HOUSE OF COMMONS
CHAMBRE DES COMMUNES
CANADA

RESPONSE TO PETITION

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

PETITION NO. **421-03104**

By: **Ms. Finley (Haldimand-Norfolk)**

DATE: **JANUARY 28, 2019**

PRINT NAME OF SIGNATORY: **MS. PAM DAMOFF**

Response by the Minister of Health

SIGNATURE
Minister or Parliamentary Secretary

SUBJECT

Hypothyroidism

ORIGINAL TEXT

REPLY

The Government of Canada is committed to strengthening Canada's health care system and to supporting the health of Canadians. This includes working with the provinces and territories to improve the affordability, accessibility and appropriate use of prescription drugs. The management of prescription drugs in Canada is a shared responsibility. The Federal Government is responsible for assessing the safety, efficacy and quality of prescription drugs before authorizing them for sale in Canada. Provincial and territorial governments are responsible for the delivery of health care for their residents, including determining which prescription drugs are reimbursed and under what conditions. In addition, the professional freedom of doctors to choose tests and treat individual patients is also a matter of provincial and territorial jurisdiction and falls under the appropriate provincial or territorial College of Physicians.

With regards to the choice of therapies now available on the Canadian market, under the *Food and Drugs Act* and *Regulations*, all products that are sold or marketed in Canada and that make a therapeutic claim need to be approved by Health Canada either as a drug, a medical device or as a natural health product. The drug authorization process is initiated when a manufacturer submits an application to Health Canada for review. Every submission is then reviewed by scientists to assess the product's safety, efficacy and quality. The process to gain access to the Canadian market is

initiated by industry; Health Canada does not have the authority to compel a company to market a particular product in Canada.

Health Canada is actively working toward improving timely access to drugs and devices though the Regulatory Review of Drugs and Devices (R2D2). Through R2D2, Health Canada is expanding the priority review process to decrease review times for products needed by the health care system, including drugs for rare diseases, generics, biosimilar drugs and biologics. Health Canada has also collaborated with health technology assessment organizations to reduce the time between Health Canada approvals and reimbursement recommendations.

On the particular issue of thyroid drugs, animal-derived thyroid tablets are currently approved for sale in Canada under the brand name Thyroid. Thyroid contains both levothyroxine (T4) and triiodothyronine (T3). Thyroid is sold by ERFA Canada Inc. as 30 mg, 60 mg and 125 mg tablets under drug identification numbers (DIN) 00023949, 00023957 and 00023965, respectively. The Prescribing Information for Thyroid can be accessed at https://pdf.hres.ca/dpd_pm/00034857.PDF.

During the drug authorization process, a submission sponsor will submit to Health Canada their proposed product monograph for the drug in question; a product monograph provides valuable information for physicians and patients on safe use of the product and is an important tool to educate physicians and patients on available and suitable treatment options. Upon verification that the product monograph is accurate and substantiated by the appropriate evidence, the product monograph is included as part of a product's labelling, and Health Canada also makes it available through its Drug Product Database, available here: https://health-products.canada.ca/dpd-bdpp/index-eng.jsp.

After a product is on the market, companies may make a submission to Health Canada to modify a product monograph, based on new data or evidence regarding the safe use of the product. In certain circumstances, Health Canada can also compel companies to make changes to a product monograph, based on new data or evidence regarding the safe use of the product. Through these actions, the Government of Canada continues to work with provincial and territorial governments and other key partners to improve the accessibility of needed prescription drugs.