EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

New fee regulation

Introductory webinar for veterinary marketing authorisation holders

Presented on 20 June 2024

Agenda

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1	**Welcome** *Jean Michel Mastio, Head of Finance Department, EMA*	**10.00 – 10:05 CEST**
2	**Introduction and background to the New Fee Regulation** *Patrick Lopez Fernandez, Procedure, Revenue and Expenditure, EMA*	**10.05 – 10:15 CEST**
3	**Changes applicable to veterinary procedures** *Anna Vecellio, Veterinary Planning and Reporting Specialist, EMA* *Paola Samassa, Accounting Officer, EMA*	**10:15 – 10:45 CEST**
4	**Further information, Q&A session and closing** *Paola Samassa, Accounting Officer, EMA* *Catarina Ferreira, Veterinary Communication and Change Management Officer, EMA*	**10:45 – 11:00 CEST**

New fee regulation

Introduction and background

Regulation review cycle background

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EU Regulations usually have a **10-year review cycle**.

The review of the general EMA fee system was due in 2010. It was **re-prioritised due to the revision of the EU pharmacovigilance legislation,** which triggered a targeted **new legal proposal for PhV fees**.

Since 2015, the European Commission (EC) has been working on **the review of the EMA fee system**, in consultation with EMA (including a "data gathering" exercise) and NCAs.

In **December 2022, EC published a proposal for a revised EMA Fee Regulation.** The proposal was reviewed by the European Parliament (EP) and Council through the ordinary legislative procedure.

EP and Council agreed on a revised EMA Fee Regulation in September 2023.

Final adoption and formal publication on 7 February 2024.

Regulation (EU) 2024/568 will become applicable on **1 January 2025**.

Drivers for a new fee regulation

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Current state

Fees levied by EMA are laid down in <u>two regulations</u>

- Council Regulation (EC) No 297/95 on the general fees for the Agency (for centrally authorised human and veterinary medicines)
- Regulation (EU) No 658/2014 for pharmacovigilance activities (centrally and nationally authorised human medicines only)

Need for harmonisation and updates

From 1 January 2025

A **single framework for a streamlined fee system** for the Agency

The fees payable to the Agency will be:

- **proportionate to the work** carried out reflecting **complex evaluations** and;
- **based on the workload and actual costs** for the services delivered by EMA and NCA (Network remuneration based on hours recorded and roles of rapporteur / co-rapporteur)

High-level changes for industry

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- **Simplification** of the fee calculation
- **Update of fee structures** now calculated per procedure and based on actual costs incurred across 30 EEA Member States and EMA
- **Modification of administrative fees** for withdrawal and for changes to the intended submission date
- **Revision of payment methods and terms** for high-volume applications *(e.g., scientific advice, certificates and parallel distribution)*
- **Removal of certain fees** *(e.g., for variations requiring assessment with reduced timetable)*
- **Introduction of new fees** *(e.g., for pre-submission, referrals, and re-examination of opinions)*
- **Introduction of a pharmacovigilance annual fee** for veterinary nationally authorised products (V)
- **Revision of the methodology to apply incentives** for veterinary medicinal products' procedures (V)

Changes applicable to veterinary procedures

Procedures impacted by minor changes (1/3)

CURRENT

FROM 1ST JANUARY 2025

INITIAL MARKETING AUTHORISATION APPLICATION

- 3 levels of basic fees with separate fees for additional strength or form and presentation

- *3 different fee levels with no separate fee for additional strength or form and presentation*
- *Reduction of 50% for limited market and immunological*
- *Fee amount changed*

MAXIMUM RESIDUE LIMIT (MRL)

- 3 fee levels

- *3 different level of fees*
- *Reduction of 50% for limited market*
- *Fee amount changed*

Procedures impacted by minor changes (2/3)

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CURRENT

VARIATIONS

- 4 fee levels
- Additional charges for strength and presentation for fee level 1 (ex-extensions)

ANNUAL FEE (CAPs)

- *Currently 3 levels of annual fees and several reductions in place*

FROM 1ST JANUARY 2025

- *No fee for VRA-R (level 4 lowest fee)*
- *3 fees for VRA, based on type of change and timetable length, no additional charges for additional presentation/strength*
- *Reduction of 50% for limited market and immunological*
- *Fee reduction for third onwards scope in grouping still applicable, WS charges still applicable*
- *Fee amount changed*

- *2 different levels of fees*
- *Reduction of 50% for limited market and immunological (on the total fee calculated in the Regulation)*
- *Reduction of 25% for the remaining products (on the total fee calculated in the Regulation)*
- *Fee amount changed*

Procedures impacted by minor changes (3/3)

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CURRENT

FROM 1ST JANUARY 2025

CERTIFICATION FOR COMPLIANCE FOR VAMFS (AND VPTMF)

- 3 fee levels

- *2 main fees for VAMFs and vPTMFs*
- *VRA fees applicable for variations to VAMF/vPTMF*
- *Reduction of 50% for limited market and immunological*
- *Fee amount changed*

SCIENTIFIC OPINION UNDER ART.138 (ON EVALUATION OF MP OUTSIDE EU)

- 3 levels of basic fees with separate fees for additional strength or form and presentation

- *Mirror initial applications*

Procedures impacted by major changes (1/4)

CURRENT

SCIENTIFIC ADVICE

- Separate fee for initial and follow-up advice

PRE-SUBMISSION ACTIVITIES

- *Currently, no fee charged*

FROM 1ST JANUARY 2025

- *Changes to payment methods and terms*
- *No distinction between initial and follow-up advice*
- *Reduction of 50% for limited market and immunological*
- *Fee amount changed*

- *These activities will be charged*
- *Reduction of 50% for limited market and immunological*
- *Introduction of an admin fee for changes to the intended submission date by more than 60 days*

Procedures impacted by major changes (2/4)

CURRENT

REFERRALS

- 1 fee level payable only when triggered by MAHs

ANNUAL PHARMACOVIGILANCE FEE

- *Currently, no fee charged*

FROM 1ST JANUARY 2025

- *5 different fee levels, calculated using chargeable units, payable by MAHs (where applicable) regardless who triggered the referral*
- *3 fess are fully waived*
- *All fees foresee remuneration to rapporteurs*
- *Fee amount changed*

- *Fee to be charged similarly to human pharmacovigilance annual fee, calculation based on chargeable units*
- *Reduction of 25% for generics and other type of products*

Procedures impacted by major changes (3/4)

CURRENT

FROM 1ST JANUARY 2025

RE-EXAMINATION OF PROCEDURES

- Currently, no fee charged

- *These procedures will be charged*
- *Applies to CVMP opinion on initial MAs, MRLs, referrals, variations*

RE-EXAMINATION OF A MARKETING AUTHORISATION FOR LIMITED MARKETS

- *Currently no fee established as limited market legal basis and related 5 years re-examination provisions are new*

- *These procedures will be charged*
- *Applies only to re-examination mandated under Art. 24 of Reg (EU) 2019/6*

Procedures impacted by major changes (4/4)

CURRENT

FROM 1ST JANUARY 2025

POST-MARKETING SURVEILLANCE STUDIES

- *Currently, no fee charged*

- *These procedures will be charged*
- *Reduction of 50% for limited market and immunological*

Chargeable Unit (Reg (EU) 2024/568 Art. 2(2))

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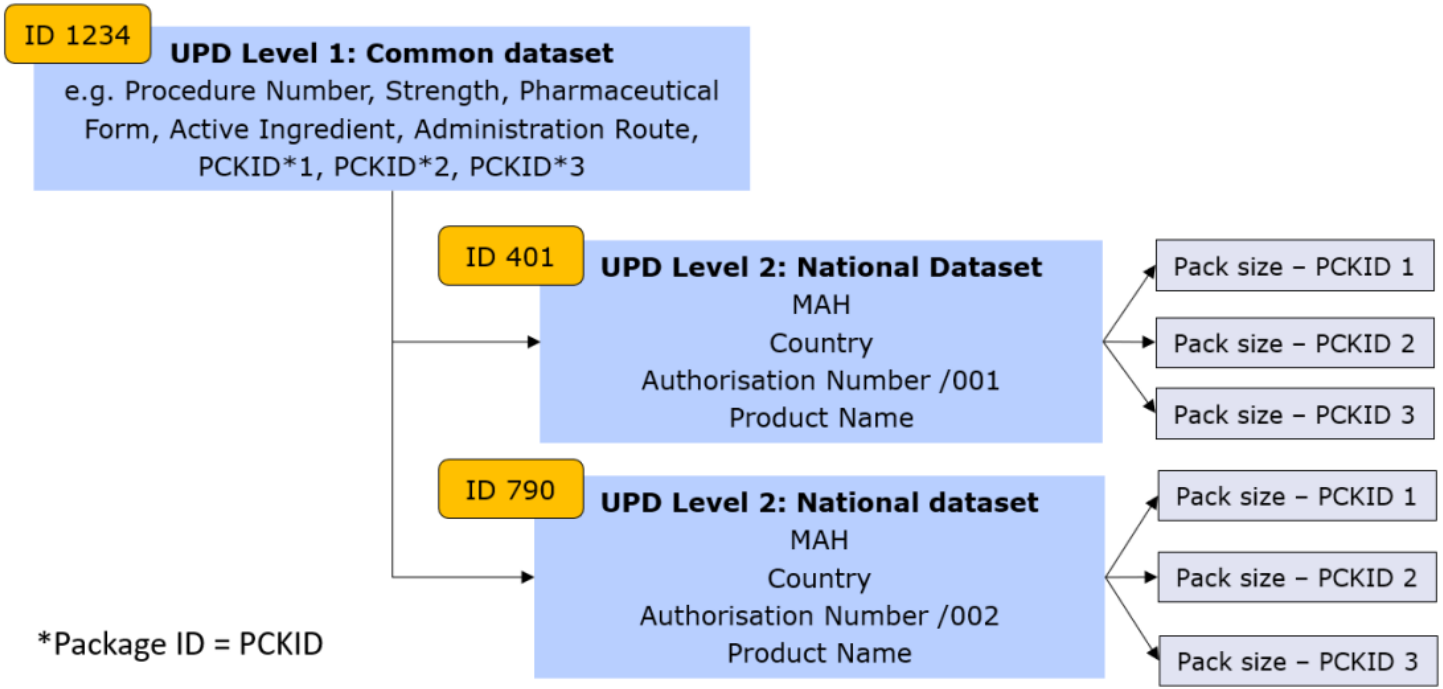
The following figure provides a visual representation of the UPD IDs, where ID 1234 stands for Product Identifier and ID 401 and ID 790 stand for Permanent Identifiers:



(from EU Implementation Guide (IG) on veterinary medicines product data - Chapter 2: Format for the electronic submission of veterinary medicinal product information)

QPPV email addresses in UPD

For pharmacovigilance annual fees and referrals, advice notes, chargeable units line listing(s) and communications will be **sent to the QPPV email address available in UPD**.

As communicated to UPD registered users on 18 June, veterinary marketing authorisation holders will be temporarily able to **enrich the QPPV details for their products in the UPD** by providing the relevant email address for future use.

New payment process for Scientific Advice and Certificates

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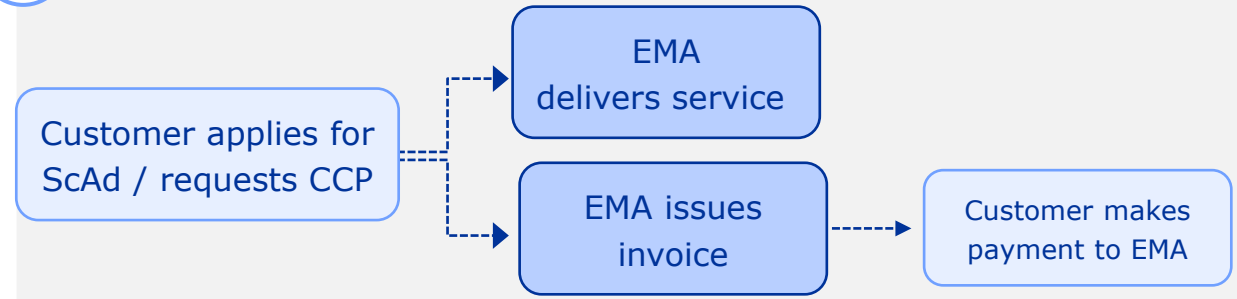
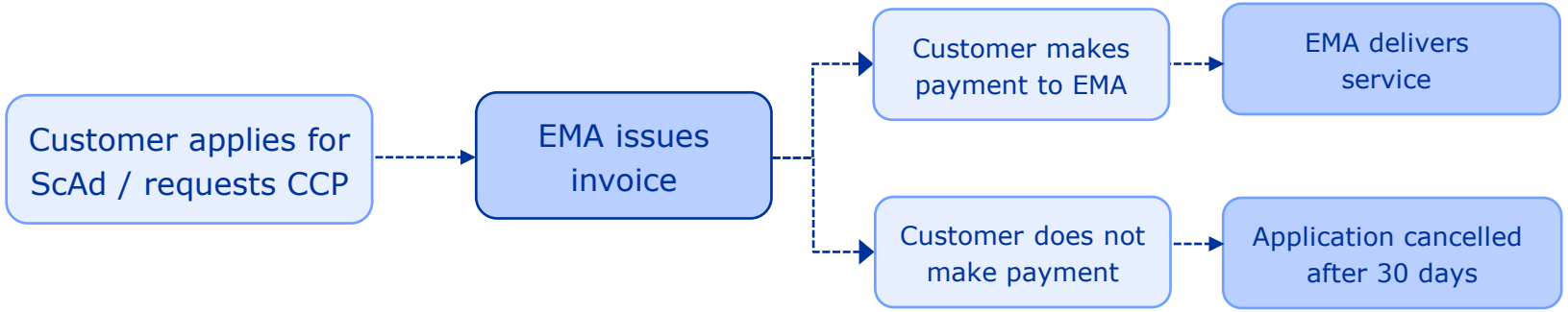
Current: provision of service is independent from fee having been paid



Future: provision of service only after fee has been paid in its entirety



New payment process for scientific advice and certificates

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Expected timelines for allocation of payments

DAY 1

Banking clearing time for **SEPA** typically **up to 24 hours**

DAY 2

Bank statement made available to EMA **next business day**

DAY 3

Bank transfer REFERENCE **MATCHES with** EMA invoice number

Customer makes payment to EMA → Payment received in EMA bank account → AUTOMATIC payment processing successful?

- AUTOMATIC payment processing successful? → EMA delivers service
- AUTOMATIC payment processing successful? → **MANUAL** processing (**++ DAYS**) → EMA delivers service

Important!

In the **bank transfer REFERENCE** the payer must quote the exact **EMA invoice number** as indicated on the invoice provided to the applicant at the submission

Further information, Q&A session and closing

Updates to available regulatory guidance

Regulatory documents will be updated and made available on EMA's website

EMA's **regulatory documents**, user guides, web pages and FAQ documents are in the process of being updated to reflect the changes brought by the new fee regulation and will be **released in Q4 2024.**

The **working arrangements**, established by the Management Board of the Agency to facilitate the application of the new fee regulation*, will be published on the **EMA website in July 2024**

*Article 8 of Regulation (EU) 2024/568 on fees and charges payable to the European Medicines Agency(NFR)

Industry stakeholders' engagement opportunities

Public System Demo

26 June 2024
18 September 2024

SME Info Day

18 October 2024

Second veterinary stakeholders
dedicated webinar

Q4 2024

For any questions, please email NFR@ema.europa.eu