EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: SME conditional fee exemptions		
Status: **PUBLIC**		Document no.: SOP/EMA/0038
Lead author	Approver	Effective date: 07-JUL-16
Name: Cathrin Budnik	Name: Constantinos Ziogas	Review date: 07-JUL-19
Signature: "on file"	Signature: "on file"	Supersedes: SOP/EMA/0038 (05-MAY-06)
Date: 05/07/2016	Date: 07/07/2016	TrackWise record no.: 1893

1. Purpose

To describe the procedure for processing conditional fee exemptions for micro-, small- and medium-sized enterprises (SMEs) pursuant to article 6 of Regulation (EC) No 2049/2005 laying down rules regarding the payment of fees to, and the receipt of administrative assistance from the Agency by micro, small and medium-sized enterprises (SMEs).

Conditional fee exemption may be granted where EMA scientific advice is followed and a marketing authorisation application is not successful (negative outcome or withdrawal).

2. Scope

This SOP applies to the SME Office (S-CS-SME) in the Corporate Stakeholder Department (S-CS) within the Stakeholders & Communication Division (S), Scientific Advice (D-DS-SCA) in the Product Development Scientific Support Department (D-DS) within the Human Medicines/Research & Development Support Division (D), the Human Medicines Evaluation Division (E), the Veterinary Medicines Division (V-VM) and the Finance and Budget Department (A-FI) within the Administration and Corporate Management Division (A).

3. Responsibilities

It is the responsibility of each Head of Office and/or Department to ensure that this procedure is adhered to within his/her own area of responsibility. The responsibility for the execution of a particular part of this procedure is identified in the right-hand column.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

4. Changes since last revision

Extensive revision.

5. Documents needed for this SOP

All templates can be found in : X:\Templates\Others\SME\Fees

- Template 1 – Memorandum for conditional fee exemption
- Template 2 – Transmission slip
- Template 3 – To accounts – Outcome of request for conditional fee exemption
- Template 4 – To SME – Outcome of request for conditional fee exemption

6. Related documents

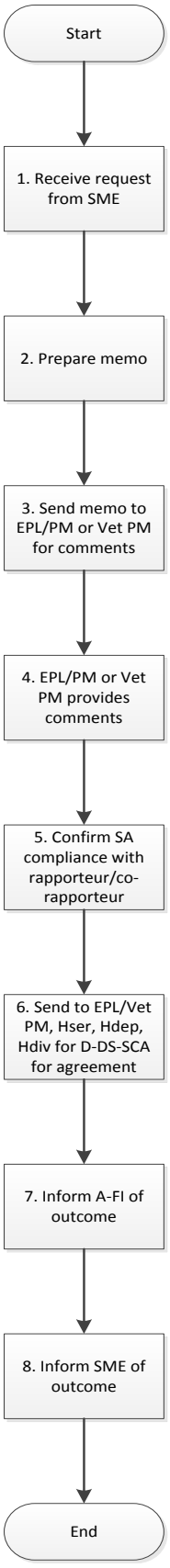
- Regulation (EC) No 2049/2005 laying down rules regarding the payment of fees to, and the receipt of administrative assistance from the EMEA by micro, small and medium-sized enterprises (SMEs)
- Regulation (EC) No 297/95 on fees payable to the EMEA, as amended
- Rules for the implementation of Council Regulation (EC) No 297/95 on fees payable to the European Medicines Agency
- Explanatory note on fees payable to the European Medicines Agency
- Executive decision on access to financial and administrative incentives for micro, small and medium-sized companies (EMA/150401/2013)
- SOP on assignment SME Status (SOP/EMA/0039)
- SOP on renewal of SME Status (SOP/EMA/0124)

7. Definitions

A:	Administration and Corporate Management
A-FI:	Administration and Corporate Management - Finance and Budget
AD:	Administrator
CXMP:	Committee for human/veterinary medicinal products (as applicable)
D:	Human Medicines Research & Development Support
D-DS:	Human Medicines Research & Development Support - Product Development Scientific Support
D-DS-SCA:	Human Medicines Research & Development Support - Product Development Scientific Support – Scientific Advice
E:	Human Medicines Evaluation
EC:	European Commission

EMA:	European Medicines Agency
EPL:	Evaluation product leader
Hdep:	Head of department
Hdiv:	Head of division
Hser:	Head of service
S:	Stakeholders & Communication
S-CS:	Stakeholders & Communication – Corporate Stakeholders
S-CS-SME:	Stakeholders & Communication – Corporate Stakeholders – SME
SCA:	Scientific advice
SME:	Small and medium-sized enterprise
SOP:	Standard operating procedure
V-VM:	Veterinary Medicines
Vet PM:	Project manager for veterinary medicinal product

8. Process map(s)/ flow chart(s)



9. Procedure

Step	Action	Responsibility
	Start of procedure	
1	Receive correspondence requesting conditional fee exemption from SME.	AD in S-CS-SME
2	Prepare memo (template 1) reviewing compliance with scientific advice taking into account the company's request, the scientific advice letter, the day 120 list of questions and the day 160 joint CXMP assessment report.	AD in S-CS-SME
3	Send memo to EPL/PM or Vet PM responsible for comments.	AD in S-CS-SME
4	EPL/PM or Vet PM provides comments to AD in S-CS-SME.	EPL/PM in E-Division Vet PM in V-VM (as applicable)
5	Confirm with rapporteur/co-rapporteur compliance with scientific advice by email (if applicable).	AD in S-CS-SME
6	Send to EPL/PM or Vet PM, Hser of scientific advice, Hdep and Hdiv for agreement (template 2).	AD in S-CS-SME
7	Inform A-FI (accountsreceivable@ema.europa.eu) of outcome (template 3).	AD-in S-CS-SME
8	Inform SME of outcome (template 4).	AD in S-CS-SME
	End of procedure	

10. Records

All documentation is filed electronically in the appropriately labelled folder in DREAM.