EUROPEAN
COMMISSION

Brussels, 17.6.2022
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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of 17.6.2022

laying down rules for the application of Regulation (EU) 2017/746 of the European Parliament and the Council with regard to fees that may be levied by EU reference laboratories in the field of *in vitro* diagnostic medical devices

(Text with EEA relevance)

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU[1], and in particular Article 100(8), first subparagraph, point (b), thereof,

Whereas:

(1) Where notified bodies and Member States request scientific or technical assistance or a scientific opinion from EU reference laboratories in accordance with Regulation (EU) 2017/746, those laboratories may levy fees to wholly or partially cover the costs incurred in carrying out requested tasks.

(2) In order to specify the structure of the fees, it is necessary to identify the categories of costs that can be covered by those fees.

(3) Where the testing activity is outsourced to national reference laboratories or other laboratories, costs incurred by those laboratories constitute part of the costs of the requested task. The EU reference laboratories should therefore be able to cover such costs by the fees levied.

(4) Given the wide variety of *in vitro* diagnostic medical devices on the Union market and the various tasks that can be assigned to EU reference laboratories, the calculation of the exact fee for each task should be at the discretion of the EU reference laboratories.

(5) Calculation of fees based on the costs incurred is the most transparent method of determining the fee level for a specific task; therefore, that method should be used for such calculation. Where the determination of the actual costs incurred in a certain category of costs would be unreasonably burdensome, the EU reference laboratories should be allowed to calculate fees on the basis of estimated average costs in that category. In order to make such calculation possible, the EU reference laboratories should make estimates of the average costs for the corresponding categories of costs.

(6) As it is impracticable to calculate precisely the incurred costs for the general operation of the laboratory for each task, the EU reference laboratories should charge such costs by calculating a percentage of the other costs combined. A maximum should be set for that percentage in order to ensure cost-effectiveness and predictability.

[1] OJ L 117, 5.5.2017, p. 176.

(7) In order to achieve transparency with regard to the structure and level of the fees, the EU reference laboratories should lay down the rules according to which the fees are calculated, including the rules for the estimation of costs based on average costs, and make them publicly available.

(8) To ensure that the fees adequately reflect the costs incurred in carrying out requested tasks, the EU reference laboratories should regularly review the rules for calculation of fees.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Committee on Medical Devices,

HAS ADOPTED THIS REGULATION:

Article 1

Structure of fees

1. The following categories of costs may be covered by the fees levied by the EU reference laboratories:

   (a) staff costs, including travel costs and associated accommodation and subsistence costs;

   (b) equipment costs, where the equipment is not provided by the manufacturer of the device to be tested;

   (c) costs of consumables, test specimens and reference materials;

   (d) shipping costs for samples;

   (e) translation costs;

   (f) general costs of the operation of the laboratory.

2. Without prejudice to paragraph 1, where the EU reference laboratory has a contract with another laboratory in accordance with Article 7(1) or (2) of Commission Implementing Regulation laying down rules for the application of Regulation (EU) 2017/746 of the European Parliament and of the Council as regards the tasks of and criteria for European Union reference laboratories in the field of in vitro diagnostic medical devices [C(2022)4311][2+], the fee levied by the EU reference laboratory may cover the amount it paid to that laboratory in accordance with that contract for the performance of the requested task.

Article 2

Level of fees

1. The fees levied by the EU reference laboratories shall be non-discriminatory, fair, reasonable and proportionate to the services rendered.

2. The EU reference laboratories shall set the fees based on incurred costs.

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[2] Commission Implementing Regulation (EU) …/… laying down rules for the application of Regulation (EU) 2017/746 of the European Parliament and of the Council as regards the tasks of and criteria for European Union reference laboratories in the field of in vitro diagnostic medical devices (OJ L …). [C(2022)4311]

[+] OJ: please complete the details of Commission Implementing Regulation … in the text and in the footnote.

Where the calculation of incurred costs is unreasonably burdensome for a particular category of costs referred to in Article 1(1), points (a) to (e), the EU reference laboratories may estimate the incurred costs based on the average costs for that category.

The amount of the fee covering the costs referred to in Article 1(1), point (f), shall be determined by calculating a percentage of the combined costs referred to in Article 1(1), points (a) to (e), and shall not constitute more than 7 % of the those costs.

Article 3

Rules for the calculation of fees

1. The EU reference laboratories shall lay down the rules according to which they calculate the fees for carrying out the requested tasks, including the rules for the estimation of incurred costs based on average costs, and shall make them publicly available on their websites.

2. The EU reference laboratories shall review the rules referred to in paragraph 1 at least every 2 years and, if needed, adjust them.

Article 4

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 17.6.2022

For the Commission
The President
Ursula VON DER LEYEN