RÉPUBLIQUE FRANÇAISE

SÉNAT

EUROPEAN
AFFAIRS COMMITTEE

Paris, 9 May 2023

POLITICAL OPINION
on the Proposal for a Regulation of the European Parliament and of the Council on fees and charges payable to the European Medicines Agency – COM(2022) 721 final

The Senate European Affairs Committee,

Having regard to Articles 114, 168 and 290 of the Treaty on the Functioning of the European Union,

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency,

Having regard to Council Regulation (EC) No 297/95 of 10 February 1995 on fees payable to the European Agency for the Evaluation of Medicinal Products,

Having regard 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,

Having regard to Regulation (EU) No 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC,

Having regard to Regulation (EU) No 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices,

Having regard to Council Regulation (EU) No 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level,

Having regard to the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions presenting its Pharmaceutical Strategy for Europe, COM(2020) 761 final,

Having regard to the 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) No 2017/745 of the European Parliament and of the Council and repealing Council Regulation (EC) No 297/95 and Regulation (EU) No 658/2014 of the European Parliament and of the Council, COM(2022) 721 final,

Having regard to the European Commission impact assessment report accompanying the 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) No 2017/745 of the European Parliament and of the Council and repealing Council Regulation (EC) No 297/95 and Regulation (EU) No 658/2014 of the European Parliament and of the Council, SWD(2022) 414 final,

Concerning the procedures for revising fee amounts

Whereas, in order to determine the amount of fees and charges payable to the European Medicines Agency (EMA), the European Commission carried out an evaluation of EMA charges and of costs borne by the National Competent Authorities (NCA);

Whereas these fees and charges are paid by human and veterinary medicine companies in return for a service provided by the EMA;

Whereas the European Union Member States are represented on the EMA Management Board;

Whereas, under the terms of Article 290 of the Treaty on the Functioning of the European Union, it is the responsibility of the legislator to define the scope of the delegated acts;

Asks that the list of items that the Commission may invoke to justify an amendment by delegated act to the amount of fees, charges and remunerations be precisely defined, and, to this end, that Article 11 (e) of the Proposal for a Regulation on fees and charges payable to the European Medicines Agency (COM (2022) 721 final) be deleted;

Asks that the special report provided for in Article 10, Paragraph 6, of the aforementioned proposal for a regulation, which the Executive Director of the EMA may deliver to the Commission, where it is considered relevant, in view of the Agency's expenditure and revenue, in order to recommend a change in the amount of any fee, charge or remuneration following a significant change in their respective costs and on the basis of which the Commission could justify such a change, be adopted by the EMA Management Board in order to enable representatives of the Member States to take up a position on the recommendations of this report;

Considers that any revision to the amount of fees must be done in a transparent and concerted manner;

Asks, consequently, that, when this special report is prepared, all stakeholders, including representatives of the pharmaceutical industry and the NCAs, should be heard by the EMA;

Hopes, in addition, that this special report will be published as soon as it is sent to the European Commission;

Concerning the amount of fees

Whereas the Commission wishes to rationalise the fee system and reduce administrative costs, such as those involved in invoicing;

Whereas the Commission intends to maintain fee reductions for medicinal products for paediatric use and orphan medicinal products, and also those granted to small enterprises;

Whereas the Pharmaceutical Strategy for Europe presented by the European Commission aims in particular to ensure the availability of medicines and protect the health sovereignty of the Union;

Whereas an increase is envisaged by the Proposal for a Regulation COM(2022) 721 final in the amount of fees for the evaluation of biosimilar medicines for their first marketing authorisation;

Whereas an increase is envisaged by the aforementioned proposal for a regulation in the amount of the annual pharmacovigilance fee for medicinal products for human use;

Whereas animal health can have an impact on human health;

Whereas an increase is envisaged by the Proposal for a Regulation COM(2022) 721 final in the fee for a first marketing authorisation, the fee for a substantial change in the marketing authorisation, and the annual fee for non-generic veterinary medicinal products;

Whereas a new annual pharmacovigilance fee is to be created covering all veterinary medicinal products marketed in the European Union, irrespective of the procedure for granting the marketing authorisation;

Whereas there is to be a period of six months between the date of entry into force of the proposed regulation and its date of application;

Welcomes the suppression of specific fees for minor changes - type IA and IB – to marketing authorisations;

Supports the initiative to propose fees that cover all strengths, all pharmaceutical forms and all presentations, while calling for discussion on the resulting increase in the amount of the fees;

Welcomes the fact that the proposal intends to maintain fee reductions granted for medicinal products for paediatric use and orphan medicinal products, and also reductions granted to small enterprises;

Hopes that the amount of fees will be determined in such a way as to promote the objectives of the Pharmaceutical Strategy for Europe, especially regarding the availability of medicines and the health sovereignty of the Union;

Asks, therefore, that the reduction in the annual pharmacovigilance fee for generic medicinal products should be increased to 50% and that the amount of the fee for the assessment of biosimilar medicinal products for a first marketing authorisation should remain limited, preferably below a ceiling of €450,000;

Also calls for a smaller increase than envisaged in the amount of fees affecting veterinary medicinal products in order to take into account the specificities of this market and the suppression of the annual pharmacovigilance fee for veterinary medicinal products which have not been granted authorisation under a centralised procedure;

Hopes to increase to 18 months the period between the date of entry into force of the text and its date of application for fees for veterinary medicinal products, and to 12 months for fees for medicinal products for human use;

Concerning the financing of the EMA

Whereas the EMA’s budget must be balanced;

Whereas the EMA’s revenue is made up of fees paid by companies and a contribution from the Union budget;

Whereas the share of public funding in Union agencies dealing with health issues seems to be determined according to the financial capacities of the companies for which these agencies provide services;

Considering the share of public funding in other agencies that also have the task of evaluating marketing authorisation applications for medicinal products and monitoring the market;

Whereas the amount collected through fees depends on companies' strategies regarding applications for product marketing authorisation and product withdrawal;

Whereas the Commission wished to reinforce the role of the EMA in preparing the Union for health crises and their management;

Whereas the share of public funding in the EMA's income should be increased in order to finance fee reductions, the aim being to achieve the objectives of the Pharmaceutical Strategy, ensure the stability of the EMA's budget and guarantee the funding of certain activities that do not directly benefit companies;

Concerning the role of NCAs in expertise

Whereas the participation of NCAs in the work of the EMA is essential;

Whereas an agency capable of providing expertise and quality support for the rapid delivery of innovative medicines to patients can make an essential contribution;

Whereas the scientific advice provided by agencies to marketing authorisation applicants to support their applications plays an essential role;

Whereas NCAs' costs have increased recently, due mainly to ever more specialised requests for expertise, and to inflation;

Whereas the evaluation of costs borne by NCAs was carried out by the Commission before the COVID-19 pandemic and the inflationary surge following the outbreak of war in Ukraine;

Asks for an overall revaluation of the amounts that the EMA pays to the NCAs to take account of inflation and the increase in costs since 2018;

Hopes that the EMA will compensate the NCAs for the contribution made by their experts to the various working groups;

Recommends that the amount of fees and the amounts paid to NCAs for the scientific advice they provide should be maintained at least at their current level.