EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Dicural

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/0020/G	This was an application for a group of variations. B.II.b.1.e - Replacement or addition of a manufacturing site for the FP B.II.b.2.a - Change to batch release arrangements and quality control testing of the FP B.II.b.1.b - Replacement or addition of a manufacturing site for the FP	22/07/2011	22/07/2011		The European Medicines Agency adopted grouped type IB variations (one type IB variation to replace the finished product manufacturer, one type IAIN variation to add a primary manufacturing site and one type IA variation to add secondary packaging and batch release testing site).
IAIN/0021	A.5.a - Administrative change - Change in the name and/or address of a manufacturer responsible for batch release	07/07/2011	07/07/2011	Annex II, PL	The European Medicines Agency adopted a type IAIN variation to change the name of the manufacturer responsible for batch release from Fort Dodge to Pfizer.
T/0019	Transfer of Marketing Authorisation	17/12/2010	21/01/2011	SPC, Annex II, Labelling, PL	The European Commission approved a transfer of the marketing authorisation from "Fort Dodge Animal Health Holland" to "Pfizer Ltd".

[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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R/0018	Renewal of the marketing authorisation	08/11/2007	15/01/2008	SPC, Annex II, Labelling, PL	Renewal
N/0017	Notification	05/07/2006	09/07/2006	Labelling, PL	Notification-change of templates
1A/0016	1A-38-a Change in test procedure of finished product-Minor change to approved test procedure	30/09/2004	30/09/2004		The European Medicines Agency accepted a type I variation to make a minor change to an approved test procedure for the finished product.
N/0015	Notification	23/04/2004	n/a	PL	Change of local representative/distributor in Sweden
R/0014	Renewal of the marketing authorisation	13/11/2002	22/07/2003	SPC, Annex II, Labelling, PL	Renewal
I/0013	20 - Extension of shelf-life (finished product)	07/12/2001	06/02/2002	SPC	The European Medicines Agency accepted a type I variation to increase the shelf life, from 18 months to 24 months. The amendments have been incorporated into the relevant sections of both the Community Decision and the EPAR.
I/0012	01 - Change in the site responsible for batch release	23/08/2001	19/10/2001	Annex II, Labelling, PL	The European Medicines Agency accepted a type I variation to change the site responsible for final packaging.
I/0009	01c - Change in site of manufacturer for the finished product	23/08/2001	03/09/2001		The European Medicines Agency approved a type I variation to change the name of the manufacturing authorisation holder responsible for batch release.
N/0010	Notification	06/10/2000	07/12/2000	PL	Change of local representatives
X/0005	X-4-I Addition or change of target species	21/06/2000	24/10/2000	SPC, Annex II, Labelling, PL	The European Commission issued a decision on an extension for solution for injection for cattle and dogs.
N/0008	Notification	22/12/1999	16/03/2000	PL	Amendment of telephone number of Italian local representative.

No	Scope	Opinion / Notification[1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
I/0007	20 - Extension of shelf-life (finished product)	26/08/1999	16/11/1999	SPC, Labelling, PL	The European Medicines Agency approved a type I Number 20 variation for an extension to the shelf life from 24 months to 36 months. The amendments have been incorporated into the relevant sections of both the Community Decision and the EPAR.
X/0001	X-3-IV Change or addition of a new pharmaceutical form	14/07/1999	16/11/1999	SPC, Labelling, PL	The European Commission issued a decision on an extension to add a new pharmaceutical form (coated tablets) in a new target species (dogs).
I/0003	01a - Change in the content of the manufacturing authorisation	25/08/1998	12/11/1998		The European Medicines Agency approved a type I Number 1 variation for the additional finished product manufacturing site to be also responsible for batch release. The amendments have been incorporated into the relevant sections of both the Community Decision and the EPAR.
I/0004	16 - Batch size of finished product	10/09/1998	10/09/1998		The European Medicines Agency approved a type I Number 16 variation for a change in the batch size of the finished product.
I/0002	01a - Change in the content of the manufacturing authorisation	07/04/1998	20/05/1998		The European Medicines Agency approved a type I No 1 variation to add a second finished product manufacturer.