



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

15 December 2016  
EMA/CHMP/847557/2016

## 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 Micro Therapeutic Research Labs Pvt. Ltd Rajam Bhavanam, No. 6 , Kamarajar Salai, Selaiyur, East Tambaram, Chennai - 600 059, India and Micro Therapeutic Research Labs Pvt. Ltd, No. 29 A, Krishna Madhuravanam, Vellokinar Pirivu, Thudiyalur, Coimbatore-641029, Tamil Nadu, India

Procedure number: EMEA/H/A31/1450

Tadalafil Mylan EMEA/H/A31/1450/C/003787/0005

Procedural step:	Date
Notifications:	01 December 2016
Start of the procedure (CHMP):	December 2016 CHMP
List of questions:	15 December 2016
Submission of responses:	09 February 2017
Re-start of the procedure:	23 February 2017
Rapporteur/co-rapporteur assessment report(s) circulated to CHMP:	08 March 2017
Comments:	13 March 2017
Updated Rapporteur/co-rapporteur assessment reports circulated to CHMP:	16 March 2017
CHMP list of outstanding issues/CHMP opinion:	March 2017 CHMP

