Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

11th December 2023

Dear [redacted]

FOI 23/874

Thank you of your email dated 13th November 2023, where you requested:

List of drugs withdrawn for safety reasons from 2014 to 2023.
Detailed reasons for the withdrawal of each drug.
Any available data on the adverse effects and risks associated with these drugs.

We can confirm that the Agency does not hold a comprehensive list of withdrawals from the UK market, and to fulfil the request we would have to run a search for cancellations in each year, which would then require manual review to determine the reason for withdrawal. We have estimated the time to fulfil this request below, which exceeds the appropriate time limit in the Freedom of Information Act. Therefore, we are exempting your request under Section 12 of the Act.

Section 12 of the Act makes provision for public authorities to refuse requests for information where the cost of dealing with them would exceed the appropriate limit, which for central government is set at £600. This represents the estimated cost of one person spending 24 working hours in locating, retrieving and extracting the information. We estimate that it will take us in excess of 24 working hours to determine appropriate material and locate, retrieve and extract the information in reference to your request. Therefore, your request will not be processed further.

We have estimated the effort to fulfil your request as follows:

We would need to run a search for all cancelled licences in each year of your request (approx 10 mins) x 10 = 1.5 hours

We estimate there will be several hundred cancellations in each year (some will be commercial decisions, change of licence ownership etc, however, we will have no way of finding this out without checking each individual case). Estimate of 5 hours per year x 10 = 50 hours

Following this we will then need to cross-reference committee papers, meeting minutes from the time and/or the Drug Safety Update from our website. It is difficult to estimate how much additional

time this would take, if there is no information on the website then we would estimate approximately 1 hour per substance to review committee papers from the time.

You may be interested to know that Drug Safety Update articles are available here: https://www.gov.uk/drug-safety-update
While this will not provide the total number of safety reviews that the MHRA has done or medicines withdrawn for reasons other than a distinct safety issue (ie, some may have been withdrawn for efficacy/commercial reasons), we hope that this will provide some information relevant to your request for you.

You may wish to refine your request by narrowing its scope: for example, by reducing the range of years you would like us to check. However, we cannot guarantee that this refinement will bring the request within the fees limit as, depending on the volume of material still falling within scope of the refinement, it might still exceed the limit based on our estimates above. In addition to this you should be aware that refining your request does not necessarily mean there will be anything held within the scope of the refinement (for example there may not have been any medicines withdrawn due to safety concerns in the refined period).

I hope the information provided is helpful, but 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 of this response; and can be addressed to this email address.

Yours sincerely,

FOI Team,
Vigilance and Risk Management of Medicines Division