FOI 23/696

Dear

Many thanks for your request for information dated 24 September, where you requested the following documentation:

i) module 2.3.S.2.3 "control of materials" for Vaxevria (ChadOx1) (PLGB 17901/0355)
ii) HCP test results supplied by AstraZeneca to the MHRA, including the HCP assays used (e.g., ELISA)
iii) MHRA specification limits for HCPs

Our response

We can confirm that we have located the following information in response to your request:

i) Module 2.3.S.2.3 "control of materials" for PLGB 17901/0355
ii) Module 3.2.S.3.2.2 "Process-Related Impurities" for PLGB 17901/0355, which includes a summary of HCP levels in the drug substance.
iii) MHRA HCP specification limit, specified in the MHRA Quality assessment report for PLGB 17901/0355.

We consider the information is exempt as s41(1) and 43(2) apply. This is in line with the Heads of Medicines Agencies (HMA)/European Medicines Agency (EMA) guidance on transparency – see the below-linked document, where it states that this information is commercially confidential information (CCI):

HMA/EMA GUIDANCE DOCUMENT ON THE IDENTIFICATION OF COMMERCIALLY CONFIDENTIAL INFORMATION (europa.eu)

Section 41(1)
Information provided to us in confidence, with the expectation that it will not be released, is exempt from disclosure under the FOI Act. Information will be covered by Section 41 if: it was obtained by the authority from any other person; its disclosure would constitute a breach of confidence; a person or organisation could bring a court action for that breach of confidence; and that court action would be likely to succeed.

Section 43(2)
Information where disclosure would be likely to prejudice the commercial interests of any person, including third parties or the public authority that holds the information. Section 43 is a qualified exemption, which means that we have considered whether the public interest in releasing the information is outweighed by the public interest in not giving the information. In favour of disclosure, we consider that there may be a general public benefit from understanding the control of materials and impurity limits of a product used in COVID-19. However, we consider that the public interest in releasing the information does not outweigh the company's/commercial enterprise's right to confidentiality and the probable damage that the company/commercial

enterprise could suffer as a result of the information being released. Releasing the information would also prejudice the Agency's commercial interests in this case and in future. As a market regulator, it is vital that the Agency can freely engage in dialogue with organisations about commercial activities. In this case we have not identified any issues which would benefit the public as a whole by being brought to their attention (examples of issues would be a major public health risk or a major procedural failure or irregularity).

We now consider this FOI request closed. If you require any further information, please respond to the FOI Licensing Team at FOILicensing@mhra.gov.uk.

If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the Agency who has not previously been involved in your request. If you wish to pursue that option, please email: info@mhra.gov.uk

After that, if you remain dissatisfied, you may write to the Information Commissioner at:
The Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

They will make a decision on whether or not we have interpreted the FOIA correctly in handling your request.

Yours sincerely,
FOI Team