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: **FOI2026/00904**

14 September 2026

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 14 August. You wrote:

> *Freedom of Information Act 2000 request*
>
> *I request recorded information held by the Medicines and Healthcare products Regulatory Agency concerning the relationship between Post-Finasteride Syndrome (PFS) and MedDRA Preferred Term (PT) 10082430, "Post 5-alpha-reductase inhibitor syndrome", within the MHRA Yellow Card/pharmacovigilance system.*
>
> *For precise identification, I refer to MedDRA Change Request 2018325008 and MedDRA PT 10082430, "Post 5-alpha-reductase inhibitor syndrome", implemented on 29 November 2018.*
>
> *The principal purpose of this request is to establish from existing MHRA records whether "Post 5-alpha-reductase inhibitor syndrome" is the broader pharmacovigilance/coding concept under which a finasteride-specific case described by a reporter as "Post-Finasteride Syndrome" or "PFS" can fall.*
>
> *I am requesting existing recorded information only. I am not asking the MHRA to create a new medical opinion, establish individual causation, or make a new determination concerning the clinical status of PFS.*
>
> *1. Implementation of MedDRA PT 10082430*
>
> *Please provide recorded information establishing:*
>
> * *whether MedDRA PT 10082430, "Post 5-alpha-reductase inhibitor syndrome", is or has been implemented within the terminology used by the MHRA for Yellow Card/pharmacovigilance reports;*
> * *the date and MedDRA version from which it became available within the relevant MHRA system;*
> * *whether PT 10082430 can be used to code, classify, retrieve, aggregate or analyse suspected adverse-reaction reports; and*
> * *its relevant MedDRA terminology status and hierarchy as implemented or used by the MHRA.*

Where this information exists as a database or terminology entry rather than a conventional document, please provide an extract, screenshot, printout or equivalent recorded representation where reasonably practicable.

2. Finasteride and PT 10082430

Please provide existing recorded information establishing whether finasteride, as a 5-alpha-reductase inhibitor, is a medicinal product whose suspected adverse-reaction reports are capable of falling within or being associated with MedDRA PT 10082430.

Specifically, please provide recorded information showing whether a Yellow Card report involving finasteride can be:

* *coded under PT 10082430;*
* *mapped to PT 10082430;*
* *retrieved through PT 10082430;*
* *aggregated or analysed using PT 10082430; or*
* *otherwise represented under PT 10082430 for pharmacovigilance or signal-detection purposes.*

3. Post-Finasteride Syndrome / PFS

This is the principal part of my request.

Where a Yellow Card report:

(a) identifies finasteride as the suspected medicinal product; and
(b) expressly describes a persistent post-treatment condition using the reporter terminology "Post-Finasteride Syndrome" or "PFS",

please provide the existing recorded information establishing whether that report is capable of being:

* *coded under;*
* *mapped to;*
* *classified under;*
* *retrieved through;*
* *aggregated under; or*
* *otherwise represented by*

MedDRA PT 10082430, "Post 5-alpha-reductase inhibitor syndrome".

If "Post-Finasteride Syndrome" or "PFS" is not itself a MedDRA Preferred Term or Lowest Level Term, please provide any existing MHRA coding rule, terminology mapping, guidance, database documentation or other recorded information identifying how reporter wording expressly describing PFS is represented.

If another MedDRA term would instead apply, please identify that term and its code where this information is held.

4. Broader/umbrella relationship

Please provide any recorded information establishing whether MedDRA PT 10082430, "Post 5-alpha-reductase inhibitor syndrome", functions as the broader pharmacovigilance or coding concept capable of encompassing a finasteride-specific report described as

Post-Finasteride Syndrome/PFS.

In particular, please provide any existing terminology hierarchy, mapping, coding rule, guidance, database documentation or other recorded information demonstrating the relationship, if any, between:

Finasteride → Post-Finasteride Syndrome/PFS → MedDRA PT 10082430 "Post 5-alpha-reductase inhibitor syndrome".

For clarity, by "broader/umbrella concept" I mean a pharmacovigilance or terminology category capable of encompassing a finasteride-specific report. I am not asking the MHRA to adopt "umbrella term" as a new clinical definition.

5. Persistent post-treatment effects and scope

Please provide any recorded definition, MedDRA documentation, coding guidance or other information held or used by the MHRA concerning the scope of PT 10082430.

In particular, please provide recorded information establishing whether PT 10082430 encompasses reports of effects or symptoms which develop during or following exposure to a 5-alpha-reductase inhibitor and persist following discontinuation.

Please also provide any recorded information establishing whether this includes reports involving finasteride.

Where held, please provide recorded information concerning the categories of persistent effects capable of being represented or associated with PT 10082430, including reported:

* *cognitive or neurological symptoms;*
* *psychiatric symptoms;*
* *sexual or reproductive symptoms;*
* *fatigue or related systemic symptoms; and*
* *any other categories recorded as falling within the scope of PT 10082430.*

For clarity, I am requesting information concerning the scope and coding of reported effects, not asking the MHRA to establish a particular biological mechanism.

6. Central question

To ensure that the principal information sought is unambiguous:

Where finasteride is the suspected medicinal product and a Yellow Card reporter describes a persistent post-treatment condition as "Post-Finasteride Syndrome" or "PFS", is that report capable of falling within, being coded or mapped to, or being retrieved or aggregated under MedDRA PT 10082430, "Post 5-alpha-reductase inhibitor syndrome"?

Please provide the existing recorded information establishing the answer.

If MHRA records establish that the answer is yes, please provide the relevant record(s), terminology entry, database extract, mapping, coding guidance or other recorded information establishing that relationship.

If MHRA records establish that the answer is no, please provide the recorded information establishing that distinction and, where held, identify the alternative MedDRA terminology

under which a report expressly described as PFS would be represented.

If the MHRA holds no recorded information establishing either position, please state explicitly that no such recorded information is held.

7. Historical information

Where held and readily identifiable, please also provide:

* *the date on which PT 10082430 was first implemented within the MHRA pharmacovigilance system;*
* *the earliest date on which the MHRA recorded a Yellow Card report under PT 10082430, without disclosure of patient-identifiable information; and*
* *any existing MHRA coding or terminology guidance specifically addressing finasteride in connection with PT 10082430.*

8. Form and provenance of disclosure

Please provide the information electronically.

Where responsive information exists as a database entry, terminology record, electronic field, coding rule or other electronic record rather than a conventional document, please provide an extract, screenshot, printout or equivalent copy where reasonably practicable.

Where reasonably practicable, please preserve identifying information associated with the disclosed records, including:

* *document titles and dates;*
* *MedDRA/terminology version numbers;*
* *database field headings;*
* *originating MHRA department where recorded; and*
* *other contextual metadata necessary to establish the source and date of the disclosed information.*

If responsive information is already publicly available, please identify the specific document, terminology record and relevant section or entry, rather than referring generally to the MHRA, Yellow Card or MedDRA websites.

If any requested information is withheld, please identify the specific exemption under the Freedom of Information Act 2000 relied upon and explain its application.

If compliance with any discrete part of this request would exceed the appropriate cost limit, please provide the remainder of the information that can be supplied and provide advice and assistance concerning how the affected portion may be refined.

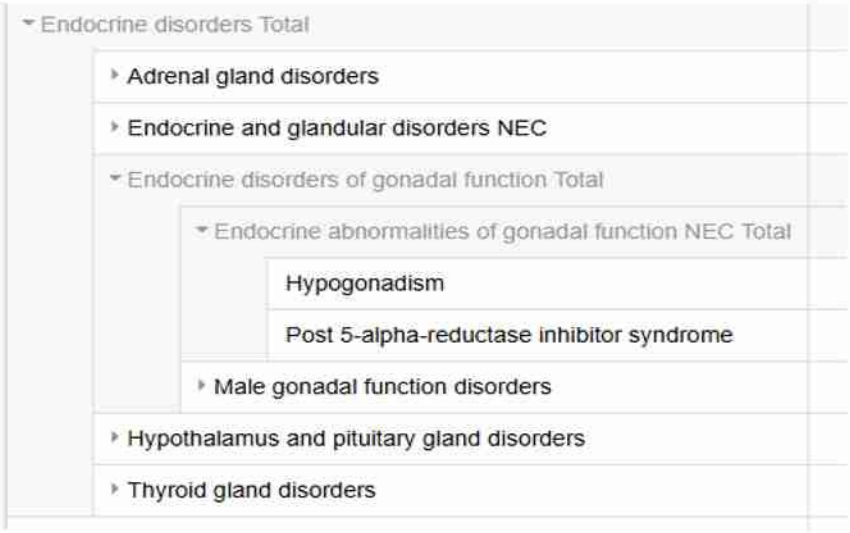
MHRA Response

We can confirm that we hold some of the information falling within the description specified in your request.

In response to questions 1 and 2 of your request, we feel it is important to provide context regarding the MHRA's use of the Medical Dictionary for Regulatory Activities (MedDRA)

dictionary. The MHRA is independent of MedDRA, and the dictionary is used 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. MedDRA MSSO is a global team that oversees the development, distribution, and support of the terminology. MedDRA is updated twice annually, and new terms can be proposed by any MedDRA users.

The term "*Post 5-alpha-reductase inhibitor syndrome"* was added to MedDRA by the MSSO as a preferred-level (PT) term in version 24.1, in September 2021, which was implemented by MHRA as a term available to users of the Yellow Card website for reporting, our internal case management systems and subsequently our signal detection system as part of routine updates. Once an update is implemented, this carries across all systems we use for pharmacovigilance activities including coding of reports, data extraction, and signal detection. The MedDRA hierarchy for this term can be seen in the below screenshot:



Pharmaceutical companies send reports to us for products they hold a license for and code their adverse drug reaction (ADR) reports using MedDRA terminology. For reports received via the Yellow Card scheme, MedDRA terminology is integrated into the Yellow Card website and as such users can select terms available at the point of reporting. All reports are added to our case management system and suspected adverse reactions coded at the lower level-term (LLT) or PT level. Reports flow through our signal detection software on a weekly basis to identify medication-event combinations of interest that require further investigation. These are subsequently assessed and discussed at length by our team of multidisciplinary specialists, where a wide range of factors and information is considered.

I can confirm that we do hold information around suspected side effects concerning finasteride that have been reported to us. The information 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 reported side effects of a drug in the form of interactive Drug Analysis Profiles (iDAPs) which can be accessed using this website: https://yellowcard.mhra.gov.uk/idaps. You can view profiles for drugs using the link and find data relating to the substance of interest including the number of reports, a complete list of all suspected adverse reactions and a filter function to further break down the data should you wish .

The iDAPs for Finasteride can be found at the following link: FINASTERIDE | Making medicines and medical devices safer. The number of reports relating to 'Post 5-alpha-

reductase inhibitor syndrome' can be viewed via on the Reaction Profile tab under the System Organ Class (SOC) "Endocrine Disorders".

When considering this spontaneous ADR data and the online iDAPs, it is important to be aware of the following points:

- 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.
- 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.

Regarding question 3 to 6, as of 1st September 2026, MedDRA version 29.1 has been released, and the term "Post-finasteride syndrome" (MedDRA code: 10093800) is now an available LLT. The new version of MedDRA will be implemented into the MHRA systems on the first weekend of November 2026.

If a reporter specifically reports Post 5-alpha-reductase inhibitor syndrome in association with finasteride when submitting a yellow card report, this will be coded verbatim. Reports are coded using MedDRA terminology as part of routine case processing. Where information provided by the reporter is not otherwise captured by an existing coded term, additional coding may be applied to ensure relevant adverse reactions are represented appropriately. Any signs and symptoms are coded and where assessors are unclear, they can contact the reporter if permission is provided, to clarify any necessary information to aid assessment. The MHRA use the general guidance and learning resources provided via the MSSO to organisations that have subscriptions to MedDRA, however, to note this does not cover guidance on individual terms.

The MHRA does not hold any separate recorded definitions, coding guidance, scope notes or documentation specific to PT 10082430 beyond the MedDRA hierarchy and terminology maintained by MedDRA MSSO. Consequently, we do not hold recorded information identifying categories of symptoms falling within the scope of this PT beyond the terminology structure itself.

MedDRA version 29.1 places the LLT "Post-finasteride syndrome" beneath the PT "Post 5-alpha-reductase inhibitor syndrome". The MedDRA hierarchy therefore establishes a broader-to-more-specific terminology relationship between these terms. Consequently, where a Yellow Card report is coded using that LLT, it would be capable of being retrieved, aggregated and analysed under PT 10082430 once MedDRA version 29.1 has been implemented within MHRA systems. Prior to implementation of version 29.1, MHRA does not hold specific coding guidance relating to the term "Post-finasteride syndrome".

For information concerning the specific inclusion of this term in the MedDRA dictionary, please contact the MedDRA MSSO: Contact | MedDRA for further information.

Regarding Question 7, the date on which PT 10082430 was first implemented within the MHRA pharmacovigilance system was September 2021. The earliest date on which a Yellow Card report was received that included PT 10082430 is 16th March 2023. Regarding your query on any existing MHRA coding or terminology guidance specifically addressing finasteride in connection with PT 10082430, as above we do not hold this information.

Please note the MHRA is not responsible for the naming or classification of medical conditions and in general it is the International Classification of Disease (ICD) 11 developed by the World Health Organisation and the Diagnostic Statistical Manual (DSM) V systems that seek to provide international standards for health data recording. The ICD-11 incorporates current medical knowledge and clinically intuitive coding structures for healthcare providers, researchers, and decision-makers. The definition and naming of new medical syndromes and conditions is a collaborative undertaking across the wider healthcare system. As mentioned, we use MedDRA to support regulatory contributions to signal detection and identification of medical conditions, which may be associated with medicine exposure.

We do not hold specific documentation in relation to much of your request and as such have attempted to explain current process, procedures and background in order to fulfil your request as best as possible.

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.

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