Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
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MHRA Website

[redacted]

Our Ref: **FOI2026/00703**

30 July 2026

Dear [redacted]

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

> *I am making this request under the Freedom of Information Act 2000.*
> *This request concerns dopamine agonist medicines, including but not limited to pramipexole, ropinirole, rotigotine, bromocriptine, cabergoline and apomorphine.*
> *Please provide the following recorded information:*

1. *The total number of UK Yellow Card reports received for each dopamine agonist since 1 January 2005 that include reports of:*
   - *impulse control disorder;*
   - *pathological gambling;*
   - *compulsive gambling;*
   - *hypersexuality;*
   - *compulsive sexual behaviour;*
   - *compulsive shopping or spending;*
   - *compulsive eating or binge eating;*
   - *punding or repetitive compulsive behaviours;*
   - *dopamine agonist withdrawal syndrome (DAWS);*
   - *suicide, suicidal ideation or suicide attempts where a dopamine agonist was recorded as a suspected medicine.*
2. *Any internal reviews, safety assessments, benefit-risk assessments or expert reports produced since 2005 concerning these adverse effects.*
3. *Copies of any meeting minutes, briefing papers or decision papers discussing whether additional warnings or prescribing restrictions should be introduced for dopamine agonists.*
4. *Copies of correspondence between the MHRA and pharmaceutical manufacturers concerning impulse control disorders or behavioural adverse effects associated with dopamine agonists.*
5. *Copies of correspondence between the MHRA and:*
   - *NHS England;*
   - *NICE;*
   - *the Commission on Human Medicines;*
   - *other UK health departments,*
6. *concerning the risks of impulse control disorders associated with dopamine agonists.*

7. *Copies of any communications issued to healthcare professionals, GP practices, pharmacists or NHS organisations concerning these risks, including any Drug Safety Updates or equivalent communications not already publicly available.*
8. *Any recorded information explaining why current prescribing advice does or does not recommend enhanced monitoring for patients considered potentially more vulnerable to impulse control disorders.*
9. *Any recorded information held regarding whether neurodevelopmental conditions, including ADHD or autism, have been considered as potential factors influencing susceptibility to dopamine agonist-induced impulse control disorders.*
10. *The dates on which the MHRA first became aware of evidence linking dopamine agonists with impulse control disorders, and the dates on which significant regulatory actions or safety communications were subsequently issued.*
11. *Any equality impact assessments, patient safety assessments or regulatory reviews concerning whether existing patient information sufficiently communicates the risk of impulse control disorders.*

If any part of this request exceeds the appropriate cost limit, please treat each numbered item separately and provide advice and assistance under section 16 of the Freedom of Information Act 2000 so that the request may be refined.

MHRA Response

The Agency has completed its search for the information you have requested and we are able to confirm that we do hold some the information you have requested. Please note that some of the information cannot be disclosed and is being exempt from release for the reasons outlined below. As requested each numbered item has been addressed separately.

In the UK there a number of dopamine agonists authorised, these include amantadine, apomorphine, aripiprazole, bromocriptine, cabergoline, pergolide, pramipexole, quinagolide, ropinirole and rotigotine. Of these, aripiprazole is a partial dopamine agonist.

1. We can confirm that the Agency holds the information requested. However, the information requested under point 1, is exempt under Section 21(1) of the Freedom of Information Act because the information is reasonably accessible to you, as it is already in the public domain. Further information can be found on ICO Section 21 Guidance.

   The MHRA publishes reported adverse reactions for medicines and vaccines in the form of interactive Drug Analysis Profiles (iDAPs) which can be accessed here: https://yellowcard.mhra.gov.uk/idaps.

   You can view iDAPs for all dopamine agonists of interest. These profiles are listed alphabetically on the website and are dynamic, allowing you to use the filters on the left-hand side to interact and filter the data, for instance you can search for specified time periods, by patient age, patient sex, case seriousness and by reporter type i.e. Healthcare professional, Patient/carer or via Industry.

   Please be aware that all reactions are coded on our database using the Medical Dictionary for Regulatory Activities[1] (MedDRA) which allows reactions to be grouped by System Organ Class (SOC), High Level Term (HLT) and Preferred Term (PT). In regard to specific reactions terms, these can be viewed from the 'Total Reaction Profile' page on the iDAP.

   [1] https://www.meddra.org/

2. and 3.

   We are unable to deal with this part of your FoI request without clarification of the information you seek. The reason for this is that the nature of your request is very broad

[1] https://www.meddra.org/

and there is already some related information in the public domain which is outlined below.

Under Section 16 of the FoI Act we should assist you in helping you focus your request. Therefore, we have provided you with details of the type of information we hold and what is publicly available. We will consider any revised request however we cannot guarantee that any revised request will fall within the cost limit.

The MHRA conducts weekly signal detection and may assess a range of safety signals or concerns. Issues are discussed at the Signal Management Review Meeting where the assessment process is agreed including whether advice needs to be sought from any of the MHRA's independent advisory committees.

Since 2005, dopamine agonists have been considered on a number of occasions. Annex 1 outlines a list of meetings that considered various aspects of the safety of dopamine agonists.

However, the majority of information requested under points 2 and 3, is exempt under Section 21(1) of the Freedom of Information Act because the information is reasonably accessible to you, as it is already in the public domain.

The MHRA publishes summary minutes from the advisory committee meetings https://www.gov.uk/government/organisations/commission-on-human-medicines/about/membership#summary-minutes

In addition a Public Assessment Report was published in November 2006 which can still be accessed in the national archive.

https://webarchive.nationalarchives.gov.uk/ukgwa/20141205211335/http://www.mhra.gov.uk/Safetyinformation/Safetywarningsalertsandrecalls/Safetywarningsandmessagesformedicines/CON2025151

4. Similarly to points 2 and 3, clarification is needed about the information you are seeking.

   Under Section 16 of the FoI Act we should assist you in helping you focus your request. Therefore, we have provided you with details of the type of correspondence we hold. We will consider any revised request however we cannot guarantee that any revised request will fall within the cost limit.

   The MHRA corresponds with marketing authorisation holders (MAHs) in a number of ways. This includes correspondence associated with Yellow Card reports, anonymised case details are shared with MAHs and further information about individual cases may be requested from the MAHs. MAHs may submit periodic safety update reports (PSURs). Details about the requirements for PSURs and the timelines for these submissions are published on the European Medicines Agency's website Periodic safety update reports (PSURs) | European Medicines Agency (EMA).

   There is also correspondence during regulatory procedures such as when varying the product information for their authorised products. This is logged within each regulatory procedure.

5. and 6.

   Similarly to earlier points, clarification is needed about the information you are seeking.

   Under Section 16 of the FoI Act we should assist you in helping you focus your request, therefore, we have provided you with details of the type of correspondence we hold. We will consider any revised request however we cannot guarantee that any revised request will fall within the cost limit.

The MHRA generally communicates safety issues with NHS England, NICE and other health departments via our publication Drug Safety Updates which are available in the public domain https://www.gov.uk/drug-safety-update?keywords=dopamine+agonist

The Commission on Human Medicines (CHM) is the MHRA's independent advisory committee. The MHRA prepares assessment reports and presents data to the CHM and its associated Expert Advisory Groups (EAGs). The MHRA provide the secretariat for these committees and in addition to the circulation of the assessment reports there is likely to be extensive correspondence regarding the dates of the various meetings, availability of members to attend, declarations of interests and where relevant, travel arrangements and expenses.

Representatives from NICE and other relevant health departments or professional bodies may be invited to attend CHM or an EAG meeting for awareness or to contribute to the discussions.

7. We can confirm that the Agency holds the information requested. However, the information requested under point 7, is exempt under Section 21(1) of the Freedom of Information Act because the information is reasonably accessible to you, as it is already in the public domain.

   The MHRA generally communicates safety issues to healthcare professionals via our publication Drug Safety Updates or via Direct Healthcare Professional Communications (sometimes referred to as Dear Doctor letters) which are available in the public domain https://www.gov.uk/drug-safety-update?keywords=dopamine+agonist.

   Details about the different types of communications issued or approved by the MHRA are available on our website https://www.gov.uk/government/publications/safety-communications-concerning-medicines-medical-devices-and-other-healthcare-products/safety-communications-concerning-medicines-medical-devices-and-other-healthcare-products

8. Similarly to earlier points, clarification is needed about the information you are seeking.

   Under Section 16 of the FoI Act we should assist you in helping you focus your request. Therefore, we have provided you with details of the type of correspondence we hold. We will consider any revised request however we cannot guarantee that any revised request will fall within the cost limit.

   The product information for each medicine outlines the information available to support its use. These are published on the MHRA's website https://products.mhra.gov.uk/search/?search=pramipexol&page=1 and other platforms such as the electronic Medicines Compendium.

   The product information consists of the Summary of Product Characteristics (SPC) for healthcare professionals and the Patient Information Leaflet (PIL) which is supplied with each pack of medicine. The product information does not contain any information about particular patients who may be at risk of impulse control disorders.

   The MHRA does not hold or approve prescribing advice and you may wish to consider whether it would be more appropriate to raise this question with NICE as they publish clinical guidance.

9. Following a search of our paper and electronic records, we have established that the information you requested is not held. We do not hold any assessments of neurodevelopmental conditions, including ADHD or autism being considered as potential factors influencing susceptibility to dopamine agonist-induced impulse control disorders.

10. Similarly to earlier points, clarification is needed about the information you are seeking.

Under Section 16 of the FoI Act we should assist you in helping you focus your request. Therefore, we have provided you with a link to the public Assessment Report from 2006 which outlines key dates the MHRA became aware of published literature and when case reports were received. We will consider any revised request however we cannot guarantee that any revised request will fall within the cost limit.

https://webarchive.nationalarchives.gov.uk/ukgwa/20141205211335/http://www.mhra.gov.uk/Safetyinformation/Safetywarningsalertsandrecalls/Safetywarningsandmessagesformedicines/CON2025151

11. Following a search of our paper and electronic records, we have established that the MHRA do not hold any equality impact assessments. The MHRA has not previously specifically reviewed whether the existing patient information leaflet (PIL) sufficiently communicates the risks of impulse control disorders.

    However, a review is currently underway to establish whether further action is required to raise awareness of the risk of impulse control disorders. The review is in the initial data gathering phase with wider stakeholder engagement planned for the autumn.

    As this review is ongoing, we are engaging an exemption from disclosure under Section 22(1) of FoI Act as the information is intended for publication at a future date.

    In applying this exemption, the agency has balanced the public interest in withholding the information against the public interest in disclosing the information and on balance we find that withholding the information from release at this time outweighs our obligation to release.

    We recognise that there is a public interest in the issue of impulse control disorders with dopamine agonists and that there are concerns that patients and their carers may not be aware of this risk. However, release of partial data associated with this ongoing review could potentially undermine the assessment and could create confusion about the existing warnings in the PIL. The PIL is intended to support the discussions between patients and healthcare professionals and is not intended to replace the discussion with a healthcare professional. It is important that any patients concerned about their medication discuss these with a healthcare professional.

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/