



## Medicines & Healthcare products Regulatory Agency

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Our Ref: **FOI2025/00195**

28th March 2025

Dear [REDACTED]

Thank you for your Freedom of Information (FOI) request received on 27<sup>th</sup> February where you asked about Yellow Card reports received in relation to Sildenafil. Your queries are detailed verbatim in the italicised points below.

### **MHRA Response**

We confirm that we hold some of the information you have requested. Unfortunately, we cannot provide this data in the requested format.

*3. How many complaints about Sildenafil (NHS website: <https://www.nhs.uk/medicines/sildenafil-viagra/>) have you received through the Yellow Card scheme*

I can confirm that for the period 2021 and 2024 inclusive the MHRA has received 477 UK suspected spontaneous adverse drug reaction (ADR) reports concerning sildenafil. Please 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. ADR reporting rates may be influenced by multiple factors including the seriousness of ADRs and their ease of recognition.

*c. Please, if known, break it down per brand of the product ingested (if Viagra, Aronix, Liberize, Nipatra, Revatio, Grandipam, hims, Kamagra or else)*

A breakdown of the brands can be found in Table 1 in the attached PDF document. Please note that the brand of a drug is not always provided by the reporter when submitting a Yellow Card Report. Please note that it is not possible to compare the safety profile of different medicines using Yellow Card data as ADR reporting rates are influenced by many factors. For example, they may be impacted by the extent of use of a particular medicine and may be stimulated by promotion and publicity about a drug. For these reasons data provided should also not be used as a basis for determining incidence of side effects.

*h. Please, indicate if the product used was licensed for use in the UK or not.*

A breakdown indicating which sildenafil brands have an active license in the UK can be found in Table 1 in the attached PDF document.

*l. Please, if known, indicate the medical condition for which the product was taken for (if erection problems, pulmonary hypertension or else)*

A breakdown of the reported medical conditions for which sildenafil was taken can be found in Table 2 in the attached PDF document. Please note that the reason for taking a medicine is an optional free text field and therefore is not always provided by the reporter when submitting a Yellow Card Report. Additionally, a reporter may provide more than one reason for taking a drug.

*q. Please also, if known, include from which pharmacy or online site the product came from*

Unfortunately, we do not hold this data.

*u. Please Include the year and if it has led to people being hospitalised and/or resulted in death.*

A breakdown of the number of reports indicating hospitalisation and/ or fatality broken down by year can found in Table 3 in the PDF document provided. The MHRA takes all reports, including those with a fatal outcome very seriously. All reports with a fatal outcome are reviewed alongside all available evidence including an assessment of post-mortem details if available, to consider whether the medicine may have caused the event, or whether the event and fatal outcome were likely to be purely coincidental and due to underlying illness.

*z. Include what the reported symptoms or adverse reactions were.*

Please find attached a Drug Analysis Print (DAP) for Sildenafil which provides further detail on the adverse reactions reported within these reports. Please refer to the attached information sheet for guidelines on how to interpret the DAP.

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

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

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

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## **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](mailto: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**

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