



Medicines & Healthcare products Regulatory Agency

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[MHRA Website](https://www.mhra.gov.uk)

Our Ref: **FOI2026/00966**

24 September 2026

Dear [REDACTED]

Thank you for your Freedom of Information (FoI) request received on 27 August. You wrote:

I would like to place a further request for assistance in relation to Annexe 24 of the EWG Report on HPT's, which refers to 235 Case Reports.

The clinical detail of 28 of these 235 reports is presented in redacted form in 2 tables in Annexe 22. Could you please provide the clinical detail of the other 208 cases in similar redacted form.

MHRA Response

[Annex 24 of the EWG report](#) is titled 'Further analysis of spontaneous reports with Hormonal Pregnancy Tests – SECOND CORRECTED'. As you have noted, the Annex refers to the 'HPT-exposed ADR dataset' which contained a total of 234 cases and analyses of the data were presented in December 2015 and August 2016. A further Yellow Card Report received following the data-lock point for the previous ADR analyses was identified, giving a total of 235 cases. The 'HPT-exposed ADR dataset', comprising of 235 cases, can be broken down into the following categories:

- MHRA safety database ('Yellow Card' scheme, n=30)
- Cases submitted through the Public Call for Evidence (n=7)
- Cases submitted by the Association for Children Damaged by HPTs (n=132)
- Information provided by UK Teratology Information Service (n=5)
- Information from non-UK regulatory authorities: Therapeutic Goods Administration (TGA, Australia, n=6), Centre for Adverse Reactions (CARM, New Zealand, n=1), World Health Organisation (WHO, n=53)

1. [MHRA safety database \('Yellow Card' scheme, n=30\)](#)

As you have noted, further detail on 28 of the 30 reports received via the Yellow Card scheme, held on the MHRA safety database, can be found within [Table 2 and Table 3 of Annex 22](#).

Additional details for the remaining two Yellow Card reports not included in Tables 2 and 3 are provided below, using the same format as that presented in Tables 2 and 3 of Annex 22.

Table 1: Details of two spontaneously reported cases of suspected ADRs for ethinylestradiol/norethisterone used as HPTs, from UK Yellow Card database, received after the data lock point used for the assessment presented in Annex 22, but assessed in Annex 24

Date submitted to MHRA	Reporter/medical confirmation	Suspect product (s)	Adverse Reactions Coded (PTs)	Other information e.g. outcome
2015	Parent/ No	Primodos	Hypospadias	Reporter given Primodos for diagnosis of pregnancy and child was born with hypospadias, which required several attempts to correct surgically and he still has scarring.
2015	Parent/ No	Primodos	Unspecified congenital anomaly of heart, Numbness, Pneumonia, Blue baby syndrome, Poor peripheral circulation	Reporter given Primodos for diagnosis of pregnancy. Child required treatment and monitoring at a hospital to the age of 9.

2. Cases submitted through the Public Call for Evidence (n=7)

The seven cases submitted through the Public Call for Evidence are exempt from release under Section 21 of the FOIA as they are already publicly available online. A summary of the seven cases is present under [Table 9 of Annex 22](#). The seven submissions can also be found in the format that they were submitted via the links below. You will note that some of the published information has been redacted. This is because this information is exempt from release as it constitutes personal data and as such, it is being withheld in accordance with Section 40(2) of the Freedom of Information Act.

Section 40(2) exempts information in response to a request if it is personal data belonging to an individual other than the requester and it satisfies one of the conditions listed in the legislation. In this case the condition contained in section 40(3A)(a) applies - that disclosure would breach one of the data protection principles, specifically that "Personal data shall be processed lawfully, fairly and in a transparent manner...".

We do not consider that disclosing this information is necessary or justified in order to satisfy your information request and the requirements of the FoI Act. In relation to this request, we consider that there is no strong legitimate interest that would override the prejudice to the rights and freedoms of the data subject.

Personal data are subject to UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018.

Links to the seven cases submitted through the Public Call for Evidence:

1. Individual 1 - <https://mhra.gov.filecamp.com/s/o/GZdoZEG9hoT4o6nZ/M7WLCXNrob3Fe0XS/pnqfx97aJ9abBXBe>
2. Individual 2 - <https://mhra.gov.filecamp.com/s/o/GZdoZEG9hoT4o6nZ/M7WLCXNrob3Fe0XS/xUGfzYRpAr7GOxGX>
3. Individual 3 - <https://mhra.gov.filecamp.com/s/o/GZdoZEG9hoT4o6nZ/M7WLCXNrob3Fe0XS/tQvJTmcphZ08KH6>
4. Individual 4 - <https://mhra.gov.filecamp.com/s/o/GZdoZEG9hoT4o6nZ/M7WLCXNrob3Fe0XS/JhSjM4EtDQrMs5Mo>
5. Individual 5 - <https://mhra.gov.filecamp.com/s/o/GZdoZEG9hoT4o6nZ/M7WLCXNrob3Fe0XS/IX6ladfvXJRuJLIZ>
6. Individual 6- <https://mhra.gov.filecamp.com/s/o/GZdoZEG9hoT4o6nZ/M7WLCXNrob3Fe0XS/i4xjQnmb0ZuUVy8h>
7. Individual 7 - <https://mhra.gov.filecamp.com/s/o/GZdoZEG9hoT4o6nZ/M7WLCXNrob3Fe0XS/vVPikVfvDEy7t532>

3. Cases submitted by the Association for Children Damaged by HPTs (n=132)

Please find attached a copy of the cases submitted by the Association for Children Damaged by HPTs. We understand that you submitted this information to the MHRA in 2015. We have considered whether any personal information within the documents should be withheld when being released under the Freedom of Information Act.

Some information has been redacted as it constitutes personal data of someone other than yourself and as such, it is being withheld in accordance with Section 40(2) of the Freedom of Information Act. Further detail is given on this exemption above. However, some of the information relates to individuals who are deceased and, as Section 40(2) of the Freedom of Information Act applies only to the personal data of living individuals, the exemption does not apply in these circumstances. The information has therefore been disclosed.

A summary of the cases submitted by the Association for Children Damaged by HPTs is already publicly available within [Section 3.2.3.2 of Annex 22](#). Further information on these cases can be found in the [additional Annex 22](#).

4. Information provided by UK Teratology Information Service (n=5)

The five cases provided by the UK Teratology Information Service (TIS) are exempt from release under Section 21 of the FOIA as they are already publicly available online. The UK TIS provided assessors at the MHRA with retrospective follow up data for five enquiries relating to therapeutic exposure to Primodos in pregnancy. The information provided to the MHRA by UK TIS on these five enquiries is published in full within the [Annex 22, Section 3.4](#).

5. Information from non-UK regulatory authorities: Therapeutic Goods Administration (TGA, Australia, n=6), Centre for Adverse Reactions (CARM, New Zealand, n=1), World Health Organisation (WHO, n=53)

The 60 reports provided to the MHRA were supplied in confidence by the organisations listed above under the terms of data-sharing agreements that support the exercise of our statutory functions. These agreements provide for the exchange of sensitive information on a confidential basis.

The information is exempt from disclosure under section 27(2) of the Freedom of Information Act 2000, as disclosure would, or would be likely to, prejudice relations between the United Kingdom and international organisations. The organisations concerned provide information to the MHRA with the expectation that it will be handled in accordance with the agreed

confidentiality provisions. Disclosure under FOIA would be likely to undermine that trust and could adversely affect the willingness of these organisations to share information with the MHRA in the future.

Such a reduction in cooperation would be likely to prejudice the UK's relations with these international partners and could impede the MHRA's ability to obtain information necessary to fulfil its regulatory functions. We therefore consider that disclosure would, or would be likely to, damage the UK's interests in maintaining effective international relationships and collaboration.

A summary of this data is available publicly within [Sections 3.6 and 3.7 of the Annex 22](#).

You may wish to contact these organisations directly for a copy of the information you require. The contact details of each organisation can be found below:

Therapeutic Goods Administration

Website: www.tga.gov.au

Email: info@tga.gov.au

New Zealand Regulatory Authority

Website: www.medsafe.govt.nz

Email: hello@regulation.govt.nz

World Health Organisation

Website www.who.int

Email: Contact the World Health Organization

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/>