

PRODUCT MONOGRAPH

^N **METHADOSE™**

Methadone Hydrochloride Oral Concentrate USP
10 mg/mL

Methadone Hydrochloride Oral Concentrate USP
Dye-Free, Sugar-Free, Unflavored
10 mg/mL

Treatment of Opioid Dependence

Mallinckrodt Canada ULC
18101 Trans-Canada Highway
Kirkland, QC, H9J 3Z4
Canada

Date of Preparation: October 11, 2012

Control No.:

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s.17; s.21

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Health
Canada

Santé
Canada

LITERATURE REVIEW



Methadone Maintenance Treatment

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s.21



File: 70325-30/metha
CLIFF# 997984

January 16, 2014

Mr. Christophe Goffoz
Market Development Manager
Mallinckrodt Canada ULC
7500 Autoroute Transcannadiene
Pointe-Claire QC H9R 5H8

Dear Mr. Goffoz:

Thank you for your submission for the inclusion of **methadone (Methadose™) 10 mg/ml solution and 10 mg/ml dye-free, sugar-free unflavored solution, DIN 02394596 and DIN 02394618**, for the treatment of methadone maintenance for opioid dependence, as eligible benefits under the British Columbia PharmaCare program.

The Ministry of Health (the Ministry) has now completed its review of these products. I wish to advise you that, effective February 1, 2014 **methadone (Methadose™) 10 mg/ml solution** will be added as an eligible benefit to the British Columbia PharmaCare program for methadone maintenance and treatment of pain.

Methadone (Methadose™) dye-free, sugar-free unflavored solution will not be an eligible PharmaCare benefit.

The above listing decision will be confirmed in a future issue of the PharmaCare Newsletter. Please ensure your sales staff are aware of this decision.

Sincerely,

Original Signed By

Eric Lun, PharmD
Executive Director, Drug Intelligence & Optimization Branch
Medical Beneficiary and Pharmaceutical Services Division, Ministry of Health

CONFIDENTIALDrug Submission # 2986

Drug Submission rec'd: yyyy/mm/dd

IS rec'd: Yesterday, December 02, 2013, 3:05:12 PM

Drug Base Update Request Form – for Benefits

Request Date: 2013/12/02		Effect Date: 2014/02/01 MV		Authorized by: tf
Drug Information:			Manufacturer: Mallinckrodt Canada ULC	
Brand Name: Methadose			Chemical / Generic Name: methadone	
DIN	Strength	Form	Full Drug Price	Full Quantity (not /unit \$)
02394596 – to be used for pain	10 mg/ml	solution	\$150	1000 ml pup .162
PIN - 66999997	10 mg/ml	solution	\$150	1000 ml pup .162
PIN – 66999998	10 mg/ml	solution	\$150	1000 ml pup .162
PIN – 66999999	10 mg/ml	solution	\$150	1000 ml pup .162
PIN – 67000000	10 mg/ml	solution	\$150	1000 ml pup .162
Mark-up	8%			
Therapeutic class of drug/s: similar to methadone PIN 66999990 – new class is 28080808K (restriction codes: MTH/MHR/NAR/TRP) for PINs and 28080808 (restriction codes MTH/MTP/NAR/TRP)J is for DIN 02394596				

Maximum Days Supply: Short Term: 35**Flags:**

Trial: No	Trial Days:	Trial Plans:
Triplicate Drug: Yes	Generic Drug: No	RDP Drug: No
Is Din an LCA Drug: No	Current LCA Price:	

Benefit Groups:

C, P, I, F, B for 02394596 (pain)

4 PINs – C, P, I, B

Category Designation:

DIN in RDP Category: No	Category: 0041	Sub-Category:
DIN in Non-RDP Category: No	Category: 9901	Sub-Category:
Create new Non-RDP Category / Sub-Category: No		9901 /

Practitioner Information:

Practitioner Exemptions: No Assumed SA: No	Practitioner ID:	ID Ref #:
Practitioner Specialty Group: No	Group ID:	

CONFIDENTIAL

Drug Submission # 2986

Note: If DIN exists as a Special Authority and a new Non-RDP Category is to be created, any existing individual DINs will require termination and re-creation under the 'new' Non-RDP Category.

Special Instructions:

HIBC: Effective February 1, 2013, a DIN for Methadose plus 4 new PINs need to be created for Methadose. As Methadose will be associated with or without witness ingestion and for delivery or not, PINs will have to be set up for appropriate reimbursement.

For example Methadose 10 mg/ml PIN for involving direct interaction with patient should be set up similar to PIN 66999990.

The addition of the PINs and DIN for Methadose need to be checked with pain / maintenance tables for the College permissions.

Please create new PINs before end of December so that we can communicate them in a PharmaCare newsletter in January before Feb. 1 effective date. Please email new PINs to Susan Healey and Tijana fazlagic when completed. DONE MV

PRODUCT MONOGRAPH

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Methadone Hydrochloride Oral Concentrate USP
10 mg/mL

Methadone Hydrochloride Oral Concentrate USP
Dye-Free, Sugar-Free, Unflavored
10 mg/mL

Treatment of Opioid Dependence

Mallinckrodt Canada ULC
Kirkland, QC, H9J 3Z4
Canada



Date of Revision: September 11, 2013

Control # 167067

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Taylor, Grace HLTH:EX

From: Goffoz, Christophe <Christophe.Goffoz@mallinckrodt.com>
Sent: July 4, 2014 11:48 AM
To: Fazlagic, Tijana HLTH:EX
Subject: RE: Methadose

Hello Tijana,

I hope this email finds you well.
I have just left you a voicemail regarding the questions below.

There is no shortage of product in BC – the pharmacy you are referring to relies on one distributor for narcotics, and this distributor had an inventory issue. Pharmacies would usually have a backup supplier in case such things happen, but this one did not and was worried they would run out of product. This is driven by their business decisions.

I have discussed with the wholesaler and sensitize them about sufficient safety stock – they have increased their inventory.

I have forwarded your other questions about Methadose to our medical affairs department which will send you a more detailed response. We are aware of the article, which is the second one published by the same author about Methadose (the first one was published just before the transition).

As you know, there is an extensive clinical experience with Methadose. The most compelling information is that although millions of doses of Methadose have been given in the US, a comprehensive query into the Pharmacovigilance database of the US and Canada about Methadose effect wearing off produced a very small number of reports of this nature.

Best regards

Christophe Goffoz | Sales Manager | Responsable des ventes
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From: Fazlagic, Tijana HLTH:EX [mailto:Tijana.Fazlagic@gov.bc.ca]
Sent: Friday, July 04, 2014 1:39 PM
To: Goffoz, Christophe
Subject: Methadose

Hi Christophe,

Hope your summer is going well.

I have couple of emerging issues on Methadose that I need your help with.

I heard yesterday that at least one pharmacy was impacted by a shortage of Methadose in BC. Please let me know what the supply situation in BC is and whether sufficient supply is available.

The second issue is regarding wearing off effects on Methadose and allegedly this leading to patients going back to heroin. You have probably seen this in the media. In order to address this issue, can you please gather and provide the following information to the Ministry:

Pharmacokinetic data Methadose vs. compounded methadone vs. other formulations of methadone;
Wearing off effect on Methadose – any data that may be available, published or not, case reports, etc.;
Information about Methadose patients going back to heroin or other drug use;
Any other issues patients may be experiencing with Methadose.

I would appreciate receiving this information as soon as possible.

Regards,

Tijana

Tijana Fazlagic, PharmD, BSP, M.Sc (Pharm)
Director, Formulary Management
Medical Beneficiary and Pharmaceutical Services Division
Tijana.fazlagic@gov.bc.ca
(604) 374-2609

Taylor, Grace HLTH:EX

From: Bouma, Susan HLTH:EX
Sent: February 13, 2014 2:06 PM
To: XT:HLTH Budd, George
Cc: Fazlagic, Tijana HLTH:EX
Subject: FW: Unflavored Methadose

Hey George:

Also went over the issue with Ed B. It would be possible to add the powder directly to the unflavored stock solution based on usual amount of powder for liquid and if the displacement is less than 5% this is considered acceptable (?confirm). The variation from dose from measuring out individual doses would likely be more than that anyway?

So, we sort of have a formula. My day is pretty good tomorrow.

Let's chat again soon.

Sue

From: Goffoz, Christophe [mailto:Christophe.Goffoz@mallinckrodt.com]
Sent: Thursday, February 13, 2014 12:02 PM
To: XT:HLTH Budd, George
Cc: Marshall, Peter C (Montreal); Fazlagic, Tijana HLTH:EX; Bouma, Susan HLTH:EX
Subject: RE: Unflavored Methadose

Hello George,

We never had the question about not diluting the unflavored Methadose, so it was sent to

Please note that Mallinckrodt has not performed any specific studies with these parameters, therefore the question was sent to Medical Information and then to R&D. Below are our thoughts about how this could be addressed:

- For observed ingestion, this is not an issue as one can add tang or juice to the dose at the time of ingestion. The dose is ingested under supervision.
- For carries, if the requirement is to dispense undiluted Methadose, one could consider adding tang powder or crystal light powder directly into the 10 mg/mL unflavored Methadose:

When preparing methadone solutions diluted with tang, Methadone dispensing guidelines recommend to use full-strength tang solutions. With this in mind, it would be acceptable to apply the same formula [tang powder weight/water volume] required to prepare the full-strength tang solutions to the [tang powder weight / Methadose volume]. This would have a minimal impact on the methadone concentration and would make a full-strength tang solution which would not lend itself easily to injection.

One could apply the same train of thoughts if using crystal light powder.

I hope this answers your question. Please feel free to call me if you want to discuss it further.

Best regards

Christophe Goffoz | Portfolio Manager | Responsable, portefeuille de produits
Mallinckrodt Pharmaceuticals

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From: George Budd [<mailto:George.Budd@bcpharmacists.org>]
Sent: Wednesday, February 12, 2014 6:51 PM
To: Goffoz, Christophe; Bouma, Susan HLTH:EX
Cc: Marshall, Peter C (Montreal); Fazlagic, Tijana HLTH:EX
Subject: RE: Unflavored Methadose

Christophe, any updates?

George P. Budd, Pharm.D.,B.Sc.(Pharm.), R.PEBC, R.Ph.
Inspector/Investigator | College of Pharmacists of BC
604.676.4214 | 866.676.4214 | www.bcpharmacists.org

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From: Goffoz, Christophe [<mailto:Christophe.Goffoz@mallinckrodt.com>]
Sent: February-07-14 12:19 PM
To: George Budd; Bouma, Susan HLTH:EX
Cc: Marshall, Peter C (Montreal); Fazlagic, Tijana HLTH:EX
Subject: RE: Unflavored Methadose

Hello George,

To my knowledge, other jurisdictions in the US use the unflavored Methadose diluted with Tang – for example, some mix Methadose with the same volume of tang solution.
I have forwarded your question to our medical affairs department and will get back to you with their guidance.

Thank you

Christophe Goffoz | Portfolio Manager | Responsable, portefeuille de produits
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From: George Budd [<mailto:George.Budd@bcpharmacists.org>]
Sent: Friday, February 07, 2014 3:09 PM
To: Goffoz, Christophe; Bouma, Susan HLTH:EX
Cc: Marshall, Peter C (Montreal); Fazlagic, Tijana HLTH:EX
Subject: RE: Unflavored Methadose

Christophe,
How do other jurisdictions including the USA deal with the allergy issue?
Would your medical dept. be able to provide a formula? This is imperative to be answered.

George P. Budd, Pharm.D.,B.Sc.(Pharm.), R.PEBC, R.Ph.
Inspector/Investigator | College of Pharmacists of BC
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From: Goffoz, Christophe [<mailto:Christophe.Goffoz@mallinckrodt.com>]
Sent: February-07-14 12:00 PM
To: Bouma, Susan HLTH:EX; George Budd
Cc: Marshall, Peter C (Montreal)
Subject: RE: Unflavored Methadose

Hello Susan,

Unfortunately there is no specific guideline or formula.

As per the monograph and pharmacy guidelines, the only requirement is to dispense methadone in a vehicle which does not lend itself easily to injection – I have not found anything more specific.

Looking at what was considered acceptable by the College of Pharmacy with the compounded solution (a given weight of tang powder or crystal light mixed in a given volume of water to prepare the vehicle used to compound methadone), one could assume that the same ratio would be considered acceptable, ie same weight of tang powder or crystal light mixed in the same given volume of unflavored Methadose.

Best regards

Christophe Goffoz | Portfolio Manager | Responsable, portefeuille de produits
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From: Bouma, Susan HLTH:EX [<mailto:Susan.Bouma@gov.bc.ca>]
Sent: Friday, February 07, 2014 2:18 PM
To: Goffoz, Christophe; XT:HLTH Budd, George
Cc: Marshall, Peter C (Montreal)
Subject: RE: Unflavored Methadose

Good Morning Christophe:

Can you please advise how much Crystal Light or other powder added is acceptable? We need an actual formula please.

Sue

From: Goffoz, Christophe [<mailto:Christophe.Goffoz@mallinckrodt.com>]
Sent: Wednesday, January 22, 2014 7:11 AM
To: XT:HLTH Budd, George; Bouma, Susan HLTH:EX
Cc: Marshall, Peter C (Montreal)
Subject: RE: Unflavored Methadose

Hello George and Dr Bouma,

As per Methadose product monograph, Methadose may be diluted with water or other liquid before oral administration. There is no specific guidance about which vehicle should be used so that the sugar-free solution does not lend itself easily to injection. In practice, Methadose sugar-free is often used with tang, fruit juices such as orange juice or apple juice, or crystal light.

Given that Methadose is a 10 mg/mL solution, any additional volume of another liquid will decrease the concentration of the final product.
10 mg/mL concentration would be maintained if a solid – for example crystal light powder – is added directly to the Methadose sugar-free solution.

Please let me know if you need any further information.

Best regards

Christophe Goffoz | Portfolio Manager | Responsable, portefeuille de produits
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From: George Budd [<mailto:George.Budd@bcpharmacists.org>]
Sent: Tuesday, January 21, 2014 7:31 PM
To: Goffoz, Christophe; Marshall, Peter C (Montreal)
Cc: Bouma, Susan HLTH:EX
Subject: Unflavored Methadose

Hello Christophe and Peter,

Copied on this email is Dr. Sue Bouma from the Ministry of Health.
We are wondering in case of an allergy to the flavoring agent or the dye, what can the pharmacists add to the unflavored Methadose to decrease the chances of diversion. Do you have a formula of how much coloring and dye they would need to add to maintain the final concentration of 10mg/ml?

George P. Budd, Pharm.D.,B.Sc.(Pharm.), R.PEBC, R.Ph.
Inspector/Investigator | College of Pharmacists of BC
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Please consider the environment before printing this email.

Taylor, Grace HLTH:EX

From: Goffoz, Christophe <Christophe.Goffoz@mallinckrodt.com>
Sent: December 20, 2013 4:39 PM
To: Fazlagic, Tijana HLTH:EX
Cc: Lun, Eric HLTH:EX
Subject: Re: Methadose listing in British Columbia

The grant is public. I believe it was annouced by BCPhA. I would refer you to Cyril Lopez to get details about how they communicated it.

Best regards

Christophe Goffoz
Market Development Manager
Mallinckrodt Canada

On Dec 20, 2013, at 7:21 PM, "Fazlagic, Tijana HLTH:EX" <Tijana.Fazlagic@gov.bc.ca> wrote:

Thank you so much for getting back to me!s.22
Is this grant confidential or are we free to mention it if asked about cost to pharmacies associated with transition?
Tijana

From: Goffoz, Christophe [<mailto:Christophe.Goffoz@mallinckrodt.com>]
Sent: Friday, December 20, 2013 04:04 PM
To: Fazlagic, Tijana HLTH:EX
Subject: Re: Methadose listing in British Columbia

Hello Tijana,

Mallinckrodt has provided a grant to the BCPhA innovation fund, through which phamacists can have access to funds supporting the purchase o new equipment.
Although not all pharmacists will need to buy a new equipment. BCPhA mentioned to me this morning that more than 500 pharmacists will benefit from such support.

Please let me know if you need further information.

Happy holidays!

Christophe Goffoz
Market Development Manager
Mallinckrodt Canada

On Dec 20, 2013, at 6:52 PM, "Fazlagic, Tijana HLTH:EX" <Tijana.Fazlagic@gov.bc.ca> wrote:

Hi Christophe,
As we are preparing for the implementation of Methadose, one of the big concerns raised by pharmacies is a cost of supplies for dispensing of Methadose. I think I brought

this issue up briefly in the summer during one of our calls and mentioned that the Ministry will not get directly involved. However, I think I mentioned that the manufacturer may address this issue through the College of Pharmacists, or the Association, or pharmacies directly. Can you please let me know if any support has been provided to pharmacies for a transition as pharmacies need to buy new measuring devices that will be suitable for measuring 10x less liquid and dispense it to patients appropriately and accurately.

s.22

so I would appreciate it if you can provide

more information s.22

Regards,

Tijana

Tijana Fazlagic, PharmD, B.Sc.(Pharm), MSc

Director

Formulary Management

Pharmaceutical Services

(604) 374-2609

Tijana.Fazlagic@gov.bc.ca

From: Goffoz, Christophe [<mailto:Christophe.Goffoz@mallinckrodt.com>]

Sent: Monday, December 16, 2013 8:18 AM

To: Fazlagic, Tijana HLTH:EX

Cc: Marshall, Peter C (Montreal)

Subject: Methadose listing in British Columbia

Hello Tijana,

I hope this email finds you well.

I am following up regarding Methadose listing in British Columbia: Mallinckrodt is working with wholesalers to build the inventory in January to prepare a seamless transition in terms of supply. We expect pharmacists will begin ordering the product in January so that they can switch to Methadose between February 1st and March 1st as directed by the College.

Would you know when PharmaCare will issue a communication about Methadose being listed? We are getting many questions about this from pharmacists in BC and I was not able to find the information on PharmaCare website.

Thank you

Christophe Goffoz | Portfolio Manager | Responsable, portefeuille de produits

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Taylor, Grace HLTH:EX

From: Goffoz, Christophe <Christophe.Goffoz@mallinckrodt.com>
Sent: November 26, 2013 5:43 AM
To: Fazlagic, Tijana HLTH:EX
Subject: RE: Methadose implementation
Attachments: JCVMET 12989_E_PatientTakeHome_S03.pdf

Hello Tijana,

Please find attached the agency pdf of a patient tool we have developed for patients: it is intended to be handed out by pharmacists to their patients.

Please note we intend to use it in several provinces: this tool was developed to address many questions patient may have and may not be 100% relevant to patients in a given province. As an example, it mentions the unflavored solution, which will not be covered in BC.

Please let me know if you have any question.

Best regards

Christophe Goffoz | Portfolio Manager | Responsable, portefeuille de produits

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From: Fazlagic, Tijana HLTH:EX [mailto:Tijana.Fazlagic@gov.bc.ca]

Sent: Tuesday, November 19, 2013 4:05 PM

To: Goffoz, Christophe

Subject: Methadose implementation

Hi Christophe,

Hope all is well with you.

The Ministry is in the process of preparing various pieces of communication for Methadose implementation and one thing in particular is an information slip for patients that we are planning to distribute through pharmacies. This will primarily focus on safety. I am wondering if you have any information you are planning to use for patient education/information? If you do, would you be able to share it with me so we can look at it as we develop our messaging?

Thank you,
Tijana

Tijana Fazlagic PharmD, B.Sc.(Pharm), MSc
Director, Formulary Management
Drug Intelligence & Optimization
Medical Beneficiary and Pharmaceutical Services Division
(604) 374-2609
Tijana.Fazlagic@gov.bc.ca

Taylor, Grace HLTH:EX

From: Goffoz, Christophe <Christophe.Goffoz@mallinckrodt.com>
Sent: November 5, 2013 12:36 PM
To: Fazlagic, Tijana HLTH:EX
Cc: Marshall, Peter C (Montreal)
Subject: RE: Methadose - Confirmation of listing

Thank you Tijana.

Beginning of December is a good timing and will give us enough time to work with the wholesalers / distributors.

Best regards

Christophe Goffoz | Market Development Manager | Chef, développement de marché

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From: Fazlagic, Tijana HLTH:EX [mailto:Tijana.Fazlagic@gov.bc.ca]

Sent: Tuesday, November 05, 2013 3:34 PM

To: Goffoz, Christophe

Cc: Marshall, Peter C (Montreal)

Subject: RE: Methadose - Confirmation of listing

Hi Christophe,

We are just reaching some final planning stages in BC. As previously discussed, the coverage for Methadose 10 mg/ml solution will be effective February 1, 2014 with a transition period from Feb. 1-28. Methadose sugar-free, color-free solution will not be an eligible benefit. We are planning to announce this change first week of December in a PharmaCare Newsletter. Just as FYI, we will provide coverage for Methadose 10 mg/ml for both methadone maintenance and pain management.

Let me know if you require additional information.

Regards,

Tijana

Tijana Fazlagic PharmD, B.Sc.(Pharm), MSc

Director

Formulary Management

Medical Beneficiary and Pharmaceutical Division

(604) 374-2609

Tijana.Fazlagic@gov.bc.ca

From: Goffoz, Christophe [mailto:Christophe.Goffoz@mallinckrodt.com]

Sent: Wednesday, October 30, 2013 10:00 AM

To: Fazlagic, Tijana HLTH:EX

Cc: Marshall, Peter C (Montreal)

Subject: Methadose - Confirmation of listing

Hello Tijana,

I am following up regarding my previous email about the listing of Methadose in BC.

Given the volume of methadone dispensed monthly in the province, Mallinckrodt would like to work ahead of time with the distributors and pharmacy chains in order to ensure a smooth transition. Our discussions with them are slowed by the fact that there is no public announcement from BC PharmaCare about the coverage of Methadose.

Could you share with us when you think the listing will be announced?

Please feel free to reach out if you want to discuss it over the phone.

Thank you

Christophe Goffoz | Market Development Manager | Chef, développement de marché

Mallinckrodt Pharmaceuticals

Mallinckrodt Canada ULC

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Tel: 514.428.8224 | Cell: 514.212.6202

christophe.goffoz@mallinckrodt.com | www.mallinckrodt.com

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From: Goffoz, Christophe

Sent: Wednesday, October 02, 2013 11:22 PM

To: 'Fazlagic, Tijana HLTH:EX'

Cc: Marshall, Peter C (Montreal)

Subject: Methadose - Confirmation of listing

Hello Tijana,

I hope this email finds you well.

Now that details about the switch to oral concentrate and its implementation in British Columbia are public information, Mallinckrodt is looking at next steps to ensure a smooth transition in February. Making sure that the distribution channel and inventory are ready is key to a strong supply chain. In order to support our discussions with distributors, wholesalers and pharmacy chains, could you confirm that BC PharmaCare is listing Methadose as of February 1st? A letter format for this confirmation would be appreciated:

Because of the Holidays at the end of the year, we would like most stakeholders involved in the distribution of Methadose to place their orders in December so that we can fill the distribution channel early in January and account for any potential hiccups. We would like to initiate discussions with the distributors soon, and the letter from PharmaCare would greatly assist us in keeping the ball rolling.

Please let me know if you have any questions.

Thank you

Christophe Goffoz | Market Development Manager | Chef, développement de marché

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From: BC Pharmacy Association [<mailto:info@bcpharmacy.ca>]

Sent: Wednesday, October 02, 2013 4:39 PM

Subject: Issue Update October 2, 2013 Methadone Maintenance Treatment (MMT)

If this email does not display properly, please [view](#) our online version.

To ensure receipt of our email, please [add](#) us to your address book.

Page 13 of 45

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Taylor, Grace HLTH:EX

From: Hebert, Philippe <Philippe.Hebert@mallinckrodt.com>
Sent: July 31, 2013 2:07 PM
To: Fazlagic, Tijana HLTH:EX
Cc: Goffoz, Christophe; Laura Fitzgerald s.22 ; Marshall, Peter C (Montreal)
Subject: RE: Methadose follow-up

Follow Up Flag: Follow up
Flag Status: Completed

Good afternoon Tijana,
I am following-up on the message sent on July 15.

s.22

Let us know when you would like to regroup on the topic below.

Our schedule is as follows:

Aug. 1 & 2 : Christophe is available

Aug. 5-9: Christophe is available

s.22

Aug. 19 – 23: Philippe is available

Regards,

Philippe

From: Hebert, Philippe
Sent: Monday, July 15, 2013 3:09 PM
To: Fazlagic, Tijana HLTH:EX
Cc: Goffoz, Christophe; Laura Fitzgerald s.22 ; Marshall, Peter C (Montreal)
Subject: Methadose follow-up

Good afternoon Tijana,

I am following-up from a conference call held on July 8 between the BC Pharmacist College and Mallinckrodt. Suzanne Solven and George Budd reported the significant progress made between the 2 colleges in the support of the transition from compounded methadone solution and Methadose for opioid addiction patients. We concluded the meeting having identified 2 action items:

- Pharmacist College will seek formal support from Mallinckrodt for their revised guidelines course planned to start with 1st session at the CSAM annual meeting in Vancouver at the end of September.
- Mallinckrodt and BC Pharmacare should explore potential solutions to assist dispensing methadone pharmacies in up-grading their measurement system(s) to ensure smooth and safe transition.

I would suggest to organize a T-con on the second point at a time convenient for you. Please provide us with your availability before the end of July and I will take care of the logistics.

Please take note that Christophe is currently on vacation returning on July 29.

Regards,

Philippe Hebert | Director Upstream Marketing – North America
Mallinckrodt Pharmaceuticals

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Taylor, Grace HLTH:EX

From: Goffoz, Christophe <Christophe.Goffoz@covidien.com>
Sent: May 16, 2013 1:22 PM
To: Fazlagic, Tijana HLTH:EX
Cc: Marshall, Peter C (Montreal); Hebert, Philippe; 'Laura Fitzgerald s.22)'
Subject: RE: Follow-up about Methadose in British Columbia

Hello Tijana,
I will be happy to connect at 9 :00 am BC time and will send you a meeting request.
Best regards

Christophe Goffoz

Chef, développement de marché / Market development manager

Office (direct): 514 428 8224

Cell: 514 212 6202

Fax: 514-428-8202

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From: Fazlagic, Tijana HLTH:EX [mailto:Tijana.Fazlagic@gov.bc.ca]
Sent: Thursday, May 16, 2013 4:21 PM
To: Goffoz, Christophe
Cc: Marshall, Peter C (Montreal); Hebert, Philippe; 'Laura Fitzgerald s.22)'
Subject: RE: Follow-up about Methadose in British Columbia

Hi Christophe,

Do you have some time tomorrow to touch base by phone? 9 AM BC time would work good for me if you are available.

Tijana

From: Goffoz, Christophe [mailto:Christophe.Goffoz@covidien.com]
Sent: Thursday, May 16, 2013 1:15 PM
To: Fazlagic, Tijana HLTH:EX
Cc: Marshall, Peter C (Montreal); Hebert, Philippe; 'Laura Fitzgerald s.22)'
Subject: Follow-up about Methadose in British Columbia
Importance: High

Hello Tijana,

I hope this email finds you well.

I am following up regarding the listing of Methadose in British Columbia and I was wondering if you have any update to share with us.

Please note that Mallinckrodt is a sponsor of the upcoming BCPHA annual conference in Kelowna the week after next. Philippe and Peter will attend the conference and manage the booth dedicated to Methadose. It could be a good opportunity to connect at some point if you are planning to attend the meeting as well.

Finally, for your information, things are progressing as scheduled with province of Alberta and we are working together towards listing Methadose in June.

Best regards,

Christophe Goffoz

Chef, développement de marché / Market development manager

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Taylor, Grace HLTH:EX

From: Goffoz, Christophe <Christophe.Goffoz@covidien.com>
Sent: April 16, 2013 5:48 AM
To: Fazlagic, Tijana HLTH:EX
Cc: Hebert, Philippe; Marshall, Peter C (Montreal); XT:HLTH Solven, Suzanne; XT:HLTH Budd, George
Subject: RXpress retraction fax
Attachments: RXpress retraction fax.pdf

Hello Tijana,

As discussed, please find enclosed the retraction fax which was sent by RXpress to the pharmacies which had received the previous fax.

Best regards

Christophe Goffoz

Chef, développement de marché / Market development manager
Office (direct): 514 428 8224
Cell: 514 212 6202
Fax: 514-428-8202

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Taylor, Grace HLTH:EX

From: Lori Tanaka <Lori.Tanaka@bcpharmacists.org>
Sent: April 3, 2013 9:52 AM
To: XT:HLTH Solven, Suzanne; 'Goffoz, Christophe'
Cc: XT:HLTH Budd, George; Hebert, Philippe; Fazlagic, Tijana HLTH:EX; Ailve M. McNestry
Subject: RE: In-person meeting in April to discuss Methadose
Attachments: 2013-03-26 Christophe Goffoz (Methadose).pdf

Here is a copy of the fax referred to below.

Thank you,

Lori Tanaka
Executive Assistant to the Deputy Registrar | College of Pharmacists of BC
604.676.4243 | 866.676.4243 | www.bcpharmacists.org

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Please consider the environment before printing this email.

From: Suzanne Solven
Sent: April-03-13 9:31 AM
To: 'Goffoz, Christophe'
Cc: George Budd; Hebert, Philippe; Fazlagic, Tijana HLTH:EX; Lori Tanaka; Ailve M. McNestry
Subject: RE: In-person meeting in April to discuss Methadose

Yes will scan and send to you.

Suzanne Solven

Suzanne Solven, B.Sc.(Pharm), R.Ph, R.PEBC
Deputy Registrar, Director Legislation, Discipline and Investigations | College of Pharmacists of BC
604.676.4202 | 866.676.4202 | www.bcpharmacists.org

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Please consider the environment before printing this email.

From: Goffoz, Christophe [<mailto:Christophe.Goffoz@covidien.com>]
Sent: April-02-13 6:12 PM
To: Suzanne Solven

Cc: George Budd; Hebert, Philippe; Fazlagic, Tijana HLTH:EX; Lori Tanaka; Ailve M. McNestry

Subject: Re: In-person meeting in April to discuss Methadose

Hello Suzanne,

I am very surprised that a fax was sent as I had a conversation with Tijana last week about the reimbursement and we agreed there was no need to send the fax. I confirmed this to the agency in charge of putting this together for us. Besides, the wording was changed as discussed in the final draft...

Could you send me a copy of what was received by the pharmacy?

I will connect with the agency tomorrow to investigate.

Best regards

Christophe Goffoz

On Apr 2, 2013, at 8:19 PM, "Suzanne Solven" <Suzanne.Solven@bcpharmacists.org> wrote:

Dear Christophe

We received a copy from a pharmacy today of your Rexpress – “Dear pharmacist” dated March 26, 2013.

This document was signed by you and contains the original wording that you had forwarded to us indicating that “After discussing with the College of Pharmacists of BC and BC Pharmacare, Mallinckrdot is pleased to inform you that:”

I had thought after our email exchange that the document as originally drafted was not going to go out, and both references to the College and PharmaCare were going to be removed. It appears this didn’t happen?

Interesting, the comment we received from the pharmacy was “very misleading”.

Can you please clarify what happened here?

Thanks

Suzanne Solven

Suzanne Solven, B.Sc.(Pharm), R.Ph, R.PEBC

Deputy Registrar, Director Legislation, Discipline and Investigations | College of Pharmacists of BC

604.676.4202 | 866.676.4202 | www.bcpharmacists.org

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From: Goffoz, Christophe [<mailto:Christophe.Goffoz@covidien.com>]
Sent: March-27-13 3:05 PM
To: Suzanne Solven
Cc: George Budd; Hebert, Philippe; Fazlagic, Tijana HLTH:EX; Lori Tanaka; Ailve M. McNestry
Subject: Re: In-person meeting in April to discuss Methadose

Hello Suzanne,

Thank you for the information.

We have also contacted PharmaCare in a separate email to see if we could meet in April.

Let us know which time and day would be convenient for you.

Best regards

Christophe Goffoz

On Mar 27, 2013, at 5:58 PM, "Suzanne Solven" <Suzanne.Solven@bcpharmacists.org> wrote:

Hello Christophe

We are happy to meet to discuss further, however as your issue relates to PharmaCare coverage I would suggest you actually would want to meet with Tijana (I have copied her on this email) directly on that issue.

As mentioned previously, the CPBC, the CPSBC and the PSD/MOH are working together to ensure safe transition to this new product. One piece of that process is PharmaCare coverage. The piece that the two colleges are concerned about is to ensure that physicians and pharmacists are educated about the differences between the current methadone solution and the Methadose concentrated product. This is a major public safety concern from the Colleges perspective, hence the notice that we sent out. The notification was not meant to reflect that Methadose was a product that would not be supported by the organizations, but rather that we needed some time to ensure adequate knowledge by the front line providers.

The 3 organizations are meeting in the near future to move this forward.

I hope this information is helpful to you.

Suzanne Solven

Suzanne Solven, B.Sc.(Pharm), R.Ph, R.PEBC
Deputy Registrar, Director Legislation, Discipline and Investigations | College of Pharmacists of BC
604.676.4202 | 866.676.4202 | www.bcpharmacists.org

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From: Goffoz, Christophe [<mailto:Christophe.Goffoz@covidien.com>]
Sent: March-27-13 1:32 PM
To: George Budd; Suzanne Solven
Cc: Hebert, Philippe
Subject: In-person meeting in April to discuss Methadose

Hello Suzanne and George,

I hope this email finds you well.

While discussing with BC PharmaCare about their reimbursement policy, we uncovered that this policy includes a translation of federal policy 0051 – similar to how it was translated in the CPBC PPP #64 – which would prevent coverage of the current solution prepared using the Active Pharmaceutical Ingredient:

Compounds eligible for coverage

- *The compounds on the list of eligible compounds below are PharmaCare benefits when:*
 - *no suitable alternative is available commercially (e.g., different brand, different drug, etc.), and*

This text would direct me to conclude that current compounded solution with methadone API is not be eligible for reimbursement since January 30th, 2013, when Methadose was announced to be commercially available. It might be the wrong interpretation as I am not as familiar as you are with these policies. However if I am correct, it seems that the current use and reimbursement of the compounded solution using methadone Active Pharmaceutical Ingredient is non-compliant with both PharmaCare policy and CPBC Professional Practice #64. The reason why these policies support in the first place the use of standardized, GMP-manufactured product is to protect public safety. It seems that the use of a commercially available solution diluted as per current guidelines (PPP #66) would not only make methadone dispensing and claim compliant with all policies (CPBC, PharmaCare, Federal Policy 0051), it would also contribute to increase the standard of care.

Philippe and I are a bit confused with the situation in British Columbia and quite surprised by the unexpected turn of events these past few months, as we feel that Mallinckrodt Canada has worked diligently with stakeholders in the province to prepare for the introduction of Methadose: as you may know, the filing of Methadose and the investment in a brand new distribution system was based on discussions with British Columbia back in 2011. Our last meeting with Bob Nakagawa when he was Assistant Deputy Minister was in December 2011. We have worked with the province before filing Methadose to validate if our product would close existing care gaps while providing opportunity to lower system costs. The conclusion was yes to both challenges. During the regulatory review by Health Canada in 2012, we met several times with CPBC and took upon ourselves to contact the methadone committee early in 2012 to inform them about our product and get their input for implementation ahead of market availability.

We would welcome the opportunity to discuss this further with you, clarify the steps for the revision of the guidelines and work collaboratively to ensure a safe transition to Methadose and minimize delays.

We could join you at your offices anytime from April 10th to April 12th. Please let us know which time and date would be the most suitable to you.

Best regards,

Christophe Goffoz

Chef, développement de marché / Market development manager

Office (direct): 514 428 8224

Cell: 514 212 6202

Fax: 514-428-8202

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Taylor, Grace HLTH:EX

From: Goffoz, Christophe <Christophe.Goffoz@covidien.com>
Sent: April 3, 2013 9:21 AM
To: XT:HLTH Solven, Suzanne
Cc: XT:HLTH Budd, George; Hebert, Philippe; Fazlagic, Tijana HLTH:EX; Lori Tanaka; Ailve M. McNestry
Subject: methadose fax - March 26

Importance: High

Hello Suzanne,

After investigation, it appears the sequence of events was as follows:

- March 25th, 3:28: Fax content sent for information to the college
- March 25th, 4.29: Final copy dated march 26 sent to the supplier. Timeline for sending was March 26th or march 27th.
- March 25th, 5:30: After email from the college requesting the deletion of reference to discussions, fax was put on hold for revision .
- March 25th, 6:40: Supplier confirmed that fax was put on hold.
- March 26th: While fax was being revised, call from BC PharmaCare with new information about reimbursement. Following this discussion, decision was taken to cancel overall communication to pharmacists.

It appears that on March 25th in the evening, there was an mistake at the supplier's level and a partial sending of the original fax was made despite the hold. Mallinckrodt was not made aware of it and did not receive a copy of the fax because it was a partial sending. Supplier told us the fax was sent to 200 pharmacists in BC.

The part of the fax discussing the use of Methadose as per CPBC guidelines is valid. The part discussing the claim process is obsolete as per the new guidance provided by Tijana on March 26th .

I would suggest we connect on the phone to discuss the situation and next steps – I am available today all day at 514 212 6202.

Please let me know your thoughts.

Best regards

Christophe Goffoz

Chef, développement de marché / Market development manager
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Fax: 514-428-8202

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From: Suzanne Solven [mailto:Suzanne.Solven@bcpharmacists.org]
Sent: Tuesday, April 02, 2013 8:19 PM
To: Goffoz, Christophe
Cc: George Budd; Hebert, Philippe; Fazlagic, Tijana HLTH:EX; Lori Tanaka; Ailve M. McNestry
Subject: RE: In-person meeting in April to discuss Methadose

Dear Christophe

We received a copy from a pharmacy today of your Rexpress – “Dear pharmacist” dated March 26, 2013.

This document was signed by you and contains the original wording that you had forwarded to us indicating that “After discussing with the College of Pharmacists of BC and BC Pharmacare, Mallinckrdot is pleased to inform you that:”

I had thought after our email exchange that the document as originally drafted was not going to go out, and both references to the College and PharmaCare were going to be removed. It appears this didn’t happen?

Interesting, the comment we received from the pharmacy was “very misleading”.

Can you please clarify what happened here?

Thanks

Suzanne Solven

Suzanne Solven, B.Sc.(Pharm), R.Ph, R.PEBC
Deputy Registrar, Director Legislation, Discipline and Investigations | College of Pharmacists of BC
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Taylor, Grace HLTH:EX

From: Goffoz, Christophe <Christophe.Goffoz@covidien.com>
Sent: March 27, 2013 1:32 PM
To: Fazlagic, Tijana HLTH:EX; Lun, Eric HLTH:EX; Shin, Sophia HLTH:EX
Cc: Hebert, Philippe
Subject: Methadose reimbursement in British Columbia

Hello Tijana,

Thank you for sending the reimbursement policy. I am happy we were able to prevent the fax from being sent, thus avoiding a confusing situation for pharmacists.

I would need your guidance on the following section regarding the reimbursement of compounded prescriptions, which attracted my attention:

Compounds eligible for coverage

- *The compounds on the list of eligible compounds below are PharmaCare benefits when:*
 - *no suitable alternative is available commercially (e.g., different brand, different drug, etc.), and*

This text would direct me to conclude that current compounded solution with methadone API is not be eligible for reimbursement since January 30th, 2013, when Methadose was announced to be commercially available. It might be the wrong interpretation as I am not as familiar as you are with these policies. However if I am correct, the use of a commercially available solution diluted as per current guidelines would better fit with PharmaCare policy.

In a similar way, Professional Practice Policy #64 from the CPBC (adapted from federal policy 0051) states:

Compounding - Pharmaceutical preparation of components into drug products that:

- *Do not circumvent regulatory requirements including the Food and Drugs Act and the Food and Drug Act Regulations, the National Drug Schedules, or intellectual property legislation.*
- *Provide a customized therapeutic solution to improve patient care without duplicating a commercially available, approved product.*

It seems that the current use and reimbursement of the compounded solution using methadone Active Pharmaceutical Ingredient is non-compliant with both PharmaCare policy and CPBC Professional Practice. The reason why these policies support in the first place the use of standardized, GMP-manufactured product is to protect public safety.

As stated above, the use of a commercially available solution diluted as per current guidelines would not only make methadone dispensing and claim compliant with all policies (CPBC, PharmaCare, Federal Policy 0051), it would also increase the standard of care at no cost for PharmaCare. PharmaCare would just need to let pharmacists know that they could submit their maintenance solution for usual reimbursement, without being subject to recovery upon audit.

Then once the guidelines are revised to allow for direct dispensing of Methadose, PharmaCare will benefit from savings generated by the revised reimbursement rate.

Finally, Mallinckrodt Canada has worked diligently with stakeholders in BC and is surprised by the unexpected turn of events these past few months: as you may know, the filing of Methadose and the investment in a brand new distribution system was based on exclusive exchange with BC Pharmacare back in 2011. We have worked with your organization before filing Methadose to validate if our product would close existing care gaps while providing opportunity to lower system costs. The conclusion was yes to both challenges.

During the regulatory review by Health Canada in 2012, we received regular phone calls from PharmaCare inquiring about expected timing of approval to have an opportunity to reflect some savings in your future budget. We also took upon ourselves to contact the 2 Colleges (physicians and pharmacists) early in 2012 to inform them about our product and get their input for implementation ahead of market availability.

I would welcome the opportunity to discuss this further with you and work collaboratively to help move the practice in BC to a higher standard, ensure a safe transition for patient and minimize delays for saving.

We could join you at your office anytime from April 10th to April 12th. Please let us know the time and date which would be the most suitable to you.

Best regards.

Christophe Goffoz

Chef, développement de marché / Market development manager

Office (direct): 514 428 8224

Cell: 514 212 6202

Fax: 514-428-8202

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Taylor, Grace HLTH:EX

From: Goffoz, Christophe <Christophe.Goffoz@covidien.com>
Sent: March 25, 2013 2:56 PM
To: Fazlagic, Tijana HLTH:EX; XT:HLTH Solven, Suzanne; XT:HLTH Budd, George
Cc: Hebert, Philippe; Mykle Ludvigsen; Lun, Eric HLTH:EX
Subject: RE: FYI - Methadose - fax to be sent on March 26th or March 27th

Hello Tijana,

As requested, the mention of contacts with PharmaCare will be removed.

Best regards

Christophe Goffoz

Chef, développement de marché / Market development manager
Office (direct): 514 428 8224
Cell: 514 212 6202
Fax: 514-428-8202

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From: Fazlagic, Tijana HLTH:EX [mailto:Tijana.Fazlagic@gov.bc.ca]
Sent: Monday, March 25, 2013 5:41 PM
To: XT:HLTH Solven, Suzanne; Goffoz, Christophe; XT:HLTH Budd, George
Cc: Hebert, Philippe; Mykle Ludvigsen; Lun, Eric HLTH:EX
Subject: RE: FYI - Methadose - fax to be sent on March 26th or March 27th

Hello Christophe,

I would like to second Suzanne's comments as I have the same concerns about implication that the Ministry of Health and PharmaCare is endorsing the information which is also not the case. I would appreciate it if you can remove reference to discussions with BC PharmaCare as well from the document.

Tijana

Tijana Fazlagic PharmD, B.Sc.(Pharm), MSc
Director
Formulary Management
Pharmaceutical Services
(604) 374-2609
Tijana.Fazlagic@gov.bc.ca

From: Suzanne Solven [<mailto:Suzanne.Solven@bcpharmacists.org>]
Sent: Monday, March 25, 2013 2:15 PM
To: 'Goffoz, Christophe'; XT:HLTH Budd, George
Cc: Fazlagic, Tijana HLTH:EX; Hebert, Philippe; Mykle Ludvigsen
Subject: RE: FYI - Methadose - fax to be sent on March 26th or March 27th

Hi Christophe,

Thanks for sending in advance.

I do have a concern, the way your communiqué is currently worded it gives the appearance that the College (and PharmaCare) are endorsing the information. I appreciate that it indicates that you had "discussions" with us, but the flow of the document lends itself to an endorsement which is not the case.

I would appreciate if you would remove any reference to discussions with the College from the document.

Thanks

Suzanne Solven

Suzanne Solven, B.Sc.(Pharm), R.Ph, R.PEBC
Deputy Registrar, Director Legislation, Discipline and Investigations | College of Pharmacists of BC
604.676.4202 | 866.676.4202 | www.bcpharmacists.org

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Please consider the environment before printing this email.

From: Goffoz, Christophe [<mailto:Christophe.Goffoz@covidien.com>]
Sent: March-25-13 12:28 PM
To: George Budd; Suzanne Solven
Cc: tijana.fazlagic@gov.bc.ca; Hebert, Philippe
Subject: FYI - Methadose - fax to be sent on March 26th or March 27th

Hello Suzanne and George,

For your information, please find enclosed the fax which will be issued to BC pharmacists either on March 26th (tomorrow) or on March 27th.

Feel free to contact me if you have any questions or feedbacks about this communication.

Best regards,

Christophe Goffoz

Chef, développement de marché / Market development manager
Office (direct): 514 428 8224
Cell: 514 212 6202

Fax: 514-428-8202

Mallinckrodt, la division Pharmaceutiques de Covidien / Mallinckrodt, the Pharmaceuticals business of Covidien
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Taylor, Grace HLTH:EX

From: Goffoz, Christophe <Christophe.Goffoz@covidien.com>
Sent: February 28, 2013 5:52 PM
To: Fazlagic, Tijana HLTH:EX
Cc: XT:HLTH Budd, George
Subject: Re: Methadose in British Columbia - Communication to pharmacists

Thank you fir the clarification Tijana.

Best regards

Christophe Goffoz

On Feb 28, 2013, at 6:40 PM, "Fazlagic, Tijana HLTH:EX" <Tijana.Fazlagic@gov.bc.ca> wrote:

> Hi George and Christophe,

>

> Please see my comment below.

>

> Tijana

>

> Sent from my iPad

>

> On 2013-02-28, at 11:51 AM, "George Budd"

<George.Budd@bcpharmacists.org<mailto:George.Budd@bcpharmacists.org>> wrote:

>

>

>

>

> Christophe,

> Below is your suggested communication including Suzanne Solven and my comments in red:

>

>

>

>

>

> · Methadose (Methadose Hydrochloride Oral Concentrate - DIN 02394618, dye-free-sugar-free, unflavored or DIN 02394596, cherry flavor they should note the strength in this bullet 10mg/mL– is now available in Canada and is indicated for the treatment of opioid dependence in adults.

>

> · In accordance with the CPBC professional practice policy #66 on Methadone Maintenance Treatment (note: see principles 3.3.2 and 3.3.4) pharmacists in British Columbia can use what powder and/or liquid Concentrate to prepare 1 mg/mL methadone solution for maintenance. Methadose must be diluted with full-strength Tang or other full strength beverage crystals to prepare the 1mg/mL maintenance solution which remains the standard for prescribing and dispensing and Pharmacare Coverage this part is inaccurate – our standards do not denote PharmaCare coverage – Please confirm PharmaCare eligibility for coverage even if diluted – Tijana?..

> PharmaCare coverage is based on a PIN for methadone for maintenance, it does not specify how a pharmacy would prepare methadone 1 mg/mL solution. Reimbursement would remain the same regardless on how they prepare it.

>

> In addition, please let us know your thoughts about the point below:

>

> · The NAPRA guidelines to pharmacy compounding and the Professional Practice Policy #64 support the use of a finished pharmaceutical product such as Methadose to prepare methadone solutions

>

> To get down to 1mg/ml concentration that would be more than 4 folds dilution. Christophe I recall you saying that the Methadose contains a preservative that would lose its efficacy if diluted. Isn't that correct?

>

> What formula would you provide to pharmacists to accurately obtain a 1mg/ml solution and in accordance to the policy?

>

>

> Please let me know if you have more questions.

>

>

> George P. Budd, Pharm.D., B.Sc.(Pharm.), R.PEBC, R.Ph.

> Inspector/Investigator | College of Pharmacists of BC

> 604.676.4214 | 866.676.4214 |

> www.bcpharmacists.org<<http://www.bcpharmacists.org>/>

>

> This email may contain confidential information which may be privileged and is intended for the exclusive use of the addressee. Any other person is strictly prohibited from disclosing, distributing or reproducing it. If the addressee cannot be reached or is unknown to you, please inform us immediately by telephone or email.

>

> Please consider the environment before printing this email.

>

>

>

>

> From: Goffoz, Christophe [mailto:Christophe.Goffoz@covidien.com]

> Sent: February-27-13 5:51 AM

> To: George Budd

> Subject: Methadose in British Columbia - Communication to pharmacists

> Importance: High

>

> Hello George,

>

> I left you a voicemail yesterday to follow-up with the communication we need to issue to pharmacists.

>

> Please let me know when you would be available to discuss: this communication is time sensitive as some key customers are waiting for more guidance about how to use Methadose in BC, with business impact for Mallinckrodt.

>

> Thank you

>

> Christophe Goffoz

>

> Chef, développement de marché / Market development manager Office

> (direct): 514 428 8224

> Cell: 514 212 6202

> Fax: 514-428-8202

>

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 >
 > From: Goffoz, Christophe
 > Sent: Thursday, February 21, 2013 5:19 PM
 > To: George Budd
 > (george.budd@bcpharmacists.org<<mailto:george.budd@bcpharmacists.org>>)
 > Cc: Hebert, Philippe
 > Subject: Methadose in British Columbia - Communication to pharmacists
 >
 > Hello George,
 >
 > It was nice talking with you this afternoon. I am fully supportive of a collaborative approach to communicate
 > effectively about methadone dispensing and Methadose.
 >
 > As discussed, please find below some bullet points about what we would like to communicate to pharmacists in BC. I
 > have attached the reference documents.
 >
 >
 > · Methadose (Methadose Hydrochloride Oral Concentrate - DIN 02394618, dye-free-sugar-free, unflavored or DIN
 > 02394596, cherry flavor – is now available in Canada and is indicated for the treatment of opioid dependence in adults.
 >
 > · In accordance with the professional practice policy #66 on Methadone Maintenance Treatment (note: see
 > principles 3.3.2 and 3.3.4) pharmacists in British Columbia can use to prepare 1 mg/mL methadone solution for
 > maintenance. Methadose must be diluted with full-strength Tang or other full strength beverage crystals to prepare the
 > 1mg/mL maintenance solution which remains the standard for prescribing and dispensing and Pharmacare Coverage.
 >
 > In addition, please let us know your thoughts about the point below:
 >
 > · The NAPRA guidelines to pharmacy compounding and the Professional Practice Policy #64 support the use of a
 > finished pharmaceutical product such as Methadose to prepare methadone solutions.
 >
 >
 > Would you be available on Monday 25th or Tuesday 26th for a follow-up call?
 >
 > Best regards
 >
 > Christophe Goffoz
 >
 > Chef, développement de marché / Market development manager Office
 > (direct): 514 428 8224
 > Cell: 514 212 6202
 > Fax: 514-428-8202
 >

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Taylor, Grace HLTH:EX

From: Goffoz, Christophe <Christophe.Goffoz@covidien.com>
Sent: November 27, 2012 11:22 AM
To: Fazlagic, Tijana HLTH:EX; Shin, Sophia HLTH:EX; Dornan, Linda HLTH:EX
Cc: 'Laura Fitzgerald s.22'; Hebert, Philippe
Subject: RE: Methadose - meeting on December 6th

Hello Tijana

It will be our pleasure. 2:00 pm on Dec 6th works well.

Laura would join us by telephone - please let me know if there will be a phone in the meeting room and which number she should dial.

Thank you

Christophe Goffoz

Chef, développement de marché / Market development manager Office (direct): 514 428 8224
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-----Original Message-----

From: Fazlagic, Tijana HLTH:EX [mailto:Tijana.Fazlagic@gov.bc.ca]
Sent: Tuesday, November 27, 2012 2:02 PM
To: Goffoz, Christophe; Shin, Sophia HLTH:EX; Dornan, Linda HLTH:EX
Cc: 'Laura Fitzgerald s.22'; Hebert, Philippe
Subject: RE: Methadose - meeting on December 6th

Hello Christophe,

Sophia and I are able to meet with you on December 6th at 2:00 pm if that still works for you. We will send you a meeting invite.

Regards,

Tijana

-----Original Message-----

From: Goffoz, Christophe [mailto:Christophe.Goffoz@covidien.com]
Sent: Mon, November 26, 2012 8:12 AM

To: Fazlagic, Tijana HLTH:EX; Shin, Sophia HLTH:EX
Cc: Laura Fitzgerald s.22); Hebert, Philippe
Subject: Methadose - meeting on December 6th

Hello Tijana and Sophia,

Philippe and I will be in Vancouver on December 6th to meet with the BC Methadone Committee. I was wondering if you would also be available to meet on December 6th: we would discuss final budget impact analysis and submission details, and provide you with an update on where we are regarding product availability, transition from compounded methadone to Methadose, and meetings with other key BC stakeholders. I think 30 minutes would give us enough time. Please let me know if you would have any other topics to add to the agenda.

Our meeting with the committee is from 10:00 to 11:00 am. Given that our flight back leaves at 5:00 pm, we could meet any time from noon until 3:00 pm.

Best regards

Christophe Goffoz

Chef, développement de marché / Market development manager Office (direct): 514 428 8224
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Taylor, Grace HLTH:EX

From: Laura Fitzgerald <s.22 - >
Sent: October 11, 2012 3:36 PM
To: Fazlagic, Tijana HLTH:EX; 'Goffoz, Christophe'; 'Hebert, Philippe'
Cc: Shin, Sophia HLTH:EX
Subject: RE: Methadose introduction in British Columbia

Good Afternoon Tijana:

I hope to have submission documents to you by very early November.

I would also like to confirm that the product, Methadose, received Health Canada approval on October 05, 2012. We are busily getting the last tidbits from Health Canada including DINS etc.

If there are any questions, will email you.

Thanks again,
Laura

-----Original Message-----

From: Fazlagic, Tijana HLTH:EX [mailto:Tijana.Fazlagic@gov.bc.ca]
Sent: September-28-12 4:04 PM
To: Goffoz, Christophe; Laura Fitzgerald s.22 ; Hebert, Philippe
Cc: Shin, Sophia HLTH:EX
Subject: RE: Methadose introduction in British Columbia

Hello Laure, Christophe, and Philippe,

We had a chance to thing about submission requirements for Methadose and the following would meet our needs:

Drug submission requirements for a line extension available at
<http://www.health.gov.bc.ca/pharmacare/formulary/drugsubline.html>
plus

Supporting clinical evidence, pharmacoeconomic evidence and/or other information the manufacturer would like the Ministry to consider (this is part of submission requirements for criteria modification).

If you have any questions, please let me know.

Tijana

-----Original Message-----

From: Fazlagic, Tijana HLTH:EX
Sent: Thu, September 27, 2012 8:42 PM
To: Goffoz, Christophe
Cc: Shin, Sophia HLTH:EX; Laura Fitzgerald s.22 ; Hebert, Philippe
Subject: Re: Methadose introduction in British Columbia

Hello Christophe,
It was a pleasure to meet you as well. Thank you for forwarding the information.

Tijana

Sent from my iPad

On 2012-09-27, at 8:32 PM, "Goffoz, Christophe" <Christophe.Goffoz@covidien.com> wrote:

> Hello Sophia and Tijana,
>
> It was a pleasure to meet with you today and discuss the benefits of Methadose™.
> Please find enclosed the presentation that was used this afternoon. It summarizes how we feel Methadose™ and
Mallinckrodt will help to improve methadone maintenance treatment while creating significant savings for the province.
Let me know if you have any question about what was presented.
>
> We look forward to working further with you on introducing this product in British Columbia.
>
> Best regards
>
> Christophe Goffoz
>
> Chef, développement de marché / Market development manager VEUILLEZ
> NOTER que mes coordonnées ont changé depuis le 3 juillet 2012 / PLEASE NOTE my contact information have changed
effective July 3rd, 2012.
> Office (direct): 514 428 8224
> Cell: 514 212 6202
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>
> <Improving MMT with Methadose.pdf>

Taylor, Grace HLTH:EX

From: Goffoz, Christophe <Christophe.Goffoz@covidien.com>
Sent: September 27, 2012 8:32 PM
To: Shin, Sophia HLTH:EX; Fazlagic, Tijana HLTH:EX
Cc: Laura Fitzgerald s.22 ; Hebert, Philippe
Subject: Methadose introduction in British Columbia
Attachments: Improving MMT with Methadose.pdf

Hello Sophia and Tijana,

It was a pleasure to meet with you today and discuss the benefits of Methadose™.
Please find enclosed the presentation that was used this afternoon. It summarizes how we feel Methadose™ and Mallinckrodt will help to improve methadone maintenance treatment while creating significant savings for the province.
Let me know if you have any question about what was presented.

We look forward to working further with you on introducing this product in British Columbia.

Best regards

Christophe Goffoz

Chef, développement de marché / Market development manager

VEUILLEZ NOTER que mes coordonnées ont changé depuis le 3 juillet 2012 / PLEASE NOTE my contact information have changed effective July 3rd, 2012.

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