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SCIENCE MEDICINES HEALTH

NFR impact on RnD processes

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Orphan and paediatric medicines – New fees introduced

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Orphan medicines

- Application for OD
- Maintenance of OD

EUR 20 000, WAIVED IN FULL

Paediatric medicines

- Initial PIP
- Modification of agreed PIP
- Product specific waiver
- Compliance check

EUR 38 100 – EUR 9 600, WAIVED IN FULL

Scientific Advice – Simplified structure

Introduction of administrative charges – all processes excl. Maintenance of OD

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withdrawn after 24 hours of its **submission** and prior to completion of the administrative validation

application rejected following the conclusion of the administrative validation

applicant claiming, or having claimed, to be entitled to a fee reduction, **fails to demonstrate that it is entitled to such a reduction**

EUR 4 400

Fee reductions for Scientific Advice

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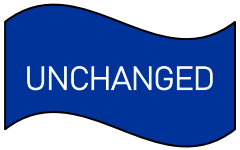
Micro, small and medium sized enterprises (SMEs)

non-orphan 90% fee reduction
orphan 100% fee reduction



Medicinal products for paediatric use

development for paediatric population, (does not include the adult population)
100% fee reduction

Advanced therapy medicinal products (ATMP)

SA non-SME 65% fee reduction
SA SME 90% fee reduction

Designated orphan medicinal products

PA non-SME 75% fee reduction
PA SME 100% fee reduction

ETF advice during a declared public health emergency

Accelerated scientific advice on main aspects of CTs & CT protocols related to a declared PHE 100% fee reduction

Fee reductions for Scientific Advice

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Fee reductions applied to entities not engaged in an economic activity

Entities and requests for scientific advice compliant with section 1.8 of the Fee Regulation Working arrangements

100% fee reduction

Pandemic vaccines

Requests related to a core dossier for a pandemic vaccine until such a human pandemic situation is duly recognised either by the WHO or by the EC

100% fee reduction

Fee reductions for Scientific Advice

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OBSOLETE

Scientific Advice for PRIME scheme

A total exemption from the payment of the fees for requests for scientific advice and follow-up requests submitted on products eligible to PRIME scheme for SMEs and applicants of the academic sector

Protocol Assistance for academia

A total exemption from the payment of the fees for Protocol Assistance for applicants of the academic sector

Prepayment for Scientific Advice

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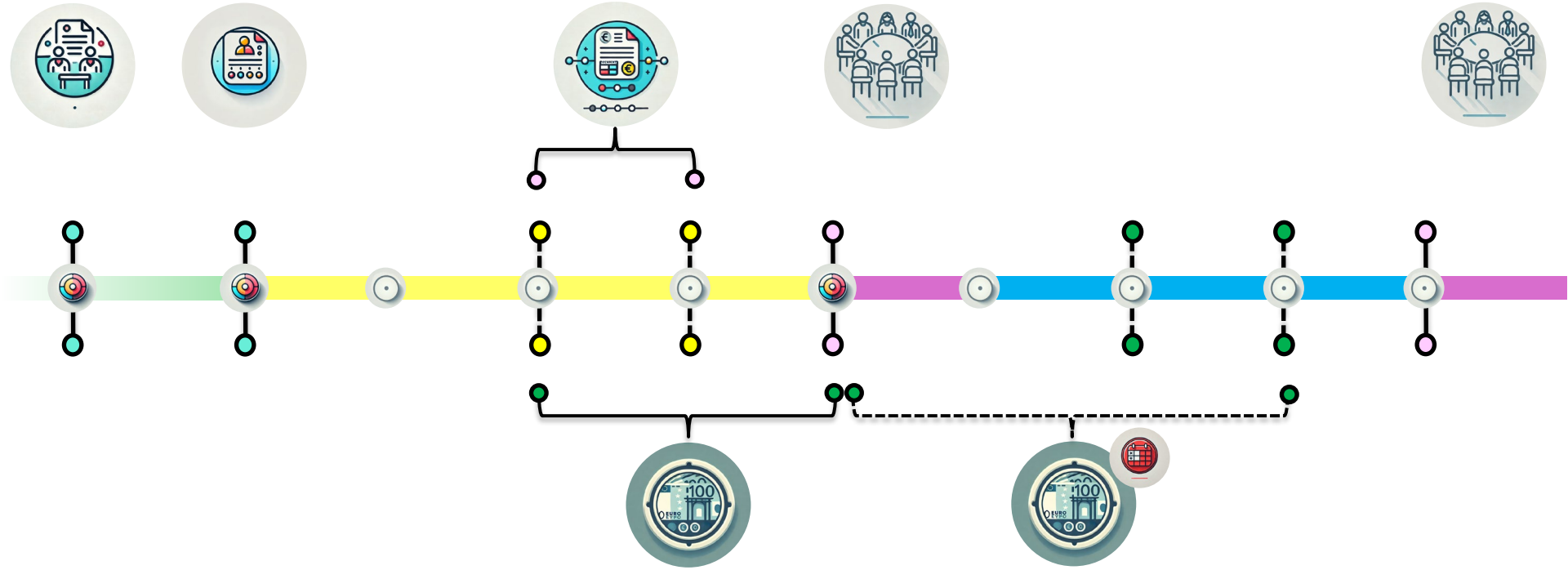
SUBMISSION

VALIDATION & INVOICE CREATION

SAWP1

INVOICE DUE DATE

SAWP2



Financial matters

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Why prepayment?

Art.71 Financial Regulation
*"The Union body shall provide **services** by virtue of the tasks entrusted to it **only after** the corresponding fee or charge has been **paid** in its entirety"*

When is the fee due?

- Fees for Scientific Advice are **due at notification of 'validation'**
- The administrative validation consists in the verification of all the elements of the SA request, which leads consequently to the **determination of the fee due**
- It is not possible to issue an invoice at submission date, i.e. before completion of the administrative validation. EMA will aim for the **shortest possible** administrative validation period

How to pay?

- Payment **after receipt of an invoice** from the Agency, by bank transfer
  - SEPA transfer (initiation to receipt of payment) up to 48 hours; aiming for **straight-through processing** of **EMA invoices** by companies i.e. prevent rejections by AP systems; check billing address, PO numbers with financial contact point(s) email prior to receiving an invoice
- Clarification to industry's concern about **SEPA direct debit** system:
  - it is **not mandatory** and its implementation is not expected earlier than late Q1/early Q2
  - SEPA DD does not mean a 'blanket' mandate: no collection before the invoice is issued and collection only for the specific invoice amount
  - system may be **more suitable for high volumes** of requests with **low unit value** although no actual restrictions
  - yes, it requires some adaptation to the process

Useful links

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Legal basis

Regulation (EU) 2024/568 of the European Parliament and of the Council of 7 February 2024 on fees and charges payable to the European Medicines Agency, amending Regulations (EU) 2017/745 and (EU) 2022/123 of the European Parliament and of the Council and repealing Regulation (EU) No 658/2014 of the European Parliament and of the Council and Council Regulation (EC) No 297/95

Working arrangements

new-fee-regulation-working-arrangements_en.pdf

Questions & Answers

01 Q&As Annex I_Fees charges and remuneration for assessment procedures and services relating to medicinal products for human usenew-fee-regulation-working-arrangements_en.pdf

NFR webpage

New Fee Regulation (from 1 January 2025) | European Medicines Agency (EMA)

How to pay

How to pay | European Medicines Agency (EMA)

Scientific Advice submission deadlines

2025 SAWP meeting dates and submission deadlines

Contact points

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Technical issues

ServiceNow

Invoicing questions/disputes for Scientific Advice

Via IRIS case

General queries on Scientific Advice

scientific.advice@ema.europa.eu

Thank you for your attention!

Any questions?