EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Rilonacept Regeneron

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
S/0006	Second Annual Re-assessment	02/05/2012	28/06/2012	Annex II	The CHMP, having reviewed the evidence of compliance with the specific obligations submitted by the MAH and having re-assessed the benefit/risk profile of the medicinal product, concluded that the benefit/risk balance for the product remains favourable.
II/0005	Update of Summary of Product Characteristics (SmPC), Annex II, Labelling and Package Leaflet (PL). Amendment of wording on discontinuation of the treatment in the case of a hypersensitivity reaction, based on a CHMP request, to "if a hypersensitivity reaction occurs, administration should be stopped immediately and permanently and appropriate therapy initiated." in SmPC Section 4.4. The PL has been amended accordingly. Additionally, editorial and QRD template related changes are implemented in the SmPC, Annex II, Labelling and the PL. Additional changes in wording of the PL are made in line with recommendations from the CHMP following assessment of Readability	15/12/2011	06/02/2012	SPC, Annex II, Labelling, PL	An evaluation of the available data from clinical trials and post-marketing experience confirmed that no serious or severe hypersensitivity reactions have been observed in patients treated with rilonacept. However, a theoretical risk of serious or severe hypersensitivity reactions, including anaphylaxis, to rilonacept does exist. Therefore, section 4.4 of the SmPC and appropriate section III of the PL have been updated to clearly indicate to stop the treatment with rilonacept immediately and permanently in case hypersensitivity reactions develops during rilonacept therapy. Also, as part of a post-marketing commitment the MAH has revised the PL to simplify the language to make it more understandable for users.

[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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No	Scope	Opinion/ Notification[1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
	Test results. C.I.3.b - 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 - Change(s) with new additional data submitted by the MAH				
S/0003	Annual Re-assessment	22/09/2011	21/11/2011		The CHMP, having reviewed the evidence of compliance with the specific obligations submitted by the MAH and having re-assessed the benefit/risk profile of the medicinal product, concluded that the benefit/risk balance for the product remains favourable.
IA/0004/G	This was an application for a group of variations. C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV, C.I.9.b - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the contact details of the QPPV, C.I.9.c - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the back-up procedure of the QPPV, C.I.9.g - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the site undertaking pharmacovigilance activities, C.I.9.h - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the pharmacovigilance system	27/07/2011	n/a	Annex II	
IA/0002	A.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs	23/07/2010	n/a	SPC, Annex II, Labelling, PL	

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II/0001	To provide results on the technology transfer of analytical methods for batch release of drug product in the EU. Quality changes	21/01/2010	15/03/2010	SPC	