benefit for these indications.
- The CDR is also currently reviewing two other drugs relevant to this discussion, budesonide (Cortiment) for Crohn's disease, and vedolizumab (Entyvio™) for the treatment of ulcerative colitis and Crohn's disease. In addition to these drugs, the CDR and BC PharmaCare currently also have more than 50 other medications for other diseases and illnesses under review.
- In light of the many other drugs under review, ongoing budget pressures, and the need to ensure that BC PharmaCare remains a sustainable program, it is imperative that the Ministry consider providing coverage for biosimilars like infliximab (Inflectra™) so we are able to be able to consider provide funding for other new drugs or other health priorities.
- Having biosimilars available provides the health system an important alternative that is equally effective but much less expensive compared to the reference product. In the instance with Inflectra™, this biosimilar is currently priced about 50 percent less than Remicade®. So

if Inflectra™ is used instead of Remicade®, patients and taxpayers could save approximately $10,000 to $43,000 (depending on the dosage) per year per patient since Remicade® therapy costs approximately $20,000 to $90,000 per year. In Fiscal Year 2014/15, BC PharmaCare spent around $950 million on all drugs and spending on Remicade® specifically was BC PharmaCare's top drug expenditure at $65 million. This information can be found in BC PharmaCare's trend report at the following site: http://www2.gov.bc.ca/assets/gov/health/health-drug-coverage/pharmacare/pcaretrends2014-15.pdf

- In general, determining which medications are most appropriate, including switching, should involve the patient and the prescriber and/or pharmacist. In making those decisions, it is important to have a balanced consideration of relevant information including clinical, cost, and coverage, and if a decision to switch is made, it is important to have a monitoring plan to ensure that switching medications are done in a safe and appropriate manner.

Program ED/Branch/Division: Eric Lun, Executive Director, Drug Intelligence & Optimization Branch, Medical Beneficiary and Pharmaceutical Services Division,
Date: October 19, 2016

MINISTRY OF HEALTH
INFORMATION BRIEFING NOTE

Cliff # 1073921

PREPARED FOR: Honourable Terry Lake, Minister - **FOR INFORMATION**

TITLE: Crohn's and Colitis Treatments and Biosimilar Drugs

PURPOSE: To provide background information on the Ministry of Health's (the Ministry) approach to PharmaCare listings of biosimilar drugs, particularly infliximab (Inflectra®), and patient switching.

BACKGROUND:

- On November 12, 2016, Mina Mawani of the Canadian Society of Intestinal Research (GI Society) published an article in the Vancouver Sun, "Crohn's and colitis treatment matter of trial and error" (Page E04).
- The article claims that "Once a patient has found a treatment that works for them, the last thing they want is to be forced to switch to another medication. Unfortunately, Pharmacare may soon ask some of the 25,000 Crohn's or colitis patients in British Columbia to do exactly that."
- The article also quotes Nova Scotia Health Minister, Leo Glavine, that "patients currently on Remicade will not be forced to switch to the biosimilar" as a condition of Nova Scotia listing Inflectra as a benefit of their drug plan.
- After the statement by Minister Glavine was made, Nova Scotia's Department of Health and Wellness, clarified to the media: *"Remicade is currently in use in Nova Scotia for the treatment of Crohn's. The biosimilar for Remicade is approved by Health Canada for use in Canada, but it is not currently approved for coverage under Nova Scotia's drug plan for the treatment of Crohn's and Colitis. We expect to be covering it for that purpose soon, but patients currently on Remicade will not be forced to switch to the biosimilar at that time".*

DISCUSSION:

- Infliximab (Inflectra) is a biosimilar drug based on the reference innovator product, infliximab (Remicade®).
- In Canada, biosimilars are regulated in the same way as innovative biological products. The Ministry relies on Health Canada's review process to assess drug safety. Health Canada's review of biosimilars is very thorough without compromise to patient safety.
- Health Canada approved Inflectra in 2014. Inflectra's reference product Remicade has been approved by Health Canada and has been marketed in Canada for many years.
- PharmaCare provides coverage for Remicade as a Limited Coverage drug for treatment of rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, plaque psoriasis, and Crohn's disease.
- Since February 2016, PharmaCare has provided coverage for infliximab (Inflectra) for rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and plaque psoriasis.

- In June 2016, Health Canada approved Inflectra for Crohn's disease and ulcerative colitis, and the review by the national Common Drug Review (CDR) was completed in October 2016. The CDR reviews efficacy, safety, and cost-effectiveness data as part of its review process, and issues a coverage recommendation to participating drug plans, including PharmaCare.
- BC, along with the other Canadian drug plans, participates in the pan-Canadian Pharmaceutical Alliance (pCPA). BC, along with Ontario, co-led pCPA negotiations with the manufacturer to ensure Inflectra provides good value for all Canadians.
- Effective November 1, 2016, PharmaCare provides coverage for Inflectra for Crohn's disease and ulcerative colitis. Before this, PharmaCare did not cover any biologics for ulcerative colitis.
- For Crohn's disease, PharmaCare covers both Remicade and Inflectra for patients who were granted a Special Authority (SA) for Remicade before November 1, 2016.
- PharmaCare covers only Inflectra for patients using infliximab for the first time for ulcerative colitis.
- At the present time, BC PharmaCare's coverage policy for biosimilars does not require patients to switch from the more expensive innovator biologic medicine to an equally effective but less expensive biosimilar.
- Public drug plans including BC PharmaCare, Health Canada, CADTH, and other government agencies all have a strong interest with biosimilars. There is an interest to explore a national approach to increase the awareness of biosimilars, better understand the evidence around switching, and explore ways to increase the use of biosimilars. In order to have meaningful discussion, it will be important to also engage patients, clinicians, private payers, and the pharmaceutical industry along the way.
- Several European countries, such as Norway and the United Kingdom, have adopted biosimilar switching without any issues, so we are aware that switching can be done safely.
- Inflectra costs about 50 percent less than the reference product Remicade. In FY 15/16, BC PharmaCare and private payers spent over $100 million on Remicade.
- PharmaCare is under significant budget pressure. Biosimilars like Inflectra represent an equally effective product but also an important cost savings opportunity for the health system, which can allow funds to be used for other health priorities.
- BC PharmaCare's Reference Drug Program (RDP) represents a different but related drug coverage policy approach, which supports the use of the most cost-effective drug within specific drug class. In the 2016 RDP modernization efforts, there were up to an estimated 90,000 patients who could consider switching within six different drug classes in order to maintain full benefit coverage. In comparison for example, in FY 14/15, there were only about 4,000 total patients on Remicade throughout BC.

ADVICE:

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Date: December 2, 2016