AWTORITÀ DWAR IL-MEDIĊINI

Malta, 20th November 2010
Circular No. P17/2010

Dear Healthcare professional

RE: 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 presence of DNA fragments from viral agents in some live attenuated vaccines which are detected when using a novel testing method. 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 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,

Medicines Authority
203 Level 3, Rue D'Argens, Gzira, GZR 1368 – Malta.
Tel. (+356) 23439000 Fax. (+356) 23439161 www.medicinesauthority.gov.mt

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 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.

The Medicines Authority has participated in these discussions held at the EMA and is in agreement with the full **press release** issued by the EMA, attached here for your perusal.

Healthcare professionals are encouraged to regularly check the Medicines Authority website for product safety updates as these are issued on an ongoing basis.

Medicines Authority
203 Level 3, Rue D'Argens, Gzira, GZR 1368 – Malta.
Tel. (+356) 23439000 Fax. (+356) 23439161 www.medicinesauthority.gov.mt