Medicines & Healthcare products Regulatory Agency

MHRA

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Dear Mr Kelly

**ICO case reference number FS50764980**

As part of the review process for the complaint you raised with the Information Commissioner's Office, the MHRA reviewed the redacted documents you were provided in response to your FOI request (18/197) and the exemptions that had been applied.

The response to FOI 18/197 misquotes the exemptions used to redact details. Section 41 was cited but referred to personal information which is exempted under section 40. It is MHRA policy that personal information such as staff members names are redacted for those grades below Senior Civil Service (SCS). However, due to the passage of time and updates to our HR system it was not possible to establish the grades of the staff members who prepared the assessment reports or issued correspondence. Therefore, all staff names are redacted. Although staff names are included on assessment reports which are considered in confidence by the expert advisory committees, the individuals are not responsible for any regulatory actions that is subsequently taken. The decision to take regulatory action is taken by the Agency based on the evidence and independent advice received from the committees. The identity of individual staff members should be protected and remain redacted on the documents provided with this letter.

The names of the marketing authorisation holders (MAHs) were also redacted in the original FOI response. This information was redacted as per Agency policy not to identify specific companies, as the information that they provide is provided in confidence and the information considered by the advisory committees could be considered commercially sensitive and could prejudice or be considered detrimental to the individual marketing authorisation.

In 2005 when the decision was taken to withdraw co-proxamol from the UK market there were 18 MAHs with a commercial interest in the product. Within the papers considered by the advisory committee examples of the product information and samples of the correspondence issued to the MAHs were provided. These were representative examples and the information was redacted to prevent prejudice of a specific company.

At the time of the regulatory action, details of the specific MAHs and particularly the MAHs that appealed the Committee on Safety of Medicine's recommendations would have prejudiced the commercial interests of the MAHs. After carefully considering the redacted information, the use of section 41 and section 43 exemptions does not meet the public interest test. The names of the MAHs

are no longer considered to be commercially sensitive and although the MAHs will have provided information in confidence, the MAH's names no longer need to be redacted. None of the information redacted in relation to the MAHs is considered to constitute a trade secret.

All of the licences for co-proxamol have been cancelled for over 10 years and therefore there is no longer a commercial interest in the information. Therefore, all redactions relating to the MAHs names have been removed.

Therefore revised versions of the following documents are provided for your information under FOI:

- CSM 2004 8th SCOP (1st pdf covers pages 1-77, 2nd pdf covers pages 78-135, 3rd pdf covers pages 136-183)
- CSM 2004 16th (1st pdf covers pages 1-25, pages 26 to 206 [annex 2 is CSM 2004 8th SCOP], 2nd pdf covers pages 207 to 222, 3rd pdf covers pages 223-258 and 4th pdf covers tabled paper II)
- CSM 2004 18th (1 pdf)

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If you have a query about the information provided, please reply to this email.

Yours sincerely

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