EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Zoledronic acid Teva Generics

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion / Notification[1] issued on	Commission Decision issued[2] / amended on	Product Information affected[3]	Summary
IAIN/0002	A.1 - Administrative change - Change in the name and/or address of the MAH	03/10/2014		SmPC, Labelling and PL	
IB/0001	Update of SmPC section 4.2 to place the information on hydration and calcium intake to the beginning of the section instead of under the subheading Paget`s disease. And update of sections 4.4 and 4.8 of the SmPC to clarify that reporting of osteonecrosis of the	06/08/2014		SmPC	

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.
[2] A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

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	jaw is not limited to cancer patients, and to add “anti-angiogenic medicinal products" to the concomitant risk factors for ONJ, according to the reference product. C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH				