I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

Further to the submission of a letter of intent by Pfizer Ltd. on 6 March 2007, the CVMP accepted on 18 April 2007 that Improvac was eligible for the submission of a dossier for granting of a Community marketing authorisation via the centralised procedure.

The Rapporteur and Co-Rapporteur appointed by the CVMP were:

Rapporteur: Dr Ellen-Margrethe Vestergaard from Denmark,

Co-Rapporteur: Dr Anna-Maria Brady (Dr. Martin Ilott /Ms Ruth Kearsley) from United Kingdom

2. Steps taken for the assessment of the product

The company Pfizer Ltd. submitted an application to the EMEA on 31 July 2007 for the granting of a Community marketing authorisation for IMPROVAC in accordance with Article 31 of Regulation (EC) No 726/2004 of 31 March 2004.

- The application was validated on 14 August 2007.
- A list of questions was adopted by the CVMP on 12 December 2007.
- The company submitted written responses on 15 August 2008.
- An oral explanation was given to the CVMP by the company on 12 February 2009.
- The CVMP adopted an Opinion on 11 March 2009
- The EC adopted a Commission Decision on granting a Marketing Authorisation on 11 May 2009

A. MANUFACTURER(S) OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer of the biological active substance(s)

Diphtheria Toxoid:
Pfizer Inc.
601 Cornhusker Highway, Lincoln,
Nebraska 68521
USA

Synthetic GnRF peptide analogue:
Auspep Clinical Peptides PTY Ltd.
15, Mareno Road, Tullamarine, 3052
Victoria
Australia

GnRF analogue-protein conjugate:
Pfizer Animal Health S.A.
1, rue Laid Burniat
1348 Louvain-la-Neuve
Belgium

Name and address of the manufacturer responsible for batch release

Pfizer Animal Health S.A.
1, rue Laid Burniat
1348 Louvain-la-Neuve
Belgium

B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE

Veterinary medicinal product subject to prescription.
The holder of this marketing authorisation must inform the European Commission about the marketing plans for the medicinal product authorised by this decision.

C. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION WITH REGARD TO SAFE AND EFFECTIVE USE

Not applicable

D. STATEMENT OF THE MRLs

As the active substance (Gonadotropin releasing factor (GnRF) analogue-protein conjugate) is intended to produce immunity as part of an immunological veterinary medicinal product it consequently does not fall within the scope of Council Regulation (EEC) No 2377/90.

The following substances contained in the final product are included in Annex II of Council Regulation (EEC) No 2377/90 or are considered as not falling within the scope of the Regulation in accordance with the following table:

Pharmacologically active substance(s)	Animal species	Other provisions
Thiomersal	All food producing species	For use as preservatives in multidose vaccines at a concentration not exceeding 0.02%
Urea	All food producing species	
DEAE-Dextran		Not within the scope of Council Regulation (EEC) No. 2377/90 at the dose included in Improvac.
Water for injection		Not within the scope of Council Regulation (EEC) No. 2377/90.