



Medicines & Healthcare products
Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
[gov.uk/mhra](https://www.gov.uk/mhra)

[REDACTED]

5 December 2023

FOI 23/923

Dear [REDACTED]

Thank you for your information request, dated November 21st 2023, where you asked for information about how the call for evidence on Hormone Pregnancy Tests (HPTs, which was open between March 2015 and June 2015) was publicised and how many people responded to the call for information.

I am pleased to provide you with the information requested, please see below.

As noted in the report of the Expert Working Group (EWG) on HPTs and annex 5 to the report (which are available on the Government website¹), the launch of the call for evidence was accompanied by a press release and the Association for Children damaged by HPTs was informed of the launch. An article in the MHRA's 'Drug Safety Update' bulletin in June 2015 also drew further attention to the call for evidence.

In response to the call for evidence, information was provided by 20 individuals or organisations, including:

- Yellow Card reports of suspected malformations and adverse effects on pregnancy reported in association with HPTs;
- Information on the malformations and adverse effects on pregnancy reported in association with HPTs in the UK and Germany and documents from the Landesarchiv Berlin (provided by the Association for Children Damaged by HPTs and by a Duogynon campaigner in Germany);
- Testimonials from people describing their experiences with HPTs;

¹ <https://www.gov.uk/government/publications/report-of-the-commission-on-human-medicines-expert-working-group-on-hormone-pregnancy-tests>



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- Assorted documents from representatives of patient organisations and other individuals including two former Chairs of the Association for Children Damaged by Hormonal Pregnancy Tests (which cover a range of topics including a chronology of events, opinion pieces, copies of company correspondence, published literature and press clippings);
- A review of the literature published since 1982 regarding the teratogenic risk of Primodos provided by the UK Teratology Information Service.

This information was considered alongside information from other sources by the EWG on HPTs.

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If you have a query about the information provided, please reply to this email

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: info@mhra.gov.uk

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely,

Safety and Surveillance