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

[redacted]

Our Ref: **FOI2026/01040**

27 October 2026

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 11 September. You wrote:

> *I am writing to request information held by the Medicines and Healthcare products Regulatory Agency (MHRA) concerning suspected adverse drug reactions (ADRs) reported through the Yellow Card Scheme in relation to medroxyprogesterone acetate (MPA).*
>
> *I understand that the MHRA has previously confirmed that detailed, appropriately anonymised Yellow Card information can be disclosed under the Freedom of Information Act. I am therefore seeking aggregate statistical information rather than any personally identifiable information.*
>
> *For clarity, I am requesting data relating to the active substance medroxyprogesterone acetate, rather than limiting the search to the individual brand name Depo-Provera. This is important because medroxyprogesterone acetate is used in different products and formulations, including Depo-Provera and Sayana Press, and I wish to understand the full pharmacovigilance reporting history associated with the substance.*
>
> *1. Total number of Yellow Card reports*
>
> *Please provide the total number of UK Yellow Card reports of suspected adverse reactions associated with medroxyprogesterone acetate, from the earliest date for which records are available up to and including 31 August 2026.*
>
> *Please provide the figures cumulatively as well as, where possible, broken down by calendar year.*
>
> *2. Annual breakdown*
>
> *Please provide the number of suspected ADR reports involving medroxyprogesterone acetate for each calendar year, from the earliest available year through to 31 August 2026.*
>
> *If the data are available in a different reporting period or format, please provide the closest equivalent and explain the period used.*

3. Breakdown by suspected adverse reaction

Please provide the number of reports associated with each suspected reaction/reaction term recorded against medroxyprogesterone acetate.

In particular, I would like the following categories specifically identified where they are present within the Yellow Card data:

- Meningioma
- Multiple meningiomas
- Intracranial tumour
- Brain tumour
- Other central nervous system/neoplastic disorders
- Neurological disorders
- Visual disorders
- Headache
- Migraine
- Seizures/convulsions
- Pituitary disorders
- Cognitive disorders
- Memory disorders
- Psychiatric disorders
- Mood disorders
- Muscle atrophy
- Lipodystrophy
- Osteoporosis
- Other bone disorders
- Diabetes/metabolic disorders
- Thromboembolic disorders
- Cerebrovascular disorders

Where the MHRA uses a specific MedDRA Preferred Term (PT), Lowest Level Term (LLT), System Organ Class (SOC), or other coding terminology rather than the wording above, please provide the corresponding coded term and explain the classification used.

I am particularly interested in ensuring that reports are not excluded simply because the reporter used wording such as "brain tumour", "intracranial tumour" or "multiple meningiomas" rather than the exact term "meningioma".

4. Product/brand information

Where this information is held, please provide a breakdown of reports according to the suspected product/formulation, including:

- Depo-Provera
- Sayana Press
- Other injectable medroxyprogesterone acetate products
- Oral medroxyprogesterone acetate products

If the MHRA's database does not permit a direct brand-level breakdown, please state this clearly and provide the closest available breakdown.

5. Route of administration

Please provide the number of reports according to route of administration, where recorded, including:

- Intramuscular
- Subcutaneous
- Oral
- Other/unknown

6. Seriousness of reports

Please provide the number of reports classified as serious and non-serious, where this classification is available.

If possible, please also provide the number of serious reports associated specifically with meningioma.

7. Reporter type

Please provide the number of reports according to reporter type, where recorded, including:

- Patient/member of the public
- Healthcare professional
- Pharmaceutical company/manufacturer
- Other reporter type
- Unknown/not recorded

Again, I would particularly welcome this breakdown for reports involving meningioma.

8. Reported outcomes

Where available, please provide aggregate information concerning the reported outcome of the suspected ADR, including:

- Hospitalisation
- Life-threatening reaction
- Disability/incapacity
- Congenital abnormality
- Fatal outcome
- Recovery
- Recovering
- Not recovered
- Recovered with sequelae
- Unknown/not recorded

I am particularly interested in the outcomes associated with reports of meningioma and multiple meningiomas.

9. Meningioma reports – before and after the October 2024 safety communication

Please provide the number of Yellow Card reports concerning meningioma associated with medroxyprogesterone acetate received:

a) before the MHRA/Pfizer safety communication issued in October 2024; and

b) from the date of that communication through to 31 August 2026.

If possible, please provide this as a year-by-year cumulative or annual breakdown so that the reporting pattern before and after the safety communication can be examined.

For example:

Period| Number of meningioma reports
Earliest available year – 2023|
2024, before October communication|
October–December 2024|
2025|
1 January–31 August 2026|

If the MHRA holds the information in a form that permits a more precise comparison, please provide that instead.

10. Historical cumulative meningioma reports

Please provide, if available, the annual cumulative number of meningioma reports associated with medroxyprogesterone acetate, from the earliest recorded report through to 31 August 2026.

I am specifically seeking to establish how the number of reported cases has developed over time and whether there was any change in reporting following the recognition and communication of the meningioma risk.

11. Multiple meningiomas

Please separately identify, where possible, reports in which multiple meningiomas were reported.

If multiple meningiomas are not separately coded from meningioma generally, please confirm this and provide the relevant coding/category used by the MHRA.

12. Historical changes in coding or reporting

If there have been changes to the coding, terminology, reporting system, product categorisation or treatment of medroxyprogesterone acetate ADR reports during the period covered by this request that could affect comparison of historical and current figures, please provide details of those changes.

13. Publicly available information

I appreciate that some Yellow Card information is available through the MHRA's public reporting tools, including iDAP.

However, this request is specifically for aggregate historical information and cross-tabulated data held by the MHRA, including annual figures, reaction-specific figures, meningioma figures, pre- and post-October 2024 comparisons, seriousness, reporter type, route and product/formulation where available.

I am therefore not requesting that I simply be directed to the publicly available iDAP search facility.

If any part of the information requested above is already publicly available, please identify precisely which information is available and provide the corresponding publication/database reference. I would nevertheless be grateful for the additional aggregate information requested above where it is held by the MHRA.

14. Data limitations

If any of the requested breakdowns cannot be provided because the MHRA does not routinely record the information, please specify which elements are unavailable rather than treating the entire request as unavailable.

If some of the requested information would exceed the appropriate cost limit, please provide the information that can be supplied within the limit and advise which elements would need to be narrowed or reformulated.

I am happy for the information to be supplied electronically, preferably in Excel, CSV or another machine-readable format, where possible.

I confirm that I am seeking aggregate, anonymised statistical information only and do not require any patient-identifiable information.

This request is being made to assist with research into the long-term pharmacovigilance history of medroxyprogesterone acetate, particularly in relation to meningioma and the development of the recognised safety information surrounding prolonged exposure.

Thank you for your assistance. I look forward to your response within the statutory timeframe.

MHRA Response

We confirm that we hold the information you have requested and have broken down this response by the questions outlined above.

Some of the information you have requested is exempt from release under Section 21 of the FOIA (information accessible by other means), as this is already publicly available. The MHRA publishes this information in the form of interactive Drug Analysis Profiles (iDAPs) which can be accessed here on the Yellow Card website. This includes all reports received from healthcare professionals, members of the public, and pharmaceutical companies. You will be able to find information here about the number of reports of suspected Adverse Drug Reactions (ADRs) on the overview page for medroxyprogesterone.

When reviewing the data within an iDAP it is important to do so in the context of the essential guidance at the bottom of the report to ensure that you do not misinterpret the data. The data shown in these interactive profiles can be very useful in helping to identify possible medicine safety issues. However, this information does not present a complete overview of the potential side effects associated with specific medicines. Conclusions on the safety and risks of medicines cannot be made on the data shown in the Interactive Drug Analysis Profile alone.

The MHRA uses the Medical Dictionary for Regulatory Activities (MedDRA) to code suspected adverse drug reactions reported by patients and healthcare professionals via the Yellow Card scheme. MedDRA is an international, clinically validated medical terminology used by regulatory authorities and the biopharmaceutical industry throughout the entire regulatory process, from pre-marketing to post-marketing safety monitoring.

When pulling the additional data provided in this response, all reports up to and including 14 September 2026 have been extracted. This is to align with the time period of the data which is currently available in the iDAP as of the date of this letter.

Question 1 – Total number of Yellow Card reports

To view the total number of Yellow Card reports for medroxyprogesterone please navigate to the **Yellow Card Overview** page in the iDAP.

Question 2 – Annual breakdown

To view an annual breakdown of medroxyprogesterone Yellow Card reports please navigate to the **Total Report Profile** under **Reports by year** in the iDAP.

Question 3 – Breakdown by suspected adverse reaction

To view a breakdown by suspected adverse reaction, please navigate to the **Total Reaction Profile** under **Reactions by System Organ Class table** in the iDAP. Each term can be expanded to view specific coded MedDRA Preferred Terms of interest such as the terms included in your FOI request.

Question 4 - Product/brand information

We searched the Yellow Card database for UK suspected spontaneous ADR reports where medroxyprogesterone was reported as the suspected or interacting drug, which were received up to and including 14 September 2026.

Please find attached Annex 1 which contains all UK spontaneous suspected ADR reports for Meningioma associated with Medroxyprogesterone, received up to and including 14 September 2026, broken down by brand. Please note that it is not mandatory to provide the brand name when reporting a Yellow Card, therefore this data represents what has been reported to us by the original reporter. Please also note that one report can contain more than one suspect drug or drug brand.

Question 5 – route of administration

iDAPs allow you to filter by route of administration. To view a breakdown of medroxyprogesterone reports by route of administration, please navigate to the **Total Reaction Profile** page in the medroxyprogesterone iDAP and apply the filter in the left column, which will enable you to view medroxyprogesterone reports by **Route of Administration**.

Please be aware that route of administration is an optional Yellow Card report field. The Yellow Card scheme relies on voluntary reporting to monitor the safety of all healthcare products in the UK and by not making all report fields mandatory, we aim to maximise the number of reports we receive. Where this is the case, these reports will appear under the ‘unknown’ route in the iDAP.

Question 6 – seriousness of reports

iDAPs allow you to filter by case seriousness. To view a breakdown of medroxyprogesterone reports by seriousness, please navigate to the Total Report Profile page in the medroxyprogesterone iDAP and apply the filter in the left column, which will enable you to view medroxyprogesterone reports by seriousness. In the Total Reaction Profile page in the

iDAP you can also apply the seriousness filter and view how many events of meningioma were reported.

Please note that a Yellow Card report is considered serious according to two criteria; firstly, a reported reaction can be considered serious according to our medical dictionary and secondly, the original reporter may consider each reported reaction to be serious according to 6 criteria. The seriousness criteria for adverse event reporting were determined by a working group of the Council for International Organizations of Medical Sciences (CIOMS). Reporters can select one or more of the following criteria by ticking the appropriate box on the Yellow Card. The criteria are: (1) patient died due to reaction (2) life threatening (3) resulted in hospitalisation or prolonged inpatient hospitalisation (4) congenital abnormality and (5) involved persistent or significant disability or incapacity or (6) if the reaction was deemed medically significant.

Question 7 – Reporter type

iDAPs allow you to filter by reporter type. To view a breakdown of medroxyprogesterone reports by reporter type, please navigate to the Total Report Profile page in the medroxyprogesterone iDAP and apply the filter in the left column, which will enable you to view medroxyprogesterone reports by reporter type. In the Total Reaction Profile page in the iDAP you can also apply the reporter type filter and view how many events of meningioma were reported.

Question 8 – Reported outcomes

We searched the Yellow Card database for UK suspected spontaneous ADR reports where medroxyprogesterone was reported as the suspected or interacting drug, which were received up to and including 14 September 2026.

Please find attached Annex 2 which contains an overview of reported outcomes for medroxyprogesterone reports. Please be aware that outcome is also an optional Yellow Card report field. In the Yellow Card reporting system, outcomes of specific reactions are selected from a drop-down list. This includes fatal, not recovered/not resolved/ongoing, recovered/resolved, recovered/resolved with sequelae, recovering/resolving and unknown. Please note that as one report can contain multiple reactions which can all report a different outcome, the total number of reaction outcomes will not equal the total number of reports.

Regarding outcomes associated with reports of meningioma and multiple meningiomas, we searched the Yellow Card database for UK suspected spontaneous ADR reports where medroxyprogesterone was reported as the suspected or interacting drug, which reported the MedDRA Preferred Terms (PTs) *Malignant neoplasm progression, Neoplasm malignant, Neoplasm, Neoplasm progression, Neoplasm recurrence, Meningioma benign, Optic nerve sheath meningioma, Intercranial meningioma malignant, Meningioma malignant, Brain neoplasm, Meningioma and Skull base tumour,* received up to and including 14 September 2026.

Please find attached Annex 3 which contains an overview of reported outcomes for medroxyprogesterone reports which reported the MedDRA PTs listed above.

Question 9 – Meningioma reports – before and after the October 2024 safety communication

Please find attached Annex 4 which contains a table displaying the number of meningioma reports for Medroxyprogesterone, reported up to and including 14 September 2026, broken

down by initial reported date of before or after 31 October 2024. The MedDRA PTs described in our response to question 8 were used to identify these reports.

Question 10 – Historical cumulative meningioma reports

iDAPs allow you to filter by year of receipt; therefore, to view cumulative meningioma reports please navigate to the **Total Report Profile** under **Reports by year** in the iDAP.

Question 11 – Multiple meningiomas

Within the MedDRA dictionary 'multiple meningiomas' is not a separate MedDRA Preferred Term code. There is however a MedDRA Lower Level Term (LLT) 'multiple meningioma', which maps to the meningioma PT. A search of our database has identified 5 cases reporting the LLT 'multiple meningioma'.

Question 12 – Historical changes in coding or reporting

When interpreting data over an extended period, it should be noted that the Medical Dictionary for Regulatory Activities (MedDRA), which is used to code suspected adverse drug reactions, is updated twice annually. These updates may introduce new terms, retire terms, or modify the placement of existing terms within the MedDRA hierarchy. As a result, similar reports submitted at different points in time may be coded differently depending on the MedDRA version in use at the time of processing. In addition, new medicinal products containing medroxyprogesterone acetate may have entered the UK market during the period covered by this request. Changes in product availability, prescribing patterns, and utilisation may influence the volume of reports received over time. The MHRA does not hold recorded information assessing the specific impact of such factors on comparisons between historical and current reporting figures.

Secondly, the reporting rate for spontaneous ADRs is variable and can depend on a multitude of factors. The actual rate of reporting is unknown and likely to be highly variable as it will be influenced by public awareness and seriousness of events as well as publicity around the use of the medicine. The MHRA takes into account the variable levels of reporting across all medicines and vaccines as part of our monitoring procedures using statistical techniques. As part of its continual assessment of the safety information of medicines and vaccines, the MHRA supplements Yellow Card safety monitoring with other epidemiology studies including analysis of data on national medicine or vaccine usage, anonymised GP-based electronic healthcare records and other healthcare data to proactively monitor safety. We also take into account the international experience based on data from other countries using the same medicines or vaccines.

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

- A reported reaction does not necessarily mean it has been caused by the medicine or medicinal product, only that the reporter had a suspicion it may have. The fact that symptoms or events occur after the use of a product, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by the product. Underlying or concurrent illnesses may be responsible and such events can also be coincidental.
- It is also important to note that Yellow Card data cannot be used to determine the incidence of a reaction or to compare the side effect profiles of different medicines or vaccines. ADR reporting rate are influenced by the seriousness of ADRs, their ease of recognition, the extent if use of a particular drug or vaccine and may be stimulated by

promotion and publicity about a drug. Reporting trends to be highest for newly introduced medicines or vaccines during the first one to two years on the market and then falls overtime.

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/