

## **EUROPEAN COMMISSION**

HEALTH & CONSUMERS DIRECTORATE-GENERAL

Directorate C - Public Health and Risk Assessment C8 - Pharmaceuticals Head of unit

Brussels, 8 October 2010

NOTE TO THE MEMBERS OF THE STANDING COMMITTEE ON MEDICINAL PRODUCTS FOR HUMAN USE/STANDING COMMITTEE ON VETERINARY MEDICINAL PRODUCTS

**Subject:** 

Adoption of COMMISSION DECISION concerning, in the framework of Article 78 of Directive 2001/82/EC of the European Parliament and of the Council, the marketing authorisations for "Pregsure BVD and associated names", veterinary medicinal products which contain the active substance "Inactivated Bovine Viral Diarrhoea (BVD) type 1 virus, cytopathogenic strain 5960"

EMEA/V/A/57-Art 78 Final Measures

The Commission has adopted the abovementioned Decision on 7 October 2010.

The Decision will be notified forthwith to the addressee(s) of the Decision.<sup>1</sup>

The Decision is going to be published for information in all official languages of the EU in the Community Register of Medicinal Products (<a href="http://ec.europa.eu/health/documents/community-register/index\_en.htm">http://ec.europa.eu/health/documents/community-register/index\_en.htm</a>) after the Decision has been notified. The attention has to be drawn to the fact that, under the general rules of the EC Treaty, a Decision is a legal act whose publication is not obligatory in order to be binding.

Patricia Brunko pp. Sanchez Martinez Nicolas

Cc: Marketing authorisation holder (Contact person, only in centralised procedure);

EMA (Product team leader, secretary)

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In case of centralised procedure: Marketing Authorization Holder; In case of referral procedure: Member States (via the Permanent Representations to the European Union)