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Press release

European Medicines Agency confirms that presence of unexpected viral DNA in live attenuated vaccines does not raise public health concerns

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has finalised a review on the impact of the detection, using a new testing method, of DNA fragments from viral agents in some live attenuated vaccines. The Committee concluded that the presence of unexpected viral DNA in these vaccines does not pose a risk to public health, because the type of virus found does not cause disease in humans.

Live attenuated vaccines are vaccines that contain viruses that have been 'attenuated' (weakened) so that they trigger an immune response but don't cause disease. Vaccines of this type that are authorised in the European Union are used to protect against diseases such as polio, measles, mumps, rubella, or gastroenteritis caused by rotavirus infection.

The review was initiated at the request of the Agency's Executive Director following the detection of viral fragments in manufactured vaccines. A team of researchers tested different vaccines using a high-tech method called metagenomics, which is normally used to survey microorganisms present in a specific environment by searching for DNA/RNA material. When this method was applied to vaccines, the researchers found unexpected viral DNA from porcine circovirus (PCV, a virus commonly found in meat and other foods) in rotavirus vaccines.

The CHMP looked at available information on the presence of viruses in biological medicines, and a group of experts on metagenomics, quality control of biologics and virology was convened to provide advice. The Committee found that porcine trypsin, a reagent used in the vaccine production process, was the most likely cause for the presence of PCV, and recommended that general guidance on this reagent should be developed.

Metagenomic testing could be used as an additional tool to the current standard testing methods for vaccines. However, given its novelty and the absence of standardisation, the CHMP considered that this technique cannot be requested as a standard for testing and control. The CHMP acknowledged that any

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unexpected findings in relation to medicines will need to be evaluated on a case-by-case basis to allow an appropriate benefit-risk assessment.

The issues identified by the Committee are common to regulators worldwide. The CHMP has started a dialogue with other authorities, including the US Food and Drug Administration, the World Health Organization and the European Directorate for the Quality of Medicines and Health Care, to start working towards a common approach for the use of metagenomic testing in biological medicines.

Notes

1. This press release together with all relevant documents is available on the European Medicines Agency's website.
2. The review was carried out on the request of the Executive Director under Art. 5 (3) of Regulation (EC) 726/2004.
3. More information on the work of the European Medicines Agency, can be found on the Agency's website: www.ema.europa.eu.

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