FAMHP Fees & Contributions – REQUEST NATIONAL SCIENTIFIC-TECHNICAL ADVICE (STA)

Legal base

1. Article 5 of the Royal Decree of 31 March 2009 to implement article 6sexies of the Law of 25 March 1964 on medicinal products.
2. Law concerning the modification of the Law of 20 July 2006 concerning the establishment and operation of the FAMHP and diverse other provisions concerning the financing of the FAMHP.
3. Law of 7 April 2019 concerning the modification of provisions concerning the issuing of scientific and technical advice by the FAMHP and concerning the financing of the FAMHP and the creation of a cannabis bureau.
4. Program Law of 20 December 2020

Amounts applicable as of 11 Juin 2026

Requesters from pharma industry who do not commit themselves to introducing a clinical trial within two years *	
– SMEs, universities, registered hospitals, public utility foundations and public authorities	
o STA type I [VII.1.11.1.4]	**730,33 €**
o STA type II [VII.1.11.1.5]	**4.381,94 €**
o STA type III [VII.1.11.1.6]	**5.842,60 €**
– other organisations and companies	
o STA type I [VII.1.11.1.1]	**2.921,29 €**
o STA type II [VII.1.11.1.2]	**17.527,76 €**
o STA type III [VII.1.11.1.3]	**23.370,37 €**
Requesters from pharma industry who commit themselves to introducing a clinical trial within two years *	
o STA type I [VII.1.11.1.7]	**0,00 €**
o STA type II [VII.1.11.1.7]	**0,00 €**
o STA type III [VII.1.11.1.7]	**0,00 €**
When not fulfilling the commitment	
o STA type I [V.3.1]	**2.782,18 €**
o STA type II [V.3.2]	**16.693,10 €**
o STA type III [V.3.3]	**22.257,49 €**
Medical device (also in combination with a medicinal product, also in vitro diagnostic, also human body material)	
o STA type I [VII.10.1.1.1]	**6.079,88 €**
o STA type II [VII.10.1.1.2.]	**20.670,23 €**
o STA type III [VII.10.1.1.3.]	**28.288,27 €**
o Consultation notified body – new product [VII.10.1.1.5]	**54.350,85 €**
o Consultation notified body – variation [VII.10.1.1.6.]	**23.762,74 €**
Borderline product [VII.10.1.1.4.]	**20.376,35 €**

* one year for COVID medicinal products

Payment

From 1 October 2021, the FAMHP uses a new invoicing method for requests for national STA type I, II and III that are managed by the unit National Innovation Office and Scientific-Technical Advice.

Specifically, this means that requesters do no longer pay a fee when introducing the request for advice. Instead, they pay based on the invoice sent by the Budget and Management control division of the FAMHP.
With each payment, the structured communication on the invoice must be mentioned, allowing us to link the payment with the correct invoice, even if a third party makes the payment.
Without structured communication the invoice will be considered as unpaid.

About the procedure

1. **Each quarter** the company receives an invoice for all requests for national STA that were submitted in the past quarter.
2. The invoice mentions the **references** of the files.
3. The fact that the FAMHP does not use **Purchase Order (PO)** numbers is not a valid reason not to pay an invoice..
4. You always receive the invoice on the **invoice address**. In the cover letter at the introduction of the advice request you can mention your email address for invoicing.
5. Have you already paid a fee for a recent advice request? Send an email to refund@fagg.be to ask for a refund of the fee.
6. Any **bank fees** for payments from abroad are never at the expense of the FAMHP. These fees are to the account of the payer.
7. If the submitter **withdraws** a STA request after its validation, the fee is due all the same.
8. If, at the end of the validation phase of the procedure, the FAMPH declares a formally submitted STA request “**invalid**”, no fee is due.