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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 17-I-2007
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NOT FOR PUBLICATION

COMMISSION DECISION

of 17-I-2007

**granting marketing authorisation under Regulation (EC) n° 726/2004 of the
European Parliament and of the Council for "Exforge - amlodipine / valsartan", a
medicinal product for human use**

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency¹, and in particular Article 10(2) thereof,

Having regard to the application submitted by Novartis Europharm Limited, on 1 March 2006, under Article 4(1) of Regulation (EC) No 726/2004,

Having regard to the opinion(s) of the European Medicines Agency, formulated by the Committee for Medicinal Products for Human Use on 16 November 2006,

Whereas:

- (1) The medicinal product "Exforge - amlodipine / valsartan" complies with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use².
- (2) It is therefore appropriate to authorise its placing on the market.
- (3) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

HAS ADOPTED THIS DECISION:

Article 1

The marketing authorisation provided for in Article 3 of Regulation (EC) No 726/2004 is granted for the medicinal product "Exforge - amlodipine / valsartan", the characteristics of which are summarised in Annex I to this Decision. "Exforge - amlodipine / valsartan" shall be registered in the Community register of medicinal products under No(s)

¹ OJ L 136, 30.4.2004, p. 1

² OJ L 311, 28.11.2001, p. 67. Directive as last amended by Directive 2004/27/EC (OJ L 136, 30.4.2004, p. 34).

| | | | |
|-----------------|--|-------------|-------------|
| EU/1/06/370/001 | Exforge-5 mg/80 mg-Film-coated (PVC/PVDC)-7 tablets | tablet-Oral | use-Blister |
| EU/1/06/370/002 | Exforge-5 mg/80 mg-Film-coated (PVC/PVDC)-14 tablets | tablet-Oral | use-Blister |
| EU/1/06/370/003 | Exforge-5 mg/80 mg-Film-coated (PVC/PVDC)-28 tablets | tablet-Oral | use-Blister |
| EU/1/06/370/004 | Exforge-5 mg/80 mg-Film-coated (PVC/PVDC)-30 tablets | tablet-Oral | use-Blister |
| EU/1/06/370/005 | Exforge-5 mg/80 mg-Film-coated (PVC/PVDC)-56 tablets | tablet-Oral | use-Blister |
| EU/1/06/370/006 | Exforge-5 mg/80 mg-Film-coated (PVC/PVDC)-90 tablets | tablet-Oral | use-Blister |
| EU/1/06/370/007 | Exforge-5 mg/80 mg-Film-coated (PVC/PVDC)-98 tablets | tablet-Oral | use-Blister |
| EU/1/06/370/008 | Exforge-5 mg/80 mg-Film-coated (PVC/PVDC)-280 tablets | tablet-Oral | use-Blister |
| EU/1/06/370/009 | Exforge-5 mg/160 mg-Film-coated (PVC/PVDC)-7 tablets | tablet-Oral | use-Blister |
| EU/1/06/370/010 | Exforge-5 mg/160 mg-Film-coated (PVC/PVDC)-14 tablets | tablet-Oral | use-Blister |
| EU/1/06/370/011 | Exforge-5 mg/160 mg-Film-coated (PVC/PVDC)-28 ablets | tablet-Oral | use-Blister |
| EU/1/06/370/012 | Exforge-5 mg/160 mg-Film-coated (PVC/PVDC)-30 tablets | tablet-Oral | use-Blister |
| EU/1/06/370/013 | Exforge-5 mg/160 mg-Film-coated (PVC/PVDC)-56 tablets | tablet-Oral | use-Blister |
| EU/1/06/370/014 | Exforge-5 mg/160 mg-Film-coated (PVC/PVDC)-90 tablets | tablet-Oral | use-Blister |
| EU/1/06/370/015 | Exforge-5 mg/160 mg-Film-coated (PVC/PVDC)-98 tablets | tablet-Oral | use-Blister |
| EU/1/06/370/016 | Exforge-5 mg/160 mg-Film-coated (PVC/PVDC)-280 tablets | tablet-Oral | use-Blister |
| EU/1/06/370/017 | Exforge-10 mg/160 mg-Film-coated (PVC/PVDC)-7 tablets | tablet-Oral | use-Blister |
| EU/1/06/370/018 | Exforge-10 mg/160 mg-Film-coated (PVC/PVDC)-14 tablets | tablet-Oral | use-Blister |
| EU/1/06/370/019 | Exforge-10 mg/160 mg-Film-coated (PVC/PVDC)-28 tablets | tablet-Oral | use-Blister |
| EU/1/06/370/020 | Exforge-10 mg/160 mg-Film-coated (PVC/PVDC)-30 tablets | tablet-Oral | use-Blister |

| | | | |
|-----------------|---|-------------|-------------|
| EU/1/06/370/021 | Exforge-10 mg/160 mg-Film-coated (PVC/PVDC)-56 tablets | tablet-Oral | use-Blister |
| EU/1/06/370/022 | Exforge-10 mg/160 mg-Film-coated (PVC/PVDC)-90 tablets | tablet-Oral | use-Blister |
| EU/1/06/370/023 | Exforge-10 mg/160 mg-Film-coated (PVC/PVDC)-98 tablets | tablet-Oral | use-Blister |
| EU/1/06/370/024 | Exforge-10 mg/160 mg-Film-coated (PVC/PVDC)-280 tablets | tablet-Oral | use-Blister |

Article 2

The marketing authorisation concerning the medicinal product referred to in Article 1 shall be subject to compliance with the conditions set out in Annex II and, in particular, with those relating to manufacture and importation, control and issue.

Article 3

The labelling and package leaflet concerning the medicinal product referred to in Article 1 shall comply with the conditions set out in Annex III.

Article 4

The period of validity of the authorisation shall be five years from the date of notification of this Decision.

Article 5

This Decision is addressed to Novartis Europharm Limited, Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom.

Done at Brussels, 17-I-2007

For the Commission
Heinz ZOUREK
Director-General