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Press Office

Press release

European Medicines Agency widens public access to documents

Policy on access to documents also sets out new approach for proactive disclosure of documents

The European Medicines Agency (EMA) has published its new policy on access to documents related to medicines for human and veterinary use. The new policy is part of the Agency's response to increasing public demand for more openness and transparency. It will give wider access than ever before to documents held by the Agency, while it ensures that personal data and commercial confidential information remain adequately protected.

"Openness and transparency are enshrined as fundamental values in the Agency's regulatory framework", says Noël Wathion, Head of Patient Health Protection at the European Medicines Agency. "They allow our stakeholders to understand the basis for the Agency's scientific decision-making and provide for the basis on which patients and healthcare professionals can have confidence in our opinions and information relating to medicines."

As a general rule, the Agency will release documents once a procedure concerning a medicine has been finalised to protect the decision-making process.

The new policy gives access to all business-related documents unless there is a need to respect arrangements with non-EU regulators or international organisations, or to protect the privacy and integrity of a natural or legal person. Documents submitted to the Agency as part of a marketing authorisation application, such as clinical trial reports, can now also be released, provided the decision-making process for the application in question is finalised. Where only parts of a document contain information that cannot be disclosed, the Agency will redact the document to protect personal data and commercial confidential information, and release the non-confidential parts.

The Agency has produced general guidance on the types of documents it holds, whether they can be made available and whether they will have to be redacted. The list in form of an 'output table' is available on the Agency's website.

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Implementation of the policy will be in a two-step approach. The first phase will focus on reactive disclosure of documents in response to written requests. During this phase the Agency will put in place arrangements to ensure that implementation of this new policy will not conflict in any way with the ability of the Agency to perform its core functions of authorisation and supervision of medicines. In the second phase, the Agency will gradually populate the electronic register with documents held by the Agency which can be disclosed.

Notes

1. This press release and all relevant documents are available on the Agency's website.
2. The `European Medicines Agency policy on access to documents (related to medicinal products for human and veterinary use)', and the `Output of the European Medicines Agency policy on access to documents related to medicinal products for human and veterinary use' are available on the Agency's website.
3. Requests for access to documents can be sent to info@ema.europa.eu
4. More information on the work of the European Medicines Agency can be found on the Agency's website: www.ema.europa.eu

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