A good clinical practice (GCP) inspection carried out by the Agency for Medicines and Health Products Safety (ANSM, France), has identified serious failure to comply with GCP in bioequivalence trials conducted since July 2008 by GVK Bio, at Swarna Jayanthi commercial complex, Ameerpet, Hyderabad 500 038, India.

Following the ANSM inspection, the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) of the European Medicines Agency (EMA) requested (30 July 2014) that, within Europe, all applicants seeking a marketing authorization for any product for which GVK Bio had conducted a bioequivalence trial since July 2008, and all holders of a marketing authorization for any product for which GVK Bio has conducted clinical studies since July 2008, provide information on the significance of these studies for the product dossier, including with respect to the validity of any evidence of bioequivalence that had been provided, and taking into account the findings of ANSM’s GCP inspection.

WHO action and advice to stakeholders

WHO has prequalified two medicinal products for which assessment of product safety and efficacy was supported by the results of clinical bioequivalence trials performed by GVK Bio.

The WHO Prequalification Team has contacted GVK Bio and the respective holder of prequalification to obtain further information, including the results of a thorough risk-assessment, regarding the extent to which deficiencies identified by ANSM apply to the prequalified products.

WHO will gather and analyse information obtained from GVK Bio and the relevant prequalification holder, and will inform regulators and other parties concerned accordingly.

At this stage of investigation no regulatory action concerning the relevant WHO-prequalified medicinal products is warranted.

Further information:

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\(^1\) Known as Clinogent since 15 July 2014.