



Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of
Information Team
10 South Colonnade
Canary Wharf
London
E14 4PU

foi.request@mhra.gov.uk

[MHRA Website](https://www.mhra.gov.uk)

Our Ref: FOI2024/00588

23 October 2024

Dear [REDACTED]

Thank you for your Freedom of Information (FoI) request received on 1 October 2024. You wrote:

"In the list below, I have selected 14 different side effects that can be reported to you as a side effect of medication under the yellow card scheme. For each of the side effects please state how many reports you received of that side-effect across all medications/drugs in the 5-year period from the 1st January 2019 to the 31st December 2023. Then for each side effect state the two drugs that recorded the most side effects, stating the name of the drug and the number of reports it was responsible for. For each side effect this should then provide a table which looks like this:

Side Effect X: 127 reports. Drug A - 62 reports, Drug B -10 reports.

The 13 side effects are listed below:

Gastrointestinal Disorders: Flatulence, bloating and distortion: Flatulence

Psychiatric Disorders: Sexual Desire disorders: (i) excessive sexual fantasies, (ii) loss of libido, (iii) hypersexuality and (iv) libido increased

Psychiatric Disorders: Impulse Control Disorders: (i) pathological gambling, (ii) compulsive shopping

Psychiatric Disorders: Paraphilias: (i) Transvestism, (ii) voyeurism

Psychiatric Disorders: Obsessive-compulsive disorders and symptoms: (i) Obsessive-compulsive disorder

Respiratory disorders: Upper Respiratory tract signs and symptoms: Yawning

Eye Disorders: Visual colour distortions: Cyanopsia

Reproductive and breast disorders: (i) Erection and ejaculation conditions and disorders: Priapism, (ii) Breast Disorder NEC: Gynecomastia."

MHRA Response

We confirm that we hold the information you have requested.

The number of spontaneous suspected adverse drug reaction (ADR) reports received via the Yellow Card scheme from 1 January 2019 to 31 December 2023 is provided in the table below, as per your request.

Table 1. UK spontaneous suspected ADR reports received by the MHRA (01/01/2019 – 31/12/2023)

(Data extraction date 07/10/2024)

ADR	Number of reports	Drug A	Number of reports	Drug B	Number of reports
Flatulence	1559	CHADOX1 NCOV-19	415	TOZINAMERAN	220
Excessive sexual fantasies	1	TESTOSTERONE	1	NOT APPLICABLE	
Loss of libido	529	FINASTERIDE	87	CHADOX1 NCOV-19	61
Hypersexuality	43	ARIPIPRAZOLE	10	LEVODOPA	4
Libido increased	53	CHADOX1 NCOV-19	9	TOZINAMERAN	9
Pathological gambling (Gambling disorder)	49	ARIPIPRAZOLE	40	PRAMIPEXOLE	5
Compulsive shopping	18	ARIPIPRAZOLE	9	CARBIDOPA, ENTECAPONE, LEVODOPA	3*
Transvestism	1	TOZINAMERAN	1	NOT APPLICABLE	
Voyeurism	0	NOT APPLICABLE			
Obsessive-compulsive disorder	70	MONTELUKAST	12	ISOTRETINOIN	9
Yawning	200	CHADOX1 NCOV-19	74	TOZINAMERAN	32
Cyanopsia	16	TOZINAMERAN	5	SILDENAFIL	4
Priapism	65	CLOZAPINE	5	TRAZODONE	5
Gynaecomastia	216	SPIRONOLACTONE	36	FINASTERIDE	23

**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:

- Reporters are asked to submit Yellow Card reports even if they only have a suspicion that the vaccine may have caused the adverse reaction. The existence of an adverse reaction report does not necessarily mean that the medicine or vaccine has caused the reaction.
- It may be difficult to tell the difference between something that has occurred naturally and an adverse reaction. Sometimes reactions can be part of the condition being treated rather than being caused by the medicine or vaccine.
- Many factors have to be considered when assessing whether a vaccine has caused a reported adverse reaction. When monitoring the safety of medicines and vaccines, MHRA staff carry out careful analysis of these factors.
- It is not possible to compare the safety of different medicines or vaccines using Yellow Card data. Reporting rates can be influenced by many factors including the seriousness of the adverse reactions, their ease of recognition and the extent of use of a particular vaccine. Reporting can also be stimulated by promotion and publicity about a product.

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review, you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.

Website: [ICO FOI and EIR complaints](#) or telephone 0303 123 1113.

Re-use of our information

The MHRA information supplied in response to your request is subject to Crown copyright. Information created by the MHRA which is disclosed under the Freedom of Information Act is made available for re-use under the Open Government Licence (OGL) v3.0, except where this is otherwise stated. There are some restrictions on re-use under the OGL and these can be viewed here:

<https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/>