

Decision Ref. no. FIMEA/2024/001666

15 March 2024

Finnish Medicines Agency Fimea's price list for services priced according to commercial criteria

The Finnish Medicines Agency Fimea may provide specialist services to its stakeholders that are not directly related to the statutory duties of a government agency. These specialist services are priced according to commercial criteria and the unit prices are indicated in the list below. Specialist services provided by Fimea are based on Fimea's competence in the pharmaceutical sector in general and in pharmaceutical safety in particular.

Under section 9 of the Act on Criteria for Charges Payable to the State, section 4 of the Decree issued by the Ministry of Social Affairs and Health on fees chargeable by the Finnish Medicines Agency (1282/2023), and section 34 of the Act on the Openness of Government Activities (621/1999), the Finnish Medicines Agency Fimea prescribes the following fees:

Price List 1 April 2024

Training services

Services charged on an hourly basis (minimum 1 hour). The price includes standard preparation for the training session and any related materials. If providing the training requires non-standard preparation (data acquisition and editing, a new subject area, lecturing in a non-native language etc.), time spent on preparations will be invoiced as work performed by an assistant.

Price list: Training services		
Tax-free/taxable price	VAT 0%	VAT 24%
Specialist	€ 220.00/h	€ 272.80/h
Assistant	€ 100.00/h	€ 124.00/h

Fees for training services are payable to Fimea. Travel expenses are invoiced separately according to government travel expense guidelines.

Fees may be partly or fully waived if the training promotes the fulfilment of Fimea's duties and it is organised by a public sector entity, a trade union or a non-profit organisation, and attendance is free of charge.

Services charged on an hourly basis (minimum 1 hour)

Price list: Consultation charges			
Tax-free/taxable price	VAT 0%	VAT 24%	
Specialist	€ 220.00/h	€ 272.80/h	
Assistant	€ 100.00/h	€ 124.00/h	

Fees for consultation services are payable to Fimea. Travel expenses are invoiced separately according to government travel expense guidelines.

Information searches carried out on request and information services relating to data and information systems, except for minor guidance and advice (incl. studies of a research nature)

Unless otherwise agreed, charging is based on hourly work (minimum 0.5 hours) and any copies of documents as follows:

Price list: Information services relating to data and information systems, except for minor guidance		
and advice (incl. studies of a research nature)		
Tax-free	VAT 0%	
Specialist	€ 100.00/h	
Assistant	€ 50.00/h	

Requests for information services are VAT exempt

Standard document requests

Copies of original documents	€ 1.00/page	
Printout of the register's list of documents	€ 1.00/page	
Delivery fee	€ 6.00/shipment	

Requests for documents are VAT exempt.

No fee is charged for sending a public document saved electronically by email to the person requesting the information. No fee is charged for sending the register's list of documents in file format by e-mail to the person requesting the information.

If the implementation of the document request requires that the documents be requested from the National Archives, the applicant will also be charged a fee for the submission of the document to Fimea. Retrieval of information and measures required by confidentiality € 100.00/h

In addition to the above copy and delivery charges, a fee is charged for the following measures according to the actual working hours:

- Retrieval of information when the requested document is not sufficiently specified in accordance with section 13 of the Act on the Openness of Government Activities.
- Removing confidential parts when they cannot be easily removed.

The aforementioned photocopying and reproduction fees may be waived in whole or in part in the case of guidance, advice, or information related to cooperation between authorities or educational activities of the educational institution.

Requests for documents are VAT exempt.

Specially ordered reports, investigations, inspections and analyses

Price list: Specially ordered reports, investigations, inspections and analyses			
Tax-free/taxable price	VAT 0%	VAT 24%	
Laboratory specialist	€ 220.00/h	€ 272.80/h	
Laboratory Assistant	€ 100.00/h	€ 124.00/h	

Specially ordered laboratory work

Price list: Specially ordered reports, investigations, inspections and analyses, specially ordered la-				
boratory work				
Tax-free/taxable price	VAT 0%	VAT 24%		
Sterility test (membrane filtration)	€ 393.00/sample	€ 487.32/sample		
Sterility test (direct inoculation)	€ 226.00/sample	€ 280.24/sample		
Sterility test (automated inoculation, alternative method)	€ 319.00/sample	€ 395.56/sample		
Total viable count	€ 242.00/sample	€ 300.08/sample		
Specific microorganisms	€ 378.00*/sample	€ 468.72/sample		
Bacterial endotoxins: gel-clot	€ 401.00/sample	€ 497.24/sample		
Bacterial endotoxins: Kinetic chromogenic	€ 310.00**/sample	€ 384.40/sample		
Bacterial endotoxins: Kinetic turbidimetric	€ 310.00/sample	€ 384.40/sample		
Particle count (Subvisible particles, LO method)	€ 214.00***/sample	€ 265,36/sample		

* If the sample shows microbial growth, microorganisms to be identified and pricing will be agreed on separately

** May include all necessary retesting and the dilutions

*** May include purity control and special glass dishes

Terms of payment: 21 days net

A penalty interest specified in the Interest Act will be charged for delayed payments.

For cash on delivery shipments, the Posti Group Corporation's charges will be added to prices.

Entry into force

This decision will enter into force on 1 April 2024 and will remain in force until further notice. This decision will invalidate the price list issued on 1 May 2022, ref.no. FIMEA/2022/001982. The current value added tax will be charged for services provided.

Lauri Kaanela Head of Unit, Finance

Rauli Nylander Controller

fimea

Asiakirjan sähköinen allekirjoitus Elektronisk underskrift av dokument Electronic signature of a document

Asia / Ärende / Case: FIMEA/2024/001666 Fimean liiketaloudellisten suoritteiden hinnasto 2024

Asiakirja / Dokument / Document: FIMEA/2024/001666-1 Fimean liiketaloudellisesti hinnoiteltujen suoritteiden hinnasto 1.4.2024

Allekirjoitukset / Underskrifter / Signatures:

Signed By:Lauri Kaanela Signed at:2024-03-15 20:26:40 +02:00 Reason:Witnessing Lauri Kaanela

Signed By:Rauli Nylander Signed at:2024-03-15 12:27:38 +02:00 Reason:Witnessing Rauli Nylander