25 June 2015
EMA/774690/2014

Outcome of the workshop on viral safety of plasma-derived medicinal products with respect to hepatitis E virus

On 28 – 29 October 2014, the European Medicines Agency (EMA) held a workshop on viral safety of plasma-derived medicinal products with respect to hepatitis E virus.

HEV infection is widespread and blood/plasma donors are often asymptomatic. Therefore, there is a risk for viraemic blood donations. HEV has been recognised as a transfusion transmissible agent since 2004 and transfusion-related cases have been documented in several countries. The published reports on frequency of viraemic blood donations and studies on plasma pools indicate that plasma pools used as starting material for manufacture of medicinal products can be contaminated with HEV. Manufacture of plasma-derived products includes process steps for inactivation/removal of non-enveloped viruses. Their effectiveness against HEV is currently under investigation. HEV is difficult to grow in cell culture and current information about susceptibility of HEV to virus inactivation/removal steps used in the manufacture of plasma-derived medicinal products is scarce. The purpose of the workshop was to obtain further information on the safety of plasma-derived medicinal products with respect to HEV.

The workshop was attended by participants representing European and American regulatory authorities, ECDC, manufacturers, industry associations, patient associations, clinicians and other experts in the field.

Participants welcomed the opportunity to meet other stakeholders and to discuss the issues concerning hepatitis E virus.

The workshop allowed the EMA and regulators to have an overview of the current knowledge in this area. The information discussed at the workshop has been used as the basis for a reflection paper to be published on the EMA website in July 2015.

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