

March 4<sup>th</sup> 2020

Dr. Marc Poitras  
Manager, Marketed Pharmaceuticals and Medical Devices Bureau  
Marketed Health Products Directorate

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Dear Dr. Poitras,

**Re: Post-SSRI Sexual Dysfunction (PSSD)**

On January 25, 2019, we received a letter from Katherine Soltys, Director of Marketed Pharmaceuticals and Medical Devices Bureau, requesting data on post-treatment sexual dysfunction after the use of serotonin reuptake inhibiting antidepressants.

We provided:

- A spreadsheet containing 298 anonymised RxISK Reports of post-treatment sexual dysfunction linked to serotonin reuptake inhibitors.
- 69 named reports, 32 of which included accompanying letters from healthcare professionals.
- A copy of the requested Dec 4, 2017 letter from Dr. A. Nathwani, Chief Medical Officer / Global Head of Medical Function / Executive Vice President of Sanofi.

Given the sensitive nature of the condition, patients are understandably very protective of their privacy. All of the individuals who completed named reports agreed to forgo anonymity, insofar as providing their name and contact details to Health Canada and agreeing to be contacted by Health Canada for follow-up, on the basis that they were making a positive contribution to a serious public health issue. It is therefore disappointing that there has seemingly been no further response or action from Health Canada on this matter.

The reality is that doctors look to regulators to provide an indication of whether a drug can cause a particular adverse event. When a drug label does not include a warning, doctors typically assume that the drug does not cause the problem. Our paper, "*Post-SSRI sexual dysfunction: Patient experiences of engagement with healthcare professionals*", is enclosed and describes some of the appalling responses that patients have received from healthcare professionals when trying to seek help for their condition. These reactions undoubtedly stem in no small part from a lack of warnings in drug labels.

The European Medicines Agency (EMA) has since asked companies to update drug labels for all SSRIs and SNRIs to include information about persistent sexual dysfunction after withdrawal of the drug. Although we welcome this decision, the warning does not go far enough. Many of

those affected with PSSD had hoped for more than the very minimal set of words that has resulted.

EMA's warning also failed to address genital anaesthesia. We therefore ask Health Canada to note that:

- SSRIs can cause genital numbness within 30 minutes of a first pill.
- As described in "*Citizen petition: Sexual side effects of SSRIs and SNRIs*", two 1990s trials showed that serotonin reuptake inhibitors reduce genital sensation.
- All of the medical literature on PSSD identifies genital numbing as a side effect of these drugs.
- The named reports we provided from PSSD sufferers consistently identified genital numbing as a side effect of the drugs.
- Dapoxetine has been licensed and other SSRIs are used on the basis of this effect.

Genital anaesthesia is not a typical feature of sexual dysfunction and neither patients or healthcare professionals would read a warning of sexual dysfunction to mean that they could lose sensation in their genitals. EMA's decision to omit this information is inexplicable. We have asked them and other regulators to provide any evidence that any psychiatric condition allows a patient to rub chilli paste into their genitals and not feel it. To date they have not provided any.

Persistent sexual dysfunction after withdrawal of an antidepressant is a serious issue that requires robust action. Every day, patients are newly prescribed serotonin reuptake inhibitors with little or no warning that they could be left with permanent alterations to their sexual function including genital numbness, pleasureless orgasm, anorgasmia, erectile dysfunction and other sexual problems.

The first known report of a post-treatment sexual dysfunction linked to an SSRI was in 1991, making it nearly 30 years without warnings and 16 years since the condition was first reported in the medical literature. It may well have appeared even earlier in Healthy Volunteer trials you were likely given as part of the original licensing applications.

We hope that Health Canada appreciates the seriousness of this issue, and will implement suitable warnings so that both patients and doctors can be better informed when making treatment decisions, and will do so soon.

Yours sincerely,

A handwritten signature in black ink that reads "David Healy". The signature is written in a cursive, flowing style.

Professor David Healy MD FRCPsych