EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 October 2014
EMA/CHMP/658332/2014

CHMP List of questions

To be addressed by the marketing authorisation holders for medicinal products for which the clinical part of bioequivalence studies has been carried out by GVK Bio-Hyderabad site, since July 2008.

Article 31 of Directive 2001/83/EC

Procedure number: EMEA/H/A-31/1408

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The GVK Bio-Hyderabad site has been subject of an inspection on GCP compliance by French and British Competent Authorities. This inspection raised concerns about the reliability of studies used to support the marketing authorisation applications of medicinal products.

The marketing authorisation holders are requested to confirm whether bio-equivalence studies in support of their marketing authorisation(s) were performed at GVK Bio-Hyderabad site, in India, since July 2008.

Please consider the table attached when providing answers to the above question.

Attachment: **Status for bio-equivalence study performed at the GVK Bio-Hyderabad facility.**

(Invented) Name	Marketing authorisation holder	Strength and/or pharmaceutical form and/or route of administration (as applicable)	Were any bio-equivalence studies performed at the GVK Bio-Hyderabad facility (India) for any of your medicinal products?		If YES			
			YES	NO				
					Name of study	Number of study (Internal number and/or EUDRACT, please indicate)	Start and end dates of study	Indicate if it was the clinical part of the study only, the analytical laboratory part only or both. Enter: Clinical or analytical or both