

FOI 23/300 - number of inspection findings related to Patient Support Programs from April 2012

ORIGINAL REQUEST

To MHRA Freedom of Information Team,

Please could you provide the following data in relation to Pharmacovigilance Inspections of Marketing Authorisation Holders:

Number of inspection findings related to Patient Support Programs
Breakdown by year since 2011, including grading of finding (Critical, Major, Minor)

NARROWED REQUEST

I would be very happy to accept the data you have available from April 2012 as mentioned

MHRA RESPONSE

28 June 2023

Dear

Thank you for your email.

The table below provides a breakdown of the 51 findings relating to patient support programmes by financial year and grading which were identified from pharmacovigilance inspections conducted by the MHRA since 01 April 2012.

This includes pharmacovigilance inspections conducted jointly by the MHRA and other EU national competent authorities. Please note that the table only includes data from inspections which were completed and closed as of 09 May 2023.

Financial year	Critical	Major	Minor
2012-2013	0	6	1
2013-2014	4	9	1
2014-2015	0	8	4
2015-2016	0	4	5
2016-2017	1	1	1
2017-2018	0	0	0
2018-2019	0	3	1
2019-2020	0	0	0
2020-2021	0	0	2
2021-2022	0	0	0
2022-2023	0	0	0
Total number of findings	5	31	15

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,

MHRA Customer Experience Centre

Communications and engagement team

Medicines and Healthcare products Regulatory Agency

10 South Colonnade, Canary Wharf, London E14 4PU

Telephone 020 3080 6000