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Press release

Zika virus infection: plasma- and urine-derived medicines safe to use

Manufacturing processes for these products successfully inactivate or remove virus

Assessments carried out by the European Medicines Agency (EMA) and competent authorities in the EU Member States have confirmed that there is no increased risk of contamination with the Zika virus for patients who take plasma-derived or urine-derived medicines.

Plasma-derived medicines are manufactured from human blood. They are used to treat and prevent serious diseases and include coagulation factors (treatments which help blood to clot) and immunoglobulins (proteins used in patients who need more antibodies in their blood to help fight infections and other diseases). Urine-derived products are manufactured from pooled human urine and include certain hormone-based treatments and urokinase products (medicines used to break up blood clots).

These medicines are produced from body fluids, which might be sourced in parts of the world where the Zika virus is prevalent. EU regulators sought reassurance that there is no risk of the virus contaminating the final product and thus affecting the patients taking it if the plasma or urine came from donors who had contracted the Zika virus.

EMA's Committee for Medicinal Products for Human Use (CHMP) has addressed the potential risk from Zika virus for plasma-derived medicinal products. The CMDh[2] has coordinated the assessment by EU Member States on the potential risk from Zika virus for urine-derived medicinal products.

The CHMP concluded at its meeting last week that the manufacturing processes used for plasma-derived products, including for example the solvent/detergent method to inactivate viruses, pasteurisation (liquid heat inactivation) and virus filtration, inactivate or remove the Zika virus from the finished product. The CHMP therefore considered that no additional safety measures such as the testing or exclusion of certain plasma donors was necessary.

Concerning urine-derived products, the CMDh, following the assessment of the data, concluded that the manufacturing processes for these products contain complementary steps with inactivation/removal capacity for enveloped viruses, which are considered sufficient for Zika virus

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safety of these products. Additional safety measures such as the screening of urine donors or donations or the deferral of donors returning from affected areas are not considered necessary.

The findings from these assessments on the viral safety of plasma-derived and urine-derived medicines are available in a report from the CHMP's Biologics Working Party (BWP) published today.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The CMDh is a medicines regulatory body representing the European Union (EU) Member States.
3. The Biologics Working Party (BWP) provides recommendations to EMA's scientific committees on all matters relating directly or indirectly to quality and safety aspects relating to biological and biotechnological medicines. More information on its role and composition is available here.
4. More information on EMA's contribution to the global response to the Zika outbreak is outlined here.
5. The BWP recommendation on plasma-derived products is in line with the guidance published in July 2016 by the European Centre for Disease Prevention and Control (ECDC) entitled "Zika virus and safety of substances of human origin - A guide for preparedness activities in Europe".
6. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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