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Delegations will find attached document SWD(2019) 336 final.

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COMMISSION STAFF WORKING DOCUMENT

EXECUTIVE SUMMARY

Accompanying the document

EVALUATION of the European Medicines Agency's fee system

{SWD(2019) 335 final}

1. INTRODUCTION AND CONTEXT

The European Medicines Agency plays a key role in the authorisation of medicines in the European Union. It is responsible for the evaluation, supervision and safety monitoring (pharmacovigilance) of human and veterinary medicines. The Agency is funded mainly through fees paid by industry for obtaining and maintaining marketing authorisations. Other sources of income are contributions from the European Union and the European Economic Area. The Agency works in close collaboration with national competent authorities and performs the majority of its scientific assessments with their direct support. The national authorities are compensated by the Agency for their services.

The fee system sets out (1) the Agency's revenue sources and general rules for compensating national authorities; (2) the services of the Agency that are covered by fees and the level of fees; (3) the rules and amounts for fees and compensation for national authorities for pharmacovigilance; and (4) rules for and levels of fee reductions for micro, small or medium-sized enterprises (SMEs).

Further fee reductions and support services exist for medicines intended for rare diseases and for children, for advanced therapy medicines and veterinary medicines.

The evaluation of the fee system was supported by an extensive data-gathering exercise with the Agency and national competent authorities, a study, an online public consultation, as well as targeted stakeholder consultations.

2. OBJECTIVE AND SCOPE

The purpose of this evaluation is to examine the functioning of the fee system. It looks at the strengths and weaknesses of the fee system. It assesses whether fees and compensations have a sound economic basis and are fair and proportionate. The evaluation further analyses whether the fee system avoids unnecessary administrative burden and whether it is financially sustainable in the future. The evaluation covers the effectiveness and efficiency, relevance, and coherence of the fee system.

The evaluation focusses specifically on the fee system, and does not include the entire legislation on the authorisation, maintenance and monitoring of medicines.

3. FINDINGS AND CONCLUSIONS

- ***Effectiveness and efficiency***

The current fee system is generally efficient and effective but it is not cost-based at the level of individual procedures.

The fee system together with the EU budget contributions allows the Agency to meet its costs after compensating national authorities.

At the level of individual procedures, the current fee system is not always cost-based. Fees for some procedures exceed the total costs of the Agency and the national authorities.

Fees for some other procedures fall short of costs. Furthermore, there are no fees and compensations for some procedural activities.

In addition, fees are not always shared between the Agency and the national authorities in proportion to their respective costs; for some activities the Agency gets a bigger share than the national authorities in proportion to their respective costs, for other activities it is the other way around.

Fee reductions and exemptions result in activities for which costs cannot be covered (fully or at all) by procedural fees. Therefore, other sources of income such as annual fees or the European Union budget contributions support covering the costs of these activities.

Overall, the Agency has paid national authorities more than their total costs for undertaking procedures. However, national authorities also undertake additional services in and outside the Agency's committees and working groups for which they are not compensated. The current aggregate compensation would not be sufficient to cover the total costs that national authorities declared for all activities they report undertaking in support of the Agency. Whether and to what extent the "additional" activities and their involvement in committees and working groups should be covered by the Agency compensation needs to be further assessed.

At the level of the individual national authority, there is a high degree of variation in the extent to which compensations align with costs. Furthermore, national authorities that undertake veterinary activities only are less likely to cover their costs.

The fee system is complex and would benefit from streamlining. The Fee Regulation has not been revised since 2005. In the meantime, several pieces of sectorial legislation have been introduced establishing additional fee reductions. In addition, the introduction of the Pharmacovigilance Fee Regulation in 2014 expanded the fee system and added to its overall complexity.

The current fee system provides a level of flexibility that is sufficient for the current operations of the Agency and national authorities but it may not be enough to guarantee their future sustainability. In particular, the existing flexibility to fund some non-fee generating and uncompensated activities as well as reductions and fee waivers is considered essential. Equally, the lower fee levels for veterinary medicines are viewed as important in order to support their development and availability.

However, the fee system lacks flexibility to address variation in workload. For example, the workload in assessing innovative medicines based on new developments in science is higher than that in assessing traditional ones. This may be a challenge for the future sustainability of the fee system.

- ***Relevance***

The fee system remains relevant to address its original needs for a sound financial basis of the Agency. But it does not fully respond to some of the current needs.

Specifically, the objective of minimising the administrative burden of operating the fee system is still relevant but not fully met by the current system. Furthermore, the fee system does not have sufficient capacity to respond and adapt to the increasing complexity of the activities undertaken stemming from innovations in science.

- ***Coherence***

The fee system is internally coherent. But it needs to accommodate changes in activities and sources of income resulting from revisions of the legislation on medicines.

The current fee system is overall internally coherent. However, some discrepancies between the rules on pharmacovigilance and other fees need addressing. In addition, the Agency's Founding Regulation has been recently revised. The resulting changes on the funding of the Agency need to be looked at.

Furthermore, the current fee system does not yet accommodate the changes in activities for veterinary medicines that will apply from 2022.