

MHRA

151 Buckingham Palace Road
Victoria
London SW1W 9SZ
United Kingdom

Email

FOILicensing@mhra.gsi.gov.uk
mhra.gov.uk

Angus Files

SENT VIA EMAIL : request-453221-7e7dbb0e@whatdotheyknow.com

22nd December 2017

Freedom of Information request FOI 17/553 – Minutes of the Committee on Human Medicines

Dear Mr Files,

Thank you for your email of 19 December 2017 where you requested information about information being withheld under Section 43 of the Freedom of Information Act 2000 and the publication of declared interests within the minutes.

The application of Section 43 of the FOI Act remains in place until such time as the Marketing Authorisation applications have reached a conclusion and any issues of confidentiality or data protection have expired or can be removed. The time frame for the full release of minutes cannot be foreseen as it is dependent upon the time taken for any applicant company to address concerns and regulatory issues raised by the Licensing Authority on the advice of CHM about the respective application. In practice extracts of the minutes can be released upon request although if an FOI exemption applies, the relevant information will be redacted. The full minutes of the CHM are subject to the rules governing the disclosure of information in line with the FOI Act 2000 but will be released to the National Archive after 20 years.

The CHM and the JCVI are unrelated committees with completely separate remits and unrelated statutory basis. Their respective Conflict of Interest policies are independent of one another. All members of the CHM, its Expert Advisory Groups and working groups are required to make a full declaration of interests on appointment and then annually during the term of their appointment. They are also required to declare any interests prior to the committees' consideration of each agenda item both before and during the respective meeting. The identity of an interest declared at this stage of the regulatory process is withheld under Section 43, as to show the declared interest from a committee member would also reveal commercially sensitive information of the issue being discussed by the committee.

The CHM is committed by legislation to producing an Annual Report of its activities every year. The Human Medicines Regulations 2012 Advisory Bodies Annual Reports are publicly available and included with that document is a full list of the declared interests of all the participants who have taken part in its expert advisory and other groups. Also within the report is the "Code of Practice for Chairmen and Members of the Commission on Human Medicines, Certain Committees and Expert Advisory Groups" which both sets out the rules and guidance on holding and declaring relevant interests as well as how these interests are managed.

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 you receive this response and addressed to: info@mhra.gov.uk. Alternatively, you may write to:

Ms Fay Norris
Secretary to the Commission on Human Medicines
4-T, MHRA
151 Buckingham Palace Road
London
SW1W 9SZ

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would 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 your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

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

Yours sincerely

Mr Robin Fraser
Unit Manager - Expert Committee Support and Service Management
Medicines and Healthcare products Regulatory Agency
4-T
151 Buckingham Palace Road
London
SW1W 9SZ
Tel: (020) 3080 7406
Email: robin.frasxx@xxxx.xxx.uk