EUROPEAN MEDICINES AGENCY

SCIENCE MEDICINES HEALTH

SME Office

Addressing the needs of small and medium-sized enterprises (SMEs) and promoting innovation

An agency of the European Union

With the aim of promoting innovation and development of new medicines by SMEs, the European Medicines Agency provides incentives for SMEs that are developing human or veterinary medicines[1].

The SME Office offers assistance to SMEs through dedicated personnel within the Agency.

SME definition

Commission Recommendation 2003/361/EC defines micro, small and medium-sized enterprises.

To qualify for SME status, companies must meet the following criteria:

- be established in the European Economic Area (EEA)
- employ less than 250 employees and have an annual turnover of not more than €50 million or an annual balance-sheet total of not more than €43 million.

Depending on the category of the enterprise, some or all of the headcount and financial data from other partner or linked enterprises may need to be counted when calculating whether the SME criteria are met.

Further information on the definition of an SME is available in the 'User guide to the SME definition'[2].

SME qualification process

The form 'Declaration on the qualification of an enterprise as a micro, small or medium-sized enterprise (SME)[3]', available from the Agency's website, should be completed and submitted to the SME Office, together with the most recent annual accounts, information on ownership, and proof of establishment in the EEA.

[1]According to Commission Regulation (EC) No 2049/2005
[2]See European Commission/Growth/Publications
[3]See SME Office area at www.ema.europa.eu

The applicant will receive an EMA-SME number once the SME status has been assigned. To maintain its SME status, the company should submit a completed declaration annually, based on its latest approved accounts.

SME support

The incentives offered by the SME Regulation apply to the human and veterinary sectors, and include:

Regulatory assistance

SMEs can benefit from direct regulatory assistance including SME briefing meetings, which aim to facilitate the interaction with the Agency and provide guidance on the EU regulatory framework and the tools to support innovation.

Scientific advice

SMEs are encouraged to seek scientific advice from the Agency early in the development process. This helps the sponsor to ensure that the appropriate studies are performed and maximises the chances of a successful marketing authorisation. A substantial fee reduction for scientific advice is available to SMEs (see table).

Other incentives include:

- fee incentives (see table)
- organisation of info days and training sessions for SMEs
- regulatory updates via SME Newsletters and mailings targeted to SMEs
- assistance with translations of the product information required for the granting of an EU marketing authorisation
- inclusion in the public SME register
- guidance on clinical data publication and provision of a free redaction tool license

Fee incentives

Activity/application	Fee incentives
Scientific advice	90% fee reduction for non-orphan products
	100% fee reduction for designated orphan products
	100% fee reduction for products granted eligibility to the Priority Medicines (PRIME) scheme
Inspection (pre-authorisation)	90% fee reduction and deferral
	100% fee reduction for designated orphan products
Application for marketing authorisation	Fee deferral
	Conditional fee exemption[4]
	100% fee reduction for designated orphan products
Post-authorisation procedures, including pharmacovigilance activities	Fee exemption for micro-sized enterprises
	40% fee reduction for small or medium-sized enterprises
	100% fee reduction for designated orphan products during the first year after marketing authorisation
Scientific services	90% fee reduction for non-orphan products
	100% fee reduction for designated orphan products
Establishment of MRLs[5]	90% fee reduction
Administrative services[6]	100% fee reduction
Inspection (post-authorisation)	90% fee reduction
MedDRA licence[7]	100% fee reduction

Details on fees and fee reductions are available in the explanatory note on general fees payable to the European Medicines Agency[8].

[4]In the event of a negative outcome, where EMA scientific advice has been sought and followed
[5]Maximum Residue Limits
[6]Excluding parallel distribution
[7]For micro- and small-sized enterprises only
[8]See fees area at www.ema.europa.eu

Useful sources of information

EMA user guide for SMEs[3]

For information on administrative and procedural aspects of the pharmaceutical legislation

SME public register[3]

For information on SME companies registered with the Agency

European Small Business Portal

For information on the whole spectrum of EU policies, legislation, programmes and initiatives relevant to Europe's SMEs:

http://ec.europa.eu/small-business/index_en.htm

Research funding

For information on EU funding:

Cordis

http://cordis.europa.eu/

Horizon 2020

https://ec.europa.eu/programmes/horizon2020/

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Further information

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