Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

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28 December 2022

Dear

FOI 22/1083 – FOI Request- MHRA Yellow Card Vaccine Monitor programme; and Safety Management Reviews

Thank you for your Freedom of Information request dated 01st November 2022, where you asked the following two questions:

1. Targeted Active Monitoring. Please can you send me the MHRA's latest report of its MHRA Yellow Card Vaccine Monitor programme (which was announced at para 3 here: https://www.gov.uk/government/publications/report-of-the-commission-on-human-medicines-expert-working-group-on-covid-19-vaccine-safety-surveillance/report-of-the-commission-on-human-medicines-expert-working-group-on-covid-19-vaccine-safety-surveillance)

2. Safety Management Reviews. Please can you send me the MHRA document which describes your periodic/routine reviews of medicine safety management. To avoid any confusion, I will elaborate. In other safety critical sectors, it is standard practice for those delegating the responsibility for product safety to conduct routine/periodic Safety Management Reviews of those delegated people/groups. The scope of these Safety Management Reviews might be all products of similar types, all products of any type managed by one group/team or some other segmentation. The routine/periodic reviews (maybe monthly, quarterly, 6-monthly or annual) will look at, *inter alia*, the top safety-related risks (product & business-related), progress with ongoing safety-related tests/trials, serious faults/incidents, staffing (recruitment/retention), skills/competence/training, audit plans and audit corrective actions. Here, for example, is the document describing all that in the Ministry of Defence: https://www.asems.mod.uk/printpdf/guidance/posms/smp02. I am requesting the MHRA's corresponding document for medicines.

Further to your first request for the MHRA's latest report of the Yellow Card Vaccine Monitor Programme, please find attached our paper to the Pharmacovigilance Expert Advisory Group (PEAG) in August 2021, outlining the progress of the Yellow Card Vaccine Monitor programme in line with our COVID-19 Vaccine Safety Surveillance Strategy. Please note to maintain patient confidentiality some information has been redacted from this paper.

In your second request you ask for a medicines safety management document. In response to your previous requests to the MHRA, which are similar in nature, we have provided documents which we felt met your request. In FOI 22/562 we provided our System Operating Procedure (SOP) which describes the steps we follow whilst carrying out our Signal Assessment of Adverse Drug Reaction (ADR) reports. This is essentially the process we follow for every identified signal and describes the process for data capture and entry through to signal assessment. It describes the signal assessment process, the meetings through which we ensure effective collaboration across internal experts and senior management oversight and the circumstances in which we seek

independent expert advice where regulatory action is thought to be required to manage a particular safety issue. The terms of reference of our Commission on Human Medicines and Pharmacovigilance Expert Advisory Group may be of interest to you. It should be noted we do not establish a safety committee for each and every signal of interest and do not therefore have an equivalent document to that which was supplied as an example.

The document you provided defines a safety committee *'as a group of stakeholders that exercise, oversees and endorses safety management and safety engineering activities'.* While we do not believe we have an equivalent structure, I should note also that Good Pharmacovigilance Practice provides the minimum standard for monitoring the safety of medicines available to the public in the UK. The following link provides the pharmacovigilance responsibilities imposed on Marketing Authorisation Holders (MAHs) which includes the reporting of UK and non-UK individual case safety reports, periodic safety update reports, risk management plans and post marketing obligations where relevant. Guidance on pharmacovigilance procedures - GOV.UK (www.gov.uk)

The objective of periodic safety update reports (PSURs) is to present a comprehensive and critical analysis of the risk-benefit balance of the product, taking into account new or emerging safety information in the context of cumulative information on risk and benefits. Marketing authorisation holders (MAHs) are legally required to submit PSURs, in line with Regulation (EU) No 1235/2010, Directive 2010/84/EU and Commission Implementing Regulation (EU) No 520/2012. PSURS are submitted according to a predefined frequency.

Article 35 of the Commission Implementing Regulation describes the structure of PSURs. Module VII of the Guidelines on Good Pharmacovigilance Practices (GVP) provides guidance on the preparation, submission and assessment of PSURs. This format is a legal requirement for both nationally authorised products and centrally authorised products.

The MHRA regularly inspects MAHs to determine whether they comply with pharmacovigilance obligations in the UK. More information can be found at the below link: Good pharmacovigilance practice (GPvP) - GOV.UK (www.gov.uk)

In addition to the SOP, we provided you with an assessment report from our external audit conducted between 28th January 2020 and 10th February 2020. As part of our response to your request in FOI 22/842 we also provided our audit reports sent to the European Commission on Pharmacovigilance carried out by The Medicines and Healthcare products Regulatory Agency of the United Kingdom between September 2017 and September 2019 and September 2019 and September 2021. These reports included information on external and internal audit programmes.

I hope the above additional information is helpful to you and provides reassurance we follow a robust process for each signal we identify and monitor the compliance of MAHs with their pharmacovigilance obligations. Unfortunately, we are unable to provide anything further at this stage as it is unclear from your request exactly what additional information the Agency can supply to address your requests. If the information is not sufficient we would be grateful if you could provide further clarity so that we may assist you further. Section 1(3) of the Freedom of Information Act does not oblige us to answer requests where we require further clarification to identify and locate the information requested. Further information about the Section 1(3) Act can be found at http://www.legislation.gov.uk/ukpga/2000/36/section/1.

I hope the information provided is helpful; however, if you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date of this response; and can be addressed to this email address.

Yours sincerely,

FOI Team,
Vigilance and Risk Management of Medicines Division

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