Lēmums lietā 2030/2015/PL par Eiropas Zāļu aģentūras atteikumu izpaust tā uzņēmuma nosaukumu, kas prasījis publisku piekļuvi drošības ziņojumiem

Lēmums
Lieta 2030/2015/PL - **Uzsākta {0}** 03/03/2016 - **Atzinuma projekts par {0}** 07/07/2017 - **Lēmums par {0}** 20/03/2018 - **Iesaistītā iestāde** Eiropas Zāļu aģentūra (Iestādes atbalstīts ieteikums) |

Lieta attiecās uz Eiropas Zāļu aģentūras (*EMA*) atteikumu izpaust tā uzņēmuma nosaukumu, kas prasījis publisku piekļuvi pēdējam "periodiskajam atjauninātajam drošuma ziņojumam" par zālēm *Zyclara* . Prasītājs ir farmācijas uzņēmums, kas laiž tirgū *Zyclara* .

EMA apstiprināja, ka kopš 2015. gada tās politika ir bijusi neizpaust to uzņēmumu nosaukumus, kuri pieprasa piekļuvi dokumentiem, lai aizsargātu to komercintereses.

Ombude konstatēja, ka atteikums izpaust tā uzņēmuma identitāti, kas pieprasa publisku piekļuvi, ir bijusi administratīva kļūme. Viņa ieteica aģentūrai pārskatīt tās bezierunu atteikumu politiku izpaust to organizāciju identitāti, kas pieprasa publisku piekļuvi dokumentiem. Tā vietā aģentūrai ir jākonsultē uzņēmums, kas ir sākotnēji pieprasījis piekļuvi, pirms lemt, vai tā nosaukums ir vai nav jāizpauž.

EMA pieņēma ombudes ieteikumu un ieviesa ierosinātās izmaiņas. Ombude atzinīgi vērtē aģentūras ātro rīcību un slēdz izmeklēšanu.

Background to the complaint
1. The complaint was made by the pharmaceutical company that markets Zyclara, a drug used to treat actinic keratosis.

2. In September 2015, the European Medicines Agency (EMA) received a request for public access to the latest 'periodic safety update reports' [1] (PSURs) on Zyclara. Following this, the complainant asked EMA for a copy of this request.

3. In October 2015, EMA gave the complainant a copy of the access to documents request, with the identity of the requester redacted. EMA said that this was necessary to protect the commercial interests of the organisation that had made the request, a pharmaceutical company. EMA stated that this was in line with its policy on access to documents [2] , which stated that EMA did not *"release information on the identity of the person or the name of the organisation requesting access to EMA documents to third parties (...)"* .

The Ombudsman's recommendation

4. The Ombudsman inquired into the complainant's concern that EMA had wrongly refused to grant access to the identity of the pharmaceutical company that had requested the PSUR.

5. Not convinced by EMA's arguments as to why it had withheld the identity of the company, the Ombudsman recommended [3] EMA to review its policy of outright refusal to release the identity of organisations that request public access to documents. She also asked EMA in such cases to first consult the company that requested access to a document and only then to decide whether its name should be withheld.

6. EMA said that its policy not to release the name of the person or entity behind an access to documents request was underpinned by a wish to increase the transparency of its activities. It added that its reference to the need to protect the commercial interests (of the requester) should have been understood as a general and abstract statement relating to the fact that pharmaceutical companies have interests that merit protection. It was not relying on the exception set out in Article 4(2) of Regulation 1049/2001 (the need to protect the commercial interests) to justify its refusal to disclose the name of the company.

7. The Ombudsman noted that Regulation 1049/2001 on public access to EU documents permits the redaction of information only if it is necessary to respect one of the exceptions set out in the regulation (as listed in Article 4). The Ombudsman expressed serious doubts that the name of a company requesting public access to PSURs could be *detailed, relevant, actionable* **[4]** information that would put at risk the company's commercial interests. In any case, the Ombudsman found that EMA cannot refuse to give access on the assumption that releasing this information would undermine the commercial interests of the person or entity making the request, but should instead consult the requester on this matter. On the basis of the reply, EMA should then decide whether releasing the name of the person or entity that had requested the document would undermine their commercial interests.

8. Against this background the Ombudsman found that EMA's refusal to release the identity of the pharmaceutical company that had requested public access to medical data constituted maladministration. She therefore made a recommendation that:

EMA should review its policy of outright refusal to release the identity of organisations which make a request for public access to documents.

EMA should consult, in accordance with Article 4(4) of Regulation 1049/2001, the company which made the initial request for access and then decide whether the name of the company should still be redacted.

9. In reply to the Ombudsman's recommendation, EMA changed its policy, and removed from its website the information stating that it would not disclose the identity of those who applied for access to documents. It also said that it would process these requests in accordance with the Ombudsman's recommendation.

10. EMA also treated anew the complainant's request for the identity of the company that did

the initial request for access. After consulting the company, EMA decided to disclose its identity to the complainant.
The Ombudsman's assessment after the recommendation
11. The Ombudsman invited the complainant to comment on EMA's reply to her recommendation. However, it did not avail itself of this opportunity.

The Ombudsman welcomes EMA's positive reaction to her recommendation and is pleased to note that EMA has taken action to implement it. Conclusion

Based on the inquiry, the Ombudsman closes this case with the following conclusion:

The European Medicines Agency accepted the Ombudsman's recommendation.

The complainant and the European Medicines Agency will be informed of this decision **.**

Emily O'Reilly

European Ombudsman

Strasbourg, 20/03/2018

[1] As part of its legal obligations as a 'marketing authorisation holder' the complainant is required to submit 'periodic safety update reports' (PSURs) to the European Medicines Agency (EMA). PSURs contain a summary of data on the benefits and risks of a medicine and include updated results of all studies carried out with this medicine. EMA then uses the information in PSURs to determine if there are new risks for a medicine and whether the balance of benefits and risks of a medicine has changed.

[2] Available at:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/document_library/document_listing/document_lis

[3] The Ombudsman's recommendation is available at:
https://www.ombudsman.europa.eu/cases/recommendation.faces/en/81123/html.bookmark

[4] See paragraph 38 of the Ombudsman's Recommendation.