A note was published on the WHO website (6 August 2014) regarding a good clinical practice (GCP) inspection of GVK Bio, at Swarna Jayanthi commercial complex, Ameerpet, Hyderabad 500 038, India, carried out by the Agency for Medicines and Health Products Safety (ANSM, France). This inspection had identified serious failure to comply with GCP in bioequivalence trials conducted since July 2008.

Following the ANSM inspection, the Committee for Medicinal Products for Human Use (CHMP) and 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. Since then, following preliminary review of the responses received from applicants and marketing authorization holders, a number of European countries have suspended the marketing authorizations granted previously for products supported by clinical data generated by GVK Bio, as a precautionary measure until a full review has been completed.2

WHO action and advice to stakeholders

The following prequalified products were supported by clinical studies performed by GVK Bio at their site located in Hyderabad:

- HA405/HA406: Lamivudine and stavudine tablets 150 mg/30 mg and 150/40 mg
- HA467: Ritonavir tablets 100 mg

Following the results of the ANSM inspection, WHO had requested risk assessments and further clinical data for the above-mentioned medicinal products since assessment of product safety and efficacy for prequalification purposes had been based on the results of clinical bioequivalence trials performed by GVK Bio. A thorough risk-assessment was undertaken to determine whether the

---

1 Known as Clinogent since 15 July 2014.
deficiencies identified by ANSM apply also to the prequalified products and final results remain to be determined.

Products HA405/406 have since been withdrawn voluntarily from the WHO List of Prequalified Medicinal Products by Mylan Laboratories Ltd.

New clinical data, obtained from a different contract research organization had already been submitted for HA467 on 23 May 2014, and is currently being assessed.

At this stage of investigation, WHO considers that no further regulatory action concerning WHO-prequalified medicinal products is warranted.

Further information:

Ms. Stephanie Croft, Inspector, WHO Prequalification Team — email: crofts@who.int; tel: +41 22 79 12246