



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 April 2016
EMA/CHMP/302886/2016

Timetable for the procedure

Referral under article 31 of Directive 2001/83/EC

Medicinal products for which clinical and bioanalytical parts of the bioequivalence studies were performed at the Semler Research Center (SRC) Private Limited located at SRC Private Limited, 75A, 15th Cross, 1st Phase, JP Nagar, Bangalore 560 078, Karnataka, India (also known as JP Nagar site) and Semler Research Center (SRC) Private Limited PA Arcade, No 21, 22, 23, Kodigehali Main Road, Sahakaranagar Post, Bangalore 560 092, Karnataka, India (also known as Sakar Nagar Clinical site)

Procedure no: EMEA/H/A-31/1443

Procedural step:	Date
Notifications:	27 April 2016
Start of the procedure (CHMP):	April, 2016 CHMP
List of questions:	28 April 2016
Submission of responses:	09 June 2016
Re-start of the procedure:	23 June 2016
Rapporteur/co-rapporteur assessment report(s) circulated to CHMP:	06 July 2016
Comments:	11 July 2016
Updated Rapporteur/co-rapporteur assessment reports circulated to CHMP:	14 July 2016
CHMP list of outstanding issues: CHMP opinion:	21 July 2016

