


**FOI 23/970**

FOILicensing &lt;FOILicensing@mhra.gov.uk&gt;

Thu 11/01/2024 16:36

To: [REDACTED] &lt;[REDACTED]&gt;

 1 attachments (36 KB)

FOI 23\_970.pdf;

Dear [REDACTED],

Thank you for your correspondence of 11 December 2023, where you requested the following information:

- a) all documents and information containing the word 'Ipstyl', manufactured or marketed by Ipsen;
- b) all documents and information containing the word 'Lanreotide', manufactured or marketed by Ipsen; and
- a) the dossier including the results of any pre-clinical tests or clinical trials conducted on 'Ipstyl', 'Lanreotide', or other products containing 'Lanreotide', as well as any bioavailability studies performed with respect to 'Ipstyl', 'Lanreotide', or other products containing 'Lanreotide', manufactured or marketed by Ipsen.

Unfortunately, we estimate that compliance with this 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 and we are therefore refusing your request.

In terms of Marketing Authorisations alone, we have identified 14 currently granted or cancelled Marketing Authorisations that fall within the scope of your request. Please find a list of these attached. In order to locate, retrieve and extract the many hundreds of documents that we hold in relation to the initial submission, assessment and subsequent variation of these 14 licences would far exceed 24 hours work.

Some of the identified licences would have been granted when we received and stored documents in paper form (rather than our current electronic databases). We would, therefore, also have to search our paper archives. An initial search of our database of paper archives generated over 200 hits for the keywords 'Ipstyl' and 'Lanreotide'. We would have to review each of these 200 hits to see if they fall within the scope of your request. We would then need to request boxes from our paper archive and manually look through the boxes to find the relevant documents.

In terms of Clinical Trials applications, we have identified over 100 applications that could potentially fall within the scope of your request. Locating, retrieving and extracting the many hundreds of documents that we hold in relation to clinical trials would also exceed 24 hours.

We acknowledge that you have offered to reimburse MHRA for reasonable costs, however we are only able to charge for specified activities such as photocopying, printing etc and we do not think it is feasible to apply a charge to the extensive amount of work that would be involved in complying with your request.

We would advise you to considerably narrow this request to ask for a particular document for one particular Marketing Authorisation e.g. the Clinical Overview for one of the licences listed.

Please note that we publish product information and public assessment reports on the following website: [Find product information about medicines - GOV.UK \(www.gov.uk\)](https://www.gov.uk/guidance/find-product-information-about-medicines)

If you do submit a refined request, this will be a new request and the 20 working days statutory time limit will begin from the date your refined request is received.

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

Or online via: <https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/>

Yours sincerely,  
FOI Team