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To:
P. Nikiforos Diamandouros
The European Ombudsman
The European Union

From:
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Reply to the opinion provided by the European Medicines Agency (EMEA) to the European Ombudsman, regarding our appeal concerning denial of access to clinical study reports and corresponding trial protocols of the anti-obesity drugs orlistat and rimonabant (complaint 2560/2207/BEH)

In the letter to the Ombudsman from 30 Jan 2008, EMEA has given its opinion on our complaints that the Ombudsman summarised in a letter to us from 25 Oct 2007.

Concerning item 1 in the Ombudsman's letter, EMEA states that:

- allowing us access would undermine the protection of commercial interests (p.1 in EMEA's letter from 30 Jan 2008),

- access to undisclosed data must be protected against unfair commercial use (p.2),

- disclosure of commercially confidential information could prejudice to an unreasonable degree the commercial interests of companies (p.2),

- the public interest in allowing us access has to be balanced against the interest in protecting the applying company that, in case of improper disclosure, would be adversely affected (p.2),

- EMEA publishes its scientific assessment of the benefits and risks of all centrally approved medicines (p.3),

- EMEA shall refuse access unless there is an overriding public interest in disclosure (p.2).

In our letter to the Ombudsman from 8 Oct 2007, we have already documented why EMEA's position will likely have the following consequences:

- patients will die unnecessarily, sometimes by the thousands, because of the treatments their doctors prescribe to them out of ignorance about what the true balance is between the benefits and harms,

- patients will be treated with inferior, and sometimes harmful drugs, by the millions, in the European Union; this also involves a huge waste of limited resources in the European Union. The fact that EMEA publishes its scientific assessment of the benefits and risks of all centrally approved medicines cannot prevent this from happening, as these documents do not contain all the information researchers need in order to provide reliable systematic reviews about the benefits and harms of drugs that enable clinicians and patients to make rational, and fully informed, decisions about use of drugs.

Concerning item 2 in the Ombudsman's letter, we, in our second letter to EMEA, and also in our letter to the Ombudsman, explicitly requested that EMEA should state its reasons why EMEA feels that commercial interests should override concerns for the welfare of the patients. We now note that EMEA has still failed to explain in what way allowing us access to clinical study reports and corresponding trial protocols would undermine the protection of commercial interests, and how it could lead to unfair commercial use, and why commercial interests should override concerns for the welfare of the patients. We are scientists and need this information in order to be able to provide doctors and patients with reliable information about the benefits and harms of the anti-obesity drugs. Currently, doctors get information about drugs by reading reports and reviews of randomized clinical trials in medical journals that, on average, are seriously flawed, compared with all the trial reports that have been submitted to EMEA in applications for marketing authorization. A systematic review from 2008 from USA, where the researchers had access to data at the Food and Drug Administration (FDA), confirms this. The effect of antidepressant drugs was exaggerated by 32%, on average, in the published literature, compared to all the data available at the FDA (1). Another systematic review, also based on FDA data, and published today, on 26 Feb 2008, found that antidepressant drugs have no effect, apart from the most severe cases of depression (2). The use of these drugs is so widepread that this means that millions of people in the European Union currently are being treated unnecessarily with these drugs.

We reiterate that there appears to be nothing of commercial interest in the study reports and protocols. Furthermore, we conclude that EMEA prioritises to protect the profits of the drug companies rather than protecting the lives and welfare of the patients, as both cannot be protected at the same time. This is particularly worrying for anti-obesity drugs, as these drugs have little effect, even when considering only the published data, and as they have serious harms. It is therefore highly likely that the balance between their benefits and harms would look different, if unpublished data were included in systematic reviews of the drugs.

As the study from USA (1) illustrates, there is far more openness and better access to data at the FDA than to data at EMEA. The extreme secrecy in European drug regulation needs to be changed, and we note that changes are already happening. For example, a European register of drug trials in children will be established, and the results submitted to the regulatory agency will be made public (3). The article that describes this furthermore notes that "This transparency is essential, as a database of paediatric clinical trials only accessible to the European Medicines Agency would not benefit children in Europe". We also note that the European Commission's Directorate General for Research is taking steps to improve access (4,5), just as it has happened for trials sponsored by the Medical Research Council in UK and by the National Institutes of Health in USA (4).

We reiterate that EMEAs attitude is ethically indefensible, as the prime duty of drug agencies is to protect patients from unnecessary harm. Disclosing the type of data that we are applying for would, as a general principle, not be anti-competitive, as all companies will be affected equally by it. But it would lead to more transparency, more rational use of resources, and less harm.

We also reiterate that the Ombudsman should consider particularly carefully that drug regulatory agencies have a conflict of interest when they deny others access to the data in their possession. When doing so, the agencies cannot be questioned over their decisions, or over the quality of the short summaries they make available to the public.

We ask the Ombudsman to ensure that we can get access to the data we applied for on 29 June 2007. Please consider also our letter to the Ombudsman from 8 Oct 2007.

Yours sincerely,

Peter C. Gøtzsche
Anders W. Jørgensen

References

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