EXPLANATORY MEMORANDUM FOR EUROPEAN UNION LEGISLATION WITHIN THE SCOPE OF THE UK/EU WITHDRAWAL AGREEMENT AND WINDSOR FRAMEWORK

COM (2022) 721

Proposal for a Regulation of the European Parliament and of the Council on fees and charges payable to the European Medicines Agency, amending Regulation (EU) 2017/745 of the European Parliament and of the Council and repealing Council Regulation (EC) No 297/95 and Regulation (EU) 658/2014 of the European Parliament and of the Council

Submitted by Department of Health and Social Care on 7 April 2023

SUBJECT MATTER

1. The proposed regulation lays down the amounts of the fees and charges established on cost-based evaluation and levied by the European Medicines Agency (EMA). The fees and charges are for assessment activities relating to obtaining and maintaining an EU authorisation to market medicinal products for human use, veterinary use and for other services provided by the Agency.

2. It also sets out the amounts of remuneration established on cost-based evaluation and payable by the Agency for the services provided by rapporteurs, co-rapporteurs and equivalent roles from competent authorities of the Member States. And finally, it provides for the monitoring of costs of activities and services provided by the Agency and of costs for remuneration.

3. This revision aims to address the following problems identified by the recent evaluation of the EMA fee system:
    a. complexity of the fee system due to the many different categories and types of fees it currently establishes;
    b. misalignment of some fees with underlying costs;
    c. lack of any fees or national competent authority remuneration for some procedural activities;
    d. misalignment with the underlying costs of certain remuneration paid to national competent authorities in Member States; and
    e. discrepancy between the main EMA Fee Regulation (Council Regulation (EC) No 297/95) and the Pharmacovigilance Fee Regulation (Regulation (EU) No 658/2014), which differ in their approach to determining the amount of national competent authority remuneration and in the approach to national competent authority remuneration in the case of reduced fees.

4. By addressing these specific problems, the general objective of this proposal is to contribute to providing a sound financial basis to support the EMA's operations, including remuneration for services to the EMA rendered by national competent authorities, in line with the applicable legislation.

5. This translates into the objective of providing for fee and remuneration amounts that are cost-based, following a thorough evaluation of the costs of the Agency. In addition, the proposal aims to streamline the system by simplifying the fee structure to the extent possible and by addressing the unnecessary complexity of the corresponding legal framework through bringing together in a single legal instrument fee rules that are currently governed by the two EMA Fees Regulations.

6. Finally, a key objective pursued by this proposal is to make the fee system futureproof by introducing regulatory flexibility in the way it is adjusted, on an objective basis

SCRUTINY HISTORY

7. An EM was submitted on 4 November 2019 on EU document 12776/19 Report on the exercise of the delegation conferred on the Commission pursuant to Regulation (EU) No 658/2014 of the European Parliament and of the Council of 15 May 2014 on fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities in respect of medicinal products for human use.

8. The House of Commons completed scrutiny without a substantive report to the House on 25 March 2020 (Report 3, 19-21). The House of Lords European Affairs Committee completed scrutiny at the Chair's Sift on 16 January 2020 (Sift 1760).

MINISTERIAL RESPONSIBILITY

9. The MHRA acts on behalf of the Department for Health and Social Care Secretary of State and the Northern Ireland Health Minister in undertaking licensing authority functions. For veterinary medicines the Veterinary Medicines Directorate (VMD) acts on behalf of the Department for Environment, Food and Rural Affairs.

INTEREST OF THE DEVOLVED ADMINISTRATIONS

10. The subject matter of this explanatory memorandum relates to medicines, which is a transferred matter in Northern Ireland and a reserved matter in the rest of the UK.

11. The MHRA is the regulator for the whole UK. As part of the Windsor Framework, all medicines for human use in the UK will be licenced by the MHRA. Once in force, novel medicines in NI will no longer need a licence from the EMA as per the old Protocol.

12. For veterinary medicines, the VMD is the Regulator for the whole of the UK. As part of the Windsor Framework, the cliff edge on veterinary medicines has been removed, protecting supply in Northern Ireland through to 2025. During this time, veterinary medicines authorised or approved in the UK, or which are moved via Great Britain, can continue to be placed on the market in NI.

13. This safeguards those supplies while providing time to establish a long-term solution which maintains the uninterrupted flow of veterinary medicines into NI from GB. In so doing the Government is clear that the only practical solution will be a solution, as with human medicines, to guarantee the existing and long-established flows of trade between GB and NI on which so many people and businesses rely.

14. This EM has been shared with officials in the Northern Ireland Executive and a nil response has been provided.

LEGAL AND PROCEDURAL ISSUES

i. Legal Base

15. The legal basis for this proposal is Article 114 and Article 168(4)(c) and (b) of the Treaty on the Functioning of the European Union (TFEU).

ii. Timetable for adoption and implementation

16. This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union. When this will be is unknown as the regulation is still making its way through the European legislature.

POLICY IMPLICATIONS

17. From the point that the regulatory provisions in the Windsor Framework come into effect (expected to be 1 January 2025), this regulation will no longer be relevant for businesses wishing to market human medicines in the UK. The Windsor Framework means that the role of the EMA in licencing human novel medicines in Northern Ireland will be removed.

18. Until then, and once this regulation comes into force, our assessment is that the revised costs associated with seeking a marketing authorisation with the EMA will not affect the continued supply, distribution and availability of medicines in Northern Ireland.

19. For small businesses, the EMA has fee reductions and incentives available for micro, small and medium-sized enterprises.

20. The UK's licensing authority, the Medicines and Healthcare products Regulatory Agency (MHRA), has also recently consulted on raising its fees. This is not expected to be contentious.

21. For veterinary medicines, to market a novel medicine in Northern Ireland, it is necessary to attain a licence from the EMA. As with human medicines set out above, the Government does not anticipate that the EMA revising its fees will have an impact on supply of veterinary medicines.

CONSULTATION

22. Due to the highly technical nature of the measures under consideration and their limited direct relevance, no public consultation was conducted during the impact assessment process. Instead, the six key stakeholder groups (EMA; national ministries and national competent authorities; EU pharmaceutical industry associations for human and veterinary medicines; research associations; and wider EU stakeholder associations, including healthcare professional and patient and consumer associations) concerned by the EMA fee system were consulted via a targeted survey. These surveys were followed up by a series of targeted interviews with seven national competent authorities, the EMA and the Heads of Medicines Agencies (HMA).

FINANCIAL IMPLICATIONS

23. There are no new financial implications for HMG

MINISTERIAL NAME AND SIGNATURE

26/04/23

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