EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Filgrastim ratiopharm

Procedural steps taken and scientific information after the authorisation

No	Scope	Opinion/ Notification[1] issued on	Commission Decision Issued[2]/ amended on	Product Information affected[3]	Summary
IB/0001/G	This was an application for a group of variations. 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 are submitted by the MAH, C.I.3.a - Implementation of change(s) requested following the assessment of an USR, class labelling, a PSUR, RMP, FUM/SO, data submitted under A 45/46, or amendments to reflect a Core SPC - Changes with NO new additional data are submitted by the MAH	21/02/2011	n/a	SPC, Labelling, PL	To implement changes requested in the PSUR 3 Assessment Report (dated 06 August 2010), as well as to bring the Product Information in line with the SmPC of the reference product (Neupogen). Minor linguistic amendments are introduced in the Package Leaflet for the following languages: CS, DA, DE, EN, ET, ES, FI, FR, HU, IT, NL, PL . In addition, the MAH amended the European Medicines Agency web address in section 10 of the SmPC.

[1] Notifications are issued for type I variations (unless part of a group or a worksharing application). Opinions are issued for all other procedures.
[2] No Commission Decision is issued for type IA and type IB variations or for type II variations and annual re-assessments that do not affect the annexes.
[3] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

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