EMA Fee System IA – Policy options and sub-options descriptions

Do minimum scenario

In the '**do minimum' scenario,** changes are limited to adjusting the fee system to the 2018 VMP Regulation to the extent possible within the current legislation, without any legislative action on EMA fees.

The scenario also takes into account the estimated budgetary effect of the financial statement of the recent proposal for a reinforced role of EMA[1] whereby related EMA costs are fully covered by an increased EU budget contribution, except for objective 3,[2] which will no longer be covered by the proposed EU budget contribution increase as of 2024.

The structure of the fee system is unchanged. The procedural fees follow the classification of procedures of the new veterinary rules and the amounts are benchmarked to the current fee system.

The approach to NCA remuneration, as well as fees for human and veterinary medicine procedures remains unchanged. The current unitary fee amounts and the current remuneration system is applied to the new veterinary classification of procedures.

Aggregate fee revenue may change due to the change of classification and frequency of procedures under the VMP regulation.

Relevant fee incentives are applied in line with existing legislation and rules.

Policy option 1

Policy option 1 was designed to **introduce the minimum legislative action required** to address recent changes to EU legislation affecting EMA activities.

The policy option as outlined in the Inception Impact Assessment included only cost-based fees for veterinary medicines under the VMP Regulation, while human fees were not impacted. However, the **recent proposal for a reinforced role of EMA** (Objective 3 of the financial statement) **potentially impacts the annual fees for human medicines from 2024**. **This potential impact is therefore also taken into account.**

This option introduces cost-based procedural and annual fees for the veterinary sector and takes account of the impact on annual fees for human medicines from 2024.

Procedural fees and NCA remuneration for **human medicines remain unchanged** as compared to the current system until 2023. The estimated potential impact on annual fees for human medicines to account for objective 3 of the recent proposal is shown as of 2024.

Relevant fee incentives (i.e. discounted fee rates) for SMEs are applied in line with existing SME legislation but general reductions and product-specific reductions *are not* applied to veterinary medicines (see sub-options).

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[1] Proposal for a Regulation of the European Parliament and of the Council on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices, COM(2020) 725 final

[2] Specific objective No 3: Allow timely access and analysis of EU-wide health data to support better decision-making throughout the product lifecycle on medicines (development, authorisation, performance monitoring) with valid and reliable real world evidence.

A pharmacovigilance annual fee for veterinary medicines is introduced to cover the cost of EMA pharmacovigilance activities in the veterinary sector. It is charged in the same way as the human pharmacovigilance annual fee in the current fee system, i.e. based on chargeable units for Nationally Authorised Products.[3]

Policy option 2

Policy option 2 introduces a cost-based fee system for all EMA activities, i.e. in both veterinary *and* human sectors. This option is the same as Option 1 and its sub-options, but a cost-based principle is used to set all fees and all NCA remuneration amounts for both veterinary *and* human medicines activities.

Cost-based fees are introduced for some activities for which fees are not currently charged (orphan, paediatric and some other procedural activities) and to which incentives are not applied (i.e. some pre-submission and re-examination activities). Cost-based remuneration per procedure for NCAs is introduced for these activities.

Costs for pharmacovigilance activities are covered by the procedural pharmacovigilance fees and the annual pharmacovigilance fee (chargeable units for Nationally Authorised Products).

The annual fee (charged on Centrally Authorised Products) is calculated based on all other costs and taking into account all available revenue sources to balance the budget.

Relevant fee incentives continue to apply in line with existing legislation and rules. Fees for some activities continue therefore to be waived. However, full remuneration is paid to NCAs (see sub-options).

NCAs are fully remunerated under the cost-based principle, including for orphan, paediatric and other activities for which they may currently not receive procedural remuneration, and the burden of the cost of incentives is assumed by the EMA budget as a cost to the Agency (see sub-options). NCAs are also remunerated via the annual fee for eligible groups of additional activities in support of EMA for human and veterinary medicines.

Policy option 3

Policy option 3 introduces a cost-based fee system for human and veterinary activities, with a simpler system structure. This option is the same as Option 2, but the fee system is simplified for both human and veterinary medicines.

[3] Chargeable units were introduced for the purpose of charging pharmacovigilance fees. A chargeable unit is defined as being equivalent to a single marketing authorisation.

(i) A reduced number of procedural fees are applied for post-authorisation non-pharmacovigilance activities for human and veterinary medicines. Procedural fees are levied only for pre-authorisation activities (human and veterinary), inspections and only some major post-authorisation activities (e.g. referrals). Due to technical complexities linked to the variety of products included in pharmacovigilance procedures and activities, pharmacovigilance procedures continue to attract procedural fees.

(ii) The annual fee for Centrally Authorised Products covers a broader set of costs as compared to the current system including those non-pharmacovigilance post-authorisation procedures that would no longer levy a procedural fee.

(iii) The annual fees for pharmacovigilance cover costs of EMA horizontal pharmacovigilance activities in both the human and veterinary sectors.

(iv) NCA remuneration for procedures charged under the Centrally Authorised Products (CAP) annual fee is no-longer per-procedure and is included in the annual remuneration paid to NCAs via the CAP annual fee.

This option has been revised since the IIA. Costs for PhV procedures were included under the PhV annual fee in the IIA. However, during the initial stages of the present study, the modelling results showed that this was not feasible from an operational point of view, as it would lead to significantly increased complexity in calculating the fees and remunerating NCAs. Therefore, procedure-based fees are presented for pharmacovigilance procedures.

Policy sub-options for veterinary medicines only

Three sub-options are being considered for veterinary medicines only, introducing general fee reductions and/or incentives.

Sub-option (a) introduces cost-based fees for veterinary medicines with a general fee reduction only. This sub-option is the same as Option 1, but a 50% general reduction for veterinary medicines is applied to all veterinary fees. No additional incentives are applied.

Sub-option (b) introduces cost-based fees for veterinary medicines with a 50% general fee reduction *and* incentives. This sub-option is the same as Sub-option 1a, but it also includes specific incentives that are applied for limited markets.

Sub-option (c) introduces cost-based fees for veterinary medicines with incentives only. This sub-option is the same as Option 1, but specific incentives are also applied for limited markets. No general reduction is applied to veterinary medicines cost-based fees.

These sub-options could apply to main option 1, 2 or 3.

Policy sub-option applying a country coefficient to NCA remuneration

This sub-option applies a country coefficient to NCA remuneration. Application of country coefficients would result in an adjustment to remuneration that is linked to real salary costs and cost of living in each Member State.

This sub-option could apply to main option 2 or 3.

Policy sub-option for sharing the cost of incentives between EMA and NCAs

This sub-option applies incentives to cost-based fees before remuneration to NCAs. This sub-option is the same as Option 2, but fee incentives are also applied to NCA remuneration so that the cost of incentives is shared in proportion to the incentive rates between EMA and NCAs.

This sub-option could apply to main policy option 2 or 3.

Policy sub-option for a 'light' version of option 3

This sub-option implements only a partial simplification of the fee system structure (i.e. a reduced version of Option 3). This option is the same as Option 3, but a more limited set of activities are covered by annual fees (mainly minor variations) and procedural fees are retained for a larger number of activities (mainly major variations). This responds to feedback received to the inception impact assessment.

This sub-option could apply to option 3 only.