29 October 2014
EMA/668741/2014
Press Office

Press release

EMA advises on development plan for GSK Ebola vaccine

Developers encouraged to request accelerated procedure for scientific advice

The European Medicines Agency (EMA) has given scientific advice to GSK on its development plan for an Ebola vaccine. This is the first time in the current Ebola outbreak that EMA has given 'rapid scientific advice' using an accelerated procedure. EMA established this procedure to contribute to the global response against Ebola and to help companies speed up the development of Ebola vaccines and treatments.

Through rapid scientific advice, developers can receive EMA's expert opinion and advice for example on clinical trial design, manufacturing-related questions as well as safety monitoring of medicines.

EMA encourages companies to request rapid scientific advice for their development plans. This will help them to generate the robust data and information needed to assess that treatments and vaccines against Ebola actually work, are acceptably safe and of high quality.

EMA will assess any data in a 'rolling review', as soon as they become available. The Agency has established this system to allow experts to continuously assess incoming data. Through this process, EMA will be able to develop increasingly robust scientific opinions based on additional data as they are provided during the assessment process. The initial review and any subsequent updates will be shared with healthcare decision-makers in countries affected by the current Ebola outbreak. This will support them to take informed decisions on whether and how they want to use vaccines and medicines in their specific situation.

Notes

1. This press release, together with all related documents, is available on the Agency's website.

Contact our press officers

Monika Benstetter or Martin Harvey

Tel. +44 (0)20 3660 8427

E-mail: press@ema.europa.eu