Health Canada | Santé Canada

Health Products and Food Branch | Direction générale des produits de santé et des aliments

250 Lanark Avenue
Graham Spry Building
A.L. 2007A
Ottawa, Ontario
K1A 0K9

JAN 1 1 2017

16-114838-597

Dear Dr. Gerace and Ms. Resnick,

Thank you for your letter of December 15, 2016 seeking clarity on Health Canada's position regarding the conditions of use for Mifegymiso. I've also taken the liberty to cc Nancy Lum-Wilson on this response. Nancy, congratulations on the new appointment, and I look forward to working with you again.

With respect to the issues raised in your letter, we understand from the company that Mifegymiso is expected to be available on the Canadian Market by the end of January 2017. The company has also indicated that the English educational program is currently available (https://sogc.org/online-courses/courses.html), with the French version to be available shortly.

The product monograph (PM), including Mifegymiso's conditions of use, are based on the data package provided by the sponsor to Health Canada. Please note that after the original approved product monograph was made available, professional organisations raised the issue that there was a potential for confusion as the wording regarding administration in Parts I and III was not fully consistent. To address this, the product monograph was revised in October 2016.

Specifically, Part I of the PM was revised to read: *"Mifepristone should be administered under the supervision of the prescriber. In the clinical trials supporting Mifegymiso efficacy and safety, mifepristone was administered under the supervision of a physician in a clinical setting"*. To better align with Part I, Part III was also revised and now states: "*As directed by your doctor or as given to you by medical staff*".

The wording in the product monograph was deliberately chosen such that physicians could use their discretion for each individual patient. It does not mandate that the medication be taken in front of the physician. Such decisions are best made by the physician ands are considered the practice of medicine.

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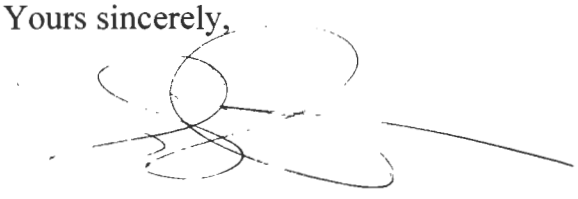
Pharmacists will be involved in the dispensing of Mifegymiso, however their role may be different than the traditional one of dispensing directly to the patient. For example, doctors may write a prescription, which is filled by a pharmacist, whereby the drug is then returned to the doctor who provides it to the patient.

The wording in the product monograph is based on the data provided to support the authorization of Mifegymiso. The product monograph is not a legally binding document. If, under the practice of medicine or pharmacy, the administration or distribution of the drug is outside of what is in the approved product monograph, the health care professional would assume any liability associated with the product being used off-label.

Revisions to the indication or conditions of use of the product will be considered if the company submits evidence supporting these changes. As with all submissions, Health Canada would apply the same rigorous scientific review to the new information.

I appreciate your organisations taking the time to write to us seeking clarity regarding the conditions of use for Mifegymiso and I hope that the above information is helpful. If you have any other questions or concerns, please don't hesitate to contact me directly.

Yours sincerely,



Dr. Supriya Sharma
Chief Medical Advisor to the Deputy Minister

cc: Nancy Lum-Wilson, Registrar Ontario College of Pharmacists