



VIA EMAIL

December 15, 2016

Dr. Supriya Sharma
Chief Medical Advisor
Health Canada
Address Locator 0900C2
Ottawa, ON K1A 0K9

Dear Dr. Sharma,

Re: Mifegymiso

The College of Physicians and Surgeons of Ontario (CPSO) and the Ontario College of Pharmacists (OCP) write in relation to Mifegymiso. We understand that the drug will become available to the Canadian public in January 2017 and wish to clarify details regarding requirements contained in the product monograph which may impact patient access to this drug.

We are aware that the product monograph submitted by Celopharma Inc. and approved by Health Canada states:

1. Mifegymiso will be prescribed and dispensed by physicians;
2. Physicians will undergo training and be registered prior to dispensing Mifegymiso;
3. The physician shall confirm gestational age by ultrasound and exclude ectopic pregnancy; and,
4. The registered physician will supervise the administration of mifepristone by the patient.

We understand that the College of Physicians and Surgeons of British Columbia and the College of Pharmacists of British Columbia have received confirmation from Health Canada that despite the product monograph, it is permissible for Mifegymiso to be dispensed by a pharmacist to the patient and delivered to the prescribing physician or dispensed directly to the patient with a prescription. Similar to our counterparts in British Columbia, we wish to confirm that Ontario physicians and pharmacists who have completed training regarding the safe use of Mifegymiso can proceed in this manner, and that this will be considered acceptable by Health Canada .

We also wish to confirm that consistent with Health Canada's 'Myths and Facts' document published online, that the product monograph requirement for 'supervision of the administration of mifepristone' does not require patients to consume the medication in front of the physician,

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but rather determining how and where the medication is to be ingested would be a treatment decision between the physician and the patient.

As professional regulatory authorities, the CPSO and the OCP have mandates to act first and foremost in the public interest. Ensuring Ontarians have access to approved medical treatments supports this mandate. Upon receiving a response from Health Canada providing confirmation on the two elements raised above, we intend to communicate with our respective members informing them of the need to complete training regarding Mifegymiso, as well as the options for dispensing this medication.

We appreciate Health Canada's assistance in clarifying these matters. As there may be others across the country who will seek similar clarification, Health Canada may wish to consider updating the current product monograph to provide more clarity around this medication's dispensing and administering procedures.

Yours very truly,



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