Beat: Health

Better monitoring of biological medicines

The European Medicines Agency

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USPA NEWS - Biological medicines - New chapter in guidelines on good pharmacovigilance practices. The European Medicines Agency (EMA) has adopted a new chapter to its guidelines on good pharmacovigilance practices (EU-GVP).

Entitled “Product- or population-specific considerations II: Biological medicinal products“. Good pharmacovigilance practices are a set of measures designed to ensure the robustness of the system of safety monitoring. The new chapter provides guidance on how to better monitor and manage the safety of biological medicines to optimise the safe and effective use of these products in Europe.

Biological medicines contain one or more active substances made by or derived from a biological source, such as blood or plasma. Some of them may be already present in the human body and examples include proteins like insulin and growth hormone. The active substances of biological medicines are larger and more complex than those of non-biological medicines. Only living organisms are able to reproduce such complexity. Their complexity as well as the way they are produced may result in a degree of variability in molecules of the same active substance, particularly in different batches of the medicine.

Therefore the guidance seeks to support those responsible for monitoring these medicines by:

highlighting specific issues and challenges for the pharmacovigilance of biological medicines, e.g. in relation to variability of the active substance or traceability of products;
providing recommendations on how to address these specificities and challenges;
outlining the roles and responsibilities of the various actors.

The GVP guidance comes into force on 16 August 2016.

The new chapter applies to biological medicines, biosimilars (medicines that are developed to be similar to an existing “reference medicine“) and medicines which contain the same or a closely related active substance but are not authorised as biosimilars. It does not apply to vaccines or advanced therapy medicinal products as separate guidance already exists for these.

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