Medicines & Healthcare products Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

[redacted]

And:

[redacted]

By email: [redacted]

22 February 2024

[redacted]

FOI 24/084 request following 23/970 (Section 12 refusal)

Thank you for your request for information where you asked:

> "In FOI Response 23/970, you informed us that the estimated cost of compliance with FOI Request 23/970 exceeded the appropriate cost limit under Section 12 of the Freedom of Information Act 2000, and advised us to narrow our Request. Accordingly, we have narrowed our Request and re-submit the following refined request.
>
> Under Section 1 of the Freedom of Information Act 2000, we respectfully request that the MHRA provides to [redacted] electronic copies of the following information that is in its possession:
>
> a) the registration dossier of '*Ipstyl*' products, manufactured or marketed by Ipsen Limited, including, in particular, Modules 1, 2 and 5 and the results of any clinical trials conducted on '*Ipstyl'* products; and

b) MHRA's Public Assesment Reports (including any Safety Public Assessment Reports) on '*Ipstyl*' products, manufactured or marketed by Ipsen Limited.

For ease of identification, we provide below the details of the '*Ipstyl*' products referred to above, as extracted from the list of licences attached to FOI Response 23/970.

Drug Substantce	Authorisation Number	Licensed Product Name	Authorisation Holder Company Name	Product Birth Date (National)	Authorisation Status
LANREOTIDE ACETATE	PL 06958/0020	IPSTYL LA 60MG, SOLUTION FOR INJECTION	IPSEN LIMITED	26/05/2004	CANCELLED
LANREOTIDE ACETATE	PL 06958/0021	IPSTYL LA 90MG, SOLUTION FOR INJECTION	IPSEN LIMITED	26/05/2004	CANCELLED
LANREOTIDE ACETATE	PL 06958/0022	IPSTYL LA 120MG, SOLUTION FOR INJECTION	IPSEN LIMITED	26/05/2004	CANCELLED

"

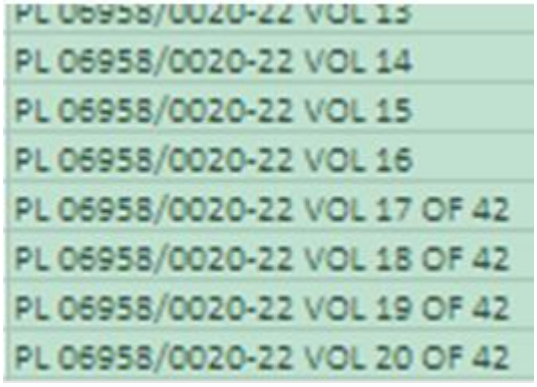
Our response

In terms of part a) of your request, this information is held in the Regulatory Dossier which for these products is held in our off-site physical paper archives.

Based on the index results for the archives, full clinical data were submitted for these initial applications, so the dossier will contain a large amount of information provided to the MHRA for their consideration.

To meet this part of your request alone, we would need to consider modules 1, 2, and 5 of the dossier in full in order to identify where exemptions may apply. As per best practice as detailed in the FOI Code of Practice, we would need to solicit views from third parties on disclosure in a formal consultation process. A key issue for the time required to undertake these activities is that exempt material is likely to be dispersed unevenly throughout the dossier. It is particularly important to ensure that all personal information is identified and correctly withheld under section 40 of the FOIA. Different types of personal information are present in many documents in terms of authors (these can be located in headers, footers, or in-text mentions), and clinical data also needs to be carefully considered to establish if any identifiers or pseudo-identifiers of trial participants or patients are present, as these may *not* be provided to us in an anonymised form. An extremely careful approach needs to be taken to ensure no names of research organisation staff are included as doing so could breach the principles of the Data Protection Act.

The index search (electronic indexing record of files in our paper archive) indicates, in particular many volumes of clinical data for the PL numbers specified in your request (82 index locations were returned on a preliminary search). Based on our knowledge of volumes of clinical trial information, past precedents and the document structure and detail required for a clinical trial, we are confident that this would run into 1000s of pages. Paper files of clinical data are most commonly stored in many ring-bound volumes. This is supported by the indexing results, please see example below:


PL 06958/0020-22 VOL 13
PL 06958/0020-22 VOL 14
PL 06958/0020-22 VOL 15
PL 06958/0020-22 VOL 16
PL 06958/0020-22 VOL 17 OF 42
PL 06958/0020-22 VOL 18 OF 42
PL 06958/0020-22 VOL 19 OF 42
PL 06958/0020-22 VOL 20 OF 42

In order to prepare the requested information for redaction we would need to scan each page of each binder; and then collate the files. Once scanned the pages in the document need to be checked carefully for missing pages, as scanners/photocopiers can be prone to the error of intaking double pages or triple pages, as a single unit**.**

Finally, we would need to go through a process for all information for disclosure to apply 'redactions' to any information withheld. This requires use of a manual mark-up tool; we do not use an automated tool due to a risk of accidental disclosure if, for example, misspelled words or names were potentially to be overlooked by automated tools. Once redactions are made, a further step is taken to make the redactions irreversible. This step has to be completed for each document that requires redaction. For a large volume of material, this last step is itself a time-consuming process, as we expect almost all documents to require some form of redaction, for example, due to the presence of personal information.

The balance of the public interest, value and serious purpose of the request versus the burden of compliance

We appreciate that there is a public interest in clinical data for medicinal products in general, however, we do not feel that the public interest in this case outweighs the resource burden required to meet your request.

According to our records there was an outgoing Mutual Recognition Procedure (MRP) (Lanreotide UK/H/0723/001 – 003 Ipstyl 60 mg, 90mg, 120mg solution for injection) granted for the requested product (PL numbers).

The MR procedure assessment reports have been previously released, in relation to an historical FOI request (FOI 12/489), and we attach this for your reference.

Our view is that the above-mentioned MR report, in addition to data included in the Summary of Product Characteristics (SmPCs) (included in the report) serves to address the public

interest in disclosure. Further, these Marketing Authorisation (MAs) for Ipstyl are cancelled in the UK, so there is no direct, or very limited UK public interest; for example, with regards to insights about these products which could affect a UK patient.

> "b) MHRA's Public Assesment Reports (including any Safety Public Assessment Reports) on '*Ipstyl*' products, manufactured or marketed by Ipsen Limited."

For part b) of your request please see the advice and assistance section below.

Advice and assistance

We would like to raise the below options for refinement:

There is a reasonable probability that the Mutual Recognition Procedure (MRP) report provided for your reference may contain information sufficient to address your needs. However, should this not be the case, a narrowed request could focus on the non-clinical and clinical overviews (summaries of the data submitted in modules 4 and 5). These documents could then be used to identify specific non-clinical or clinical studies that might be of interest to you. Equally the report provided could be used in the same manner. However, please bear in mind that Clinical Study Reports (CSRs) are likely to run to 1000s of pages and therefore requests for all information on 'x' trial may lead to a refusal dependent on the specific burden associated with any future request.

In line with our previous response, we will not be able to provide any data that is commercially confidential or provided to the MHRA in confidence. Exemptions may apply to parts of any documentation disclosed under FOIA. A refinement based on the overviews is an option which has often been recommended to members of the public requesting large amounts of information on regulatory approvals, and is the same advice that we recommended for their previous request.

In terms of part b) of your request,

> "b) MHRA's Public Assesment Reports (including any Safety Public Assessment Reports) on '*Ipstyl*' products, manufactured or marketed by Ipsen Limited."

We would like to mention that the requirement to publish Public Assessment Reports (PARs) only arose in 2005, and these marketing authorisations pre-date that requirement.

Safety PARs between 2006 and 2024 are published here on the MHRA website. Between 2012 and 2022, most safety issues were assessed at an EU level and reports for these issues can be found on the European Medicines Agency (EMA) or Head of Medicines Agency websites.

We trust that you will find this explanation of use. However, if you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask us to review our actions and decisions by writing to: info@mhra.gov.uk, and requesting an internal review.

Please note that your internal review request must be in a recordable format (email, letter, audio tape etc.), and that you have 40 working days upon receipt of this letter to ask for a

review. We aim to provide a full response to your review request within 20 working days of its receipt. Please quote the reference number above in any future communications.

If you are not content 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 in writing to:
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