



05 December 2013
EMA/PRAC/127280/2013 Rev.2

Timetable for the procedure

Referral under article 31 of Directive 2001/83/EC resulting from
pharmacovigilance data

Domperidone containing medicinal products

Procedure no: EMEA/H/A-31/1365

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| Notification: | 01 March 2013 |
| Start of the procedure (PRAC): | March 2013 PRAC |
| List of questions: | 07 March 2013 |
| Submission of responses: | 02 May 2013 |
| Re-start of the procedure: | 13 May 2013 |
| Rapporteur and Co-rapporteur assessment report(s) circulated to PRAC and to CMDh ¹ : | 21 June 2013 |
| Comments: | 02 July 2013 |
| Updated Rapporteur and Co-rapporteur assessment report(s) circulated to PRAC and to CMDh: | 05 July 2013 |
| PRAC list of outstanding issues: | 11 July 2013 |
| Submission of responses: | 11 October 2013 |
| Re-start of the procedure: | 06 November 2013 |

¹Co-ordination Group for Mutual Recognition & Decentralised Procedures - Human



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| Joint Rapporteur and co-rapporteur's assessment report circulated to PRAC and to CMDh: | 20 November 2013 |
| Comments: | 25 November 2013 |
| Updated Joint Rapporteur and Co-rapporteur's assessment report circulated to PRAC and to CMDh: | 28 November 2013 |
| 2 nd PRAC list of outstanding issues: | 05 December 2013 |
| Submission of responses: | 03 February 2014 |
| Re-start of the procedure: | 07 February 2014 |
| Joint Rapporteur and co-rapporteur's assessment report circulated to PRAC and to CMDh: | 21 February 2014 |
| Comments: | 26 February 2014 |
| Updated Joint Rapporteur and Co-rapporteur's assessment report circulated to PRAC and to CMDh: | 28 February 2014 |
| PRAC recommendation to CMDh / Oral Explanation: | March 2014 PRAC |