Written contributions from delegations

Comments from the Danish delegation

Former DK proposal:

Article 15 – Repeal

"Regulation (EC) No 297/95 and (EU) No 658/2014 are repealed ***with the exception of:****.*

- ***Article 10, para 1, 2nd section of Regulation (EC) No 297/95, which shall remain in force until [OP: please insert 1 year from the date of application]***

References to Regulation (EC) No 297/95 shall be construed as references to this Regulation and read in accordance with the correlation table in Annex VII to this Regulation.

Article 16 – Transitional provisions

"This regulation shall not apply to ***~~annual fees set out in Annex III,~~*** *procedures and services for which the payable amount became due before [OP: please insert date of application].*

Article 15, 16 and 17 – Repeal, transitional provisions and entry into force and date of application

The most likely scenario is agreement and entering into force of the new fee Regulation by the end of 2023. This means application from 1st January 2025 (cf. art 17). Since Regulation 297/95 with the current proposal would thus be repealed from the very same date (cf. art 15) we have no legal basis to levy an annual fee for 2024. This will result in one year of underfinancing bearing in mind that annual fees are charged for services related to the previous calendar year according to Regulation 297/95.

We do understand the rationale behind the transitional provision in Article 16, but from our perspective this will not provide us with a legal basis to levy the annual fees for 2024.

On the contrary, we are concerned that Article 16 would create doubts in terms of its legal intent with regard to the annual fees, including in the new Regulation. The reference to the annual fees in Article 16 need be deleted as fees according to Regulation 658/2014 are levied 1st July in the calendar year.

From a Danish perspective Regulation 297/95 shall be repealed with the exception of Article 10, para 1, 2nd section that shall remain in force until 1 year from the date of application (whatever that may be). Article 10, para 1, 2nd section prescribes that the annual fee shall be due on the first and each subsequent anniversary of the notification of the marketing authorization decision. It shall be payable within 45 days of the due date. The annual fee shall relate to the preceding year.

If this legal basis is maintained we may levy fees for the year that precedes the year of application.

Comments from the German delegation

With a view to the upcoming WP on the EMA fees proposal on Thursday, we would like to reiterate our position on Article 11 and ask for it to be considered. This position is supported by Austria, Croatia, Czech Republic, Finland, Hungary and Malta in full and with the exception of paragraph 1 (subpara 2) by France, Portugal, Slovenia and Spain.

Below is the proposal for your reference:

Article 11

Revision

*1. The Commission is empowered to adopt delegated acts in accordance with Article 13 to amend the Annexes where it ~~deems it~~ **is** justified **on the basis of** ~~in view of any of the following~~:*

(a) *a special report received by the Commission in accordance with Article 10(6);*

(b) *the findings from the monitoring of the inflation rate referred to in Article 10(5);*

~~(c) a change in the statutory tasks of the Agency leading to a significant change in its costs;~~

~~(~~already considered in the compromise text)

(d) *the budgetary reporting of the Agency.*

By means of delegated acts, the percentage distribution of fees between the competent authorities of the Member States and the Agency cannot be changed to the detriment of the national competent authorities.

*2. Any revision of the fees and charges and of the remuneration paid to competent authorities of the Member States provided for in this Regulation shall be based on the Commission's evaluation of the Agency's costs and revenues and of the ~~relevant~~ **full** costs of the services provided to the Agency by the competent authorities of the Member States, taking into account also the sustainability of the Union regulatory network including a fair and objective allocation of fees, charges and remuneration.*

Comments from the Italian delegation

COMMENTS ON THE TEXT OF THE PROPOSAL FOR A REGULATION 2022/0417(COD)

Please find below some comments on the text of the proposal for a regulation on fees and charges for the European Medicines Agency (8903/23), forwarded by the Presidency to the Delegations on 3 May 2023.

Firstly, we thank the Swedish Presidency for the work done and — as indicated at the Working Party Pharmaceuticals and Medical Devices held on 27 April — it is noted that the recently submitted proposal to amend the **annexes**, correctly transposes the contributions provided by the Delegations.

As regards the **main text of the proposal**, we would like to point out that we share the changes introduced by the Presidency, as confirmed in the last version submitted, which in some cases also incorporate the Italian position already expressed, including:

- the correction of the definition of "public health emergency";
- the simplification of the text referred to in Article 10(3) and the amendment introduced in Article 8, which provides for the adoption by the EMA Management Board of a "common format", based on a transparent methodology, to be used by NCAs to transmit financial information in accordance with Article 10(3);
- the strengthening of the role of the EMA Management Board, through the amendment introduced to Articles 10(6) and 10(8), in the phase relating to the revision of fees;
- the amendment of the time limit laid down in Article 10(6) for the EMA to draft the special report;
- the introduction of point (d) of Article 10(9), which allows for a reduction in the time frame for the submission of the special report, where evidence is provided of significant changes in costs by the NCAs;
- the limitation of the powers delegated to the European Commission, through the elimination of Article 11(1)(e) and the clarification that fee revisions must also take into account the sustainability of costs for NCAs, ensuring fair allocation of fees (Article 11(2)).

On the other hand, it should be noted that the proposed amendment to **Article 6 (2)** should be more limited, as it could generate some uncertainties relating to when the EMA may waive the corresponding fee or charge.

In addition to the above, it is deemed necessary to state that the XII Committee of the Italian Chamber of Deputies has expressed a favourable assessment with conditions and observations of the above proposal. Such assessment was approved on 20 April pursuant to Article 7 of Law No 234 of 24 December 2012 and is published on the European Parliament website[1]. Therefore, in line with certain conditions laid down by the XII Committee of the Chamber of Deputies, it is suggested that the text of the proposal be amended in accordance with the following **recital No (17).** Furthermore, we emphasize the importance of maintaining in the subsequent stages of evaluation of the proposal those provisions supplemented by the Swedish Presidency which ensure:

- a remodulation of fees and charges, in particular those on which the most critical issues have been identified, such as to ensure adequate coverage of the costs incurred by the NCAs, balancing the distribution of remuneration between NCAs and the EMA;
- with regard to empowering the European Commission to amend tariffs by delegated acts, mechanisms ensuring transparency of the relevant procedures and involvement of national competent authorities, offsetting regulatory flexibility in the fee revision.

Finally, it should be noted that the text of the Swedish Presidency did not accept certain proposals for amendments tabled by this delegation. In particular:

i. the proposed amendments to **Articles 8 and 10** (6) aimed at providing for the completion of a procedure for the consultation of the NCAs, respectively before the adoption by the EMA Management Board of the common format and before the adoption of the special report, referred to in Article 10, were not transposed in the text submitted;

ii. the proposal was not approved, also supported by other delegations including the German and French delegations, which proposed to limit the power of the European Commission to adopt delegated acts under **Article 11**, provided that the latter could not change the percentage of the distribution of fees to the detriment of the NCAs.

[1] Available at the following link: https://connectfolx.europarl.europa.eu/connefof/app/exp/COM(2022)0721

It should be noted that the proposal (ii) was not intended to prohibit changes relating to the percentage of the distribution of fees allocated to the NCAs, in breach of the principle of the so-called cost-based. On the other hand, the objective of the proposal was to ensure that any change in the percentage of the distribution of tariffs allocated to the NCAs, to the detriment of the latter — if necessary to comply with the cost-based approach — was adopted through the ordinary legislative procedure, since the latter would allow for greater involvement of the Member States (compared to the one envisaged for the adoption of a delegated act). As an alternative to accepting the proposal in question, it should be provided for certain mechanisms that directly protect the NCAs, such as the completion of a procedure for consulting the NCAs on the special report, before approval by the EMA Management Board, referred to in Article 10(6). This appears, moreover, in line with the observations made by the XII Committee of the Chamber of Deputies.

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

[...]

Whereas:

[...]

(17) The Management Board of the Agency should be empowered to provide further fee or charge reductions for justified reasons of protection of public and animal health **or for the support of specific types of products or applicants**. A favourable opinion from the Commission should be mandatory before granting further fee reductions, in order to ensure alignment with Union law and with overall policies of the Union. **In this regard, it is of particular importance that the fees payable in respect of designated orphan medicinal products are waived, in part or in total, in accordance with Regulation (EC) No 141/2000 of the European Parliament and of the Council.** In addition, in duly justified exceptional cases, such as imperative reasons of public or animal health, it should also be possible for the Executive Director of the Agency to reduce certain types of fees on the basis of a critical examination of the situation specific to each case.

Comments

In line with the conditions formulated by the XII Committee of the Chamber of Deputies, the importance is stressed of ensuring support for research and innovation, necessary for the definition of therapies for rare and ultra-rare diseases, by continuing to apply the exemptions and fee reductions adopted for orphan drugs, in line with the rules laid down in Regulation (EC) No 141/2000 — and, in particular, pursuant to Article 7, which provides that "*A special contribution from the Community, distinct from that provided for in Article 57 of Regulation (EEC) No 2309/93, shall be allocated every year to the Agency. The contribution shall be used exclusively by the Agency to waive, in part or in total, all the fees payable under Community rules adopted pursuant to Regulation (EEC) No 2309/93. A detailed report of the use made of this special contribution will be presented by the Executive Director of the Agency at the end of each year. Any surplus occurring in a given year shall be carried forward and deducted from the special contribution for the following year*"— and last implemented with the Decision of the Executive Director on fee reductions for designated orphan medicinal products (EMA/135645/2020).

It should also be assessed, where appropriate, to supplement and revise those reductions also in the light of the new fees provided for in this Regulation.

Council of the European Union
General Secretariat

Interinstitutional files:
2022/0417 (COD)

Brussels, 10 May 2023

WK 6211/2023 INIT

LIMITE

PHARM
SAN
MI
COMPET
CODEC
VETER

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

CONTRIBUTION

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices (Attachés) Working Party on Pharmaceuticals and Medical Devices (EMA fees)
Subject:	EMA fees proposal - comments from delegations

Delegations will find attached comments from delegations on the EMA fees compromise proposal (8903/23).