What does this proposal cover?

(1) EMA fees and charges

- both pharmacovigilance and non-pharmacovigilance fees, in one single legal instrument

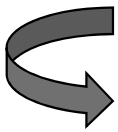
- charges: introduced to align with EMA founding regulation (e.g. for administrative services provided by EMA)

(2) Remuneration for the services provided by national competent authorities (NCAs)

(4) Fee reductions and waivers

- e.g. SMEs, some veterinary fees;

- reductions in 'sectoral' legislation continues to apply (e.g. orphan, pediatric, ATMPs, SME)



(5) Cost monitoring provisions

(6) Flexibility

- amendment of annexes through delegated acts, based on objective criteria

General objectives

- Contribute to a **sound financial basis supporting EMA's operations**, including **remuneration for services** rendered by NCAs to the EMA for the completion of its mandate.
- **Cost-based fee and remuneration amounts,** following a thorough evaluation of the costs of the EMA and its various statutory tasks and the cost of the NCA contributions to EMA's work.
- **Simplify the fee structure** and minimise the unnecessary complexity of the corresponding legal framework.

Specific objectives

- Address problems identified by the evaluation:
  - complexity of the fee system;
  - misalignment of some fees / NCA remuneration with underlying costs
  - lack of fees or NCA remuneration for some procedural activities
  - discrepancies between the main EMA Fee Regulation (Council Regulation (EC) No 297/95) and the Pharmacovigilance Fee Regulation (Regulation (EU) No 658/2014).
- Align to:
  - recent changes to the EMA Founding Regulation 726/2004
  - Regulation (EU) 2019/6 (VMP Regulation)

Current EMA Fee Framework ➡ Proposal

SectoralSectoral legislation on reductions

- Main EMA Fee Regulation (Council Regulation (EC) No 297/95)
  - Implementing rules: remuneration to NCAs
  - Adjustment of amounts: co-decision; automatic adjustment to inflation only
- Pharmacovigilance Fee Regulation (Regulation (EU) No 658/2014).
  - No implementing rules (remuneration to NCAs in legislation)
  - Adjustment of amounts: co-decision; delegated acts based on monitoring of inflation only

⬇

- Proposal: A **single legal instrument** bringing together all fees and respective remuneration.
  - Working arrangements (remuneration to NCAs in legislation)
  - Adjustment of amounts: delegated acts based on monitoring of inflation or monitoring of costs or changes to the legal mandate

The Commission Proposal

Regulation structure

17 Articles

- Subject matter
- Definitions
- Types of fees and charges
- Additional fees and charges
- Payment of remuneration to competent authorities of the Member States for the provision of services to the Agency
- Reductions
- Payment of fees and charges
- Working arrangements
- Due date and measures in case of non-payment
- Transparency and monitoring
- Revision
- Estimate of the Agency's budget
- Exercise of the delegation
- Amendment to Regulation (EU) No 2017/745
- Repeal
- Transitional provisions
- Entry into force and application

7 Annexes

- Fees, charges and remuneration for assessment procedures and services relating to medicinal products for human use
- Fees, charges and remuneration for assessment procedures and services relating to veterinary medicinal products
- Annual fees and remuneration (medicinal products for human use and veterinary medicinal products)
- Other fees and charges for medicinal products for human use, veterinary medicinal products and consultations on medical devices
- Fee reductions
- Performance information
- Correlation table

Main body of the draft regulation : zoom-in 1/7

- **Article 1** *Subject matter*
  - Fees, charges, remuneration, established on cost-based evaluation
  - Monitoring of costs, including cost for remuneration
- **Article 2** *Definitions*
  - ‘Chargeable unit’, defined also for veterinary medicinal products
- **Article 3** *Types of fees and charges*
  - Mapping of annexes: Human/Veterinary/Annual/Other (includes consultations for medical devices)
- **Article 4** *Additional fees and charges*
  - Flexibility: if a new scientific service is not covered by a fee or an administrative service needs to be covered by a charge. Must be within a range provided for in the annexes. Set by the EMA Management Board, following a favourable opinion by the Commission. Must be taken into account by Commission in a subsequent review.

Main body of the draft regulation : zoom-in 2/7

- **Article 5** *Payment of remuneration to NCAs for services to EMA*
  - Fee-related remuneration amounts: in annexes
  - Principle followed: NCA remuneration (provided for in annexes) not reduced when fee reductions apply (NCA workload is not affected by the fee reduction)
    - Support to products/applicants benefiting from reductions financed by overall EMA budget

- **Article 6** *Reductions of fees and charges*
  - Reduction rates, set out in annex, apply in addition to reductions laid down in sector-specific legislation: the most favourable apply.
  - Fees waived in case the assessment is requested by a MS or an EU institution
    - Remuneration paid nevertheless (pursuant to Article 5)

Main body of the draft regulation : zoom-in 3/7

- **Article 6** *Reductions of fees and charges (continued)*
  - Flexibility: beyond reductions provided for in the annexes, two possibilities for additional reductions:
    - Granted by EMA MB, on a duly justified proposal by the EMA Executive Director, following a favourable opinion of the Commission
    - Granted ad-hoc by the EMA Executive Director, in exceptional circumstances and for imperative health-related reasons
      - Except for PhV referrals, PSUR, PASS and post-marketing surveillance studies (Vet) and PhV annual fees. For all these fees the chargeable unit will be used for the calculation of the fee per marketing authorisation holder.
- **Article 7** *Payment of fees and charges* and **Article 9** *Due date and measures in case of non-payment*
  - Technical provisions e.g. due date for payment of fee/charge; deadline considered as complied with only if payment made in full; possibility of suspension of services in case of unpaid fees.

Main body of the draft regulation : zoom-in 4/7

- **Article 8** *Working arrangements*
  - Technical document adopted by the EMA Management Board, following a favourable opinion by the Commission, facilitating the application of the regulation
    - Greater level of technical detail, such as due dates
    - Amounts of additional fees/charges as per Art. 4, within the range provided for in the respective annex of the Regulation
    - Additional reductions granted by the Board pursuant to Art. 6
    - Detailed technical rules for payment of NCAs remuneration pursuant to Art. 5 (amounts in annexes of the Regulation)

Main body of the draft regulation : zoom-in 5/7

- **Article 10** *Transparency and monitoring*
  - EMA to provide detailed and substantiated information on the costs to be covered by fees and charges that are within the scope of this Regulation (in the annual activity report)
  - NCAs may provide every year, or les frequently, evidence of significant changes in the costs of services provided to EMA
    - excluding inflation and excluding activities that do not constitute a service to EMA,
    - in a common format to be provided by EMA + possible supporting information,
    - the information to be used for the special report below.
  - Every three years, EMA Executive Director may provide the Commission with a special report with recommendations to amend the annexes. Those recommendations need to be duly justified and supported by verifiable information and quantification.
    - Reporting frequency may be shortened in case of a public health emergency, a change of the legal mandate of EMA or in case there is clear and compelling evidence of significant changes in the costs or the cost-revenue balance of the Agency, including costs for cost-based remuneration to competent authorities of the Member States.

Main body of the draft regulation : zoom-in 6/7

- **Article 11** *Revision*
  - Flexibility: amendment of the annexes through delegated acts, when justified in view of:
    - the special report in accordance with Article 10,
    - the findings from the monitoring of the inflation rate,
    - a change in the statutory tasks of EMA leading to a significant change in its costs,
    - the budgetary reporting of EMA,
    - other relevant information, in particular on practical aspects for the execution of activities for which EMA collects fees or charges.
  - First occasion most likely the upcoming review of the basic pharmaceutical legislation
- **Article 12** *Estimate of EMA budget*
  - EMA to provide detailed information on income from each type of fees and charges and respective remuneration.
- **Article 13** *Exercise of the delegation (under Art. 11)*
  - Standard clause, 5-yearly report

Main body of the draft regulation : zoom-in 7/7

- **Article 14** *Amendment to Regulation (EU) No 2017/745 (MDR)*
  - Provides that fees for expert panels activities are payable to EMA (instead of to the Commission-consistency)
    - No other changes to that article of the MDR.
  - Such fees are not introduced by this proposal. Will be calculated and introduced at a later stage, in line with Art 106(13) of the MDR.
    - The fees in Annex IV of this proposal are for consultation on medical devices as part of a marketing authorisation, i.e. not for expert panels activities.
- **Articles 15,16,17** *Repeal, Transitional provisions, Entry into force and application*
  - Two current EMA fee regulations repealed.
  - References in sector-specific regulation to the current main fee regulation (Regulation (EC) No 297/95) continue to apply: correlation table
  - Cut-off dates (avoid double payment under the current/new rules)
  - 20 days + 6 months for applicability (EMA, industry and NCAs to prepare for changes)

Annexes – 1/3

- The final option implemented in the proposal can be seen as a compromise between the objectives '*simplification*' (less detailed fee grid) and '*cost-based*' (more detailed fee grid).

Examples:

- *Simplification*: A single authorisation fee covers all strengths / forms / presentations (V – all target species) included in the same application
- *Simplification*: Annual fee and respective remuneration includes costs for minor post-authorisation procedures
  - Type I Variations (H) / Renewals (H) / Variation not requiring assessment (V)
- *Cost-based*: rapporteur remuneration may be different than co-rapporteur remuneration (based on significant difference in data)

Annexes – 2/3

- All amounts based on impact assessment – generated data
  - Workload and cost estimations (EMA MBDG => evaluation => impact assessment)
  - Updated and developed further since the evaluation (including based on inflation, more detail)
  - Ensuring a balanced EMA budget, taking into account estimated costs, frequencies, fee reductions and EU budget contribution
- Stages
  - Draft amounts presented in detail during consultations
  - Cost-based approach **updated** post-consultation to take into account NCA feedback to consultations:
    - stabilising role of annual fee in **overall remuneration** not sufficiently taken into account
    - no reduction in overall NCA revenue
    - no specific input on procedural amounts provided by NCAs

revised approach to cost estimation for annual fee remuneration

Annexes – 3/3

- Revised cost-based approach to annual fee remuneration, to take into account the NCA feedback
  - Stability proxy: stable annual fee remuneration as a proportion of total fee remuneration received by NCAs.
  - Cost for annual fee remuneration was adjusted so that the approximate 1/3 ratio (at aggregate system level) was preserved. This led to an upward adjustment of unitary annual remuneration (and, therefore, of unitary annual fees), as compared to the amounts presented for consultations.
  - **Cost-based check**: the resulting higher annual fee remuneration of NCAs per year, as estimated by the study model, falls within the overall maximum envelope of ca. EUR 53 million covering all non-procedural activities declared, including both 'eligible' (cost of contribution to EMA) and 'non-eligible' (cost of implementation of EU legislation) activities. As a consequence, the full amount for non-procedural activities declared by NCAs is now included in the annual fee remuneration.
  - **One-off approach**: this choice meant that some costs were accepted as 'eligible', whereas, had complete quantification been possible, they might not have been. However, in view of the difficulty to perform a full analysis of all non-procedural activities declared by NCAs, combined with the arguments raised in the consultation feedback, this was accepted for the purpose of the impact assessment. The monitoring mechanism will take over for future adjustments.
    - Reflecting the cost of eligible non-procedural activities in the annual fee remuneration paid to rapporteurs is supported by the observation made during the evaluation study that, for a given NCA, the level of engagement in non-procedural activities is likely to be proportionate to the level of engagement in procedural activities.

Conclusion

- Fee legislation becomes more detailed
  - Technical nature: requires close coordination with NCAs
- Simplification
  - One legal instrument, minor procedures under annual fee, grouping of some fee levels
- Flexibility for agile adjustment based on objective data (sustainability)
  - Including possibility to implement changes related to review of basic legislation
- All assessments now remunerated (orphan, paediatric, re-examination, etc.)
- Non-procedural services to EMA covered by the annual fee remuneration
- Press release link: Daily News 13 / 12 / 2022 (europa.eu)

Council of the European Union
General Secretariat

Interinstitutional files:
2022/0417 (COD)

Brussels, 16 December 2022

WK 17738/2022 INIT

LIMITE

PHARM
SAN
MI
COMPET
CODEC

This is a paper intended for a specific community of recipients. Handling and further distribution are under the sole responsibility of community members.

INFORMATION

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices (Attachés)
Subject:	EMA fees - presentation by the Commission

Delegations will find attached, for information, a presentation from the Commission on the EMA fees Regulation ahead of the first meeting on EMA fees which is scheduled for 17 January 2023.

The Commission has made it clear that "this is provided by the Commission as background material for the meeting and cannot be considered as an interpretation of the legal text or possibly expressing views and position from the Commission that could be regarded as not in line with the proposal for a regulation".