London, 30 July 2014
Doc. Ref.: EMA/CMDh/462354/2014

To: Marketing Authorisation Holders (MAHs) / Applicants

Dear Madam/Sir,

Subject: Bioequivalence studies conducted at GVK Biosciences Private Limited (GVK Bio), Swarna Jayanthi commercial complex, Ameerpet, Hyderabad 500 038, India (new name since 15 July 2014: Clinogent)

A GCP inspection by the ANSM (Agency for Medicines and Health Products Safety, France), has raised serious concerns regarding the GCP compliance of the conduct of the clinical part of bioequivalence trials at GVK Bio, Hyderabad, India in the period July 2008 - 2014.

Member States are undertaking a process to identify all medicinal product dossiers, both approved or pending approval, that include studies conducted at the above mentioned facility followed by a benefit-risk-assessment taking into account the findings of the GCP inspection.

As part of this process, all MAHs and Applicants are requested to provide information on whether the clinical part of a pivotal bioequivalence study in any of their dossiers was conducted at the CRO GVK Bio Hyderabad, India in the defined period. Please note that the enquiry is specific to the clinical facility at the above address and it does not concern the bioanalytical facility as the same site.

The following information should be provided to the RMS for MRP/DCP products or to the National Competent Authority for national only products using the provided template:

- The product / active substance and trade name (or proposed trade name where applicable)
- Mutual Recognition or Decentralised Procedure number (including additional numbers if it is a variation or line extension etc.) and/or national marketing authorisation number
- Marketing authorisation status as of the time of the reply
- Marketing status as of the time of the reply
- The protocol number/study number(s) as used by GVK Bio
- The full protocol title
- The response should cover clinical activities that GVK Bio conducted in Hyderabad, India from July 2008 onwards till the present.
- In case the MAH/Applicant identifies studies conducted from July 2008 onwards till the present at the aforementioned GVK Bio Hyderabad facility in any of their dossiers submitted to National Competent Authorities they are requested to provide information on the importance of these studies for the dossier and on the potential impact on the evidence of bioequivalence mitigated by other information in the dossier.

If the clinical facility of the CRO is not involved in any of their dossiers, no action is required.

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Please send your responses (by using the provided template) to the contact points appended to this letter with the subject: **GVK Bio/Name of the product/Name of the Marketing authorisation holder or Applicant**, no later than the **8th of September 2014.**

Looking forward to hearing from you soon.

Yours faithfully,

Signature on file

Dr. Peter Bachmann
Chair of CMDh

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