Guidance on fees in relation to Medical Devices

1. Fees pertaining to medical devices procedures

The fees pertaining to medical devices procedures and applications payable to the Medicines Authority are laid out in Subsidiary Legislation S.L.458.46, as amended by Legal Notice 245 of 2025 under schedule 5. Audit or Inspection fees refer to announced, unannounced or 'for-cause local reviews.

2. Effecting Payment

Fees must be paid to the Medicines Authority bank account details:

Bank: HSBC Malta plc.
Gżira Branch
Malta
Account No. 039-011176-002
Swift Code MMEBMTMT
IBAN MT78MMEB44392000000039011176002

Please also note that whenever a payment is effected in respect of an application which is submitted to the Medicines Authority, the following details need to be submitted to finance.medicinesauthority@gov.mt and mdforms.medicinesauthority@gov.mt:

- The name of the company effecting payment
- The name of the company on behalf of which the payment is effected (where applicable)
- The amount paid
- Date of payment
- Payment details e.g., type of application and reference no.; invoice number (where applicable)

A copy of the proof of payment should accompany the submission.
If the fees paid are more than those that are due, credit is given, and the applicant is informed.
If the fees paid are less than those that are due, the applicant is informed to pay the correct fee.

3. Annual fees

An invoice for annual fee is issued by the Finance and Corporate Services Unit once the initial application procedure is processed by the Authority. Annual fees can be paid directly into the bank account of the Medicines Authority.

A) Procedure for Annual fees relevant to:

- Organisation Registration (MT-MDF02);
- Medical Device Registered Person (MT-MDF11);
- Notified Bodies (MT-MDF06)
- Designated premises for Covid testing (MT-MDF07)
- Notification of Covid tests (MT-MDF10)

Once the initial application is approved by the Authority, a pro-rata annual fee invoice is issued by the Finance and Corporate Services Unit up to December of that year. Subsequently an invoice by the Authority is issued annually for the year January to December.
In the case where an economic operator or Medical Device Registered Person wishes to withdraw the registration, the Authority should be informed about the withdrawal through the appropriate procedure before December to avoid being invoiced for the subsequent year. Annual fees are payable in full, and no pro-rata adjustments apply.

B) Procedure for Annual fees relevant to Product Notification (MT-MDF05):

Once the initial application is approved by the Authority, an annual fee invoice is issued by the Finance and Corporate Services Unit for the product year. For example, on completion of the initial product notification application eg May 2025, the annual fee invoice is issued to cover Period: May 2025 – April 2026 and so on thereafter.
In the case where an economic operator wishes to withdraw a particular product, the Authority should be informed about the withdrawal through the appropriate procedure before the elapse of the product's year end to avoid being invoiced for the subsequent year. Annual fees are payable in full, and no pro-rata adjustments apply.

4. References

Cap 458 Act no VII of 2020, An Act to amend the Medicines Act
https://legislation.mt/eli/act/2020/7/eng

Subsidary Legislation S.L. 458.59 Medical Devices and In-Vitro Diagnostic Medical Devices Provision On The Maltese Market Regulations
https://legislation.mt/eli/sl/458.59/eng

Subsidiary Legislation S.L. 458.61 – Testing of Covid-19 Regulations, Legal Notice 357 of 2021, as amended by Legal Notice 118 of 2022
https://legislation.mt/eli/sl/458.61/eng

Subsidiary Legislation S.L. 458.46 as amended by Legal Notice L.N. 254 of 2025 Medicines Act (Cap. 458) - Various Laws relating to Fees in respect of Private Medical Premises and Medicines (Amendment) Regulations, 2025, Schedule 5 - Fees related to Medical Devices and In Vitro Diagnostic Medical Devices
https://legislation.mt/eli/ln/2025/254/eng

EU legislations
https://health.ec.europa.eu/medical-devices-sector/new-regulations_en

European Commission Communication from the Commission: Guidelines on the adoption of Union-wide derogations for medical devices in accordance with Article 59 of Regulation (EU) 2017/745 (2020/C 171/01).
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020XC0519%2801%29

Signatures on File

List of Appendices N/A