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To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
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Delegations will find attached document SWD(2022) 413 final.

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COMMISSION STAFF WORKING DOCUMENT

Subsidiarity Grid

Accompanying the document

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

{COM(2022) 721 final} - {SEC(2022) 440 final} - {SWD(2022) 414 final} - {SWD(2022) 415 final}

Subsidiarity Grid

1. Can the Union act? What is the legal basis and competence of the Unions' intended action?
1.1 Which article(s) of the Treaty are used to support the legislative proposal or policy initiative?
The proposed regulation has a dual legal basis: Article 114 of the Treaty on the Functioning of the European Union (TFEU): the regulation is aimed at supporting the smooth functioning of the internal market and the common post-marketing surveillance of medicinal products and Article 168(4)(c) and (b) of the Treaty on the Functioning of the European Union (TFEU): the proposed regulation aims to support the goal of setting high standards of efficacy, quality and safety of medicinal products and measures in the veterinary fields that have as their direct objective the protection of public health.
1.2 Is the Union competence represented by this Treaty article exclusive, shared or supporting in nature?
In the case of human health protection, the Union's competence is supporting. In the case of the internal market, the Union's competence is shared.
2. Subsidiarity Principle: Why should the EU act?
2.1 Does the proposal fulfil the procedural requirements of Protocol No. 2[1]: -
A wide consultation reaching out to all stakeholders to whom the EMA fee system may be relevant has been carried out during the impact assessment that preceded the proposal. The explanatory memorandum and the impact assessment contain a section on the principle of subsidiarity.
2.2 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the conformity with the principle of subsidiarity?
The EMA is a decentralised agency of the EU. Therefore, decisions on its funding and the fees it may charge can only be taken at EU level. Only the EU can act to enable the Agency to charge fees and to define the levels of those fees. EU action is therefore justified and necessary.

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12016E/PRO/02&from=EN

2.3 Based on the answers to the questions below, can the objectives of the proposed action be achieved sufficiently by the Member States acting alone (necessity for EU action)?
The objectives can only be achieved at EU level.
(a) Are there significant/appreciable transnational/cross-border aspects to the problems being tackled? Have these been quantified?
The opinions issued by EMA are the basis for Commission decisions regarding the regulatory status of medicinal products that are valid throughout the Union. EMA fees are a substantial part of EMA funding which provides a financial basis for providing these scientific opinions.
(b) Would national action or the absence of the EU level action conflict with core objectives of the Treaty[2] or significantly damage the interests of other Member States?
The absence of EU action on setting cost-based EMA fees would damage the interests of both the EMA and Member States and in particular the competent authorities responsible for medicines regulations. EMA is widely funded through fee and they need to be cost-based. National competent authorities of the Member States are remunerated by EMA for assessment services they provide through EMA committee rapporteurs. Such remuneration also needs to be cost-based.
(c) To what extent do Member States have the ability or possibility to enact appropriate measures?
Since the EMA is an EU body, only the Union can act to establish its fees.
(d) How does the problem and its causes (e.g. negative externalities, spill-over effects) vary across the national, regional and local levels of the EU?
To the extent that EMA remunerates national competent authorities for the scientific services provided by rapporteurs of EMA scientific committees, the legislation laying down EMA fees and remuneration amounts are relevant to the national level only.
(e) Is the problem widespread across the EU or limited to a few Member States?
A rapporteur in EMA scientific committees may originate from the competent authority of any Member State.
(f) Are Member States overstretched in achieving the objectives of the planned measure?
EMA fees are charged only by the EMA.
(g) How do the views/preferred courses of action of national, regional and local authorities differ across the EU?
Only the national level is relevant, to the extent that national competent authorities receive remuneration from the EMA.
2.4 Based on the answer to the questions below, can the objectives of the proposed action

[2] https://europa.eu/european-union/about-eu/eu-in-brief_en

be better achieved at Union level by reason of scale or effects of that action (EU added value)?
EMA is a decentralised agency of the EU, therefore only the EU can act to set its fees.
(a) Are there clear benefits from EU level action?
EU level action is the only possible when it comes to setting EMA fees, therefore the benefits are clear.
(b) Are there economies of scale? Can the objectives be met more efficiently at EU level (larger benefits per unit cost)? Will the functioning of the internal market be improved?
Setting EMA fees cannot be done at national level, since only the Union is competent to set EMA fees.
(c) What are the benefits in replacing different national policies and rules with a more homogenous policy approach?
When it comes to EMA fees, there are no national policies, since only the Union can act.
(d) Do the benefits of EU-level action outweigh the loss of competence of the Member States and the local and regional authorities (beyond the costs and benefits of acting at national, regional and local levels)?
There is no loss of competence of the Member States, Member States can continue to set their own fees for national activities.
(e) Will there be improved legal clarity for those having to implement the legislation?
The legal clarity will be the same, since EMA already charge fees.
3. Proportionality: How the EU should act
3.1 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the proportionality of the proposal and a statement allowing appraisal of the compliance of the proposal with the principle of proportionality?
The proposal does not go beyond what is necessary to achieve the general objective pursued, i.e. to introduce fees to ensure the necessary funding for the proper implementation of EU pharmaceutical legislation. The proposal addresses the problems that have been identified only in respect of EMA fees, based on costs related to EMA activities. Contributions and respective costs of national competent authorities are taken into account only insofar as they contribute to an EMA activity. Thus, to achieve its aims, the EU only takes those actions that it needs to take and does not go beyond them.
3.2 Based on the answers to the questions below and information available from any impact assessment, the explanatory memorandum or other sources, is the proposed action an appropriate way to achieve the intended objectives?

Yes, in view of its scope limited to setting EMA fees and remuneration amounts, the proposed regulation is the appropriate way to achieve the objective of setting EMA fees and remuneration.
(a) Is the initiative limited to those aspects that Member States cannot achieve satisfactorily on their own, and where the Union can do better?
Yes, the proposal sets EMA fees and remuneration to EMA rapporteurs only.
(b) Is the form of Union action (choice of instrument) justified, as simple as possible, and coherent with the satisfactory achievement of, and ensuring compliance with the objectives pursued (e.g. choice between regulation, (framework) directive, recommendation, or alternative regulatory methods such as co-legislation, etc.)?
Since the Treaty on the Functioning of the European Union became applicable, all legislative procedures are normally based on the previous 'co-decision procedure' involving both the Council and the European Parliament. Therefore, for legal certainty, it is proposed to create a new Regulation of the Council and the European Parliament, which will be subject to the ordinary legislative procedure (Article 294 of the TFEU).
(c) Does the Union action leave as much scope for national decision as possible while achieving satisfactorily the objectives set? (e.g. is it possible to limit the European action to minimum standards or use a less stringent policy instrument og approach?)
Yes, while setting EMA fees and remuneration to EMA rapporteurs, the Union action leaves as much scope to Member States to set their national fees as possible, i.e. for activities performed at national level (as opposed to activities that constitute a service to the EMA scientific committees).
(d) Does the initiative create financial or administrative cost for the Union, national governments, regional or local authorities, economic operators or citizens? Are these costs commensurate with the objective to be achieved?
The initiative does not create any additional cost.
(e) While respecting the Union law, have special circumstances applying in individual Member States been taken into account?
N.A.