EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Poulvac FluFend H5N3 RG

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
R/0010		05/05/2011	27/07/2011		The European Commission approved a renewal of the marketing authorisation for Poulvac FluFend H5N3 RG.
IA/0008/G	This was an application for a group of variations. A.5.a - Administrative change - Change in the name and/or address of a manufacturer responsible for batch release, A.4 - Administrative change - Change in the name and/or address of a manufacturer or supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance	26/10/2010	24/01/2011	Annex II, PL	The European Medicines Agency accepted a grouped variation for a change to the name of the manufacturer of the finished product and the site for batch release, as well as changes to the name of the antigen manufacturing sites.
T/0007	Transfer of Marketing Authorisation	29/10/2010	13/12/2010	SPC, Labelling, PL	The European Commission approved a transfer of the marketing authorisation from "Fort Dodge Animal Health Ltd" 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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IB/0009	C.I.8.b - Introduction of a new Pharmacovigilance system - which has been assessed by the relevant national competent authority/EMEA for another product of the same MAH	26/10/2010	26/10/2010		The European Medicines Agency accepted a type IB variation for the provision of a new pharmacovigilance system associated with the transfer of the marketing authorisation from "Fort Dodge Animal Health" to "Pfizer Ltd".
S/0006	Annual reassessment	14/07/2010	30/09/2010	Annex II	The CVMP reviewed the specific obligations and concluded that, overall, the evidence continues to support a favourable benefit/risk profile for Poulvac FluFend H5N3 RG. Full approval will, however, remain conditional on the fulfilment of the outstanding specific obligations as outlined in Annex II E of the opinion as well as the fulfilment of the list of commitments and additional issues that need to be addressed in order to remove the requirement for annual review of the authorisation under exceptional circumstances as outlined in Annex II of the original CVMP assessment report. Amendments have been incorporated into the relevant sections of the Commission Decision and the EPAR.
S/0004	Annual reassessment	15/07/2009	15/07/2010		The CVMP reviewed the specific obligations and concluded that, overall, the evidence continues to support a favourable benefit/risk profile for Poulvac FluFend H5N3 RG. Full approval will, however, remain conditional on the fulfilment of the outstanding specific obligations as outlined in Annex II E of the opinion as well as the fulfilment of the list of commitments and additional issues that need to be addressed in order to remove the requirement for annual review of the authorisation under exceptional circumstances as outlined in Annex II of the original CVMP assessment report. Amendments have been incorporated into the relevant sections of the Commission Decision and of the EPAR.

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IB/0005	1B-42-a-1 Change in shelf life of finished product-as packaged for sale	17/06/2009	14/01/2010	SPC	The European Medicines Agency approved a type IB No.42 variation for a change of shelf life of the finished product from 1 year to 2 years.
S/0003	Annual reassessment	17/09/2008	17/09/2008		The CVMP reviewed the specific obligations and concluded that, overall, the evidence continues to support a favourable benefit/risk profile for Poulvac FluFend H5N3 RG. Full approval will, however, remain conditional on the fulfilment of the outstanding specific obligations as outlined in Annex II E of the opinion as well as the fulfilment of the list of commitments and additional issues that need to be addressed in order to remove the requirement for annual review of the authorisation under exceptional circumstances as outlined in Annex II of the original CVMP assessment report. Amendments have been incorporated into the relevant sections of the Commission Decision and the EPAR.
II/0002	II - New Indication (same therapeutic area)	18/06/2008	31/07/2008	SPC, Labelling, PL	The European Commission approved a type II variation to broaden the target species from "Pekin Ducks" to "Ducks" and to change the duration of immunity in ducks from being "not established" to "14 weeks after second injection". Amendments have been incorporated into the relevant sections of the Commission Decision and the EPAR.
S/0001	Annual reassessment	11/07/2007	09/10/2007	SPC, Labelling, PL	The CVMP approved most of the specific obligations and concluded that, overall, the evidence supports a favourable benefit/risk profile for Poulvac FluFend H5N3 RG. Full approval will, however, remain conditional on the fulfilment of the outstanding specific obligations as outlined in Annex II E of the opinion as well as the fulfilment of the list of commitments and additional issues that need to be addressed in order to remove the requirement for

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					annual review of the authorisation under exceptional circumstances as outlined in Annex II of the original CVMP assessment report. Amendments have been incorporated into the relevant sections of the Commission Decision and of the EPAR.