EUROPEAN MEDICINES AGENCY
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Press release

EMA ready to start assessment of Ebola vaccines and treatments as soon as data are made available

Rapid scientific advice to speed up development

During the past months, the European Medicines Agency (EMA) has put in place a system to give the best possible scientific advice to companies that are currently developing possible vaccines and/or treatments to fight Ebola virus disease.

The Agency has also established a form of rolling review that allows experts to continuously assess incoming data and develop increasingly robust scientific opinions based on the additional data provided during the process. The initial review and subsequent updates will be shared with healthcare decision-makers in the most affected and other countries. This will enable them to take informed decisions on whether and how they want to use the vaccines/medicines in the current Ebola outbreak taking into account their specific situation.

"We are ready and keen to assess data as soon as companies start submitting them," explains EMA Executive Director Guido Rasi. "We have put in place regulatory processes that allow the best experts from across Europe to accelerate the assessment of data once we receive them."

The March 2014 outbreak of Ebola virus disease in West Africa is the largest and most complex outbreak to date. It is unprecedented in terms of scale and geographical spread of the disease. At the moment, there are no approved medicines to protect from or treat Ebola. EMA is working together with regulatory authorities around the world to support the World Health Organization (WHO) in the fight against Ebola.

"Companies are expected to put efforts into demonstrating that vaccines and treatments against Ebola actually work and are acceptably safe and of high quality, because we need to be reassured that the benefits of these medicines outweigh their risks," stresses Tomas Salmonson, Chair of the Agency's Committee for Medicinal Products for Human Use (CHMP). "However, in the current emergency situation we accept that the benefit-risk balance is determined largely by the public health need."

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EMA's role in the Ebola outbreak

Together with other regulatory authorities EMA is advising WHO on possible pathways for more rapid development, evaluation and approval of medicines to fight Ebola. This work aims at ensuring the consistency of different regulatory approaches.

A group of European experts with specialised knowledge in vaccines, infectious diseases and clinical trial design was established by the Agency to contribute to the global response against Ebola. This group is involved in the provision of rapid scientific advice and will also be responsible for the accelerated assessment of data generated by developers.

Since August 2014, EMA has been in close contact with developers of treatments and vaccines against Ebola. The Agency is actively encouraging early dialogue through its orphan designation and scientific advice programme to agree on the best possible development plans for potential Ebola medicines and vaccines.

Through rapid scientific advice, an accelerated scientific advice procedure, developers can request advice for example on clinical trial design, manufacturing-related questions such as scaling-up production or batch release as well as post-authorisation safety monitoring of medicines.

In addition to the efforts in speeding up development of treatments and vaccines, EMA started to review available information on Ebola treatments already under development to support decision-making by health authorities in the current emergency.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. A rolling review means that pharmaceutical companies submit data to the EMA for evaluation as they become available, instead of all data at once as is normally the case. A similar approach was used during the 2009 pandemic influenza to speed up assessment of influenza vaccines.
3. Developers of Ebola treatments and vaccines can submit applications either for an EU marketing authorisation or under the so-called Article 58 procedure. The latter type of application allows the CHMP to carry out scientific assessments and give opinions, in cooperation with WHO, on medicines that are intended exclusively for use outside the EU. When assessing these medicines, the CHMP applies the same rigorous standards as for medicines intended for patients in the EU.
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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