
From: xxxx
To: <info@mhra.gov.uk>
Sent: 30/10/2022 00:10
Subject: 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.

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.

Mr xxxx

----- Original Message -----

From: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>

To: xxxxx

Sent: 28/10/2022 17:52:02

Subject: FOI 22/1007 - FOI Competency

Dear Mr xxxxxx,

Please find attached our response to your FOI request. The attachments referenced below are available to view in the second attachment.

Appendices

Note: The below are a non-exhaustive list of job descriptions for roles in HQA and S&S which involve assessment activities. The Job descriptions help to illustrate the requirements for entry to the role, please also note Medical Assessor, Innovative Medicines, is an example of the requirements for medical assessors across all of Innovative Medicines.

Healthcare Quality and Access (HQA)

Safety and Surveillance (S&S)

Competency Development Frameworks (CDF)

Kind Regards

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

From: xxxxxx
Sent: 02 October 2022 16:46
To: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Subject: FOI 22/1007 - FOI Competency

This is a request under the Freedom Of Information Act.

Please can you send me MHRA's internal document(s) which describes the skills, qualifications, experience and training which MHRA requires of those people in MHRA with the delegated power to Authorise medicines for public use, and the process for assessing and reviewing this.

Please can you also send me the following :

a) the current number of posts where the role includes the Authorisation of medicines for public use which are : i) filled; ii) vacant

b) the current number of filled posts where the incumbent has been assessed as competent to Authorise medicines for public use;

c) of a), the current number where the incumbent has been in post for less than 3 months

To be clear, this FOI request covers only medicines not medical products.

Mr xxxx