RESPONSE TO PETITION

Prepare in English and French marking 'Original Text' or 'Translation'

PETITION NO.: **421-01996**

BY: **MS. MATHYSSEN (LONDON-FANSHAWE)**

DATE: **JANUARY 29, 2018**

PRINT NAME OF SIGNATORY: **MR. BILL BLAIR**

Response by the Minister of Health

SIGNATURE
Minister or Parliamentary Secretary

SUBJECT

Health Care Services

ORIGINAL TEXT

REPLY

Protecting the health and safety of Canadians, including women who choose to end a pregnancy, is a fundamental priority for the Government of Canada. This includes working with the Provinces and Territories to improve the affordability, accessibility and appropriate use of prescription drugs.

Prescription drugs are a shared responsibility in Canada. The Federal Government is responsible for assessing the safety, efficacy and quality of drugs before authorizing them for sale in Canada. It also regulates the price of patented drugs in Canada through the Patented Medicine Prices Review Board to ensure that prices are not excessive. Provincial and Territorial governments are responsible for the delivery of health care for their residents, including determining which drugs are reimbursed and under what conditions. It is within this context that Canada's governments are working together and in their respective spheres, to provide Canadians with affordable access to the prescription medications they need.

Following a review of safety, efficacy and quality based on information provided by the manufacturer, Mifegymiso was first approved for sale in Canada in July 2015, for use in the termination of pregnancies of up to 49 days gestation. At that time, physician-only dispensing and education, patient information and mandatory follow-up were required. More recently, in November 2017, Health Canada issued a decision extending the indication for use of Mifegymiso up to 63

days of gestation and amended the dispensing conditions. The drug can now be dispensed directly to patients by a pharmacist or other health professional with a prescription. The manufacturer no longer requires health professionals to register with them in order to prescribe or dispense it, health professionals are no longer required to complete an education program and the requirement for written patient consent has been removed. At the same time, to protect patient safety, there are requirements in place for patient counselling, patient information material, accurate confirmation and dating of pregnancy, emergency care access and clinical follow-up. The requirements in place to help reduce the risks to women who choose to use the drug are well aligned internationally. Health Canada remains open to reviewing new evidence which may be submitted by the company to modify the terms of their marketing authorization. As well, once the product is on the market, additional information will continue to be gathered to inform future decisions.

In deciding which drugs to cover, public drug plans administered by federal, provincial and territorial governments typically rely on the recommendations of the Common Drug Review (CDR) operated by the Canadian Agency for Drugs and Technologies in Health (CADTH). Prior to listing a drug, each public drug plan considers the recommendation by CADTH and other factors, such as program mandate, jurisdictional priorities and budget impact before making its drug coverage decision.

CADTH issued its final recommendation supporting reimbursement of Mifegymiso in April 2017. As a result, the drug is now covered by most public plans for the populations they serve. This includes the Federal Government's Non-Insured Health Benefits program which provides coverage to registered First Nations and recognized Inuit for a specified range of medically necessary items and services that are not covered by other plans and programs.

It should also be noted that governments are working collaboratively to lower drugs costs. In 2016, the Federal Government joined the pan-Canadian Pharmaceutical Alliance (pCPA), a drug price negotiation body established by Provincial and Territorial governments in 2010. The pCPA combines governments' purchasing power to achieve greater savings for all publicly-funded drug programs and Canadians. Mifegymiso is among the 163 drugs for which price negotiations had been successfully completed as of July 2017.

In addition, the Government of Canada is taking direct action to modernize the way the Patented Medicine Prices Review Board works, to better protect Canadian consumers from excessive prices. The Patented Medicines Regulations, which together with the Patent Act provide the Patented Medicine Prices Review Board with the tools it needs to assess the prices of patented drugs like Mifegymiso, will be updated for the first time in more than 20 years.

Furthermore, the Advisory Council on the Implementation of National Pharmacare is intended to produce recommendations which will help ensure that all Canadians have consistent, equitable and affordable access to medications.