Medicines & Healthcare products
Regulatory Agency

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

By email: [redacted]

19 January 2022

1. Introduction

Dear,

I am writing in response to your request for a review of the Medicines and Healthcare products Regulatory Agency's ('the Agency') reply to your FOI request (**22/1007]**).

We apologise for the delay whilst we conducted this internal review.

The purpose of this review is to determine whether the Agency dealt properly and fairly with your request under the Freedom of Information Act (FOIA). In particular, it will examine the reasons why information was withheld from you.

Your original request and the Agency's response are annexed.

You stated in your request for this review that:

"My request was about competency requirements for posts where the role includes the Authorisation of medicines. You have interpreted that as roles which include a "direct contribution" to Authorisation. That is not what I asked.

Let me spell it out. The Secretary of State for Health is personally accountable to Parliament under the Human Medicines Regulations for the safety of medicines. This accountability is delegated to MHRA. I assumed that, as with any other organisation operating in a safety critical sector, this accountability for safety is flowed down via specific safety delegations, to individuals who are therefore legally empowered to sign off the various types of Certification/Authorisation issued to companies producing and supplying products - medicines in MHRA's case - and are accountable for the consequences of any safety issues which might arise.

Your answer gives the impression that medicines are assessed by groups of individuals within MHRA with no single person having accountability for the decision to issue an Authorisation.

So, if that process (of delegated safety accountability to individuals) does not exist within MHRA, then the answer to my questions is zero. Otherwise, please provide the requested information about posts where the role (via delegated accountability for safety from SofS) includes the Authorisation of medicines.

Finally, I also asked for a copy of MHRA's process for "assessing and reviewing" the competence requirements of those with the delegated power to Authorise medicines for public use. You provided competence requirements used in the recruitment process but that is not what I asked. For example, not all people recruited will meet all of the essential competence requirements for a post on Day 1. So, if MHRA has a process for reviewing 'development progress' against post competence requirements, please provide it - or just state that there isn't one."

2. Consideration of the issues

Has the Agency answered the request and have any exemptions been properly applied?
Aside from the redaction and removal of personal information (Section 40) no other exemptions were applied. This exemption was applied to the names of staff who had drafted the documents.

Has the Agency fulfilled its general obligation to be helpful?
In compiling the response we assumed that that you were primarily interested in staff numbers that contributed to medicines assessments directly, rather than say support staff. However, you have challenged our interpretation of the request and have mentioned that our answer "gives an impression that medicines are assessed by groups of individuals with no single person having accountability for the decision to issue an authorisation".

However, we feel that this impression is the correct one, applications are assessed by groups of individuals e.g. primarily assessors that specialise in the interpretation of quality, non-clinical and clinical data, there are also assessors that study the statistical designs and tests laid out in medicine applications (marketing authorisation applications). The decision to grant is based on each discipline responsible for assessment being satisfied that the product's benefits outweigh the risks, and in reality, there is often cross-over and co-dependency between these disciplines. When necessary and in accordance with the Human Medicines Regulations, the members of Commission on Human Medicines (CHM) review the decision and engage their knowledge and expertise to either support the decision or to request further data / information, in some cases it may be suggested advised that an application should be refused or withdrawn.

Please also note, all decisions of the MHRA are taken by the Secretary of State under the Cartriona Principle. This Principle does not require a final 'sign off' although principles of accountability do apply. Grant letters to companies do carry a signatory but this most often provided by support staff and is simply an administrative formality.

In terms of your latter question (included in your request for an internal review), you state that “not all people will meet all of the competence requirements of a post on Day 1”. This is correct; although the essential criteria for the role will need to be satisfied by an employee at the point of employment with MHRA, learning and development in-role of course is also essential. It is for this reason that we also provided the competency development framework documents which include the criteria that assessors are gauged measured against as they advance develop in their roles. In terms, of the process of reviewing staff against the (in-role) competency requirements we accept that this was not included in the original response. We now provide a copy of the policy as an attachment, the text which introduced this information on our internal system can be located in appendix 2 of this letter.

3. Conclusion and recommendations

We believe that the information in the above section of this review, clarifies mis-assumption that medicines applications are assessed in a hierarchal fashion with single individual at the MHRA being ultimately responsible for the overall decision on a regulatory approval.

We have also provided the policy which describes how the competency development frameworks are implemented, this is material that is supplied in addition to the framework documents provided in the original response. There appears to be no overt need for any recommendations in this case, aside from reminding staff to check all aspects of the FOI questions asked. However, when considering FOI requests with multiple questions and multiple elements to single questions, human error and oversight can occur.

We appreciate that despite our best efforts there remains a chance that we may not have fully understood the specific data or information that you are seeking. Therefore, please do not hesitate to contact us if you feel that further discussion / clarification is required.

If you remain dissatisfied, you may ask the Information Commissioner (ICO) to make a decision on whether or not we have interpreted the FOIA correctly in dealing with the request and subsequent internal review. The ICO’s address is:

The Information Commissioner’s Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely

MHRA Customer Experience Centre
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU

Appendix 1: request history.

From:
Sent: 30 October 2022 08:10
To: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Subject: Internal Review of FOI 22/1007 - Re: FOI 22/1007 - FOI Competency

This is to request an Internal Review of your response to my FOI (22/1007).

My request was about competency requirements for posts where the role includes the Authorisation of medicines. You have interpreted that as roles which include a "direct contribution" to Authorisation. That is not what I asked.

Let me spell it out. The Secretary of State for Health is personally accountable to Parliament under the Human Medicines Regulations for the safety of medicines. This accountability is delegated to MHRA. I assumed that, as with any other organisation operating in a safety critical sector, this accountability for safety is flowed down via specific safety delegations, to individuals who are therefore legally empowered to sign off the various types of Certification/Authorisation issued to companies producing and supplying products - medicines in MHRA's case - and are accountable for the consequences of any safety issues which might arise.

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Mr xxxxxx

Appendix 2

The CDF process for accreditation

Policy-Competency DevelopmentFrameworkCDF (1).pdf

The CDF process for accreditation

When management and/or a mentor feels that an individual is demonstrating the required competencies to move from a trainee to an accredited role, a conversation should take place and the individual should submit an application form (standard internal application form), to their manager, demonstrating how they meet the required competencies of the role.

The application should be reviewed and endorsed by the unit manager and mentor, in consultation with the group manager. The application should then be sent to the divisional director/deputy director to review and approve if agreed.

If employees are unable to meet the criteria to move to the accredited grade within an 18-month to two-year period, the individual’s position may be terminated and this should be managed in line with the poor performance and misconduct policy.