European Ombudsman reaction to EMA's 12 June 2014 statement issued after its Management Board meeting

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13 June 2014

The European Ombudsman, Emily O'Reilly, notes the statement EMA published after its management board meeting on 12 June.

As EMA now intends to finalise a revised wording for its proactive clinical trial data policy, the Ombudsman cannot yet comment in detail on what may emerge.

However, the Ombudsman notes that she shares the grave concerns expressed by members of the scientific community about EMA's draft disclosure policy. In her view, it was defective on three fronts:
- It allowed data only to be seen on-screen using an interface, thereby preventing researchers from downloading the data. According to EMA's 12 June statement this point seems to be subject to change by "giving the possibility to download, save and print trial data for academic and non-commercial research purposes". If implemented, the Ombudsman would welcome this change.
- It imposed broad legal conditions on the access to and use of such data.
- It only allowed limited access to clinical trial data by redacting significant information.

The Ombudsman welcomes the fact that the Management Board of EMA seems to have responded to the concerns of the scientific community concerning on-screen access.

The Ombudsman is unaware whether the Management Board has suggested any changes relating to the other two concerns.

The change to the draft policy requested by the Management Board will now require EMA to make changes to the draft Terms of Use. The Ombudsman will carefully examine the Terms of Use when they are modified to reflect the outcome of the Management Board meeting. The Ombudsman will also, in that context, examine how EMA intends to redact the documents.

The Ombudsman also notes EMA's assertion that its new policy is without prejudice to the right to request public access to documents. In 2012, subsequent to a request to release clinical study reports relating to two medicines (Humira and Esbriet), EMA decided to release these

clinical study reports with only limited redactions. It recently agreed, as part of a compromise deal with a pharmaceutical company, to make more extensive redactions to the Humira documents. The Ombudsman is currently carrying out an inquiry to determine the legality of those additional redactions.

The Ombudsman remains puzzled as to why EMA abandoned its original draft disclosure policy from 2012 and substituted it with a different draft policy, more in line with the pharmaceutical industry's wishes.