

## FOI 23/274 – Early Access to Medicines Scheme

**Request**  
**11 April 2023**

Under the freedom of information act 2000, I'm requesting the following information on the Early Access to Medicines Scheme:

1. How many Promising Innovative Medicines (PIM) applications has the MHRA received as part of the Early Access to Medicines Scheme (EAMS) each year between April 2014 and April 2023?
  - a. For each year, how many of these applications have been granted?
  - b. For each year, how many of these applications have been refused?
  - c. For each year, how many of these applications have been withdrawn?
  - d. How many of these applications are pending?
2. How many Scientific Opinion applications has the MHRA received as part of the Early Access to Medicines Scheme (EAMS) each year between April 2014 and April 2023?
  - a. For each year, how many of these applications have been granted?
  - b. For each year, how many of these applications have been refused?
  - c. For each year, how many of these applications have been withdrawn?
  - d. How many of these applications are pending?

**MHRA RESPONSE**  
**26 April 2023**

Dear

Thank you for your email.

Please see below answers to the questions you have raised.

1. How many Promising Innovative Medicines (PIM) applications has the MHRA received as part of the Early Access to Medicines Scheme (EAMS) each year between April 2014 and April 2023?
  - a. For each year, how many of these applications have been granted?

2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	total
2	10	13	23	19	9	15	21	10	2	124

- b. For each year, how many of these applications have been refused?

2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	total
0	4	3	3	6	2	2	1	1	1	23

- c. For each year, how many of these applications have been withdrawn?

2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	total
	1	1		2						4

d. How many of these applications are pending?

2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	total
		2			1	1		3	3	10

2. How many Scientific Opinion applications has the MHRA received as part of the Early Access to Medicines Scheme (EAMS) each year between April 2014 and April 2023?

a. For each year, how many of these applications have been granted?

2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	total
	5	5	8	3	7	7	7	5		47

b. For each year, how many of these applications have been refused?

2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	total
	1	1		1					1	4

c. For each year, how many of these applications have been withdrawn?

2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	total
			1	3		3	1	2	2	12

d. How many of these applications are pending?

2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	total
									2	2

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

**MHRA Customer Experience Centre**

Communications and engagement team

Medicines and Healthcare products Regulatory Agency

10 South Colonnade, Canary Wharf, London E14 4PU