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

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

Amgen, Inc.
One Amgen Center Drive
Thousand Oaks
CA
91320
United States

Amgen Singapore Manufacturing Pte. Ltd.
1 Tuas View Drive
Singapore 637026
Singapore

Name and address of the manufacturer(s) responsible for batch release

Aimovig 70 mg, 140 mg solution for injection in pre-filled syringe:

Novartis Manufacturing NV
Rijksweg 14
2870 Puurs-Sint-Amands
Belgium

Novartis Pharma GmbH
Roonstrasse 25
D-90429 Nuremberg
Germany

Novartis Pharma GmbH
Sophie-Germain-Strasse 10
90443 Nuremberg
Germany

Aimovig 70 mg, 140 mg solution for injection in pre-filled pen:

Sandoz GmbH
Biochemiestrasse 10
6336 Langkampfen
Austria

Novartis Pharma GmbH
Roonstrasse 25
D-90429 Nuremberg
Germany

Novartis Pharmaceutical Manufacturing GmbH
Biochemiestrasse 10
6336 Langkampfen
Austria

Novartis Pharma GmbH
Sophie-Germain-Strasse 10
90443 Nuremberg
Germany

The printed package leaflet of the medicinal product must state the name and address of the manufacturer responsible for the release of the concerned batch.

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Medicinal product subject to restricted medical prescription (see Annex I: Summary of Product Characteristics, section 4.2).

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

- **Periodic safety update reports (PSURs)**

The requirements for submission of PSURs for this medicinal product are set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and any subsequent updates published on the European medicines web-portal.

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

- **Risk management plan (RMP)**

The marketing authorisation holder (MAH) shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the marketing authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:

- At the request of the European Medicines Agency;
- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.