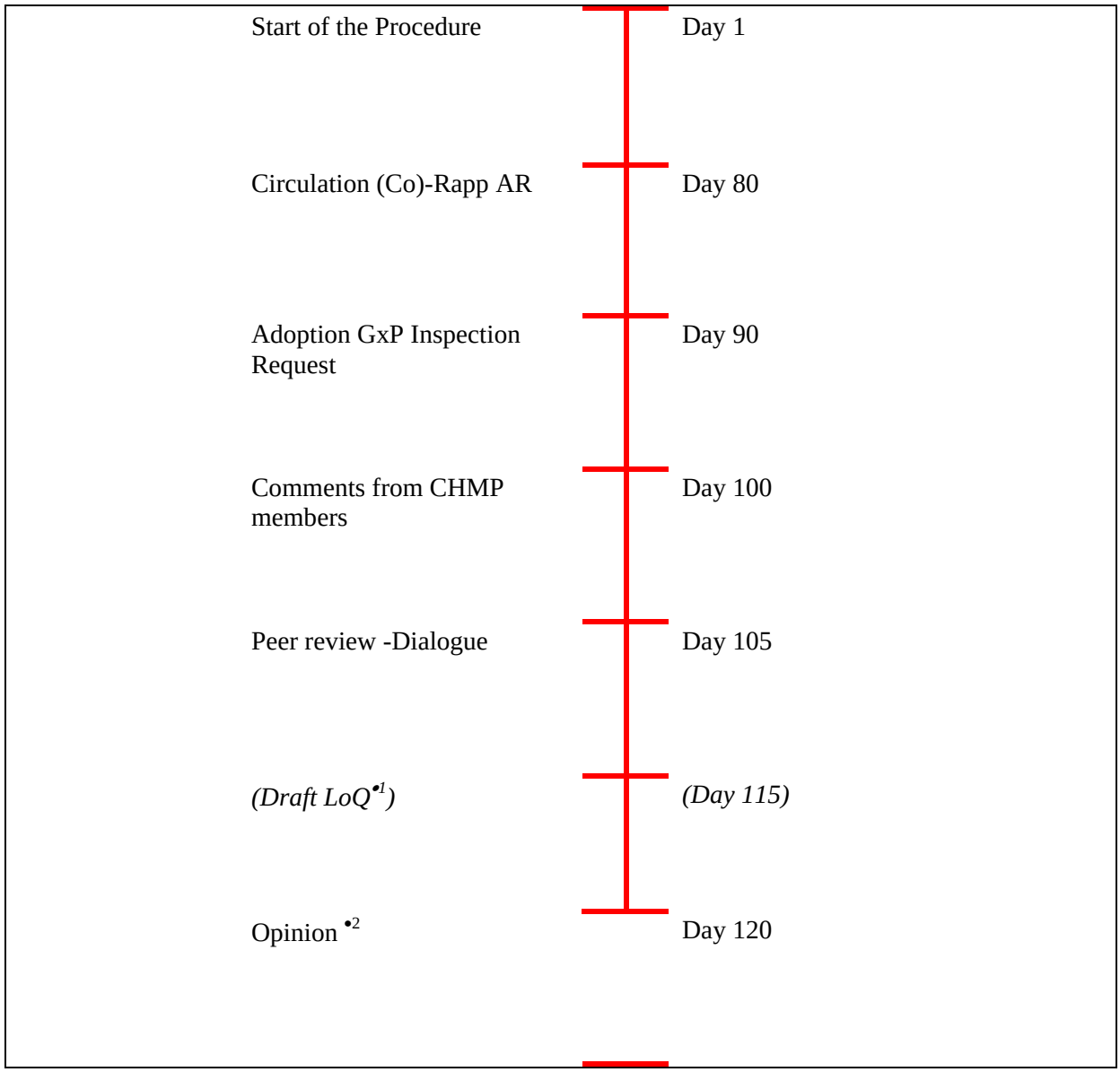
European Medicines Agency
Evaluation of Medicines for Human Use

London, 20 December 2005
EMEA/327896/2005

TIMETABLE FOR GENERICS APPLICATIONS

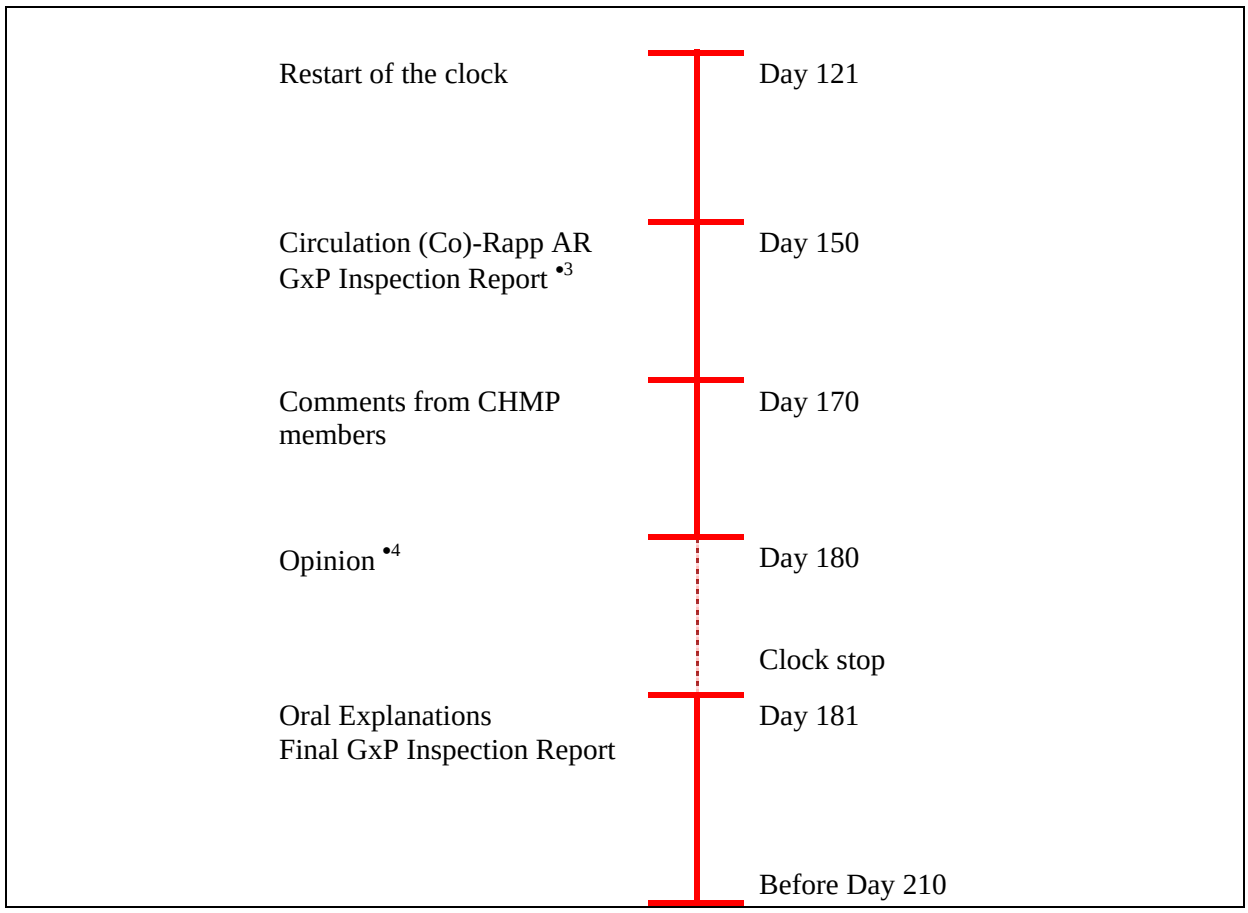
Timetable for the evaluation of 'generic applications' under Article 10(1) of Directive 2001/83/EC, as amended via the Centralised Procedure:



•1 If applicable

•2 Unless "major" objections or GxP Inspection issues are identified

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 85 45
E-mail: mail@emea.eu.int http://www.emea.eu.int

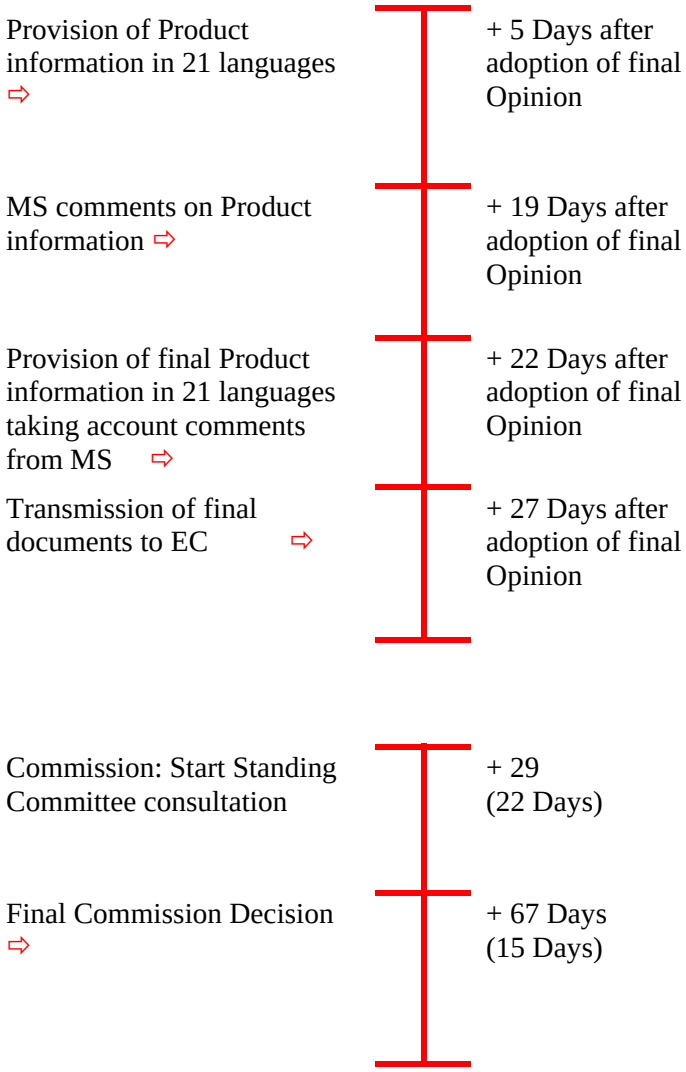


Target dates for the submission of the application/responses are published on the EMEA Website (http://www.emea.eu.int/ – Human Medicines - Application Procedures - 'Pre-Submission Guidance').

•3 If available at this time point

•4 Unless "major" objections are identified to be addressed in writing or during an OE and/or outstanding GxP issues

PIPIT and Decision making Timetable



For 'hybrid applications' under Article 10(3) of Directive 2001/83/EC, as amended the timetable for a new application applies for the first evaluation phase. For the second evaluation phase, a shortened timetable could be agreed upon on a case-by-case basis.