FOI 23/768

Dear

> *"I am writing to submit a second Freedom of Information request following FOI 23/688. With regard to the FOI 23/688 request, I received a list of new medicines (new active substances/originators) approved in the UK between January 1987 and December 2004.*
>
> *Regarding the same list of medicinal products approved during this time frame, I would like to request the following information: for each medicinal product included in the list, I am seeking the name (and/or ID, in whichever format you have it) and location(s) of the clinical trial(s) submitted by the authorisation holder company for the first indication approval."*

Having reviewed your request, we estimate that compliance with the request would exceed the appropriate costs limit under S.12 Freedom of Information Act 2000. Public authorities are not obliged to work past the appropriate costs limit under section 12(1) of the Freedom of Information Act 2000.

This is because your request in its present form covers:

- the name (and/or ID, in whichever format you have it) and location(s) of the clinical trial(s) submitted by the authorisation holder company for the first indication approval for the list of Marketing Authorisations previously provided in FOI 23/688

The list of Marketing Authorisations provided in response to FOI 23/688 contained over 3000 entries.

We would have to manually check our records for each of the Marketing Authorisations to locate the clinical study data that was submitted at the time of authorisation. As the Marketing Authorisations are for older products (granted between 1987 and 2004), it is likely that we do not hold the information electronically and this would involve retrieving and searching our paper archives for the information.

We have reached our conclusion based on previous precedents set in relation to the location, retrieval, and extraction of information from our electronic and paper records.

Advice and Assistance

It would be advisable to significantly narrow the request to information for a small number (1-2) of Marketing Authorisations that you are interested in, we recommend one or two specific PL numbers.

Some information about the clinical trials that were conducted may be found in Section 5.1 of the Summary of Product Characteristics (SmPCs) for each product.

SmPCs can be found by searching on our products website: Find product information about medicines - GOV.UK (www.gov.uk)

Details of ongoing clinical trials are listed publicly on the following databases:
https://www.clinicaltrials.gov/
This is a database of federally and privately supported clinical trials conducted in the United States and around the world. The database is managed by the National Institutes of Health in the United States.

https://www.clinicaltrialsregister.eu/ctr-search/search
A database of interventional clinical trials that are conducted in the European Union (EU) and the European Economic Area (EEA) and clinical trials conducted outside the EU/EEA that are linked to European paediatric-medicine development.

https://scanmedicine.com/

ScanMedicine is a comprehensive database of clinical trials, developed by the National Institute for Health and Care Research Innovation Observatory (NIHRIO), The University of Newcastle upon Tyne.

If you do submit a refined request, then we will treat it as a substitute request to your original request and the 20 working day statutory time limit will begin from the date your refined request is received. In the absence of a refined request, we will send an official response to your original request, engaging the costs limit exemption under section 12(1) of the Freedom of Information Act 2000 within the 20 working day limit.

If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask for an internal review. Please reply to this email, within two months of this reply, specifying that you would like an Internal Review to be carried out.

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 online via an electronic form: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/
Or by writing to:
Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely

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Communications and engagement team
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