



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/225719/2020  
Executive Director

## Decision of the Executive Director

### On fee reductions for Good Manufacturing Practice (GMP) on-site inspections due to COVID-19 pandemic

#### 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)<sup>1</sup> and in particular Article 57(1)(i) 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 Medicines Agency and other measures, and in particular Annex IV thereof,

Having regard to the extraordinary worldwide public health measures implemented, to identify, isolate and test contacts in order to contain the outbreak of the infection of COVID-19, including travel restrictions and social distancing rules;

Having regard to the consultation with the Committee for Medicinal Products for Human Use (CHMP) on 30 April 2020 and with the Committee for Medicinal Products for Veterinary Use (CVMP) on 5 May 2020 regarding the exceptional circumstances and the imperative reasons of public health for inspections to be carried out despite travel restrictions to assess compliance with good manufacturing practice at manufacturing sites and blood establishments,

Having regard to the published 'Questions and answers on regulatory expectations for medicinal products for human use during the COVID-19 pandemic' of 10 April 2020 and 'Questions and answers on regulatory expectations for veterinary medicinal products during the COVID-19 pandemic' of 30 April 2020 of the European Commission, Heads of Medicinal Agency (HMA) and the Agency, according to which European Economic Area's National Competent Authorities may carry out distant assessments at the request of EMA following adoption of an inspection request by the CHMP or CVMP, respectively,

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<sup>1</sup> OJ L 136, 30.04.2004, p. 1



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 and animal health that GMP inspections are carried out to confirm that medicinal products are manufactured in compliance with the provisions on good manufacturing practice,

HAS DECIDED:

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

Reduced fee levels shall be introduced for GMP on-site inspections, in cases where a distant assessment had been conducted for the said site during the period where access to sites for inspections were restricted due to COVID-19 pandemic, but where based on this distant assessment GMP compliance could not be confirmed due to the limitations of a distant assessment, consequently no GMP certificate could be issued, and thus a subsequent on-site inspection is required to confirm compliance.

Plasma Master Files inspections are also in the scope of this initiative and will follow the same principle, if applicable.

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

The applicable fee for the on-site inspection in accordance of Article 1 above shall be reduced by 100%.

### **Article 3 – Remuneration of national competent authorities (inspectors)**

During the initiative, the remuneration to national competent authorities shall not be reduced, if the national competent authority provides a comprehensive inspection report for the distant assessment and a subsequent independent report for the on-site inspection.

### **Article 4 - Processing of fee reductions**

During the initiative, any request for inspection covered by this decision will be assigned the applicable reduced fee. No separate request for fee reduction by the applicant or Marketing Authorisation Holder is required during this period.

### **Article 5 - Entry into force**

This decision shall be effective as of 12 May 2020.

Amsterdam,

[Signature on file]

Guido Rasi  
Executive Director