EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Processing of requests for fee reduction falling under paragraph 1 of Article 9 of Council Regulation (EC) No 297/95		
Status: **PUBLIC**		Document no.: SOP/EMA/0028
Lead author	Approver	Effective date: 23-JUL-20
Name: Claudia Galeazzo	Name: Nerimantas Steikunas	Review date: 23-JUL-22
Signature: On file	Signature: On file	Supersedes: SOP/EMA/0028 (09-MAR-17) (TW5216)
Date: 23-JUL-20	Date: 23-JUL-20	TrackWise record no.: 5531

1. Purpose

To describe the procedure for processing requests for fee reductions that may be granted by the Executive Director in exceptional circumstances and for imperative reasons of public or animal health under the terms of paragraph 1 of Article 9 of Regulation (EC) No 297/95 on fees payable to the European Medicines Agency.

This procedure does not cover the total or partial fee exemptions that may be granted under the terms of paragraph 2 of Article 9 of Regulation (EC) No 297/95 and are defined in the "Rules for the implementation of Regulation (EC) No 297/95 on fees payable to the European Medicines Agency and other measures" (such fee reductions do not require an Executive Decision and applicable fees are determined during validation of applications).

2. Scope

This SOP applies to:

- Administration and Corporate Management Division,
- Human Medicines Division,
- Veterinary Medicines Division,
- Office of Executive Director.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

3. Responsibilities

It is the responsibility of each Head of Division, Head of Department and Head of Office/Service to ensure that this procedure is adhered to within their own division, department and office/service. The responsibility for the execution of a particular part of this procedure is identified in the right-hand column of section 9.

4. Changes since last revision

- Revision of the previous version (further clarification of responsibilities e.g. involvement Head of Service/Office in Human/Veterinary Divisions; HDiv consultation with ED prior to CXMP consultation is replaced with an acknowledgment procedure; greater degree of granularity of steps in case of divergent opinion of CXMP)
- Paper workflow has been replaced by electronic workflow (removal of paper transmission slip, introduction of electronic workflow and electronic signatures in processing form (template 1))
- Updated roles, responsibilities and references in line with new organisational structure as of 1 March 2020 following re-organisation.

5. Documents needed for this SOP

Template 1: Article 9 (para 1) template for fee reduction processing form (located at Cabinets/06. Corporate Governance/06.2 Integrated Management System/2. IMS Manual/2. Corporate controlled documents/4. SOPs and WINs/*0001 – 0999 EMA (cross-Agency)/ 0028 SOP – Processing of requests for fee reduction […]) https://docs.eudra.org/webtop/drl/objectId/090142b2825c83c4)

Template 2: Article 9 (para 1) template for Executive Decision on granting of fee reduction (located at Cabinets/06. Corporate Governance/06.2 Integrated Management System/2. IMS Manual/2. Corporate controlled documents/4. SOPs and WINs/*0001 – 0999 EMA (cross-Agency)/ 0028 SOP – Processing of requests for fee reduction […]) https://docs.eudra.org/webtop/drl/objectId/090142b2822de3e2)

Template 3: Article 9 (para 1) template for Executive Decision on non-granting of fee reduction (located at Cabinets/06. Corporate Governance/06.2 Integrated Management System/2. IMS Manual/2. Corporate controlled documents/4. SOPs and WINs/*0001 – 0999 EMA (cross-Agency)/ 0028 SOP – Processing of requests for fee reduction […]) https://docs.eudra.org/webtop/drl/objectId/090142b2822de3e5)

Template 4: Record of Article 9 (para 1) requests for fee reduction (located at Cabinets/06. Corporate Governance/06.2 Integrated Management System/2. IMS Manual/2. Corporate controlled documents/4. SOPs and WINs/*0001 – 0999 EMA (cross-Agency)/ 0028 SOP – Processing of requests for fee reduction […]) https://docs.eudra.org/webtop/drl/objectId/090142b28262e318)

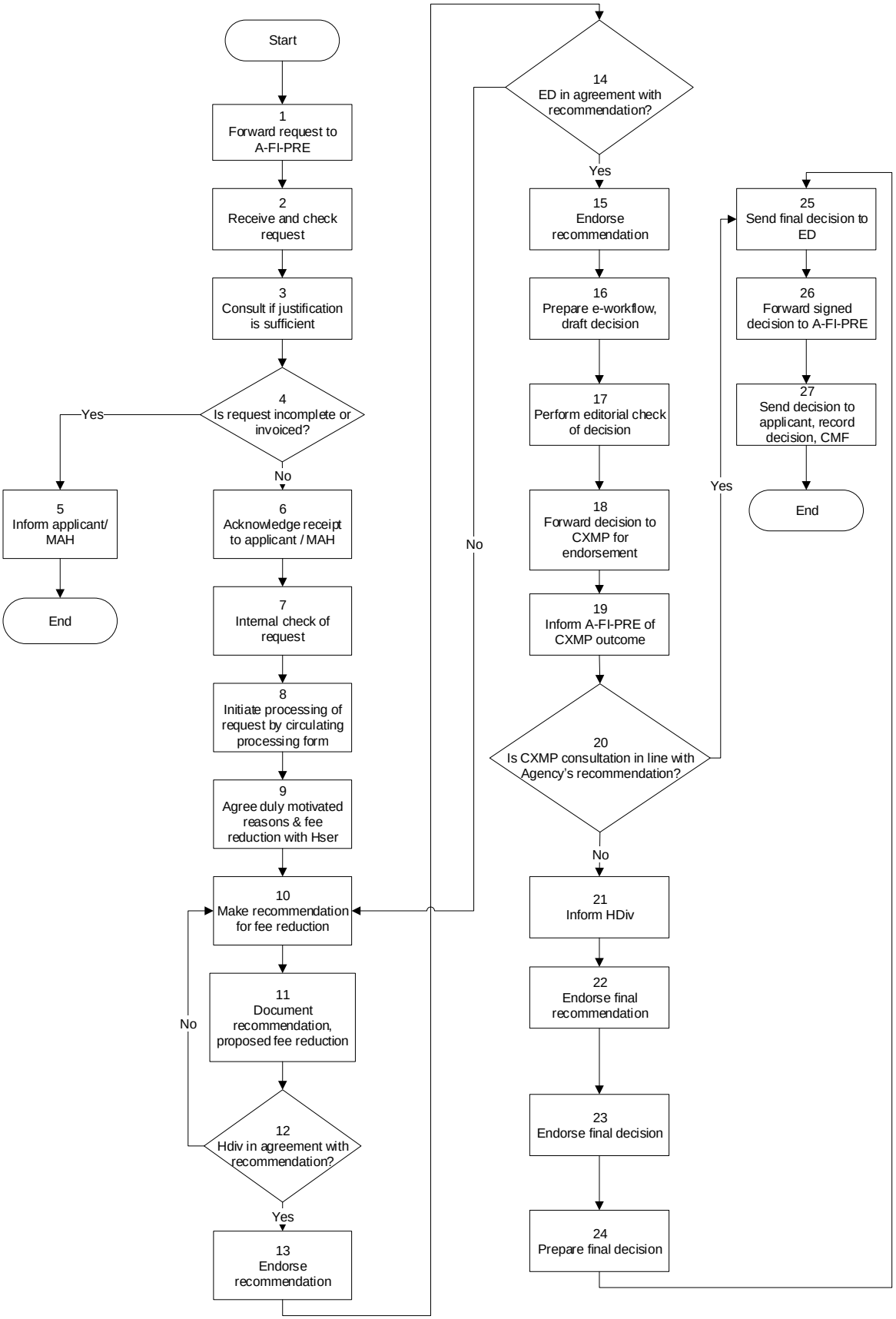
Related documents

- Regulation (EC) No 297/95 on fees payable to the European Medicines Agency (consolidated version: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2011/03/WC500103547.pdf
- Rules for the implementation of Regulation (EC) No 297/95 on fees payable to the European Medicines Agency and other measures (http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000327.jsp&mid=WC0b01ac0580024596)
- Explanatory note on fees payable to the European Medicines Agency http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000327.jsp&mid=WC0b01ac0580024596

6. Definitions

A-FI-PRE:	Procedures Revenue and Expenditure Service (Financial Team)
A-SG-QRM:	Quality and Risk Management Service
Applicant:	Applicant for a procedure
CXMP:	Committee on Medicinal Products for Human Use, Committee on Medicinal Products for Veterinary Use, Committee for Advanced Therapies or Committee for Herbal Medicinal Products
DREAM:	Document records electronic archive management system
ED:	Executive Director
ED-EXO:	Executive Office
HDiv:	Head of Division (H-, A- or V-Division)
HOff	Head of Office
HSer	Head of Service
MAH:	Marketing authorisation holder
PL (hum):	Product lead in Human Division
PSM:	Product shared mailbox
SAA:	Scientific advice administrator
SL (vet):	Scientific lead in Veterinary Division
SMEs:	Micro- small & medium-sized enterprises

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



8. Procedure

Notes:

Applicants and MAHs are required to send a formal request for fee reduction addressed to the Executive Director citing Article 9 paragraph 1, providing details of the product, procedure type and applicable fee, and the reason(s) for the request that justify exceptional circumstances and imperative reasons of public or animal health.

It is strongly recommended that the request be sent at least 2 months before the date of submission of the relevant application. Further details for applicants and MAHs are available in the Explanatory note on fees payable to European Medicines Agency.

In accordance with Article 62(4) of the Financial Regulation, the Executive Director cannot delegate the decision on those fee reductions as they are routinely above the value of EUR 5,000.

Step	Action	Responsibility
	Handling of request and initial recommendation	
1	On receipt forward formal request for fee reduction (or missing information, if returning from step 5) to A-FI-PRE.	ED-EXO
2	On receipt of the request from ED-EXO, check the request for completeness and whether the procedure(s) of the related request(s) have not yet started or been invoiced (*reject request if the procedure has started or been invoiced (go to step 6))* Save all received documents in relevant DREAM Product folder (path example: 01. Evaluation of Medicines/H-C/G-I/Product name/05 Post Authorisation/Post Activities/Art 9.1 fee reduction requests, or if product folder not available: 14. Working areas/14.09 A-Division/02. A-FI-Activities/ A-FI-PRE/ 02.Financial/Operations/Art 9.1 Fee reduction requests) Prepare Processing form (Template 1) Complete section A of processing form (Template 1). Update Record of Art. 9.1 requests for fee reduction (Template 4) with a new request	A-FI-PRE
3	Consult HSer/HOff and cc PL(hum)/SL(vet)/SAA if sufficient justification is provided (when in doubt)	A-FI-PRE
4	If request is incomplete or procedure has already started or been invoiced, go to step 5. If request is complete, go to step 6.	A-FI-PRE
5	Inform applicant/MAH that request is incomplete or received outside the allowed time and indicate required details. End of process.	A-FI-PRE

Step	Action	Responsibility
6	Send acknowledgement of receipt to Applicant by return e-mail.	A-FI-PRE
7	Perform consistency check Propose fee reduction amount Sign electronically Section A of processing form	HSer (A-FI-PRE)
8	Provide HSer/HOff cc PL(hum)/SL(vet)/SAA (as applicable) and Product shared mailbox PSM with link to Applicant's request letter and processing form asking to complete section B of processing form (Template 1).	A-FI-PRE
9	Check against previous requests in Record of Art. 9.1 requests for fee reduction (Template 4) to ensure consistency of decisions and non-discriminatory handling of the request. Agree with HSer/HOff concerned the duly motivated reason(s), proposed fee reduction amount (if applicable).	PL(hum)/SL(vet)/SAA
10	Make recommendation for a fee reduction: either positive (i.e. to be accepted) or negative (i.e. to be refused).	HSer/HOff
11	Complete and sign electronically section B of processing form (Template 1) with: (i) the duly motivated reason(s) for acceptance or refusal of the request (ii) the agreed proposed fee reduction amount Notify completion by e-mail to HDiv cc A-FI-PRE	HSer/HOff
12	If HDiv is in agreement with recommendation in section B, go to step 13 If HDiv is not in agreement with recommendation, go to step 10	HDiv
13	Sign electronically recommendation in section C of Processing form (Template 1) Notify completion by e-mail to ED-EXO cc A-FI-PRE	HDiv
14	If ED is in agreement with recommendation in section -B of Processing form, go to step 15 If ED is not in agreement with the recommendation, go to step 10.	ED-EXO
15	Acknowledge recommendation in processing form section B (Template 1) Sign electronically recommendation processing form section C (Template 1) and notify A-FI-PRE	ED-EXO
16	Prepare electronic workflow via email including the below documents and circulate for electronic signatures	A-FI-PRE

Step	Action	Responsibility
	• Applicant's request letter • Processing form (Template 1) with inclusion of the duly motivated reason(s) for acceptance or refusal, proposed fee reduction amount (if applicable) and recommendation on CXMP consultation. • Executive Decision on granting of fee reduction (Template 2) or Executive Decision on non-granting of fee reduction (Template 3) • Record of Art. 9.1 requests for fee reduction (Template 4)	
17	Perform editorial check of draft Executive Decision Sign electronically processing form Section C Notify completion via email to A-FI-PRE	HSer (A-SG-QRM)
	Consultation with CXMP	
18	1) Request Agenda item from CXMP Secretariat Table in MMD request from MAH (for information) and draft Executive Decision (template 2 or 3) for silent adoption. Or alternatively, 2) in case of urgent request use CXMP written procedure, send draft Executive Decision and request from applicant/MAH by Eudralink to CXMP members and provide a deadline. Note: CXMP considers request on the basis of the justifications provided and previous outcomes. Members send their comments in writing by Eudralink. If no comments received, the request is considered accepted. Go to step 18.	A-FI-PRE
19	Inform A-FI-PRE of the CXMP consultation outcome by the end of CXMP meeting.	PL(hum)/SL(vet)/SAA
	Finalisation of Executive Decision	
20	If CXMP consultation is in line with Agency's recommendation, go to step 25. If CXMP consultation is not in line with Agency's recommendation, go to step 21.	A-FI-PRE
21	Inform HDiv concerned of CXMP's consultation divergent outcome and provide further recommendation in processing form Section D box.	HOff/HSer
22	Endorse electronically final recommendation in processing form Section D Send updated processing form to ED for final decision and signature and cc A-FI-PRE	HDiv

Step	Action	Responsibility
23	Sign electronically final recommendation in processing form Section D box. Notify completion via email to A-FI-PRE	ED-EXO
24	Prepare final Executive Decision in line with processing form Section D	A-FI-PRE
25	Email final Executive Decision to ED-EXO for ED's signature.	A-FI-PRE
26	When Executive Decision is signed electronically by ED -retain a copy for ED-EXO files. Forward via email signed Executive Decision to A-FI-PRE.	ED-EXO
27	On receipt of the signed Executive Decision from ED-EXO, send via Eudralink to applicant/MAH. If the final decision is not in line with CXMP's consultation outcome, copy CXMP secretariat for the attention of CXMP. Inform PL(hum)/SL(vet)/SAA (as applicable) of final decision. Save in DREAM signed Executive Decision (template 2 or 3) Record decision in the Record of Art.9.1 requests for fee reduction (Template 4). Complete section E of processing form (Template 1). Core Master File documents as per point 10	A-FI-PRE

9. Records

The below should be Core Master Filed in DREAM.

At least the following documents should be archived in the DREAM Core Master file:

- applicant's/MAH's original request;
- acknowledgement of receipt email;
- signed processing form (Template 1);
- signed Executive Decision.
- Email dispatch of the ED Decision to MAH