



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

Publication of clinical reports

EMA adopts landmark policy to take effect on 1 January 2015

The European Medicines Agency (EMA) has decided to publish the clinical reports that underpin the decision-making on medicines. Following extensive consultations held by the Agency with patients, healthcare professionals, academia, industry and other European entities over the past 18 months, the EMA Management Board unanimously adopted the new policy at its meeting on 2 October 2014. The policy will enter into force on 1 January 2015. It will apply to clinical reports contained in all applications for centralised marketing authorisations submitted after that date. The reports will be released as soon as a decision on the application has been taken.

“The adoption of this policy sets a new standard for transparency in public health and pharmaceutical research and development,” said Guido Rasi, EMA Executive Director. “This unprecedented level of access to clinical reports will benefit patients, healthcare professionals, academia and industry.”

The new EMA policy will serve as a useful complementary tool ahead of the implementation of the new EU Clinical Trials Regulation that will come into force not before May 2016. EMA expects the new policy to increase trust in its regulatory work as it will allow the general public to better understand the Agency’s decision-making. In addition, academics and researchers will be able to re-assess data sets. The publication of clinical reports will also help to avoid duplication of clinical trials, foster innovation and encourage development of new medicines.

According to the policy’s terms of use, the public can either browse or search the data on screen, or download, print and save the information. The reports cannot be used for commercial purposes. In general, the clinical reports do not contain commercially confidential information. Information that, in limited instances, may be considered commercially confidential will be redacted. The redaction will be made in accordance with principles outlined in the policy’s annexes. The decision on such redactions lies with the Agency.

The policy will be implemented in phases. The first phase starts on 1 January 2015. Once a medicine has received a marketing authorisation, EMA will publish the clinical reports supporting applications for authorisation of medicines submitted after the policy’s entry into force. For line extensions and extensions of indications of already approved medicines, the Agency will give access to clinical reports for applications submitted as of 1 July 2015 after a decision has been taken.



In future, EMA plans to also make available individual patient data. To address the various legal and technical issues linked with the access to patient data, the Agency will first consult patients, healthcare professionals, academia and industry. It is critically important for EMA that the privacy of patients is adequately protected before their data are released.

The policy does not replace the existing EMA policy on access to documents. It will be reviewed in June 2016 at the latest.

Notes

1. This press release, together with the final policy and a 'question and answer' document, is available on the Agency's website at:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_00_0555.jsp&mid=WC0b01ac0580607bfa
2. In line with its commitment to transparency, the Agency has published all contributions received as part of the public consultation exercise carried out from June to September 2013, together with an overview of the comments. In addition, a summary of the second round of targeted consultation held in May 2014 with patients and consumers, pharmaceutical industry, academics and scientific journal editors has also been published.
3. More information on the work of the European Medicines Agency can be found on its website:
www.ema.europa.eu

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