EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

European Medicines Agency releases for public consultation its draft policy on the publication and access to clinical-trial data

The European Medicines Agency has released a draft policy on the publication and access to clinical-trial data for a three-month public consultation. Stakeholders have until 30 September 2013 to send their comments on the draft policy to the Agency.

Comments should be made using this form and sent no later than 30 September 2013 to ctdatapolicy@ema.europa.eu.

The Agency has committed to the proactive publication of data from clinical trials submitted in support of a marketing-authorisation application, once the decision-making process has ended. The Agency has embarked on this process because it believes that the release of data is about establishing trust and confidence in the system.

The Agency has taken a considered approach to developing a draft policy which is based on respecting the views and concerns brought forward by a broad range of stakeholders and European bodies. The draft policy has been designed to balance out the commitment to give widest possible access to data for independent scrutiny with the need to protect personal data as well as legitimate commercially confidential information.

In its draft policy, the Agency has defined three categories of clinical-trial data corresponding to different levels of access.

Category 1: 'commercially confidential information'

This category covers clinical-trial data, information or documents that may contain commercially confidential information. These include for example the details of the investigational medicinal product itself, some in-vitro studies or bioanalytical data characterising the product.

Category 2: 'open access'

This category covers any clinical-trial data, information or documents that do not contain patients' personal data. This information will be downloadable from the Agency's website, at the time of

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publication of the European public assessment report (EPAR) for positive decisions, negative decisions, or withdrawals.

Category 3: 'controlled access'

This category covers clinical-trial data, information or documents containing patients' personal data. These include individual patient data sets, individual patient line-listings, individual case report forms, and documentation explaining the structure and content of data sets. Protection of personal data is a fundamental right of EU citizens, enshrined in the EU legislation. For this category, two complementary levels of protection are foreseen to provide best-possible assurance against retroactive patient identification. Firstly, data will need to be adequately de-identified according to a recommended minimum standard. Secondly, access to these data will only be granted after the requester has fulfilled a number of requirements, including the signing of a data-sharing agreement.

The draft policy has now been released for a three-month public consultation. Publication of the final policy is expected by the end of 2013, once comments have been considered.

The Agency expects the policy to come into force on 1 January 2014. However, its implementation will be impacted by the outcome of two other closely related events.

A number of court cases are currently ongoing that challenge the Agency's 2010 access-to-documents policy. These cases will bring the opportunity for legal clarification of the concept of commercially confidential information.

Another event which may impact the Agency's policy is the ongoing legislative process to replace the current European directive on clinical trials. At the end of May 2013, the European Parliament's Committee on Environment, Public Health and Food Safety agreed its position on the European Commission's proposal, which includes that "in general the data included in clinical-trial study reports should not be considered commercially confidential once a marketing authorisation has been granted or the decision-making process on an application for marketing authorisation has been completed".

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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