RESPONSE TO PETITION

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

PETITION NO.: **421-02274**

BY: **MR. SHIELDS (BOW RIVER)**

DATE: **APRIL 26, 2018**

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

Response by the Minister of Health

SIGNATURE
Minister or Parliamentary Secretary

SUBJECT

Medical devices

ORIGINAL TEXT

REPLY

Canada's medical devices regulatory system is one of the most rigorous in the World. It involves a stringent set of pre-market requirements for licensing of medical devices before they can be sold in Canada, including the requirement for a third party certified quality management system for the highest risk (Class II, III, and IV) devices including surgical meshes and monitoring once on the market. Canada's medical devices regulatory framework has been developed to meet Canadian healthcare system needs and priorities. Regulatory decisions are made independently based on information submitted by manufacturers.

Surgical meshes are used to support organs or other tissues during surgery. For example, inguinal hernias, abdominal hernias, and organ prolapses. Surgical mesh products are also implanted transvaginally for the treatment of stress urinary incontinence (SUI) and pelvic organ prolapse (POP). These medical devices are subject to detailed pre-market review of safety and effectiveness information in accordance with the *Food and Drugs Act* and the *Medical Device Regulations* (MDRs) before being issued a licence for sale in Canada.

All medical devices, including surgical meshes, have benefits and risks associated with their use. In assessing a marketed health product, Health Canada looks at the balance between possible risks and potential benefits for Canadian users of

the product. When risks associated with a health product under its current conditions of use are determined to no longer be acceptable, necessary regulatory actions are taken.

Each individual's situation must be assessed by the appropriate healthcare professionals to help ensure an acceptable product has been selected. When healthcare professionals prescribe any health product, the benefit must always be considered against the possible risk to the patient. These prescribing decisions fall under the practice of medicine and are outside the scope of Health Canada's mandate.

Health Canada is aware of reported complications associated with surgical mesh products, and has completed several post-market safety reviews on these products. These reviews have led to the issuance of risk communications and improved product labelling, as well as working with healthcare professional associations on this issue. Health Canada's decisions are made taking into account the most up-to-date safety and effectiveness information available at the time, including information from foreign regulators. Health Canada continues to monitor all available safety and effectiveness data of these devices, and will take appropriate action, if deemed necessary, to protect the health and safety of Canadians.

The following are the responses to the specific recommendations in your petition.

Recommendation 1: Restrict the use of urogynecological surgical mesh materials to use within clinical studies with a duration follow up of no less than 5 years.

Response 1: Health Canada considers that restricting the use of urogynecological mesh materials to clinical studies would limit the availability and access to meshes. This could result in a potential gap in treatment options for patients who could benefit from the use of a mesh for the treatment of SUI and POP. When assessing a new medical device for the Canadian market, Health Canada requests a comprehensive data package that includes an appropriate and statistically significant clinical analysis of well-designed device-specific trials and comparative clinical studies, which should include data on the follow-up of patients for an acceptable length of time. Health Canada also assesses relevant literature and any available post-market studies, to support the premarket safety and effectiveness of all medical devices, including surgical meshes. Post-market surveillance by Health Canada continues for the lifespan of these devices.

Recommendation 2: Temporarily suspend the licensing use of polypropylene surgical meshes as used in vaginal mesh implants until an oversight committee assures the benefit over risk ratios are assessed for patient quality of life, versus durability of quick mesh fixes.

Response 2: The safety and effectiveness of all surgical meshes for use in the treatment of SUI and POP were reviewed in 2009, 2012 and 2014. In the context of these reviews, new information was evaluated by Health Canada and consideration was given to recommendations made by the societies representing the Canadian medical experts, i.e., the Society of Obstetricians and Gynaecologists of Canada and the Canadian Urological Association.

The professional medical societies referred to above have determined that the use of a transvaginal mesh as an option to treat SUI is supported by clinical evidence. As part of medical practice, a detailed discussion of the risks versus the benefits of using a transvaginal mesh is still required with each patient.

With regards to the review of the use of meshes to treat POP, it concluded that this is a very specialized clinical situation and that meshes should be used at the discretion of the healthcare professional under the practice of medicine.

Health Canada and healthcare professionals recognize that there are risks associated with these procedures, as there are with any surgical intervention, and that patients must be fully informed of the potential complications that can result from the procedure or from the use of the surgical meshes.

Following the reviews, Health Canada determined that the benefits of surgical meshes continue to outweigh the potential risks. Suspending the licence for these products at this time would lead to a gap in treatment options. At this time, Health Canada considers that adequate evidence of safety and effectiveness has been provided thus far, and the Department continues to closely monitor the safety of surgical meshes. Health Canada is aware that meshes for treatment of POP and only the "mini sling" meshes for SUI have been suspended in Australia as of the end of 2017. No other jurisdictions have suspended meshes; however, most are monitoring these devices and are involved in post-market surveillance activities similar to Health Canada. The United States Food and Drug Administration is conducting a larger post-market study and Health Canada is keeping up to date on their progress. Health Canada will take further steps as appropriate, as new information emerges.

Recommendation 3: Implement a mandatory registry system for all implant materials and devices.

Response 3: In Canada, all devices are subject to requirements for the maintenance of distribution records by the manufacturer, importer, and distributor. In addition, there are mandatory systems in place for the reporting of device-related problems to Health Canada under the MDRs. Similar problem reporting mechanisms exist at the provincial level regarding the provision of medical services and physician care.

Currently, some high risk devices, notably heart valves, pacemakers, and other active implanted cardiac devices, are listed on Schedule 2 of the MDRs. These devices are subject to additional tracking requirements, and the voluntary distribution and maintenance of device registry cards by manufacturers. These devices have been selected because their failure could lead to immediate death.

Health Canada is monitoring reported problems and trends from the clinical literature for surgical meshes. This is considered to be an appropriate risk management measure given the nature of surgical complications and the involvement of the professional medical societies.

Recommendation 4: Close the ISO loophole in the approval process for fast tracked Class II and III permanent implant devices and materials.

Response 4: Health Canada does not consider that there is a loophole in the approval process. Section 33 of the MDRs was put in place in anticipation of a time in the future when the Minister is able to recognize authorizations from other regulatory authorities. To date, no regulatory authorities have been recognized by the Minister under Section 33. At this time all manufacturers who wish to sell Class II, III or IV medical devices in Canada are required to comply with Section 32 of the MDRs and must file a licence application with a detailed data package (for Class III and IV devices) and information for review by Health Canada prior to being licensed for sale in Canada.

Recommendation 5: Establish a patient registry for all implantable devices to enable long term patient follow-up notification and surveillance.

Response 5: Under the MDRs, manufacturers are expected to submit to Health Canada the results of robust clinical trials to establish the safety and effectiveness of all implantable devices. Manufacturers, importers, and distributors are also responsible for tracking individual devices to the physicians or retailers who have purchased them. Additionally, manufacturers are required to monitor and report on problems related to medical devices sold in Canada. These measures are considered sufficiently robust to monitor the long-term safety of implantable devices.

Patient registries to track and follow specific clinical outcomes have been set up voluntarily for certain types of implantable devices (e.g., those for joint replacement), but none have been implemented for surgical meshes. The Minister of Health is currently permitted to impose and amend terms and conditions on authorizations for medical devices. This could include mandating a patient registry if one is considered to be beneficial for the monitoring of the safety and performance of a medical device. The decision to mandate patient registries is not taken lightly given the regulatory burden of such a measure in the context of the availability of other safety monitoring tools.

In addition to current tools, Health Canada is in the process of designing and implementing modified regulations under the *Protecting Canadians from Unsafe Drugs Act* (Vanessa's Law) to improve the reporting of adverse reactions by healthcare institutions. This will result in more data and information being consistently available and will allow the Department to continue to closely monitor the safety of implantable devices such as surgical meshes, and take further action as deemed necessary to protect the safety of Canadians.

Furthermore, with the Regulatory Review of Drugs and Devices initiative, Health Canada is modernizing the MDRs to allow for better risk management of devices throughout their lifecycle by creating opportunities for more active surveillance through the enhanced use of real world evidence. The modifications to the regulations will improve Health Canada's ability to efficiently collect post-market safety information and to take appropriate action when a serious health risk is identified.

In conclusion, I would like to thank you for taking the time to present your concerns. Canada's regulatory system for medical devices, including implantable devices, is one of the most stringent in the World. We believe the current regulatory system provides Canadians with access to safe, effective and high quality medical devices.