Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
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MHRA Website

[redacted]

Our Ref: **FOI2026/00645**

6 July 2026

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 16 June. You wrote:

> *I am writing to request information under the Freedom of Information Act 2000.*
> *I refer to your previous response FOI2025/00079 to [redacted] which provided Yellow Card data for:*
>
> * *Restless leg augmentation syndrome*
> * *Impulse-control disorder*
> * *Gambling*
> * *Gambling disorder*
> * *Binge eating*
> * *Hyperphagia*
> * *Hypersexuality*
>
> *associated with pramipexole, ropinirole, rotigotine and carbidopa/levodopa when used for Restless Legs Syndrome.*
> *I would now like to request equivalent information for two other indication groups, excluding augmentation (as I understand that term is specific to RLS):*
> *Please provide, for the period 1 January 2020 up to and including the most recent date available (or up to 24 February 2025 if easier for consistency):*
>
> 1. *Parkinson's disease*
>
> *For each of the medicines below:*
>
> * *Pramipexole*
> * *Ropinirole*
> * *Rotigotine*
> * *Cabergoline*
> * *Bromocriptine*
> * *Apomorphine*
> * *Carbidopa/levodopa*
>
> *please provide the number of UK spontaneous suspected adverse drug reaction (ADR) reports on the Yellow Card system in which:*
>
> * *the indication is recorded as Parkinson's disease, and*
> * *at least one MedDRA Preferred Term is one of the following:*

* *“Impulse-control disorder”*
* *“Gambling”*
* *“Gambling disorder”*
* *“Binge eating”*
* *“Hyperphagia”*
* *“Hypersexuality”*

Please present the data in a similar tabular format to FOI2025/00079, showing for each year (2020, 2021, 2022, 2023, 2024, and 2025 to date), each medicine, each relevant PT, and the number of ADR reports.

1. *Pituitary tumours / hyperprolactinaemia (e.g. prolactinomas)*

For each of the medicines below:

* *Cabergoline*
* *Bromocriptine*
* *Quinagolide (if applicable)*

please provide the number of UK spontaneous suspected ADR reports on the Yellow Card system in which:

* *the indication is recorded as pituitary tumour, prolactinoma, hyperprolactinaemia or another clearly related pituitary prolactin disorder (please specify which indication terms are included), and*
* *at least one MedDRA Preferred Term is one of the following:*

    * *“Impulse-control disorder”*
    * *“Gambling”*
    * *“Gambling disorder”*
    * *“Binge eating”*
    * *“Hyperphagia”*
    * *“Hypersexuality”*

Again, please present the data as annual totals by year and medicine, listing the PTs and the number of ADR reports for each.

General points

* *If the indication is captured using MedDRA terms or other structured fields, please state which indication terms you have used for (1) Parkinson’s disease and (2) pituitary tumour / prolactin disorders.*
* *If any part of this request would exceed the cost limit, please let me know, as I would be happy to refine or narrow the request.*

I would be grateful if you could confirm receipt of this request and process it under the Freedom of Information Act.

MHRA Response

We confirm that we hold the information you have requested.

The MHRA codes suspected Adverse Drug Reactions (ADRs) within Yellow Card reports using the medical dictionary MedDRA. We have conducted a search of our database and can confirm that from 1 January 2020 up to and including 2 July 2026, the MHRA has received 42 UK spontaneous suspected ADR reports associated with Pramipexole, Ropinirole, Rotigotine, Cabergoline, Bromocriptine, Apomorphine and Carbidopa/Levodopa, and the MedDRA Preferred Terms (PTs) Impulse-control disorder, Gambling, Gambling disorder, Binge eating, Hyperphagia, and Hypersexuality, where the indication was recorded as Parkinson's disease. The information requested is provided in Tables 1–5 below. There were no UK spontaneous suspected ADR reports associated with Cabergoline or Bromocriptine and the Preferred Terms (PTs) Impulse-control disorder, Gambling, Gambling disorder, Binge eating, Hyperphagia, and Hypersexuality, where the indication was recorded as Parkinson's disease, during this period.

We have also conducted a search for reports associated with Cabergoline, Bromocriptine and Quinagolide where the indication was recorded as a pituitary tumour or prolactin-related disorder. From 1 January 2020 up to and including 2 July 2026, the MHRA has received 3 UK spontaneous suspected ADR reports associated with Cabergoline and the MedDRA Preferred Terms (PTs) Impulse-control disorder, Gambling, Gambling disorder, Binge eating, Hyperphagia, and Hypersexuality. The information you have requested is provided below.

For the purposes of this search:

- For Parkinson's disease, the indication term used was "Parkinson's disease".
- For pituitary tumour/prolactin disorders, the indication terms used were "Pituitary tumour", "Prolactinoma", and "Hyperprolactinaemia".

Please be aware that, when submitting Yellow Card reports, the indication is not a mandatory field and therefore may not always be reported.

There were no UK spontaneous suspected ADR reports associated with Bromocriptine or Quinagolide and the Preferred Terms (PTs) Impulse-control disorder, Gambling, Gambling disorder, Binge eating, Hyperphagia, and Hypersexuality from 1 January 2020 up to and including 2 July 2026 where the indication was recorded as Pituitary tumour, Prolactinoma, or Hyperprolactinaemia.

Please note that a single Yellow Card report may list more than one suspect medicine and may therefore be represented in more than one medicine-specific table. Consequently, the totals shown in the tables should not be summed to derive the number of unique reports

Table 1: UK spontaneous suspected ADR reports associated with Apomorphine, where the indication was recorded as Parkinson's disease, received between 1 January 2020 and 2 July 2026.

Year	Adverse drug reaction (ADR)	Number of ADR reports
2021	Impulse-control disorder	1
2022	-	0
2023	-	0
2024	Gambling disorder	1
	Impulse-control disorder	1
2025	Impulse-control disorder	3
2026	-	0
Total		**6**

Table 2: UK spontaneous suspected ADR reports associated with Carbidopa/levodopa, where the indication was recorded as Parkinson's disease, received between 1 January 2020 and 2 July 2026.

Year	Adverse drug reaction (ADR)	Number of ADR reports
2021	Impulse-control disorder	14
2022	Hypersexuality	2
	Impulse-control disorder	5
2023	Hypersexuality	1
	Impulse-control disorder	1
2024	-	0
2025	Impulse-control disorder	1
2026	Hypersexuality	1
	Impulse-control disorder	1
Total		**26**

Table 3: UK spontaneous suspected ADR reports associated with Pramipexole, where the indication was recorded as Parkinson's disease, received between 1 January 2020 and 2 July 2026.

Year	Adverse drug reaction (ADR)	Number of ADR reports
2021	-	0
2022	-	0
2023	Hypersexuality	1
2024	Gambling	1
	Impulse-control disorder	1
2025	-	0
2026	Hypersexuality	1
Total		**4**

Table 4: UK spontaneous suspected ADR reports associated with Ropinirole, where the indication was recorded as Parkinson's disease, received between 1 January 2020 and 2 July 2026.

Year	Adverse drug reaction (ADR)	Number of ADR reports
2021	Impulse-control disorder	10
2022	Hypersexuality	2
	Impulse-control disorder	5
2023	Hypersexuality	1
	Impulse-control disorder	1
2024	Gambling	1
	Hypersexuality	2
2025	Hypersexuality	1
	Impulse-control disorder	1
2026	Hypersexuality	1
Total		**25**

Table 5: UK spontaneous suspected ADR reports associated with Rotigotine, where the indication was recorded as Parkinson's disease, received between 1 January 2020 and 2 July 2026.

Year	Adverse drug reaction (ADR)	Number of ADR reports
2021	Impulse-control disorder	2
2022	-	0
2023	Hypersexuality	1
2024	Hypersexuality	1
2025	-	0
2026	Impulse-control disorder	1
Total		**5**

Table 6: UK spontaneous suspected ADR reports associated with Cabergoline, where the indication was recorded as Pituitary tumour, Prolactinoma, or Hyperprolactinaemia, received between 1 January 2020 and 2 July 2026.

Year	Indication	Adverse drug reaction (ADR)	Number of ADR reports
2023	Pituitary tumour	Hypersexuality	1
2026	Prolactinoma	Impulse-control disorder	2
Total			**3**

When considering the attached 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 medicine, only that the reporter had a suspicion it may have. The fact that symptoms occur after use of a medicine, 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. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular medicine, and may be stimulated by promotion and publicity about a drug. Reporting tends to be highest for newly introduced medicines during the first one to two years on the market and then falls over time.

The MHRA continuously monitors the safety of medicines 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 individually assessed and cumulative information reviewed at regular intervals. If appropriate, regulatory action would be taken if any serious risks were confirmed.

As these data do not necessarily refer to proven side effects, you should refer to the product information which can be found here: https://products.mhra.gov.uk/ for details on the possible side effects of the medicine.

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