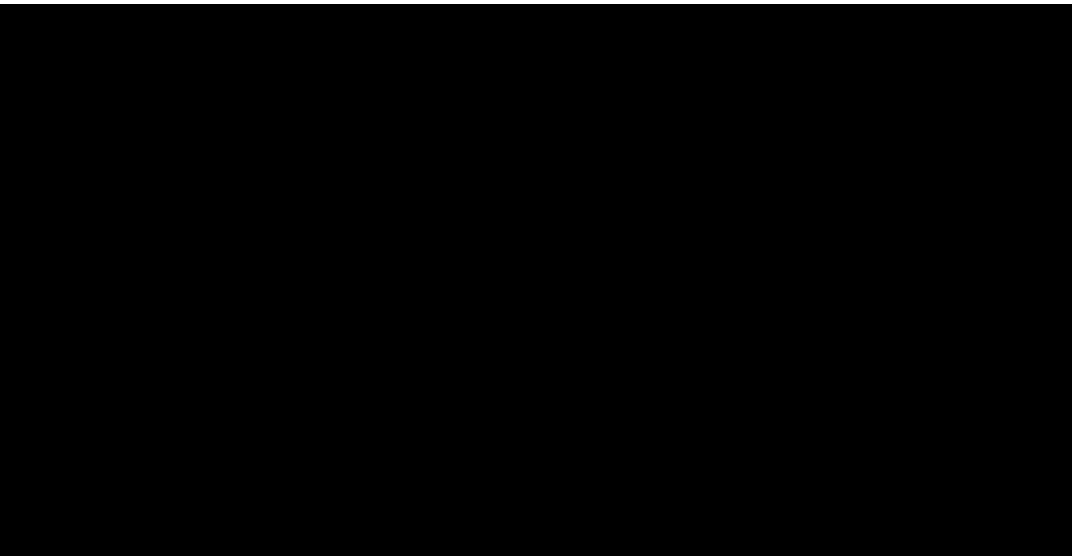




Medicines & Healthcare products  
Regulatory Agency

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25 September 2023

Dear 

**RE: FOI 23-463 Pregnancy Prevention Programme**

Thank you for your request of 29 June 2023 under the Freedom of Information Act for the following:

- How many prescription medications have a Pregnancy Prevention Program?
- How long have those prescription medications had their PPP attached?
- What is their success rate over their life time?

Please find answers to your questions below.

- How many prescription medications have a Pregnancy Prevention Program (PPP)?

Eight UK prescription medicines have formal PPPs: sodium valproate / valproic acid, thalidomide, lenalidomide, pomalidomide, vismodegib, isotretinoin, acitretin, alitretinoin

- How long have those prescription medications had their PPP attached?

Active Substance	Year PPP introduced
valproate	2018
thalidomide	2008
lenalidomide	2007
pomalidomide	2013
vismodegib	2013
isotretinoin	2003
acitretin	2018
alitretinoin	2018

- What is their success rate over their life time?

No PPP is 100% effective. Depending on the clinical setting of the medicine and the nature of the PPP, there are different mechanisms for monitoring their effectiveness. The Marketing Authorisation Holders and the MHRA continually monitors the effectiveness of PPPs and takes action as needed to prevent harm from these medicines.

For valproate the Medicines and Pregnancy Registry<sup>1</sup> monitors the implementation of, and adherence to, the valproate PPP in England. In the 6 months between April and September 2022, 18 pregnancies were newly identified as exposed to valproate. Further work is ongoing to increase clinical oversight of valproate prescribing to ensure that it is not used in women of childbearing potential unless other treatments are ineffective or not tolerated.

Thalidomide, lenalidomide and pomalidomide are indicated for multiple myeloma, in addition, lenalidomide is indicated for myelodysplastic syndromes, mantle cell lymphoma and follicular lymphoma. Women of childbearing potential must have pregnancy tests before and monthly during treatment and must use effective contraception. Each prescription for thalidomide, lenalidomide or pomalidomide must be accompanied by a prescription authorisation form (PAF), which must be completed and signed by the prescriber and pharmacist. The PAF requires the prescriber and pharmacist to confirm that a woman of childbearing potential has had a negative pregnancy test. Marketing Authorisation Holders are required to perform audits of the completed PAFs at regular intervals and provide anonymised results to MHRA and other regulators. Healthcare professionals are asked to report any cases of suspected or confirmed pregnancy or foetal exposure through the Yellow Card Scheme.

Vismodegib is indicated for the treatment of basal cell carcinoma. Women of childbearing potential must have pregnancy tests before treatment and monthly during treatment. They must use two methods of recommended contraception including one highly effective method and a barrier method during Erivedge therapy and for 24 months after the final dose. Prescriptions for women of childbearing potential are limited to 28 days. Prescribers are asked to report any pregnancies through the Yellow Card Scheme.

Isotretinoin, acitretin and alitretinoin are retinoids, a class of medicines used in the treatment of skin conditions. Isotretinoin is indicated for severe forms of acne (such as nodular or

<sup>1</sup> [\[MI\] Medicines and Pregnancy Registry - Antiepileptic use in females aged 0 to 54 in England: April 2018 to September 2021 - NHS Digital](#)

conglobate acne or acne at risk of permanent scarring) resistant to adequate courses of standard therapy with systemic anti-bacterials and topical therapy. Acitretin is indicated for severe psoriasis and alitretinoin is indicated for severe, chronic hand eczema. Women of childbearing potential must have pregnancy tests before and during treatment and must use effective contraception throughout treatment and for a period after stopping treatment (1 month in the case of isotretinoin and alitretinoin, and 3 years in the case of acitretin). Healthcare professionals are asked to report through the Yellow Card Scheme any pregnancies occurring during treatment and for the period of using contraception after treatment has stopped.

The table below provides the number of spontaneous, suspect UK cases for the transplacental route of administration from the first of January the year the PPP was introduced up to the 23<sup>rd</sup> August 2023.

Active Substance	Year PPP introduced	Number of reports
valproate	2018	130
thalidomide	2008	0
lenalidomide	2007	0
pomalidomide	2013	0
vismodegib	2013	0
isotretinoin	2003	23
acitretin	2018	0
alitretinoin	2018	0

Please note that it is inappropriate to compare rates of reporting with different products as the likelihood of pregnancies occurring will depend on the population in which the medicine is used (eg the extent of use of the medicine in women of childbearing age) as well as whether treatment is for a shorter term such as 6-12 months or potentially lifelong.

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](mailto: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 & Surveillance**