



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/534263/2021  
Executive Director

## Decision of the Executive Director

On fee reductions for scientific advice requests for medicines for COVID-19 not covered by Article 16(2) of Regulation (EU) 2022/123

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 use and establishing a European Medicines Agency, 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 Regulation (EU) 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, and in particular Article 16 thereof;

Having regard to the Executive Decision on granting fee reductions for scientific advice requests on products for the prevention and/or treatment of COVID-19 of 16 September 2021 (EMA/452996/2021) which ceases to be valid following the adoption and implementation of Regulation (EU) 2022/123 (as per Article 5 of said Decision);

Having regard to the consultation with the Committee for Medicinal Products for Human Use on 22 April 2022, which confirmed that the exceptional circumstances and imperative reasons of public health that justify the above-mentioned Decision are still present;

Whereas the European Medicines Agency ('EMA' or 'Agency') shall provide, free of charge, scientific advice on the main aspects of clinical trials and clinical trial protocols submitted (or intended to be submitted) in a clinical trial application for medicinal products intended to treat, prevent or diagnose COVID-19 as part of an accelerated scientific advice process, pursuant to Article 16(2) of Regulation (EU) 2022/123;

Whereas scientific advice on quality and non-clinical aspects for medicinal products for COVID-19 fall outside the scope of Article 16 of Regulation (EU) 2022/123 and, therefore, is not subject to the fee reduction foreseen in said provision;

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, as stated in Article 9(1) of Council Regulation (EC) No 297/95;



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, and therefore it is considered necessary to grant fee incentives also on quality and non-clinical aspects for medicinal products for COVID-19;

HAS DECIDED:

### **Article 1 - Scope of the initiative**

Reduced fees shall be granted for scientific advice for medicinal products intended to treat, prevent or diagnose COVID-19 falling outside the scope of Article 16(2) of Regulation (EU) 2022/123 (namely, scientific advice on quality and non-clinical aspects for said products).

### **Article 2 - Fee reductions**

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

### **Article 3 – Remuneration of national competent authorities**

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**

This Decision shall take effect on 25 April 2022 and shall be valid until the World Health Organization declares that the outbreak of COVID-19 no longer constitutes a public health emergency of international concern.

Amsterdam,

Emer Cooke  
Executive Director