



London, 4 February 2009  
EMEA/63200/2009

### **EMEA Public Statement on Fee Reductions for Designated Orphan Medicinal Products**

Orphan medicinal products designated in accordance with Regulation (EC) No 141/2000 of 22 January 2000, are eligible for fee reductions for all fees payable under Community rules pursuant to Regulation (EEC) 2309/93, as amended. This includes fees for pre-authorisation activities such as protocol assistance (scientific advice), and for products using the centralised procedure: the application for marketing authorisation, inspections and post-authorisation activities such as variations, annual fees, etc.

With effect from 1 February 2009, the fee reduction policy for designated orphan medicinal products has been revised to reinforce support to micro, small and medium-sized enterprise (SME).

In the revised policy for 2009, the fee reduction for new applications for marketing authorisation to SMEs is increased to 100%. The fee reduction for post authorisation activities including annual fees to SMEs in the first year after granting a marketing authorisation is also increased to 100%. The 100 % fee reduction for protocol assistance and 100% fee reduction for pre-authorisation inspections are maintained for all applicants. The 50% fee reduction for new applications for marketing authorisation submitted by applicants that are not SMEs is also maintained.

#### **Fee exemptions with effect from 1 February 2009**

Subject to the availability of funds from the Community grant, the following levels of fee reductions have been agreed by the Executive Director of the EMEA and shall take effect on 1 February 2009:

- Full (100%) reduction for protocol assistance and follow-up
- Full (100%) reduction for pre-authorisation inspections
- 50% reduction for new applications for marketing authorisation to applicants other than small and medium-sized enterprises
- Full (100%) reduction for new applications for marketing authorisation only to small and medium-sized enterprises
- Full (100%) reduction for post authorisation activities including annual fees only to small and medium sized enterprises in the first year after granting a marketing authorisation

#### **How to inform the EMEA of the intention to submit an application eligible for a fee reduction**

Sponsors of orphan medicinal products intending to request protocol assistance, to apply for a marketing authorisation or post-authorisation procedure, or that will be subject to an inspection should inform the EMEA by means of a **letter of intent regarding a fee reduction** addressed to the attention of:

*Dr Agnès Saint Raymond*  
*Head of Scientific Advice and Orphan Drug Sector*

It should be noted that fee reductions can only be processed once the decision on orphan medicinal product designation has been granted by the European Commission. In addition, the application should fall within the scope of the orphan condition. The applicant or marketing authorisation holder must be the sponsor of the designation in order to be eligible for the fee reduction. If this is not the case, the

transfer of sponsorship of the designation should be completed prior to submitting the application for a procedure.

The letter of intent regarding a fee reduction should be received by the EMEA not more than 2 months and not less than 2 weeks prior to the planned protocol assistance/centralised application/variation. For inspections, the letter regarding a fee reduction should be sent out as soon as the CHMP inspection request is issued. Further information on how to submit a letter of intent regarding a fee reduction is provided in Annex I.

To be eligible for fee reductions on post-authorisation applications in the first year after granting a marketing authorisation the sponsor will need to meet the definition of SME as defined in Commission Recommendation 2003/361/EC of 6 May 2003. It should be noted that fee reductions can only be processed once the applicant has been assigned SME status by the EMEA<sup>1</sup>.

Please note that only SME marketing authorisation holders will be eligible to a fee reduction on the first year annual fee. A letter of intent regarding a fee reduction for the first year annual fee should be sent to the EMEA once SME status has been assigned.

For orphan medicinal products authorised via the mutual recognition procedure, the national competent authorities in Member States may offer fee reductions for orphan medicinal products. Further information is available in the 'Inventory of Community and National Incentive Measures to Aid the Research, Marketing, Development and Availability of Orphan Medicinal Products', which is available on the European Commission website.

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<sup>1</sup> Information on how to be assigned SME status is available on the EMEA web-site.

### **What should I include in my letter of intent regarding a fee reduction for an orphan medicinal product?**

The submission of a letter of intent regarding a fee reduction for an orphan medicinal product should be sent to the EMEA. The letter should include the following information:

- Name of the medicinal product as designated
- Name of the sponsor, with its contact details (telephone; fax; e-mail)
- Orphan indication
- EU Designation Number
- EMEA-SME Number (if applicable)

A copy of the Decision on designation (in English) should be attached to all letters of intent regarding a fee reduction. Depending on the nature of the application concerning the orphan medicinal product, the following additional information should be provided:

#### *1. Protocol Assistance*

- Scope of request for protocol assistance
- Planned submission date of request for protocol assistance

#### *2. Application for marketing authorisation (MAA)*

- Name of applicant (should be same as designated sponsor)
- Proposed tradename
- Proposed therapeutic indication (Section 4.1 of the draft Summary of Product Characteristics)
- Description of pharmaceutical form(s), strength(s) and pack size(s)
- Planned submission date of MAA

#### *3. Inspections*

- Proposed tradename
- EMEA Centralised Procedure Reference Number
- Nature of inspection (GMP, GLP, GCP)

#### *4. Variations Type I or Type II*

- Tradename
- EU Marketing Authorisation Number
- Scope of variation
- Planned submission date of variation

### **To whom should I send or fax my letter of intent regarding a fee reduction?**

All letters of intent should be sent to the EMEA, to the attention of:

*Dr Agnès Saint Raymond,*  
*Head of Scientific Advice and Orphan Drug Sector*  
 EMEA  
 7 Westferry Circus  
 Canary Wharf,  
 London, E14 4HB  
 Fax: + 44 (0) 20 7523 7040  
 E-mail: **feereductionsomp@emea.europa.eu**

The EMEA will check the letter of intent, particularly that the applicant and the sponsor of the designation are identical and will only send an acknowledgement of receipt, via fax or e-mail.