To:
P. Nikiforos Diamandouros and B. Hofstötte
The European Ombudsman
The European Union

Follow up on the telephone conversation with B. Hofstötte, regarding our appeal concerning denial of access to clinical study reports and corresponding trial protocols of the anti-obesity drugs, orlistat and rimonabant

Complaint 2560/2007/BEH

From:
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Dear P. Nikiforos Diamandouros and Bernhard Hofstötte,

To follow up on our telephone conversation on the 31 July 2009, we would like to provide you with information on the data that we obtained from the Danish Medicines Agency last week. We applied for access to the clinical study reports of the placebo-controlled clinical trials and corresponding trial protocols of the anti-obesity drug, sibutramine.

Germany was the first country in the EU to approve this drug (1999), but sibutramine was suspected to increase the risk of abuse and cardiovascular disease and only after the Committee for Proprietary Medical Products had reviewed the drug was it approved in Denmark in 2001.

We applied for access in June 2007, and were granted access from the Danish Drug Agency in June 2008. The company (Abbott) complained to the Ministry of Health, but on 3 July 2009, the minister upheld the Agency's decision.

We have received 36 binders (14,309 pages) that include 56 clinical study reports (see the attached Excel file). We did not receive the appendices (that also include the protocols), and have therefore repeated our request that we also need the protocols. From our experience, a protocol consists of less than 100 pages.

Of the 56 study reports, 27 primarily investigated weight reduction or maintenance, 9 cardiovascular risks, 3 risk of abuse and 4 tolerability and safety. The remaining 13 were

less important to our project; 4 were on depression (sibutramine was originally developed for treating depression) and 7 measured less relevant outcomes.

We can confirm that the clinical study reports are finely structured as stated in our previous letters and it therefore cannot be "a long and complex work to redact the documents", as EMEA claims. It should be a quick and easy task. We will mail you by special delivery an example of a clinical study report on a pivotal trial (SB1047).

The clinical study reports and tables that describe the two pivotal trials BPI852 and SB1047 consist of 1430 and 283 pages respectively. BPI852 is by far the largest study report as the average size of a study report with tables is only 256 pages. We expect the clinical study reports on orlistat and rimonabant to be of similar sizes.

You asked us to specify in more detail the material we are applying for. We would like to have access to the clinical study reports, including appendices and protocols, of the phase III studies as specified in the Scientific Discussion of the EPARs on orlistat (1) and rimonabant (2).

This comprises 7 studies on orlistat (see table on page 5 in ref. 1) and 8 on rimonabant (see table on page 32 in ref. 2). Thus, we are only interested in 15 studies. For comparison, we have obtained reports on 56 studies on sibutramine from the Danish Drug Agency. In the copies we received from the Danish Drug Agency, patient numbers and descriptions of individual adverse events were redacted. We believe this precaution is completely unnecessary, as we have no way of knowing which concrete patients that have been described, and, for example, a whole page with adverse events that should have been redacted (p67 in SB1047) but was overlooked did not provide any clues that might lead to identification of individual patients.

Please do not hesitate to call if you need further information.

Yours sincerely,

Peter C Gøtzsche
Anders W Jørgensen

1. http://www.emea.europa.eu/humandocs/PDFs/EPAR/Xenical/106698en6.pdf

2. http://www.emea.europa.eu/humandocs/PDFs/EPAR/acomplia/H-666-en6.pdf