



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/133106/2021
Executive Director

Decision of the Executive Director

On fee reductions for scientific advice requests on products for the prevention and/or treatment of COVID-19

THE EXECUTIVE DIRECTOR

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 and veterinary use and establishing a European Medicines Agency (hereafter 'the Agency') (Founding Regulation) ¹ and in particular Article 57(1)(n) thereof,

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, and in particular Article 9(1) thereof,

Having regard to the Rules for the implementation of Council Regulation (EC) No 297/95 on fees payable to the European Agency for the evaluation of medicinal products, and in particular Annex I thereof,

Having regard to the extraordinary public health measures implemented in some EU/EEA countries, to identify, isolate and test contacts in order to contain the outbreak of the infection of COVID-19,

Having regard to the consultation with the competent scientific committee (namely, the Committee for Medicinal Products for Human Use) on 11 March 2021, whereby the existence of exceptional circumstances and imperative reasons of public health for granting fee reductions for scientific advice requests on products for the prevention and/or treatment of COVID-19 in the European Union was confirmed,

Whereas the Executive Director may, without prejudice to more specific provisions of Union law, in exceptional circumstances and for imperative reasons of public or animal health, grant fee reductions case by case after consultation of the competent scientific committee,

Whereas it is imperative for the protection of public health that medicinal products for the prevention and/or treatment of COVID-19 are developed as quickly as possible,

HAS DECIDED:

¹ OJ L 136, 30.04.2004, p. 1



Article 1 - Scope of the initiative

Reduced fee levels for scientific advice for medicinal products for the prevention and/or treatment of COVID-19 shall be granted as a six-month initiative.

Article 2 - Fee reductions

The applicable fee for scientific advice shall be reduced by 100%.

Article 3 – Remuneration of national competent authorities (rapporteurs)

During the initiative, the remuneration to national competent authorities shall not be reduced.

Article 4 - Processing of fee reductions

During the initiative, any request for scientific advice covered by this decision will be assigned the applicable reduced fee. No separate request for fee reduction by the applicant is required during this period.

Article 5 - Entry into force

The duration of the initiative shall be six (6) months. This decision will enter into force on 16 March 2021 and shall be valid until 15 September 2021.

Amsterdam,

Emer Cooke
Executive Director