13 March 2015
EMA/171030/2015

PSUR/PSUSA submissions (*) and expected PRAC outcome dates for bisphosphonates and denosumab

Active substance	PSUR submission frequency	Data Lock Point	Expected Submission	Expected End date of the procedure (PRAC phase)
Denosumab (indicated for bone resorption, osteoporosis and postmenopausal)	1 year	26/09/2014	5/12/2014	10/04/2015
Denosumab (indicated in fractures, bone neoplasm metastasis)	1 year	26/09/2014	5/12/2014	10/04/2015
Zoledronic acid (indicated for osteoporosis)	1 year	31/08/2014	09/11/2014	12/03/2015
Zoledronic acid (indicated for cancer and fractures)	1 year	31/08/2014	09/11/2014	10/04/2015
Ibandronic acid / sodium ibandronate	3 years	24/06/2015	22/09/2015	14/01/2016
Alendronic acid/colecalciferol (**)	5 years	15/01/2016	14/04/2016	04/08/2016

(*) According to EURD List of 6 March 2015

(**) Submission requirement for generics and well-established use products is detailed in the EURD list

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