Medicines & Healthcare products
Regulatory Agency

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gov.uk/mhra

[redacted]

29 May 2024

MHRA reference: FOI2024/00113

Dear [redacted]

Thank you for your information request, which we received on 7 May. You asked for:

> *"I am a Global Health journalist at The Bureau of Investigative Journalism (TBIJ), a non-profit pressroom based in London, UK.*
>
> *I'm contacting you in order to get some clarification on the process of import of medicines from non-UK and non-EU countries. I understand that firms from which the UK wants to import drugs needs a series of authorizations released by your agency, the MHRA. Is it correct?*
>
> *Would it be possible for you to clarify how the process works, what kind of compliance certifications are necessary and in which cases MHRA has to issue inspection to factories located abroad and what exactly has to be inspected?*
>
> *I'd also like to ask about one more specific case: I see in your website that the Indian firm Medopharm has two GMP records referring to the same inspection that occurred in 2019. One says that its labs comply<https://cms.mhra.gov.uk/mhra/gmp/uk-gmp-31201-insp-gmp-31201349094-0009h> with the GMP, another one seems to not.<https://cms.mhra.gov.uk/mhra/gmp/uk-gmp-31201-insp-gmp-31201349094-0009-ncr>*
> *This is the CERTIFICATE NUMBER: UK GMP 31201*
> *INSP GMP 31201/349094-0009[H]"*
>
> *What exactly do those two documents mean?*

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Does Medopharm currently have a GMP compliance certificate from MHRA?

Would it be possible to get all the documents related to Medopharm, also related to MHRA inspections?"

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

We confirm that we hold some of the information you have asked for, and we are disclosing this information in full. We are unclear on part of your request and are seeking clarification from you (please see below).

We have identified the following questions within your request:

1. *Clarification on the process of import of medicines from non-UK and non-EU countries. I understand that firms from which the UK wants to import drugs needs a series of authorizations released by your agency, the MHRA. Is it correct?*

Our response: We confirm that we hold the information you have asked for; however, this information is available to you as it is published by MHRA. Section 21 of the FOIA applies when the information is already reasonably accessible the requester and we do not need to provide a copy of the information; the link to access this information is below:
Apply for manufacturer or wholesaler of medicines licences - GOV.UK (www.gov.uk)

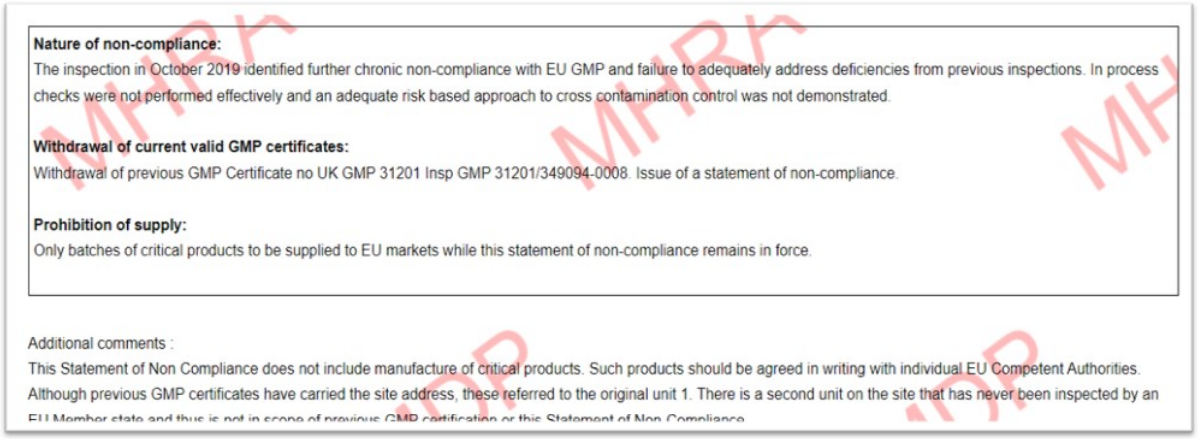
2. *Would it be possible for you to clarify how the process works, what kind of compliance certifications are necessary and in which cases MHRA has to issue inspection to factories located abroad and what exactly has to be inspected?*

Our response: We confirm that we hold the information you have asked for; however, this information is available to you as it is published by MHRA. Section 21 of the FOIA applies when the information is already reasonably accessible the requester and we do not need to provide a copy of the information; the link to access this information is below:
Apply for manufacturer or wholesaler of medicines licences - GOV.UK (www.gov.uk)

3. *I'd also like to ask about one more specific case: I see in your website that the Indian firm Medopharm has two GMP records referring to the same inspection that occurred in 2019. One says that its labs comply<https://cms.mhra.gov.uk/mhra/gmp/uk-gmp-31201-insp-gmp-31201349094-0009h> with the GMP, another one seems to not.< UK GMP 31201 Insp GMP 31201/349094-0009 NCR | MHRA>*
This is the CERTIFICATE NUMBER: UK GMP 31201
INSP GMP 31201/349094-0009[H]"

Our response:
The reason there are two documents (a GMP certificate and a statement of non-compliance) is because after the inspection in 2019 we issued two documents:

- A statement of non-compliance was issued because the site was *not* in compliance with GMP.
- A restricted GMP certificate was also issued, to allow the company to continue to manufacture only those products which were deemed critical to patients, as determined by the Department of Health and Social Care (DHSC) in the UK and, where relevant, the competent authorities in EU member states. (see except from public certificate below under title 'prohibition of supply'.



Nature of non-compliance:
The inspection in October 2019 identified further chronic non-compliance with EU GMP and failure to adequately address deficiencies from previous inspections. In process checks were not performed effectively and an adequate risk based approach to cross contamination control was not demonstrated.

Withdrawal of current valid GMP certificates:
Withdrawal of previous GMP Certificate no UK GMP 31201 Insp GMP 31201/349094-0008. Issue of a statement of non-compliance.

Prohibition of supply:
Only batches of critical products to be supplied to EU markets while this statement of non-compliance remains in force.

Additional comments :
This Statement of Non Compliance does not include manufacture of critical products. Such products should be agreed in writing with individual EU Competent Authorities. Although previous GMP certificates have carried the site address, these referred to the original unit 1. There is a second unit on the site that has never been inspected by an

4. *Does Medopharm currently have a GMP compliance certificate from MHRA?*

   Would it be possible to get all the documents related to Medopharm, also related to MHRA inspections?"

Our response: Please kindly refer to the above response *a* restricted GMP certificate was also issued for Medopharm. Section 21 of the FOIA applies when the information is already reasonably accessible the requester and we do not need to provide a copy of the information; the link to access this information is below.

UK GMP 31201 Insp GMP 31201/349094-0009[H] | MHRA

In terms of the second limb of your question "Would it be possible to get all the documents related to Medopharm, also related to MHRA inspections?" We require

clarification from you before we can process this part of your request. All documents related to a company (Medopharm) is a very broad request and we note that your other questions all relate to GMP/inspections, therefore, where you mention 'also related' to MHRA inspections, was this an error and the intended word was in fact 'only'? In our opinion, this would be more in keeping with the overall context of your request.

We will close this request, and if/once you provide a clarification this will be logged as a new FOI request. Please note, if the currently worded request for 'all documents' is correct then we would expect this to trigger Section 12 of FOIA due to the time taken to, identify (if held), locate, extract and retrieve the information. However, we will only be able to confirm this once we have checked all reasonable avenues for this information.

We hope this response/information is useful for you. 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 Group
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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Re-use of our information