



31 March 2015
EMA/CHMP/591005/2014 Rev.5

Timetable for the procedure – re-examination

Referral under Article 31 of Directive 2001/83/EC

Medicinal products for which the clinical part of bioequivalence studies have been carried out by GVK Bio-Hyderabad site

Procedure no: EMEA/H/A-31/1408

Procedural step:	Date
Notification:	04 August 2014
Start of the procedure (CHMP):	September, 2014 CHMP
List of questions to GVK Bio:	25 September 2014
Submission of responses:	03 October 2014
Rapporteur and co-rapporteurs' assessment reports circulated to CHMP:	13 October 2014
Comments:	15 October 2014
Updated rapporteur and co-rapporteurs' assessment reports circulated to CHMP:	16 October 2014
List of questions to MAHs:	23 October 2014
List of outstanding issues to GVK Bio:	23 October 2014
Submission of responses:	04 November 2014
Re-start of the procedure:	11 November 2014



Procedural step:	Date
Rapporteur and co-rapporteurs' assessment reports circulated to CHMP:	13 November 2014
Comments:	14 November 2014
List of outstanding issues to MAHs:	November 2014 CHMP
Submission of responses:	04 December 2014
Re-start of the procedure:	23 December 2014
Co-Rapporteurs assessment reports circulated to CHMP:	12 January 2015
Rapporteur overall assessment report circulated to CHMP:	14 January 2015
Comments from CHMP:	16 January 2015
CHMP opinion:	January, 2015 CHMP
Re-examination - receipt of letters of intent from MAHs by:	14 February 2015
Re-examination - Receipt of detailed grounds from MAHs by:	30 March 2015
Re-examination - Start of re-examination procedure:	31 March 2015
Re-examination – Rapporteur assessment report and co-rapporteur assessment report circulated to CHMP:	27 April 2015
Re-examination – comments:	6 May 2015
Re-examination - Joint Assessment Report:	12 May 2015
Re-examination - Oral explanation/CHMP final opinion:	May 2015 CHMP