Medicines & Healthcare products Regulatory Agency

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United Kingdom
gov.uk/mhra

[redacted].
By email: [redacted]

[redacted]

7 May 2024

MHRA reference: 24/355

Dear [redacted]

Thank you for your information request, which we received on Sunday, April 14, 2024. You asked for:

- *"Studies on Depo Provera.*
- *Information held by the MHRA on the contraceptive.*
- *The number of yellow card reports submitted for the product.*
- *The reported side effects from the yellow card reporting system.*
- *The policy of the MHRA on when the contraceptive can be safety administered.*
- *All and any other information held on the Depo Provera Contraceptive Injection."*

We have dealt with your request under the Freedom of Information Act 2000 (FOIA).

I confirm that MHRA holds information on this request and are exempting this information on the basis of Section 14(1) FOIA. On this occasion, a detailed assessment of your request has determined that the scope and breadth of the information you have requested is so great that compliance with this request would create a 'disproportionate burden'.

In cases such as this, a public authority may apply Section 14(1) to the request, as the request falls to be termed 'vexatious' under FOIA. We stress that this is solely on the basis of the burden that would be created by compliance, due to the voluminous amount of information that would need to be retrieved and then reviewed in detail in order to comply with your request.

The Information Commissioner's guidance explains that:

> *"You cannot claim Section 12 for the cost and effort associated with considering exemptions or redacting exempt information. Nonetheless, you may apply Section 14(1) where you can make a case that the amount of time required to review and prepare the information for disclosure would impose a grossly oppressive burden on your organisation.[1]*
>
> And:
>
> *15. The Commissioner's guidance on Section 14 states that there is a high threshold for refusing a request on such grounds. It says that a public authority is most likely to have a viable case where:*
> *• the requester has asked for a substantial volume of information; and*
> *• the authority has real concerns about potentially exempt information, which it will be able to substantiate if asked to do so by the Commissioner; and*
> *• any potentially exempt information cannot easily be isolated because it is scattered throughout the requested material.[2]"*

The guidance above is particularly relevant to your request and we will explain how this applies here in some detail below. In the final section, we will also provide some further advice and assistance as to how you could proceed with a significantly narrowed request for information.

1. **Preliminary Search and evidence for disproportionate burden**

During a preliminary search of our records, we identified two PL numbers for this product, PL 00057/0965 (the current granted marketing authorisation (MA)) and PL 00032/0082 which was previously registered by another company and is cancelled/transferred to PL 00057/0965. Under the cancelled MA we hold both electronic and paper records, and under the currently granted MA (we hold electronic records).

Electronic records

In terms of the electronic records some files are ~ 100 pages long, and include information related to the renewal of this authorisation, variations (changes to the authorisation) and other registration and administrative information. We would need to check through these records carefully to remove personal information and information related to the quality of the product that relates to commercial trade secrets for example detailed information about the manufacture of the product--given the number of pages and detail within this would be a highly time-consuming

process. Please also note, that personal information is disparate throughout these records and based on our knowledge of medicines applications/dossiers the same is expected for the paper (physical) records.

Marketing authorisation lifecycle
We also hold lifecycle entries for this product: 54 entries under PL 00032/0082 and 47 under PL 00057/0965. Each entry will hold varying levels of information e.g relating to variations where the company may have submitted clinical, non-clinical, or quality, and/or administrative information to support changes to the marketing authorisation. Other changes and updates may also be included in the lifecycle such as periodic safety update reports, renewals, corrections of errors etc.

Paper records (physical)
In terms of the paper records we identified ~33 entries on our electronic index, we estimate this to be a very substantial volume of information based on experience with previous requests.

2. Summary

The above preliminary search was conducted based on the following part of your request for information:

> "*All and any other information held on the Depo Provera Contraceptive Injection."*

Following the identification of the records as detailed above in the 'preliminary search', the search was then ceased because the extent of information held was deemed to clearly exceed the burden which would be placed on the Agency to comply with your request. The records identified above, do not therefore, represent the full extent of the information likely to be held by the Agency for this product 'Depo Provera'. Indeed, we expect that records of this product will also be held by other operating groups, for example, Safety and Surveillance, Clinical Investigations and Trials, Communications, and Expert Committee Support.

3. Further ICO guidance

The ICO identifies that the key consideration in the case of a single burdensome request is whether the value and purpose of the request justifies the distress, disruption or irritation that would be incurred by complying with it. In the First Tier Tribunal, *Independent Police Complaints Commissioner vs The Information Commissioner* (EA/2011/0222, 29 March 2012)[3] the Tribunal found that:
"A request may be so grossly oppressive in terms of the resources and time demanded by compliance as to be vexatious, regardless of the intentions or bona fides of the requester." (paragraph 15).

Similarly, in *Cabinet Office vs Information Commissioner and Ashton* [2018] UKUT 208 (AAC)[4] the Upper Tribunal agreed that even when there may be a public

interest in the information, the burden of compliance may still be so great that the request would fall to be considered vexatious:

> *"In some cases, the burden of complying with the request will be sufficient, in itself, to justify characterising that request as vexatious, and such a conclusion is not precluded if there is a clear public interest in the information requested. Rather, the public interest in the subject matter of a request is a consideration that itself needs to be balanced against the resource implications of the request, and any other relevant factors, in a holistic determination of whether a request is vexatious."*

We recognise that there is a public interest in information on medicines, and in particular contraceptives. However, the present request is so broad that it encompasses such a range of information (and a large proportion of the information captured by the scope of your request is perceived to be of low value to the public interest e.g. application forms, administrative information related to manufacturing site changes, tables of present and proposed change etc.) that the burden which would be exacted by handling the request would outweigh the perceived benefit of releasing the information. The burden associated with the processing of your request would necessitate the redirection of finite resources away from other duties and responsibilities that are important for the protection of public health.

Public domain information
Please be aware of the following information in the public domain which may be of interest to you.

- Every medicine pack includes a Patient Information Leaflet (PIL), which provides information on using the medicine safely. PILs are based on the Summaries of Product Characteristics (SPCs) which are a description of a medicinal product's properties and the conditions attached to its use. MHRA publish the most up-to-date product information for a medicine according to its licence history here: MHRA Products | Search results.

    - The current clinical data to support the authorisation of a product are also summarised in Section 5.1 of the Summary of Product Characteristics above.
    - Possible side effects are also listed in Section 4.8 of the SmPC.
    - The indications for use, including any contraindications or precautions and warning for use are also covered in Section 4 of the SmPC which aligns with your question, "*The policy of the MHRA on when the contraceptive can be safety administered."*

- For suspected side effects being reported for medicines, the MHRA publishes this information in the form of interactive Drug Analysis Profiles (iDAPs). The iDAP for medroxyprogesterone, the substance within Depo-Provera, can be found here: https://info.mhra.gov.uk/drug-analysis-profiles/dap.html?drug=./UK_EXTERNAL/NONCOMBINED/UK_NON_000767899847.zip&agency=MHRA

    - It is important to note that reported adverse reactions have not been proven to be related to the drug and should not be interpreted as a list of known side effects.

The ICO instructs that when Section 14(1) applies due to the burden created by the request, it is important to provide advice and assistance to assist the requester make a smaller request for a proportionate amount of information.

4. Section 16 Advice and assistance

If the above publicly available information listed in the previous section of this letter is not sufficient for your needs, we would advise narrowing your request to one of the following options below:

- Request information on a specific issue that you are interested in that we would hold information on as part of the regulatory history of this product, for example, to request a copy of the clinical and or non-clinical overviews for this product, as formerly known as expert statements to support the initial licence.
    - Please note, Given the age of this product (renewed in 1986, and therefore, likely first registered in the UK 1981/2) we cannot guarantee that these documents are held, we would need to retrieve the physical records to check. This product was previously authorised for a broader range of indications, including indications outside of contraceptive purpose/use; it would be beneficial in any new request to confirm if the information being requested should only relate to indications related to contraception only, and within this specify long-term contraceptive, short-term contraceptive use or both.
- A short window of time e.g. information related to Depo Provera submitted in a window of a few months. Please note, depending on how much information was submitted within a certain time-window, we cannot guarantee that Section 12 or 14 would not be applied to a new request. We would not recommend this option, as the probability of selecting a time window that aligns with information you are interested in is likely low. However, if you provide more detail on the type of information you are most interested in, in any new request this may help us to meet a refined request.

- A Product Analysis Print (PAP) for Depo-Provera, which contains a list of all UK spontaneous suspected Adverse Drug Reactions (ADRs) reported to the MHRA and the number of reports received for each reaction, specifically for the product Depo-Provera. This includes all reports received from healthcare professionals, members of the public, and pharmaceutical companies.

Please be aware that i) Any refined request may still be a subject to an exemption/s under FOIA and ii) a refined request is processed as a new request. This means that the statutory time for compliance begins on the date of the receipt of that new request.

References:
[1] https://ico.org.uk/for-organisations/foi-eir-and-access-to-information/freedom-of-information-and-environmental-information-regulations/dealing-with-vexatious-requests-Section-14/how-do-we-deal-with-a-single-burdensome-request/
[2] https://ico.org.uk/media/action-weve-taken/decision-notices/2023/4025038/ic-197426-f8v9.pdf
[3] https://informationrights.decisions.tribunals.gov.uk/DBFiles/Decision/i725/20120329%20Decision%20EA20110222.pdf
[4] https://assets.publishing.service.gov.uk/media/5b57139a40f0b6339963e8cf/GIA_2782_2017-00.pdf

This concludes our response to your request.

If you have a query about this response, please contact us at foi.request@mhra.gov.uk.

Please remember to quote the reference number at the top of this letter in any future communications. Details of your appeal rights are below.

Yours sincerely,

Healthcare Quality, and Access
Medicines and Healthcare products Regulatory Agency

Appeal rights

If you are dissatisfied with the handling of your request, you can ask us to conduct an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: foi.request@mhra.gov.uk

If you remain dissatisfied with the outcome of the internal review, you 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 a request unless the requester has first asked us to conduct an internal review.

The Information Commissioner can be contacted through their online webform at: 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

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