Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

24 October 2023

Dear [redacted]

FOI 23/526

Thank you for your email dated 5 October 2023, requesting information for the following:

- number of reports received via the Yellow Card scheme for 14 different side-effects (flatulence, excessive sexual fantasies, loss of libido, hypersexuality, libido increased, pathological gambling, compulsive shopping, transvestism, voyeurism, obsessive-compulsive disorder, yawning, cyanopsia, priapism and gynecomastia) from 1st January 2018 to 31st December 2022.

The number of spontaneous suspected adverse drug reaction (ADR) reports received via the Yellow Card scheme from 1 January 2018 to 31 December 2022 is provided in the table below, as per your request.

Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Table 1. UK spontaneous suspected ADR reports received by the MHRA (01/01/2018 – 31/12/2022)

(Data extraction date 9/10/2023)

ADR	Number of reports	Drug A	Number of reports	Drug B	Number of reports
Flatulence	1457	CHADOX1 NCOV-19	414	TOZINAMERAN	215
Excessive sexual fantasies	1	TESTOSTERONE	1	NOT APPLICABLE	
Loss of libido	470	FINASTERIDE	69	CHADOX1 NCOV-19	59
Hypersexuality	30	ARIPIPRAZOLE	10	ROPINIROLE, LEVODOPA	3*
Libido increased	52	CHADOX1 NCOV-19	9	TOZINAMERAN	9
Pathological gambling (Gambling disorder)	24	ARIPIPRAZOLE	13	PRAMIPEXOLE	5
Compulsive shopping	10	ROPINIROLE	3	ARIPIPRAZOLE, CARBIDOPA, SODIUM CHLORIDE, SODIUM BICARBONATE, POTASSIUM CHLORIDE, CHADOX1 NCOV-19, ENTACAPONE, LANSOPRAZOLE, LEVODOPA, MACROGOL, MIRTAZAPINE	2*
Transvestism	1	TOZINAMERAN	1	NOT APPLICABLE	
Voyeurism	0	NOT APPLICABLE			
Obsessive-compulsive disorder	76	MONTELUKAST	16	ISOTRETINOIN	11
Yawning	203	CHADOX1 NCOV-19	74	TOZINAMERAN	31
Cyanopsia	16	TOZINAMERAN	5	SILDENAFIL	4
Priapism	58	RISPERIDONE	7	CLOZAPINE METHYLPHENIDATE TRAZODONE	5*
Gynaecomastia	194	SPIRONOLACTONE	25	FINASTERIDE	18

**Equal number of reports for Drug B*

The MHRA continuously monitors the safety of medicines and vaccines through a variety of pharmacovigilance processes, including the Yellow Card scheme. As part of our signal detection processes, all adverse reaction reports received by the Yellow Card scheme are assessed, and cumulative information is reviewed at regular intervals. If appropriate, regulatory action would be taken if any serious risks were confirmed.

When considering the above spontaneous data, it is important to be aware of the following points:

- A reported reaction **does not** necessarily mean it has been caused by the vaccine, medicine, or device only that the reporter had a suspicion it may have. The fact that symptoms occur after use of a vaccine, medicine, or device, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by it. Underlying or concurrent illnesses may be responsible and such events can also be coincidental.

- It is also important to note that the number of reports received via the Yellow Card scheme does not directly equate to the number of people who suffer adverse reactions and therefore cannot be used to determine the incidence of a reaction or compare the safety profile of different vaccines, medicines, or devices. ADR and Device incident reporting rates are influenced by the seriousness of adverse

reactions, their ease of recognition, the extent of use of a particular medicine or device, and may be stimulated by promotion and publicity. Reporting tends to be highest for newly introduced medicines during the first one to two years on the market and then falls over time.

I hope the information provided is helpful, but if you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date of this response; and can be addressed to this email address.

Yours sincerely,

FOI Team,
Safety and Surveillance

If you have a query about this email, please contact us. If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the Agency who has not previously been involved in your request. If you wish to pursue that option please write to the Communications Directorate, 4-T, Medicines and Healthcare products Regulatory Agency, (via this email address). After that, if you remain dissatisfied, you may ask the Information Commissioner at:

The Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF