25 September 2014
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Press Office

Start of community reviews

CHMP meeting of 22-25 September 2014

Start of harmonisation procedures

Name	INN	Type of procedure	Scope
Cymevene IV and associated names	ganciclovir	Article 30 of Directive 2001/83/EC	The Committee started a harmonisation exercise for Cymevene IV and associated names. The review was triggered by the European Commission, due to the need of harmonisation of the Summary of Product Characteristics across Member States.

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Start of reviews for non-centrally authorised medicines

Name	INN	Type of procedure	Scope
GVK Biosciences		Article 31 of Directive 2001/83/EC	Procedure triggered by the European Commission in relation to findings of non-compliance with good clinical practice (GCP) at GVK Biosciences site in Hyderabad, India. This follows an inspection by the ANSM (Agency for Medicines and Health Products Safety, France) which raised concerns about study data used to support the marketing authorisation applications of generic medicines.

Start of scientific review

Name	INN	Type of procedure	Scope
Ebola therapeutics		Article 5(3) of Regulation (EC) 726/2004	Procedure triggered by the Executive Director of the European Medicines Agency, asking for a scientific review of the available information on Ebola treatments currently under development, in view of providing an overview of the current state of knowledge about the various experimental medicines to support decision-making by health authorities.