



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 December 2011
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Human Medicines Development and Evaluation

Procedural advice 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 reductions on all fees payable under Union rules pursuant to Regulation (EC) No 726/2004. 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.

The fee reductions for designated orphan medicinal products were last revised on 1 April 2011 in line with the funding received through the special contribution from the European Union. The Executive Decision on fee reductions was revised again on 16 December 2011 in order to inform on reductions applied by the Agency to paediatric-related protocol assistance.

The fee reductions for protocol assistance and new applications for marketing authorisation to micro, small and medium-sized companies (SMEs) are maintained at 100%. The fee reductions for post authorisation activities including annual fees to SMEs in the first year from granting of a marketing authorisation are also maintained at 100%. Different rates apply for protocol assistance requests and new applications for marketing authorisation from sponsors that do not have SME status assigned by the Agency. All sponsors (SME and non-SME) continue to benefit from a 100% fee waiver for pre authorisation inspections.

Subject to the availability of funds from the Union grant, the following levels of fee reductions have been agreed by the Executive Director with effect from 1 January 2012:



| Procedure or service | Fee reduction applicable to | Percentage fee reduction |
|--|---|---------------------------------|
| Protocol assistance, initial and follow up requests | SME sponsors for all assistance | 100% |
| | Non-SME sponsors for non-paediatric-related assistance* | 75% |
| | Non-SME sponsors for paediatric-related assistance* | 100% |
| Pre authorisation inspection | All sponsors | 100% |
| Initial marketing authorisation application | SME sponsors | 100% |
| | Non-SME sponsors | 10% |
| Post authorisation applications and annual fee, in the first year from granting of a marketing authorisation | SME sponsors | 100% |

* Paediatric-related protocol assistance is restricted to development of an orphan medicinal product for the paediatric population, where the advice requested does not include the adult population.

How to inform the EMA 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 are advised to inform the EMA by means of a letter of intent regarding a fee reduction addressed to the attention of:

Dr Agnès Saint Raymond

Head of Human Medicines Special Areas

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.

It is strongly encouraged that the letter of intent regarding a fee reduction is received by the EMA 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 EMA¹.

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 EMA 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.

¹ Information on how to be assigned SME status is available on the EMA web-site.

Annex 1

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 EMA. 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
- EMA-SME Number (if applicable)

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 trade name
- 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 trade name
- EMA 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 EMA, to the attention of:

Dr Agnès Saint Raymond,

Head of Human Medicines Special Areas

European Medicines Agency

7 Westferry Circus

Canary Wharf

London, E14 4HB

Fax: + 44 (0) 20 7523 7040

E-mail: feereductionsomp@ema.europa.eu

The EMA 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.