EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Processing of requests for fee reduction falling under paragraph 5 of Article 6 of Regulation (EU) 2024/568		
Status: **PUBLIC**		Document no.: SOP/EMA/0028
Lead author	Approver	Effective date: 01-JAN-2025
[On file]	[On file]	Review date: 01-JAN-2028
Signature: [Signature on file]	Signature: [Signature on file]	Supersedes: SOP/EMA/0028 (23-JUL-2020) (TW5216)
		Doc ref: EMA/78251/2024

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 5 of Article 6 of Regulation (EU) 2024/568 on fees and charges payable to the European Medicines Agency.

This procedure does not cover the total or partial fee reductions that may be granted under the terms of Annex V to Regulation (EU) 2024/568 (such fee reductions do not require an Executive Decision and the applicable fees are determined at the relevant timepoint depending on the type of procedure (e.g. submission, validation).

2. Scope

This SOP applies to:

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

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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 8.

4. Changes since last revision

- Revision of the previous version dated 23rd July 2020 to align the procedure with the New Fee Regulation (EU) 2024/568 on fees and charges payable to the European Medicines Agency:
  - removal of CXMP consultation step,
  - update of legislative references,
  - introducing the provision of making information on such reductions of the fees, including the reasons for the reductions, publicly available on the Agency's website, after deletion of all information of a commercially confidential nature (in an aggregated form within the Agency's Annual Activity Report).
- Further clarification of responsibilities e.g. delegation of acknowledgement of recommendation from Head of Division to Head of Department (for Human Medicines Division),
- Introduction of DocuSign electronic signatures in processing form (template 1)), which replaces electronic signatures in pdf file format of the processing form,
- Update of roles, responsibilities and references in line with the latest organisational structure as of 1st October 2024.

5. Documents needed for this SOP

Template 1: Article 6 (para 5) 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/090142b285fc219c)

Template 2: Article 6 (para 5) 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/090142b285fc238c)

Template 3: Article 6 (para 5) 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/090142b285fc23f0)

Template 4: Record of Article 6 (para 5) 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)

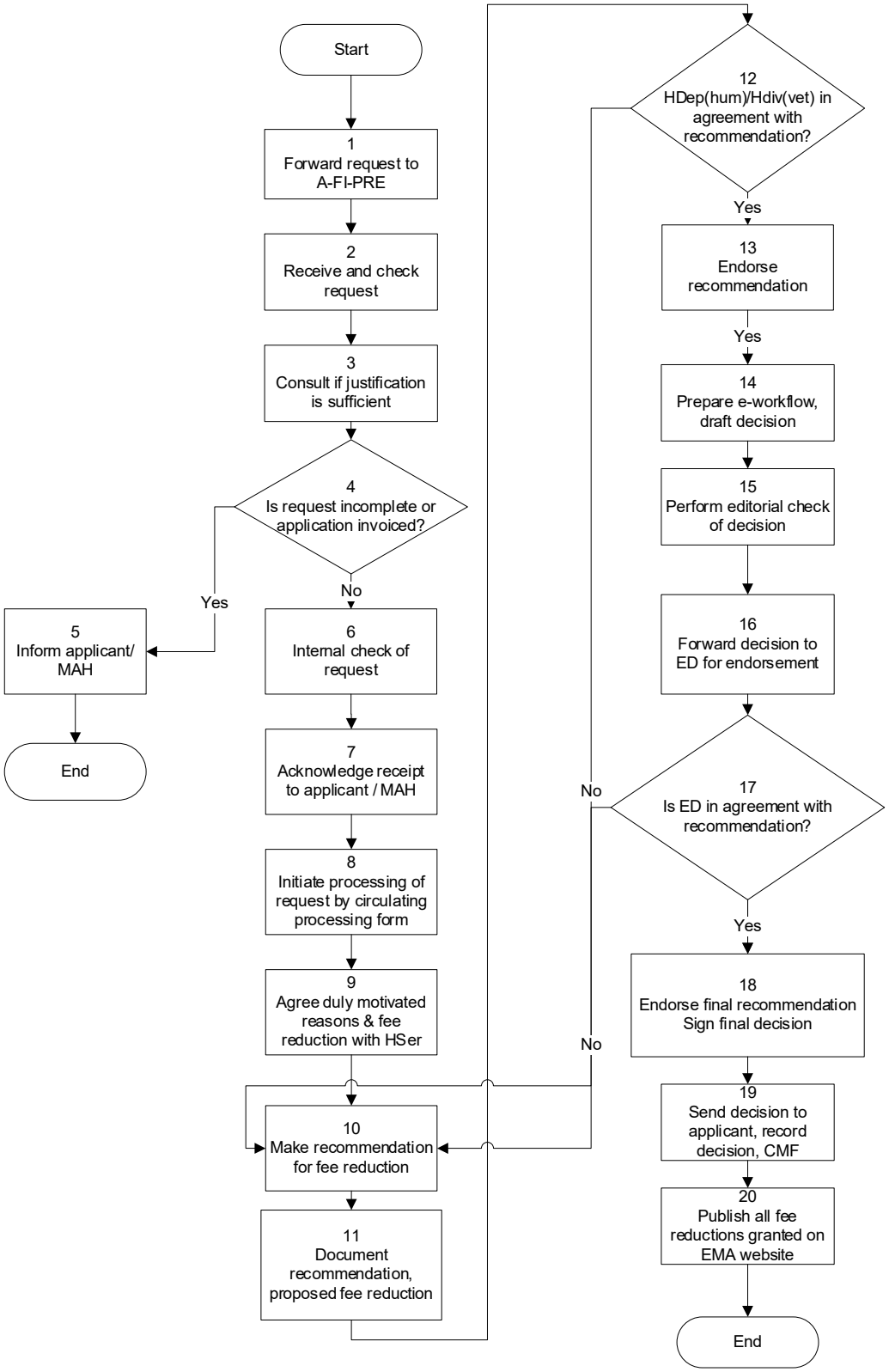
Related documents

- Regulation (EU) 2024/568 on fees and charges payable to the European Medicines Agency (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32024R0568)
- New Fee Regulation working arrangements (https://www.ema.europa.eu/en/about-us/fees-payable-european-medicines-agency/new-fee-regulation-1-january-2025#working-arrangements-70276)
- NFR Question and Answer document (https://www.ema.europa.eu/en/about-us/fees-payable-european-medicines-agency/new-fee-regulation-1-january-2025#new-fee-regulation-questions-and-answers-70278)

6. Definitions

A-FI-PRE:	Procedures Revenue and Expenditure Service (Financial Team)
A-SG-QRM:	Quality and Risk Management Service
A-SG-SPB:	Strategic Planning and Budget Service
Applicant:	Applicant for a procedure
DREAM:	Document records electronic archive management system
ED:	Executive Director
ED-EXO:	Office of the Executive Office
HDiv:	Head of Division
HDep:	Head of Department
HOff	Head of Office
HSer	Head of Service
MAH:	Marketing authorisation holder
PL (hum):	Product lead in Human Medicines Division
PSM:	Product shared mailbox
SAA:	Scientific advice administrator
SL (vet):	Scientific lead in Veterinary Medicines Division
SMEs:	Micro, small & medium-sized enterprises
TRS-ACD	Regulatory Science and Academia Service
V-VSS (vet):	Veterinary Strategic Support Office

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



8. Procedure

Notes:

Applicants and MAHs may request the Executive Director to grant an ad hoc fee reduction under the provisions of paragraph 5 of Article 6 of Regulation (EU) 2024/568.

Applicants of said fee reductions are required to provide sufficient justification to demonstrate that the request is made (1) in exceptional circumstances and (2) for imperative reasons of public or animal health. The request will be considered by the Executive Director, who will decide each request on a case-by-case basis.

In accordance with Article 5(3) point (vii) of the "Decision of the Executive Director on internal rules on the implementation of the budget of the European Medicines Agency" the Executive Director cannot delegate the decision on those fee reductions.

In view of the administrative procedure that must be followed, applicants are required to make their request for Article 6, paragraph 5, of Regulation (EU) 2024/568 in a letter to the Executive Director submitted at least six weeks before the date of submission of the relevant application or six weeks before the anniversary of the European Birth date of the Marketing Authorisation for Annual fees. The applicant should cite Article 6, paragraph 5, of Regulation (EU) 2024/568 and provide 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.

Applicants are informed that late requests may not be processed in time and may not be taken into consideration when determining the fee. Applicants are also informed that requests submitted after the receipt of an invoice or after the procedure has started will not be considered.

Further information on fees and fee reduction is available on the Agency's website (https://www.ema.europa.eu/en/about-us/fees-payable-european-medicines-agency)

Step	Action	Responsibility
	Handling of request and initial recommendation	
1	On receipt, forward a 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 5))* 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 6.5 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 6.5 Fee reduction requests) Prepare Processing form (Template 1) Complete section A of processing form (Template 1) Update Record of Art. 6.5 requests for fee reduction (Template 4) with a new request.	A-FI-PRE
3	When in doubt if sufficient justification has been provided, consult HSer/HOff and cc PL(hum)/SL(vet) and a nominated V-VSS Administrator(vet)/SAA and HSer TRS-ACD (for requests from not-for-profit organisation and the academic sector) and Product shared mailbox PSM	A-FI-PRE
4	If request is incomplete or the 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 the request is incomplete (and indicate required details) or that it has been received outside the allowed timeframe. End of process.	A-FI-PRE
6	Perform consistency check Propose fee reduction amount Sign electronically via DocuSign Section A of processing form.	HSer (A-FI-PRE)
7	Send acknowledgement of receipt to Applicant by return e-mail.	A-FI-PRE
8	Provide HSer/HOff and cc PL(hum)/SL(vet) and a nominated V-VSS Administrator(vet)/SAA and HSer TRS-ACD (for requests from not-for-profit organisation and the academic sector) and Product shared	A-FI-PRE

Step	Action	Responsibility
	mailbox PSM with link to Applicant's request letter and processing form asking to complete section B of processing form (Template 1).	
9	Concerned HSer/HOff(hum) or SL(vet) or SAA checks against previous requests in Record of Art. 6.5 requests for fee reduction (Template 4) to ensure consistency of decisions and non-discriminatory handling of the request. SL(vet) agrees with HSer/Hoff(vet) the duly motivated reason(s), proposed fee reduction amount (if applicable).	HSer/HOff (hum)/SL(vet)/SAA
10	Concerned HSer/HOff makes 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 via DocuSign 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 HDep (hum)/HDiv (vet) cc A-FI-PRE.	HSer/HOff
12	If concerned HDep (hum)/HDiv (vet) is in agreement with recommendation in section B, go to step 13 If concerned HDep (hum)/HDiv (vet) is not in agreement with recommendation, go to step 10.	HDep (hum)/HDiv (vet)
13	Concerned HDep (hum)/HDiv (vet) signs electronically via DocuSign recommendation in section C of Processing form (Template 1) And notifies completion by e-mail to A-FI-PRE.	HDep (hum)/HDiv (vet)
14	Prepare electronic workflow via email including the below documents and circulate for electronic signatures via DocuSign to HSer (A-SG-QRM): • 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) • Draft Executive Decision on granting of fee reduction (Template 2) or Executive Decision on non-granting of fee reduction (Template 3) • Record of Art. 6.5 requests for fee reduction (Template 4).	A-FI-PRE
15	Perform editorial check of draft Executive Decision Sign electronically via DocuSign processing form Section C Notify completion via email to A-FI-PRE.	HSer (A-SG-QRM)

Step	Action	Responsibility
16	Email Executive Decision to ED-EXO for ED's signature.	A-FI-PRE
17	If ED is in agreement with recommendation in section B of Processing form, go to step 18 If ED is not in agreement with the recommendation, go to step 10.	ED-EXO
	Finalisation of Executive Decision	
18	Acknowledge recommendation in processing form section B (Template 1) Sign electronically via DocuSign: - recommendation in the processing form section C (Template 1) - Executive Decision 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
19	On receipt of the signed Executive Decision from ED-EXO, send via Eudralink to applicant/MAH. 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.6.5 requests for fee reduction (Template 4) Complete section E of processing form (Template 1) Core Master File documents as per section 9.	A-FI-PRE
20	Each year publish information on all fee reductions granted within the past year in the Agency's Annual Activity Report Compile the list of all ED decisions on granted fee reductions within the past year, including reasons for the reductions. Delete all the commercially confidential information. Send to Strategic Planning and Budget Service (A-SG-SPB) for inclusion in the Annual Activity Report., and subsequent publication on Agency's website.	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 (Template 2 or Template 3);
- email dispatch of the ED Decision to Applicant/MAH.