03 December 2018
EMA/770394/2018

# Overview of comments received on Output of the European Medicines Agency policy on access to documents non-related to medicinal products for human and veterinary use (EMA/768660/2018)

Interested parties (organisations or individuals) that commented on the draft document as released for consultation.

| Stakeholder no. | Name of organisation or individual |
|---|---|
| 1 | Bundesverband der Arzneimittel-Hersteller e.V. |
| 2 | CPME - Standing Committee of European Doctors |
| 3 | European Federation of Pharmaceutical Industries and Associations (EFPIA) |
| 4 | Duke Clinical Research Institute |
| 5 | German Environment Agency (UBA) |
| 6 | Groupe-LFB, France |
| 7 | Health Action International (HAI) |
| 8 | Health Care Without Harm (HCWH) Europe |
| 9 | Hellenic Cancer Federation – ELL.O.K |
| 10 | IFAH-Europe and HealthforAnimals |
| 11 | Institut für Qualität und Wirtschaftlichkeit/ Institute for Quality and Efficiency in Health Care (IQWiG) |
| 12 | The International Society of Drug Bulletins (ISDB) |
| 13 | Dr. Juergen O. Kirchner |
| 14 | NoGracias |
| 15 | The Nordic Cochrane Centre |

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| Stakeholder no. | Name of organisation or individual |
|---|---|
| 16 | Medicines for Europe |
| 17 | Medicines Evaluation Board, NL |
| 18 | Oekotoxzentrum, Switzerland |
| 19 | Prescrire |
| 20 | SEC Associates, Inc |
| 21 | Mr. Paul Ulrich |

# 1. General comments – overview

| Stakeholder no. | General comment (if any) | Outcome (if applicable) |
|---|---|---|
| 7, 12, 14, 15, 19 | General comment:<br><br>We call upon EMA to prioritise proactive, rather than reactive, disclosure. This is equally valid for documents of a corporate nature. We also urge EMA to take in due consideration the principle of the overriding public interest in disclosure at all times. | The comment does not mention what documents should be prioritised. Given that the Agency already proactively publishes a large number of corporate documents on its webpage, including annual reports, work programmes, accounts, policies and procedures, and even documents discussed and/or adopted by the Management Board after each meeting, it considers that it already prioritises proactive disclosure of the main corporate documents.<br>In addition, other corporate documents are disclosed, when applicable, upon request.<br><br>The Agency considers that no additional action can be taken on the basis of the nature of the comments and the level of transparency for corporate documents. |
| 3 | EFPIA has no comments to make on the output table for corporate documents. | It is noted that EFPIA has no comments. |
| 16 | The documents listed include procurement related documents, conflict of interest declarations, SOPs and WINs and other corporate documents available on the EMA website (EMA annual report, work programme, annual budget, etc.). Our understanding is that 'corporate documents' means only EMA corporate documents, not manufacturer/third party corporate documents. The procurement related documents seem not to pertain to procurement of medicines or other health commodities, and instead are in reference to EMA procurement of services (i.e. consultants or other project-based service providers), but this is not explicitly confirmed and should be clarified. | The Agency will clarify that some documents may be third party documents as they may involve Member States or contractors' documents and/or comments.<br><br>Proposed action: define third party documents as not only MAH.<br><br>"Some of those documents may be third party documents, such as contracts signed between the Agency and a contractor. Those documents would be consulted with the relevant third party, as it is currently done with the consultation with the Marketing Authorisation Holder for |

| Stakeholder no. | General comment (if any) | Outcome (if applicable) |
|---|---|---|
| | Otherwise, the Medicines for Europe has no comments to make on the output table for corporate documents. | documents related to medicinal products, in line with Regulation EC (No) 1049/2001". |

## 2. Specific comments on text

| Line no. | Stakeholder no. | Comment and rationale; proposed changes | Outcome |
|---|---|---|---|
| Line 13 | 10 | It is noted the document is intended to be a living document subject to continuous change. In which case how will stakeholders be informed of planned changes and have the chance to comment on changes? | The Output Table should be considered as a “living” document which is aimed at increasing the transparency of the Agency's classification of documents. It will be updated through a public consultation on a continuous basis taking into account further experience, as well as the legal interpretation of Regulation (EC) No 1049/2001 given by the Court of Justice of the European Union.<br><br>Stakeholders are informed of EMA public consultation and be invited to comment through announcements at the EMA website under News & Events. |