Dear [redacted]

Re: Your request for access to information under Part II of the Access to Information and Protection of Privacy Act (the Act) [Our File #: HCS 019 2014]

This is to confirm that on April 3, 2014, the Department of Health and Community Services (the Department) received your request for access to the following records/information:

“Any and all records relating to subsequent entry biologics, SEBs, follow on biologics or biosimilars (hereinafter referred to as “SEBs”) dated January 1, 2012 until the date of this request, including but not limited to:

- Any and all records of internal Health and Community Services ("Ministry") (or related agencies or boards within the purview of the Ministry) discussions, memoranda (including cabinet memos), briefing documents, policy, white papers research papers, internal research reports, consultation documents, agendas, proposals, meetings (including board and advisory committee meetings) or correspondence regarding SEBs; and

- Any and all records of Ministry correspondence, discussions, memoranda, briefing documents, agendas, proposals, meetings or submissions to, from or with the Canadian Agency for Drugs and Technologies in Health ("CADTH"), CADTH staff, other federal or provincial authorities, industry or any other individuals or organizations regarding SEBs.”

On April 23, 2014, the Department wrote to notify you that it was extending the 30-day time limit for responding to your request for an additional 30 days. The Department advised at that time that it expected to respond to your request by or before June 3, 2014.
On May 8, 2014, the Department wrote to notify you that the records you requested may have contained information that, if disclosed, might affect the business interests of a third party and, as required by section 28 of the Act, the Department had given written notice to a third party in that regard. On May 14, 2014 the third party provided consent to disclose those records.

The Department has reviewed your request in the context of the Act and is able to provide you with partial access to the information that you have requested. Portions of the enclosed records have been removed in accordance with subsections 23(1)(a)(i), 23(1)(b) and 27(1)(b) of the Act. Those sections provide as follows:

"23 (1) The head of a public body may refuse to disclose information to an applicant if the disclosure could reasonably be expected to

(a) Harm the conduct by the government of the province of relations between that government and the following or their agencies:

(i) The government of Canada or a province,

[...]

(b) Reveal information received in confidence from a government, council or organization listed in paragraph (a) or their agencies.

[...]

"27 (1) The head of a public body shall refuse to disclose to an applicant information that would reveal

[...]

(b) commercial, financial, labour relations, scientific or technical information of a third party, that is supplied, implicitly or explicitly, in confidence and is treated consistently as confidential information by the third party;

[...]

Please note that the following information has been fully redacted from the package:

- Pages 116 - 133, 186 – 209, 293 – 295, 298 - 304 have been fully redacted under Subparagraph 23(1)(a)(i) and Subsection 23(1)(b) of the Act.

Pages 153, 213, 232, 294, 303 have been withheld in their entirety as non-responsive and pursuant to s.23(1)(a)(i), 23(1)(b).

As per our conversation on May 16, 2014 we are providing the links to the attachments referenced on page one of the records package. These attachments are all available on the Health Canada Website. We are also providing a link to the document Subsequent Entry Biologics – Emerging Trends in Regulatory and Health Technology Assessment Frameworks Environmental Scan.

Section 43 of the Act provides that you may ask the Information and Privacy Commissioner to review this partial refusal of access or you may appeal the refusal to the Supreme Court Trial Division. A request to the Information and Privacy Commissioner shall be made in writing within 60 days of the date of this letter or within a longer period that may be allowed by the Commissioner.

The address and contact information of the Information and Privacy Commissioner is as follows:

Office of the Information and Privacy Commissioner
34 Pippy Place
P. O. Box 13004, Stn. A
St. John’s, NL. A1B 3V8

Telephone: (709) 729-6309
Facsimile: (709) 729-6500

Please be advised that a copy of our response to your request will be published on the Office of the Public Engagement’s website five business days after the response is mailed to you. If you have any further questions, please feel free to contact Cheryl Joy, the Department’s ATIPP Coordinator, at (709) 729-7010, or by email at cheryljoy@gov.nl.ca.

Sincerely,

Bruce Cooper
Deputy Minister

/cj
/Encl.
NOTICE - Release of Guidance for Sponsors: Information and Submission Requirements for Subsequent Entry Biologics (SEBs)

Health Canada is pleased to announce the release of the finalized Guidance for Sponsors: Information and Submission Requirements for Subsequent Entry Biologics (SEBs).

(See attached file: seb-pbu_e 2010.pdf)

The objective of this document is to provide guidance to sponsors to enable them to satisfy the information and regulatory requirements under the Food and Drugs Act and Regulations for the authorization of subsequent entry biologics (SEBs) in Canada.

Two draft versions of this guidance document have been shared for consultation purposes on February 27, 2008, and March 27, 2009. Consultation Reports are available upon request to the address below. As no transition period is required, the guidance will be effective on the date of publication.

Note: The "Guidance for Sponsors: Information and Submission Requirements for Subsequent Entry Biologics (SEBs)" is being published concurrently with the following two updated guidance documents.

Publication of Updates to Guidance Document: Data Protection under C.08.004.1 of the Food and Drug Regulations (See attached file: data_donnee_protection-eng 2010.pdf)

Publication of Updates to Guidance Document: Patented Medicines (Notice of Compliance) Regulations (See attached file: pmreg3_mbreg3-eng 2010.pdf)

BGTD_PPD_DPP@HC-SC.GC.CA
Special Projects Unit,
Office of Policy and International Collaboration Biologics and Genetic Therapies Directorate Health Canada Address Locator 0702A
200 Tunney’s Pasture Driveway
Ottawa ON, K1A 0L2

Telephone: 613-946-5155
Fax: 613-952-5364

AVIS - Publication des Lignes directrices à l’intention des promoteurs :
Exigences en matière de renseignements et de présentation relatives aux produits biologiques ultérieurs (PBU)

Santé Canada a le plaisir d'annoncer la publication dans leur version définitive des Lignes directrices à l'intention des promoteurs : Exigences en matière de renseignements et de présentation relatives aux produits biologiques ultérieurs (PBU).

(See attached file: seb-pbu_f_2010.pdf)

Ce document fournit aux promoteurs qui veulent faire homologuer un PBU les directives leur permettant de satisfaire aux exigences en matière de renseignements à fournir et aux dispositions de la Loi sur les aliments et drogues et de son règlement.

Deux versions préliminaires ont été diffusées à des fins de consultation le 27 février 2008 et le 27 mars 2009. Les rapports sur les résultats de ces consultations peuvent être obtenus sur demande à l'adresse fournie ci-après. Comme aucune période de transition n'est requise, les lignes directrices entrent en vigueur à compter de leur date de publication.

Remarque : Les Lignes directrices à l'intention des promoteurs : Exigences en matière de renseignements et de présentation relatives aux produits biologiques ultérieurs (PBU) sont publiées en même temps que les deux lignes directrices modifiées suivantes.

Publication des mises à jour apportées à la Ligne directrice : La protection des données en vertu de l'article C.08.004.1 du Règlement sur les aliments et drogues
(See attached file: data_donnee_protection-fra_2010.pdf)

Publication des mises à jour apportées à la Ligne directrice : Règlement sur les médicaments brevetés (avis de conformité) (See attached file: pmreg3_mbreg3-fra_2010.pdf)

BGTD_PPD_DPP@HC-SC.GC.CA
Unité des projets spéciaux
Bureau de la politique et de la collaboration internationale Direction des produits biologiques et des thérapies génétiques Santé Canada Indice de l'adresse 0702A 200, promenade du pré Tunney Ottawa (Ontario) K1A 0L2

Téléphone : 613-946-5155
Télécopieur : 613-952-5364
Publicly available on Health Canada Website

Links to the attachments provided to applicant


Pages 90 – 115

French version of documents


Dear Patricia,

Join us at our National Summit on Subsequent Entry Biologics (SEBs) on May 14 at the Fairmont Chateau Laurier in Ottawa. This program has been designed to explore the scientific analysis and implications related to the entry of this new generation of biologic therapies.

We are providing you with a national forum for dialogue. Presenting panels consisting of scientists, clinicians, regulatory, health technology assessment and payer experts will convene to focus on issues for consideration when evaluating SEB products. Chaired by Dr. Jonathan Kay of the University of Massachusetts Medical School, this inaugural event will help establish a scientific discussion of the key issues stemming from the creation of the Draft Health Canada Guidance as posted in March 2010.

A copy of the program is available here. I would like you to consider attending this important gathering. Your perspective and expertise would be a valuable contribution to the outcomes from the program.

Please let Matt Aleksic (matt.aleksic@biotech.ca) know whether or not you or a designate can make it to this exciting event. I hope to see you there.

Sincerely,

Peter A. Brenders
President & CEO
BIOTECanada

This e-mail was sent from BIOTECanada (peter.brenders@biotech.ca) to pclark@gov.nl.ca.
Hi, please see below and provide your thoughts on whether this is something we should participate in.

Thanks, C 😊

From: Laura Gibson [mailto:laura.gibson@pdc.ca]
Sent: Tuesday, May 08, 2012 5:52 PM
To: Stockley, Colleen L.
Cc: Courtney Nelson
Subject: Interview Request for Subsequent Entry Biologics Study

Dear Ms. Colleen Stockley,

PDCI Market Access is seeking your participation in an important study on generic biologic drugs that will be entering the market over the next few years.

Biologic drugs account for approximately 18 percent of the global pharmaceutical market and a significant number of patents on these products will expire in the next five years. The global market for subsequent entry biologics (SEBs) has been estimated to grow to almost $20 billion USD by 2014. SEBs, which are also referred to as biosimilars, have been expected to improve patient access to biologic drugs while providing substantial cost-savings for payors. However, almost three years since Canada’s first SEB received its NOC, some critics are unsure the projected benefits of increased SEB use will come to fruition.

We are seeking input from key payors on this important issue and will be conducting short (20-30 minute) interviews aimed at understanding their perceptions of the evolution of SEBs in Canada. We will share the anonymized results of our interviews with all participants so that a better appreciation of how regulators, payors, clinicians, and patients foresee this issue evolving over the next few years can be achieved. Payors will particularly benefit by gaining insights on how other drug plans view the evolution of SEBs and their cost-saving potential.

Some of the questions this study intends to answer include:

- What are the implications of expanding use of SEBs for public drug plans in Canada?
- What kinds of reimbursement and pricing policies might be implemented to maximize the cost-saving potential of SEBs?
- How will interchangeability policies be addressed given they are often tied to Health Canada’s statement that a product is bioequivalent?

PDCI intends to publish this study, but will maintain confidentiality such that participants will be identified only by their stakeholder category (payer, clinician, politician, industry industry organization member, patient/patient advocate) and province.

Your participation in this study is greatly appreciated. Please feel free to respond via email or phone at the coordinates below. We will follow up later this week by phone to confirm your participation.
Please do not hesitate to contact us with any questions you may have.

Laura Gibson
Research Assistant
PDCI Market Access Inc.

Tel: +1 613 742 8225 Ext. 48 Fax: +1 613 742 7675
340 Albert Street, Suite 1950, Ottawa, ON K1R 7Y6 Canada
www.pdci.ca
Joy, Cheryl

From: Ryan, Colleen
Sent: Wednesday, May 09, 2012 10:45 AM
To: Kavanagh, Kelly; Clark, Patricia
Cc: Stockley, Colleen L.
Subject: RE: Subsequent Entry Biologics--CDR submission requirements survey--due Friday, May 11, 2012

Please respond to the two questions below. Your comments on this will be welcome.

1. Is your jurisdiction in agreement with a review of an indication for a SEB based on extrapolated evidence (when it is acceptable to Health Canada)? I guess if HC is comfortable and accepts this info I see no reason why we would not.
2. Does your plan require clinical data for each indication under consideration for a coverage decision? I think we would require clinical data for each indication.

Colleen Ryan, BSc. Pharm
Supervisor
Pharmaceutical Services Division
Department of Health and Community Services
57 Margaret's Place
P.O.Box 8700
St. John's, NL A1B 4J6
http://www.health.gov.nl.ca/health/prescription

Phone: 709-729-1645
Fax: 709-729-2851
Email: colleenryan@gov.nl.ca

From: Kavanagh, Kelly
Sent: Wednesday, May 09, 2012 9:19 AM
To: Clark, Patricia; Ryan, Colleen
Cc: Stockley, Colleen L.
Subject: RE: Subsequent Entry Biologics--CDR submission requirements survey--due Friday, May 11, 2012

I don't believe SEBs will be applying for interchangeability. From my little amount of knowledge on these products, I don't believe HC will be issuing a CRP for these products. So these will all be going through CDR for review.

I don't know anything about the 2 questions below. They are outside of my scope 😊

From: Clark, Patricia
Sent: Wednesday, May 09, 2012 8:30 AM
To: Ryan, Colleen; Kavanagh, Kelly
Cc: Stockley, Colleen L.
Subject: FW: Subsequent Entry Biologics--CDR submission requirements survey--due Friday, May 11, 2012

Hi Colleen/Kelly

Can you review and provide feedback?
Thanks
Trish

Patricia Clark, Ph.C
Manager
Program Policy and Professional Services
Department of Health and Community Services
T: 709-729-6507  F: 709-729-2851
pclark@gov.nl.ca

From: Elaine MacPhail [mailto:ElaineM@cadth.ca]
Sent: Tuesday, May 08, 2012 7:55 PM
To: DPAC Formulary Working Group
Cc: Elaine MacPhail
Subject: Subsequent Entry Biologics--CDR submission requirements survey--due Friday, May 11, 2012

Hi All,

In follow up to today’s teleconference call, please respond to the brief survey near the bottom of this email by end of day, Friday, May 11, 2012, to indicate whether your jurisdiction requires clinical data in support of each Health Canada approved indication for subsequent entry biologics (SEBs).

In the inquiry that we have received, the manufacturer has indicated that it is going to submit a SEB for approval to Health Canada. The manufacturer has clinical data for two or the three indications for which it is seeking approval. The manufacturer is going to ask Health Canada to approve the third indication by extrapolation. As I mentioned, Health Canada can approve SEBs by extrapolating information. The manufacturer has asked us if Health Canada approves the third indication using extrapolated data, will the drug be eligible for review through the CDR process without clinical data for the third indications. In order to respond we need to know whether your jurisdiction would require clinical data for the third indication for a coverage decision. For your information, I’m attaching the document that was circulated as background for Subsequent Entry Biologics agenda item today.

Please respond to the two questions below. Your comments on this will be welcome.

1. Is your jurisdiction in agreement with a review of an indication for a SEB based on extrapolated evidence (when it is acceptable to Health Canada)?
2. Does your plan require clinical data for each indication under consideration for a coverage decision?

Again, please get back to me by end of day Friday, May 11, 2012.

Thanks,

Elaine

Elaine MacPhail
Senior Advisor, Programs
Canadian Agency for Drugs and Technologies in Health
600-865 Carling Ave
Ottawa ON K1S 5S8
Tel: (613) 226-2553, ext. 1230
Email: (elainem@cadth.ca)
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Joy, Cheryl

From: Dennis Chan <dennis@pathwayadvisory.com>
Sent: Thursday, January 17, 2013 5:19 PM
To: Judy McPhee; Leanne Jardine; brcairns@gov.pe.ca; kevin.potheier@gnb.ca; Ryan, Colleen; Clark, Patricia; Kathleen.Shipp@gov.ns.ca
Subject: Follow on from meeting on Remicade SEB
Attachments: Celltrion clinical trials Jan 16 2013.pdf

Hi Everyone,

I hope you've all had a great start to the new year.

I wanted to follow up on the meeting of late November with some materials on the clinical trials conducted for Remsima, which you may recall is the Subsequent Entry Biologic for Remicade. I apologize for the time taken to get this to you. My client worked hard on this, but he had many necessary internal approvals from within his organization to navigate around, and the Christmas vacation period posed additional difficulties.

Attached are two abstracts from Celltrion's (the manufacturer of Remsima) presentation of data from the Remsima trials. No information has been omitted, and my client has attached a hyperlink in the document to the EULAR abstract site for your reference.

Should you find the attached information to be helpful, my client has no concerns with you forwarding it to any of your counterparts in other provinces for their reference as well.

If you have any questions on this or the overall issue, or if there is anything else I can do, please do not hesitate to contact me.

Lastly, thanks again for your suggestions on a different email address (i.e. moving away from my salon's email address)! Please note I am sending this from dennis@pathwayadvisory.com.

Thanks,

Dennis
As per your request, two Abstracts from Celltrion’s infliximab Second Entry Biologic (SEB) CT-P13 clinical program presented at the European League Against Rheumatism (EULAR) Congress hosted in Berlin, Germany, from June 6-9, 2012 are enclosed.

**Abstract 1**

**FR10143**
A RANDOMIZED, DOUBLE-BLIND, PHASE 3 STUDY DEMONSTRATES CLINICAL EQUIVALENCE OF CT-P13 TO INFliximab WHEN CO-ADMINISTERED WITH METHOTREXATE IN PATIENTS WITH ACTIVE RHEUMATOID ARTHRITIS

D. Yoo 1,*, P. Miranda 2, M. Piotrowski 3, E. Raminterre 4, V. Kovalenko 5, N. Prodanovic 6, M. Tee 7, S. Gutierrez-Ureña 8, R. Jimenez 9, O. Zamani 10, S. Lee 11, H. Kim 12, W. Park 13, U. Müller-Ladner 14
1Hanyang University Medical Center, Seoul, Korea, Republic Of, 2Centro de Estudios Reumatologicos, Santiago, Chile, 3REUMED, Lubin, Poland, 4Brookshire Memorial Hospital, Davao City, Philippines, 5National Scientific Center, Kiev, Ukraine, 6Clinical Center Banja Luka, Banja Luka, Bosnia and Herzegovina, 7Medical Center Manila, Manila, Philippines, 8Antiguo Hospital Civil de Guadalajara, Guadalajara, Mexico, 9Centro de Estudios Investigaciones Clinicas, Viña del Mar, Chile, 10Rheuma Zentrum Favoriten, Vienna, Austria, 11University of New Mexico, Albuquerque, United States, 12Celltrion, 13Inha University Hospital, Incheon, Korea, Republic Of, 14Kerchoff-Klinik GmbH, Bad Nauheim, Germany

**Background:** CT-P13 was developed as a biosimilar product to infliximab (Remicade®), a chimeric monoclonal antibody approved in the European Union in 1999 for the treatment of rheumatoid arthritis (RA), ankylosing spondylitis, Crohn’s disease, ulcerative colitis, psoriasis, and psoriatic arthritis.

**Objectives:** To compare the clinical efficacy and overall safety of CT-P13 with those of infliximab in patients with active RA.

**Methods:** Six hundred six patients with active RA despite previous treatment with disease-modifying anti-rheumatic drugs including methotrexate were randomized 1:1 to receive either CT-P13 or infliximab (3 mg/kg, 2-hour IV infusion per dose) plus methotrexate and folic acid. The treatment period consisted of a dose-loading phase (weeks 0, 2, and 6) and a maintenance phase (weeks 14, 22, and 30). The primary endpoint was the proportion of patients achieving 20% improvement in ACR20 at week 30. The exact binomial test with 95% confidence intervals (CIs) for ACR20 within a margin of ± 15% was used to define equivalence between the 2 treatments. Secondary efficacy and safety endpoints (including ACR50/70; frequency of adverse events [AEs]) were also evaluated. This report presents results up to study week 30 (as approved by the European Medicines Agency).
Results: At week 30, ACR20 response rates were 60.9% for CT-P13 vs 58.6% for infliximab (2% difference; 95% CI −6% to 10%) in the intent-to-treat population, and 73.4% vs 69.7% (4% difference; 95% CI: −4% to 12%) in the per-protocol population. Outcomes for the secondary efficacy and safety endpoints were also comparable as follows. ACR50 rates in the per-protocol population were 42.3% vs 40.6% (2% difference; 95% CI −7% to 10%), and ACR70 rates were 20.2% vs 17.9% (2% difference; 95% CI −5% to 9%) in the CT-P13 and infliximab arms, respectively, all indicating equivalence in clinical efficacy at week 30. AEs considered by the investigators to be related to study treatment were reported for 106 (35.2%) patients and 108 (35.9%) patients in the CT-P13 and infliximab arms, respectively. Related AEs due to infection were reported in 46 (15.3%) patients and 51 (16.9%) patients in the CT-P13 and infliximab arms, respectively. 15 (5%) CT-P13-treated and 17 (6%) infliximab-treated patients experienced at least 1 infusion reaction. Tuberculosis was reported in 3 patients in the CT-P13 arm and in 1 patient in the infliximab arm.

Conclusions: CT-P13 and infliximab are equivalent in terms of ACR20 in patients with RA. In addition, CT-P13 was well tolerated, with an efficacy and safety profile comparable to that of infliximab up to week 30.


Citation: Ann Rheum Dis 2012;71(Suppl3):359

Abstract Session: RA anti-TNF
Abstract 2

OP0167
A RANDOMIZED, DOUBLE-BLIND, PHASE 1 STUDY DEMONSTRATES EQUIVALENCE IN PHARMACOKINETICS, SAFETY, AND EFFICACY OF CT-P13 AND INFlixIMAB IN PATIENTS WITH ANKYLOSING SPONDYLITIS

W. Park 1,* P. Hrycay 2, V. Kovalenko 3, P. Miranda 4, S. Gutierrez-Ureña 5, Y. Lee 6, M. Lim 1, C. Ahn 7, H. Kim 8, D. Yoo 9, J. Braun 10
1Inha University Hospital, Incheon, Korea, Republic Of, 2Prywatna Praktyka Lekarska Reumatologiczno-Immunologiczna, Poznań, Poland, 3National Scientific Center, Kiev, Ukraine, 4Centro de Estudios Reumatológicos, Santiago, Chile, 5Antiguo Hospital Civil de Guadalajara, Guadalajara, Mexico, 6Kyung Hee University Hospital, Seoul, Korea, Republic Of, 7UT Southwestern Medical Center, Dallas, United States, 8Celltrion, Incheon, 9Hanyang University Medical Center, Seoul, Korea, Republic Of, 10Praxis Dr. Jürgen Braun, Mainz-Gonsenheim, Germany

Background: CT-P13 was developed as a biosimilar product to infliximab (Remicade®), a chimeric monoclonal antibody approved in the European Union in 1999 for the treatment of rheumatoid arthritis (RA), ankylosing spondylitis (AS), Crohn's disease, ulcerative colitis, psoriasis, and psoriatic arthritis.

Objectives: To compare the pharmacokinetic (PK) profile of CT-P13 with that of infliximab at steady state in terms of area under the concentration-time curve over a dosing interval (AUCr) and observed maximum serum concentration (Cmax,ss), and evaluate the efficacy and overall safety of both treatments in patients with AS.

Methods: Two hundred fifty patients with active AS were randomized 1:1 to receive either CT-P13 or infliximab (5 mg/kg, 2-hour IV infusion per dose) at weeks 0, 2, and 6 (dose-loading phase) and at weeks 14, 22, and 30 (maintenance phase). Ratios of geometric means of primary PK parameters (AUCr and Cmax,ss) from the 2 treatment arms between weeks 22 and 30 were subjected to ANCOVA analysis at 90% confidence intervals (CIs). Efficacy measures (including ASAS20 and ASAS40) and safety parameters (including the incidence of adverse events [AEs]) were also evaluated. This report presents PK, efficacy, and safety results up to week 30 (as approved by the European Medicines Agency).

Results: The mean (% CV) AUCr was 34855.45 (34.3%) µg-h/mL and 34688.71 (45.4%) µg-h/mL in the CT-P13 and infliximab arms, respectively. The mean (% CV) Cmax,ss was 153.52 (27.6%) µg/mL and 150.39 (26.9%) µg/mL in the CT-P13 and infliximab arms, respectively. The ratio (%) between the geometric means of the AUCr and Cmax,ss values in the CT-P13 and infliximab arms were 104.1% (90% CI 93.9% to 115.4%) and 101.5% (90% CI 94.6% to 108.9%), respectively, between weeks 22 and 30, indicating PK equivalence in terms of AUCr and Cmax,ss.
Secondary parameters at week 30 were also comparable, including ASAS20 and ASAS40 response rates (70.5% for CT-P13 vs 72.4% for infliximab and 51.8% vs 47.4%, respectively). AEs considered by the investigators to be related to study treatment were reported in 57 (44.5%) patients and 58 (47.5%) patients in the CT-P13 and infliximab arms, respectively. Related AEs due to infection were reported for 24/128 (18.8%) patients and 22/122 (18.0%) patients in the CT-P13 and infliximab treatment groups, respectively. AEs due to infusion reactions considered related to study drug were reported in 5 patients in the CT-P13 arm, and 6 patients in the infliximab arm. Tuberculosis was reported in 2 patients in the CT-P13 arm and in 1 patient in the infliximab arm.

Conclusions: CT-P13 and infliximab are equivalent in terms of AUCt and Cmax,ss in patients with AS. In addition, CT-P13 was well tolerated, with an efficacy and safety profile comparable to that of infliximab up to week 30.

Disclosure of Interest: W. Park: None Declared, P. Hrycay: None Declared, V. Kovalenko: None Declared, P. Miranda: None Declared, S. Gutierrez-Ureña: None Declared, Y. Lee: None Declared, M. Lim: None Declared, C. Ahn: None Declared, H. Kim Employee of: Celltrion, D. Yoo: None Declared, J. Braun: None Declared

Citation: Ann Rheum Dis 2012;71(Suppl3):111

Abstract Session: Spondyloarthritis Clinical aspects and treatment

In the following sections, Janssen has offered some points of consideration – and has posed some questions, based on Health Canada's 2010 Guidance on Submission Requirements for Subsequent Entry Biologics1. At this point in time, detailed analysis of the Celltrion clinical program is hindered by the limited data contained in these abstracts. Publication in a peer-reviewed journal may provide further disclosure of details, and allow for a more thorough analysis of these data.

Celltrion Phase 3 Trial in Rheumatoid Arthritis2

The objective of this trial was to compare the clinical efficacy and overall safety of CT-P13 with REMICADE® in patients with active Rheumatoid Arthritis (RA).

- The primary end-point evaluated was the American College of Rheumatology 20% improvement score (ACR20)2 at week 30. Clinical experts have commented on primary endpoints for assessing similarity:

  "Dr. Feagan and Dr. Kay discussed suitable clinical trial endpoints, and suggested that continuous outcomes (e.g., change in DAS28 over time in rheumatoid arthritis) rather than dichotomous outcomes (e.g., ACR20 in rheumatoid arthritis or a fall of the Crohn's Disease Activity Index (CDAI) of >70 points defining response in Crohn's disease) may be more sensitive for the determination of clinical comparability." 4
• Given that ACR20 was evaluated at week 30, one may ask if the trial design allowed for sufficient assessment of potential differences in onset of action prior to week 30?

• The protocol evaluated CT-P13 and REMICADE® concomitant with methotrexate, and did not compare CT-P13 monotherapy vs REMICADE® monotherapy

• A single dose (3 mg/kg) of CT-P13 was studied:
  a. Given the broader range of approved REMICADE® dosing (up to 10 mg/kg), this trial does not adequately assess potential differences in potency.
  b. Similarly, this trial does not evaluate CT-P13 dose escalation, limiting comparisons versus REMICADE® at higher doses

• The immunogenicity rates observed at week 30 were similar between CT-P13 and REMICADE® (40.2% vs 39.9% respectively). However, this is significantly higher than the rates observed in REMICADE® trials (approximately 10% of patients developed anti-drug antibodies)⁵. What factors may account for the different rate of immunogenicity reported for REMICADE®? It may be appropriate to inquire with the authors if the assay used in this trial had been appropriately validated for the detection of both CT-P13 and REMICADE® antibodies.

**Celltrion Phase 1 Trial in Ankylosing Spondylitis**⁶

The objective of this trial was to compare the pharmacokinetic (PK) profile of CT-P13 with that of REMICADE® at steady state in terms of area under the concentration-time curve over a dosing interval (AUCτ) and observed maximum serum concentration (Cmax,ss).

• The Celltrion study design featured:
  a. repeated-dose, with Cmax measured at steady-state (between weeks 22-30)
  b. parallel design
  c. 90% Confidence Intervals

• One should review the Celltrion clinical trial design in the context of Health Canada’s guidance document to SEB sponsors published in 2010 and public commentary to stakeholders:

  “Dr. Wang stated that comparative PK studies should be conducted to detect potential differences between the SEB and RBD by performing single-dose, cross-over studies in sensitive, homogenous populations using a dose that is most sensitive to detect differences through subcutaneous or intramuscular routes of administration... Dr. Wang clarified that Health Canada recommends 95 percent instead of 90 percent confidence intervals for PK/PD studies when determining similarity for SEBs... Furthermore, a demonstration of similarity in clearance and half-life may be required for assessing the risk of differences in elimination rate for these products.”⁴
Celltrion’s clinical trial program for CT-P13 relates only to the indications of rheumatoid arthritis and ankylosing spondylitis. One may ask if it is appropriate to consider using CT-P13 for other disease states wherein REMICADE® is indicated? (as REMICADE® is active at different sites in the body and may involve different mechanisms of action in other disease states5)

A contrast in available data is presented in Table 1, which summarizes the patient exposure through company sponsored clinical trials for REMICADE® at time of Canadian approval (June 2001), and patient exposure publically available to date for Health Canada’s assessment of CT-P13.

Table 1: Number of patients exposed to drug in company-sponsored trials prior to Canadian Notice of Compliance (REMICADE®: NOC -June 2001; CT-P13: NOC – To Be Determined)

<table>
<thead>
<tr>
<th>Condition</th>
<th>REMICADE® (infliximab)</th>
<th>CT-P13 (infliximab SEB)</th>
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<tr>
<td></td>
<td>Patients</td>
<td>Number of Studies</td>
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<tr>
<td></td>
<td></td>
<td>Phase I/II Phase III</td>
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<td>Pediatric Crohn’s Disease</td>
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<td>Ulcerative Colitis</td>
<td>8</td>
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<tr>
<td><strong>TOTAL</strong></td>
<td><strong>1 858</strong></td>
<td><strong>14</strong></td>
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</table>
References


7 Elliott et al. Randomised double-blind comparison of chimeric monoclonal antibody to tumour necrosis factor ex (cA2) versus placebo in rheumatoid arthritis Lancet 1994; 344: 1105-10


11 Isern et al. Safety and Tolerability of a Rapid Infusion of REMICADE (Infliximab) in the Treatment of Rheumatoid Arthritis. Presented at EULAR 2001


Potential copyright material

If you wish to obtain a copy please contact the ATIPP Office at (709) 729-7072 or atippoffice@gov.nl.ca.
Joy, Cheryl

From: Rodway, Kathy
Sent: Tuesday, June 25, 2013 10:39 AM
To: Sheppard, Keith;'Fanjoy, Trish (DH/MS)' (Trish.Fanjoy@gnb.ca)
Cc: Legge, Wanda; Reddick, Vanessa
Subject: FW: Agenda Items: PT HSC Call
Attachments: 23(1)(a)(i), 23(1)(b)

Hi Keith/Trish;

MB has provided us with the attached see e-mail below from MB. We will let you know when the call is scheduled and hopefully you can join in. Please let us know if you have any preliminary comments. As noted below, it will eventually be forwarded to DMs for approval by e-mail.

Thanks
Kathy

From: Langen, Geof (HEALTH) [mailto:Geof.Langen@gov.mb.ca]
Sent: Monday, June 24, 2013 1:18 PM
To: 'Redford, Vinessa (MOHLTC)'; 'Dimitracopoulos, Louis (MOHLTC)'; 'Kanakaratnam, Mahindan (MOHLTC)'; 'Brown, Liana C. (MOHLTC)'; 'Sotiropoulos, Evan (MOHLTC)'; 'Stoutley, Alex (MOHLTC)'; 'Hsiung, Terence (MOHLTC)'; 'Allen, Katy (MOHLTC)'; 'Nandiall, Barb (MOHLTC)'; 'Gayle.Downey@gov.bc.ca'; 'Danielle.Edwards@gov.bc.ca'; 'Maureen.Neuman@gov.bc.ca'; 'Patrick.Anderson@gov.bc.ca'; 'Heather.Scheffer@gov.bc.ca'; 'lyn.bilida@gov.ab.ca'; 'Erin.Murphy@gov.ab.ca'; 'shauna-leigh.wright@gov.ab.ca'; 'Inka.fakuade@gov.ab.ca'; 'Linda.Malloy@gov.ab.ca'; 'josh.burger@gov.ab.ca'; 'traci.schmekel@health.gov.sk.ca'; 'mark.goossens@health.gov.sk.ca'; 'Tara.Gereaux@health.gov.sk.ca'; 'sbruash@health.gov.sk.ca'; 'Irvine, Jessica (HEALTH); Angeleau, Regina (HEALTH); Shearer, Elizabeth (HEALTH); Napier, Janet (HEALTH); 'johanne.caseault@mssss.gouv.qc.ca'; 'nicolas.seney@mssss.gouv.qc.ca'; 'Trish.Fanjoy@gnb.ca'; 'Marlien.McKay@gnb.ca'; 'vijay.bhashyakarla@gov.ns.ca'; 'Kirstin.Nucklaus@gov.ns.ca'; 'Patti.Ryan@gov.ns.ca'; 'lee-ann.petersenboulton@gov.ns.ca'; 'anne.dechamp@gov.ns.ca'; 'smacneill@gov.pe.ca'; 'bdbertelsen@gov.pe.ca'; 'Legge, Wanda; Dyall, Simone; Power, Tara; Cooper, Mary; Rodway, Kathy; Reddick, Vanessa; Bodnar, Cameron; 'Denise_canuel@gov.nt.ca'; 'Erin_Shea@gov.nt.ca'; 'Dan_Wong@gov.nt.ca'; 'mdoucette@gov.nu.ca'; 'Violet.VanHees@gov.yk.ca'; 'Kim.Dolhan@gov.yk.ca'
Subject: RE: Agenda Items: PT HSC Call

Dear PT HSC,

As per the brief update on the HSC call last week – attached is a prepared by CADTH after the May 28th call with Drug ADMs. The purpose of the note is to provide additional background and answer questions that were posed by the Drug ADMs.

As next steps:

- We would like to set up a call with HSC, CADTH, and HC to review the note (we are going to leave it to you to invite your drug ADMs to the call), and would like to do so after the HSC call either this week or next.

- The goal would be to finalize a note and hopefully move to DMs for approval by email.

Thanks

gEOF
From: Redford, Vinessa (MOHLTC) [mailto:Vinessa.Redford@ontario.ca]
Sent: June-24-13 8:16 AM
To: Dimitracopoulos, Louis (MOHLTC); Kanakaratnam, Mahindan (MOHLTC); Brown, Liana C. (MOHLTC); Sotiropoulos, Evan (MOHLTC); Stoutley, Alex (MOHLTC); Hsiung, Terence (MOHLTC); Allen, Katy (MOHLTC); Nandlall, Barb (MOHLTC); Gayle.Downey@gov.bc.ca; Danielle.Edwards@gov.bc.ca; Maureen.Neuman@gov.bc.ca; Patrick.Anderson@gov.bc.ca; Heather.Scheffer@gov.bc.ca; lyn.bilida@gov.ab.ca; Erin.Murphy@gov.ab.ca; shauna-leigh.wright@gov.ab.ca; inka.fakuade@gov.ab.ca; Linda.Malloy@gov.ab.ca; josh.burger@gov.ab.ca; traci.schmekel@health.gov.sk.ca; mark.goossens@health.gov.sk.ca; Tara.Gereaux@health.gov.sk.ca; sbuzash@health.gov.sk.ca; Langen, Geof (HEALTH); Irvine, Jessica (HEALTH); Angeleau, Regina (HEALTH); Shearer, Elizabeth (HEALTH); Napier, Janet (HEALTH); johanne.caseault@msss.gouv.qc.ca; nicolas.seney@msss.gouv.qc.ca; Trish.Fanjoy@gnb.ca; Marlien.McKAY@gnb.ca; vijay.bhaskar@gmail.com; Kirstin.Nucklaus@gov.ns.ca; Patti.Ryan@gov.ns.ca; lee-ann.petersonboulton@gov.ns.ca; anne.dechamp@gov.ns.ca; smacNeill@gov.pe.ca; bdberge@gov.pe.ca; wliege@gov.nl.ca; SimoneDyall@gov.nl.ca; Tara.Power@gov.nl.ca; mcooper@gov.nl.ca; krodway@gov.nl.ca; vanessareddick@gov.nl.ca; cameronbodnar@gov.nl.ca; Denise.canuel@gov.nt.ca; Erin.Shea@gov.nt.ca; Dan_Wong@gov.nt.ca; mdoucette@gov.nu.ca; Violet.VanHees@gov.yk.ca; Kim.Dolhan@gov.yk.ca
Subject: Agenda Items: PT HSC Call

Colleagues,

For our PT HSC Call on June 27, 2013 please submit your agenda items and supporting materials by end of day today, and include the purpose/objective of each item.

Thank you,

Vinessa Redford
Health Support Committee Lead
Intergovernmental Relations Unit
Assistant Deputy Minister’s Office
Health System Strategy and Policy Division
Ontario Ministry of Health and Long-Term Care
vinessa.redford@ontario.ca
Phone: (416) 327-7551
# MINUTES

Pharmaceutical Directors Forum Teleconference Call

Wednesday, December 4, 2013

## Present:

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<td>Kevin Pothier for Leanne Jardine</td>
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<td>Michele Evans</td>
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<td>Judy McPhee</td>
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<td>Harold Boudreau for Susan Pierce</td>
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<td>Mark Harasymuk (FWG)</td>
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<td>Judith Fisher (OUWG)</td>
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## Guests:

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<td>Anne Decrouy (BCANS)</td>
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## Regrets:

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## CADTH

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<tr>
<td>Elaine MacPhail</td>
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<td>Jeannette Smith</td>
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<td>Chander Sehgal</td>
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## Agenda Item and Description

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<td>Work on tailored reviews for SEBs and fixed dose combinations is in progress.</td>
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Dear FWG Members,

As discussed at today’s teleconference, please see the attached draft document *CDR Update 92, Common Drug Review Consultation - Subsequent Entry Biologics* for your review. This document has been developed to engage CADTH stakeholders for their input on key issues surrounding the establishment of a CDR procedure and process for SEBs. We would appreciate your feedback by the end of day on Thursday (please send any comments to brendanm@cadth.ca).

Thank you,
Brendan McIntosh

Brendan McIntosh
Lead, Recommendations and Procedures
Common Drug Review
Canadian Agency for Drugs and Technologies in Health (CADTH)
Tel: (613) 226-2553, ext. 1539
Email: brendanm@cadth.ca

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Common Drug Review Consultation - Subsequent Entry Biologics

The Canadian Agency for Drugs and Technologies in Health (CADTH) is inviting stakeholder comments and feedback on the establishment of a Common Drug Review (CDR) procedure and process for reviewing Subsequent Entry Biologics (SEBs).

Please email your feedback by to be confirmed (10 business days), to feedback@cadth.ca. All feedback will be considered by CADTH.

How to submit your feedback:

- To provide feedback, you must identify yourself — feedback provided by individuals who do not identify themselves and the organization they represent will not be considered.
- Only one response per organization will be considered. If more than one response is received, only the first response that is received will be considered.
- Feedback should be provided in a Microsoft Word document using 11-point font.
- The maximum length of feedback is three (3) pages.
- Feedback should be presented clearly and succinctly.

If you have any questions about the feedback process, please email feedback@cadth.ca. We thank you in advance for your interest.

Background

As originally stated in CDR Update 59, SEBs should be submitted to CDR for consideration by the participating plans in accordance with the CDR Submission Guidelines for Manufacturers for new drug submissions. A CDR review is needed for SEBs because these products are not analogous to generic drugs and according to Health Canada, “Authorization of an SEB is not a declaration of pharmaceutical or therapeutic equivalence to the reference biologic drug.” In addition, there is considerable uncertainty regarding the cost-effectiveness of SEBs relative to the reference products.

Since the CDR’s SEB pilot process was introduced in fall 2009 (see CDR Update — Issue 62), only a single submission was received during the past four years. CADTH anticipates that a number of new SEBs will be reviewed by Health Canada and marketed in the near future. It is also anticipated that SEBs will be reviewed by Health Canada for multiple indications. In addition, CADTH has recently received a number of inquiries from stakeholders regarding possible CDR submissions for SEBs, including the following questions:

- What is the current status of the CADTH’s SEB pilot project?
- Does CADTH anticipate making changes to the CDR procedure and/or CDR submission requirements for SEBs?
  - If so, when would these changes be implemented?
- For an SEB with multiple indications, are separate CDR submissions required for each indication or is one CDR submission encompassing all indications acceptable?
- How does the CDR submission process for an SEB differ from the submission process for other drugs?

In light of the above, CADTH recognizes the need to revisit the SEB pilot process and establish a standardized procedure and process prior to undertaking further reviews of SEBs. To facilitate
these changes, CADTH is consulting with CDR-participating drug plans. CADTH acknowledges the importance of engaging stakeholders in the CDR process and, therefore, has initiated this consultation. Stakeholders are requested to note the following considerations when providing feedback.

**Issues for Consideration**

1. Pros and cons of the following two alternative submission procedures to address cases where an SEB is submitted to CDR for multiple indications$^1$:
   - Separate CDR submission for each approved indication
   - Single CDR submission for all approved indications

2. Regulatory approval of SEBs relies in part on comparative and historical information from a product already authorized based on a complete data package (i.e., a reference product).$^1$ Given this aspect of the regulatory approval pathway for SEBs, CADTH will consider the relative merit of conducting a tailored review$^2$ versus a comprehensive review for SEBs for each indication. The decision regarding the type of review would be made on a case-by-case basis and would involve the following considerations:
   - The number of indications and the similarity of different indications
   - Indications that have been approved based on extrapolation$^a$ of clinical data
   - The presence or absence of an existing CDR review of the reference product for the same indication(s)
   - 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

3. The critical elements that need to be included in a CDR submission for an SEB for each of the following:
   - Pharmacological data (e.g., pharmacokinetics, pharmacodynamics)
   - Clinical data (e.g., safety and efficacy studies)
   - Pharmacoeconomic data
     - Cost-minimization analyses would likely be sufficient in the majority of scenarios for SEBs; however, please consider scenarios where cost-utility analyses would be required for SEBs (e.g., indications for which no health technology assessment has been conducted by CDR and/or CDR-participating drug plans).

4. CADTH considers the issue of interchangeability and substitutability of SEBs to be an implementation issue that is best addressed by the CDR-participating drugs plans.

See *CDR Update — Issue 62* for details of the CDR pilot SEB review process

---

$^1$ Regardless of the number of CDR submissions received for an SEB with multiple indications, CADTH may choose to issue separate recommendations for each indication.

$^2$ A reference product is a biologic drug that was authorized on the basis of a complete quality, non-clinical, and clinical data package, to which an SEB is compared in studies to demonstrate similarity. In appropriate circumstances, a biologic drug that is not authorized for sale in Canada may be used as a reference biologic drug. Please see Guidance for Sponsors: Information and Submission Requirements for Subsequent Entry Biologics (SEBs). Ottawa: Health Canada; 2010 Mar. 5. Available from:
iii A tailored review for SEBs would involve the manufacturer completing a template to provide key data regarding the pharmacology, safety, efficacy, and, pharmacoeconomics for the drug under review. Tailored reviews are currently used for submissions in the category of New Combination Products (Funded Components). Please see Appendix 16 of the *Common Drug Review Submission Guidelines for Manufacturers* for complete details of the template currently used for tailored CDR reviews.

iv Regulators have indicated that it may be possible to extrapolate clinical data to other indications where rationales are sufficiently persuasive
## MINUTES

Pharmaceutical Directors Forum Teleconference Call  
Wednesday, January 8, 2014

### Present:

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<td>Kevin Wilson &amp; Perry Behl &amp; Arlene Kuntz</td>
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<td>Trish Clark &amp; Keith Sheppard</td>
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### 2. CADTH Related Items

2.1 Update on Queuing and Letter to Rx&D

- CADTH is developing a discussion paper on prioritization and
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<td>tailored reviews for SEBs and fixed dose combinations for the January DPAC call. Tailored reviews of me-too drugs is more challenging.</td>
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Subsequent Entry Biologics – Emerging Trends in Regulatory and Health Technology Assessment Frameworks Environmental Scan

http://www.cadth.ca/media/pdf/ES0284_SEBs_es_e.pdf
Hi Keith,

Attached is some feedback we compiled from Wanda Legge, Cathi Bradbury and Mike Bannister on the CADTH focus group questions.

Peggy

From: Breen, Seamus
Sent: Saturday, February 08, 2014 8:16 AM
To: Sheppard, Keith; Baikie, Peggy
Cc: Clark, Patricia
Subject: Re: CADTH Strategic Planning Process for 2015-18 - invitation to provide customer input

Tks keith. Excellent input. Yes please proceed. Can I give u some info to provide on mine and cathi bradbury’s behalf? it’s probably better u folks participate as opposed to me. No point in all of us doing this...Tks, seamus
Department of Health & Community Services
Executive Council
Government of Newfoundland and Labrador
P.O.Box 8700
St.John’s, NL
Canada
A1B 4J6

From: Sheppard, Keith
Sent: Friday, February 07, 2014 09:07 PM Newfoundland Standard Time
To: Breen, Seamus; Baikie, Peggy
Cc: Clark, Patricia
Subject: RE: CADTH Strategic Planning Process for 2015-18 - invitation to provide customer input

Sorry for the late response Seamus. Here are our responses.

Non-responsive
3. As noted above, a review methodology for DRD’s is needed. Cancer drugs should already be considered as prioritized as pCODR is being moved under CADTH and should carry on as it currently does. In terms of priorities between the 2 areas:
   a. DRD’s
   b. SEB’s
4. As new processes are introduced to deal with DRD’s and SEB’s these should be a focus for ongoing education and workshops.

Trish and I had been scheduled to participate in one of the sessions – should we proceed?

Keith

From: Breen, Seamus
Sent: Tuesday, February 04, 2014 4:35 PM
To: Sheppard, Keith; Legge, Wanda; Bannister, Michael (HCS)
Cc: Baikie, Peggy
Subject: FW: CADTH Strategic Planning Process for 2015-18 - invitation to provide customer input

Hi folks,
I am the department’s representative on CADTH’s Policy Advisory Committee and in this role I have been asked to provide input into the development of CADTH’s 2015-18 Strategic Plan. Following consult with Cathi Bradbury who is on the board of CADTH, I was asked to distribute this discussion guide to you for your review and input. It would be greatly appreciated if you could answer the questions in the attached guide and provide your individual responses directly to Peggy Baikie (whom I have copied on this e-mail) by Friday at Noon who will be consolidating all of your responses. We then plan on sending this consolidated input to CADTH.

Thanks for your help with this in advance. If you have any questions or concerns, please give me a call.

Seamus
6866

From: Sheila Tucker [mailto:SheilaT@cadth.ca]
Sent: Monday, February 03, 2014 10:06 AM
To: Breen, Seamus
Subject: CADTH Strategic Planning Process for 2015-18 - invitation to provide customer input

Dear Seamus:

CADTH has begun to develop its strategic plan for 2015-18. As a CADTH customer, you are invited to participate in a virtual focus group by teleconference to share your experiences and perspective on key priorities for our organization. Your insights will be a valuable input to our planning process.

Focus Group Sessions will take place on the following dates:
    Thursday, February 6, 3:00 – 4:00 p.m. EST
    Friday, February 7, 11:00 a.m. – 12:00 p.m. EST
The discussion questions are attached to provide some detail about the anticipated nature of the dialogue. The themes identified during these sessions will be used to help shape the strategic plan.

The sessions will be open to CADTH customers across Canada and will be facilitated by a CADTH representative. Dr. Brian O’Rourke, President & CEO; Ms. Lynda Jobin, VP, Corporate Services; and Ms. Sally Brown, Chair of the Board Governance & Nominations Committee and public member; will be invited to attend the sessions as observers.

RSVP for one of the times above by email at Sheilat@cadth.ca or by phone at 691-3055. We hope you will be able to participate and look forward to your contributions.

Thank you for your consideration of this request.

Sincerely,
Sheila

Liaison Officer for Newfoundland & Labrador
Canadian Agency for Drugs & Technologies in Health
St. John’s, NL
E-mail: Sheilat@cadth.ca
Phone : (709) 691-3055
Toll Free : 1-866-988-1444
Mailing Address: c/o CADTH, 865 Carling Ave., Suite 600, Ottawa, Ontario, K1S 5S8
www.cadth.ca
Follow us on Twitter: @CADTH_ACMTS
CADTH is an independent, not-for-profit agency that delivers timely, evidence-based information to health care leaders about the effectiveness and efficiency of health technologies.

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3. CADTH has recently expanded its drug review portfolio to include subsequent entry biologics (large molecule drugs that follow an original product to market), expensive drugs for rare diseases and cancer drugs. Beyond the efficiencies that could be generated through the alignment of existing processes, what opportunities are there for CADTH to offer enhanced value in these areas? What would you do first?

- No comment – not applicable (Wanda)
- In addition to conducting an assessment of the clinical benefits of drugs, an economic impact assessment should also be conducted (Cathi)
Hi all,

Please find attached, the agenda and call details for tomorrow’s teleconference. Please let me know if any further items need to be added.

I have also attached an email from BC, containing links to SEB-related information, for discussion on tomorrow’s call.

Regards,

Brad

Brad Alyward, BSc (Pharm), MBA
Manager, Pharmacare Business Solutions

Nova Scotia Department of Health and Wellness
Pharmaceutical Services Branch
1894 Barrington Street, 6th Floor, Barrington Tower
PO Box 488
Halifax, NS B3J 2R8

(902) 424-2647 (office)
(902) 717-2407 (mobile)
(902) 428-3400 (fax)

E-mail: brad.alyward@gov.ns.ca
Hi,

Some relevant articles re: SEBs that we wanted to share with PTs and to facilitate discussions at the pan-can meeting:

1. Canadian approval of SEB infliximab
   - biosimilar has been available in South Korea since 2012;
   - 30% lower than brand

2. Norwegian investment to facilitate Infliximab switching
   http://www.biopharma-reporter.com/Markets-Regulations/Norway-to-facilitate-switch-to-biosimilars-with-3m-
   Remicade-study
   http://www.firstwordpharma.com/node/1183727#axzz2sHMd2NZL
   - price point of 40% lower than brand

Regards,
Dom
PAN-CANADIAN BRAND DRUG PRICING ALLIANCE

TELECONFERENCE AGENDA

11 February 2014
12:00 – 1:30 pm (Eastern)

Dial-in: 1-888-653-2299
Participant Pass Code: 3847561#

1. Administrative/Logistical Items:
   - SEBs - Infliximab (Celltrion and Janssen) (BC)

   Non-responsive
Dear Keith,

As part of our SEB discussions on Monday I would like to offer Dr. Wayne Gulliver to join us for the meeting for the first 30 minutes. I look forward to seeing you soon.

Dale
Sent from my iPad

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Hi Keith – Attached are two more notes for the DMs call on Thursday. They are both information notes. Please advise if you have any concerns.

Thanks
Kathy

From: Erin Murphy [mailto:erin.murphy@gov.ab.ca]
Sent: Monday, March 03, 2014 2:16 PM
To: Alex Stoutley; Amy Hope; Brian Bertelsen; Bodnar, Cameron; Craig Fink; Hart, Daphne; Denis Canuel; Evan Sotiropoulos; Gayle Downey; Geof Langen; Heather Scheffer; Inka Fakuade; Janet Napier; Jessica Irvine; Jessica Marriott; Joanne Boomer; Johanne Caseault; Karen Moore; Rodway, Kathy; Katy Allen; Kim Dolhan; Kirstin Nucklaus; Kristina Babich; Lee-Ann Peterson Boulton; Lori Fawcett; Louis Dimitracopoulos; Lyn Bilida; Mahindan Kanakaratnam; Mark Goossens; Mark Iocchelli; Marlien McKay; Maureen Neuman; Michael Kary; Michelle Doucette Issaluk; Monte Kehler; Nicolas Seney; Patrice Beaton; Patrick Anderson; Patti Ryan; Previn Francis; Regina Angeleau; Shangqing Wang; Shaun MacNell; Dyall, Simone; Sophie Buzash; Susan Allebone; Susan Jacka; Power, Tara; Terri Lynn Almeda; Tomasz Cybruk; Traci Schmeikel; Trish Fanjoy; Reddick, Vanessa; Vijay Bhashyakarla; Vinessa Redford; Violet Van Hees; Legge, Wanda; Yvette Ng
Subject: RE: March 6 PT DM Teleconference - CADTH Items

Hi HSC,

Please see attached two draft CBNs for the March 6 PT DM Teleconference CADTH agenda items

Please note these are also available on SharePoint at the following path:

Deputy Minister Teleconferences and Meetings – March 2014 – March 6, 2014.

Cheers,

Erin
Erin Murphy
Senior Policy Advisor
Intergovernmental Relations Branch
Strategic Services Division
Alberta Health
Phone 780-643-1566  Fax 780-422-0849

Save a tree. Please do not print this email unnecessarily.
FYI - Revised notes on CADTH reflecting Quebec's position.

K

From: Erin Murphy [mailto:erin.murphy@gov.ab.ca]
Sent: Tuesday, March 04, 2014 2:36 PM
To: Alex Stoutley; Amy Hope; Brian Bertelsen; Bodnar, Cameron; Craig Fink; Hart, Daphne; Denis Canuel; Evan Sotiropoulos; Gayle Downey; Geoff Langen; Heather Scheffer; Inka Fakuade; Janet Napier; Jessica Irvine; Jessica Marriott; Joanne Boomer; Johanne Caseault; Karen Moore; Rodway, Kathy; Katy Allen; Kim Dolhan; Kirstin Nucklaus; Kristina Babich; Lee-Ann Peterson Boulton; Lori Fawcett; Louis Dimitracopoulos; Lyn Bilida; Mahindan Kanakaratnam; Mark Goossens; Mark Iacchelli; Marlien McKay; Maureen Neuman; Michael Kary; Michelle Doucette Issaluk; Monte Kehler; Nicolas Seney; Patricia Beaton; Patrick Anderson; Patti Ryan; Previn Francis; Regina Angeleau; Shangqin Wang; Shaun MacNeill; Dyall, Simone; Sophie Buzash; Susan Allebone; Susan Jacka; Power, Tara; Terri Lynn Almeda; Tomasz Cybruk; Traci Schmekel; Trish Fanjoy; Reddick, Vanessa; Vijay Bhashyakarla; Vinessa Redford; Violet Van Hees; Legge, Wanda; Yvette Ng
Subject: RE: March 6 PT DM Teleconference - CADTH Items

Hi,

Please find attached revised CADTH CBNs for agenda items. Please note these CBNs have been revised to incorporate edits from QC.

Also available on SharePoint.

Cheers,
Erin

Erin Murphy
Senior Policy Advisor
Intergovernmental Relations Branch
Strategic Services Division
Alberta Health
Phone 780-643-1566 Fax 780-422-0849

Save a tree. Please do not print this email unnecessarily.
Hi,

These two CADTH CBNs have been finalized; the draft watermarks have been removed. Please note these final CBNs are also available on SharePoint.

Cheers,
Erin

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From: Erin Murphy  
Sent: Monday, March 03, 2014 10:46 AM  
To: Alex Stoutley; Amy Hope; Brian Bertelsen; Cameron Bodnar; Craig Fink; Daphne Hart; Denis Canuel; Evan Sotiropoulos; Gayle Downey; Geoff Langen; Heather Scheffer; Inka Fakuade; Janet Napier; Jessica Irvine; Jessica Marriott; Joanne Boomer; Johanne Caseault; Karen Moore; Kathy Rodway; Katy Allen; Kim Dolhan; Kirstin Nucklaus; Kristina Babich; Lee-Ann Peterson Boulton; Lori Fawcett; Louis Dimitracopoulos; Lyn Bilida; Mahindan Kanakaratnam; Mark Goossens; Mark Iocchelli; Marlien McKay; Maureen Neuman; Michael Kary; Michelle Doucette Issaluk; Monte Keehler; Nicolas Seney; Patricia Beaton; Patrick Anderson; Patti Ryan; Previn Francis; Regina Angeleau; Shangqing Wang; Shaun MacNeill; Simone Dyall; Sophie Buzash; Susan Allebone; Susan Jacka; Tara Power; Terri Lynn Almeda; Tomasz Cybruk; Traci Schmekel; Trish Fanjoy; Vanessa Reddick; Vijay Bhashyakarla; Vinessa Redford; Violet Van Hees; Wanda Legge; Yvette Ng  
Subject: RE: March 6 PT DM Teleconference - CADTH Items

Hi HSC,

Please see attached two draft CBNs for the March 6 PT DM Teleconference.

Please note these are also available on SharePoint at the following path:

Deputy Minister Teleconferences and Meetings – March 2014 – March 6, 2014.

Cheers,
Erin
Erin Murphy  
Senior Policy Advisor  
Intergovernmental Relations Branch  
Strategic Services Division
MINUTES
Pharmaceutical Directors Forum Teleconference Call
Wednesday, March 5, 2014

Present:
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<td>Kevin Wilson (Chair) &amp; Perry Behl</td>
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<td>Trish Clark</td>
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<td>Leanne Jardine</td>
<td>NB</td>
<td>Judy McPhee</td>
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<td>Jeff Onyskiw &amp; Kathy McDonald</td>
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<td>Susan Pierce</td>
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<td>Eric Lun</td>
<td>BC</td>
<td>Kathy Vesterfelt</td>
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Observers:
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<td>Lisa Thompson for Frances Hall</td>
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Regrets:
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<td>David King</td>
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<td>Michele Evans &amp; Mark Harasymuk</td>
<td>AB</td>
<td>Brent Fraser</td>
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<td>Matthew Brougham</td>
<td>Chander Sehgal</td>
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<td>Elaine MacPhail</td>
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### Agenda Item and Description

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<th>Agenda Item and Description</th>
<th>Discussion/Decision/Action</th>
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<tr>
<td>2.1 CADTH Update</td>
<td>Following is the CADTH update:</td>
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<td></td>
<td>- SEB review process and submission requirements are being finalized for posting by March 7, 2014. Patient input will be finalized later.</td>
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