EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

5 September 2013
EMA/PRAC/283428/2013 rev1

Timetable for the procedure

Review under Article 20 of Regulation (EC) No 726/2004, following the procedural steps laid out in Article 31 of Directive 2001/83/EC

Procedure number: Protelos EMEA/H/A20/1371/C/000560/0039
Osseor EMEA/H/A20/1371/C/000561/0034

INN: strontium ranelate

Procedural step:	**Date**
Notification:	25/04/2013
Start of procedure (PRAC):	16/05/2013
List of questions:	16/05/2013
Submission of responses:	12/06/2013
Re-start of the procedure	08/07/2013
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP:	26/07/2013
Comments:	14/08/2013
Updated rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP:	20/08/2013
PRAC List of Outstanding Issues:	September 2013 PRAC
Ad-hoc expert meeting:	10/09/2013

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Procedural step:	**Date**
Submission of responses:	04/11/2013
Re-start of the procedure	11/11/2013
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP:	01/12/2013
Comments:	15/12/2013
Updated rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP:	19/12/2013
Oral Explanation PRAC List of Outstanding Issues or PRAC recommendation to CHMP:	January 2014 PRAC