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

IN EXERCISE of the powers conferred by article 106 of the Medicines Act, the Minister responsible for public health, after consultation with the Licensing Authority, has made the following regulations:-

Citation.

1. The title of these regulations is the Various Laws relating to Fees in respect of Private Medical Premises and Medicines (Amendment) Regulations, 2025.

PART I
Amendment to the Licensing Fees for Private Medical Premises Regulations

Amends the Licensing Fees for Private Medical Premises Regulations. S.L. 458.26.

2. This Part amends the Licensing Fees for Private Medical Premises Regulations and it shall be read and construed as one with the Licensing Fees for Private Medical Premises Regulations, hereinafter in this Part referred to as the "principal regulations".

Amends the Schedule to the principal regulations.

3. In the Schedule to the principal regulations the item "Pharmacy" shall be substituted by the following new item:

"Pharmacy € 215".

PART II
Amendments to the Medicines Authority (Fees) Regulations

Amends the Medicines Authority (Fees) Regulations. S.L. 458.46.

4. This Part amends the Medicines Authority (Fees) Regulations and it shall be read and construed as one with the Medicines Authority (Fees) Regulations, hereinafter in this Part referred to as the "principal regulations".

Amends regulation 2 of the principal regulations.

5. Regulation 2 of the principal regulations shall be amended as follows:

(a) immediately after the definition "concerned Member State" there shall be added the following new definition:

" "decentralised procedure" means the decentralised

procedure for human medicinal products provided for in Directive 2001/83/EC, as may be amended from time to time;";

(b) immediately after the definition "marketing authorisation transfer" there shall be added the following new definition:

" "mutual recognition procedure" means the mutual recognition procedure for human medicinal products provided for in Directive 2001/83/EC, as may be amended from time to time;";

(c) in the definition "variation to the terms of the marketing authorisation" the words "Article 6(2) of Regulation (EC) No726/2004, point (a) of Article 7(1) and Article 34(1) of Regulation(EC) No 1901/2006 of the European Parliament and of the Council and Articles 7 and 14(1) of Regulation (EC) No 1394/2007 of the European Parliament and of the Council" shall be substituted by the words "as defined in Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products, as may be amended from time to time,";

Amends regulation 3 of the principal regulations.

6. Regulation 3 of the principal regulations shall be amended as follows:

(a) sub-regulation (1) thereof shall be substituted by the following new sub-regulation:

"(1) The fees listed in the Schedules shall be paid to the Medicines Authority.";

(b) sub-regulation (2) thereof shall be substituted by the following new sub-regulation:

"(2) The validation and, or processing of applications shall commence only upon receipt by the Medicines Authority of proof of payment.";

(c) immediately after sub-regulation (5) thereof there shall be added the following new sub-regulations:

"(6) The failure to remit payment of any annual fee pertaining to marketing authorisations or other product licences may result in administrative measures on

authorisations or licences.

(7) Where any fee or charge payable in accordance with these regulations remains outstanding after the due date, the Medicines Authority may, without prejudice to any other legal remedy available for the recovery thereof, suspend or decline to provide any service or to undertake any regulatory procedure until such time as the full amount due, together with any applicable interest, has been received.".

7. Schedule 1 to the principal regulations shall be substituted by the following new Schedule:

Substitutes Schedule 1 to the principal regulations.

"**SCHEDULE 1**
(regulation 3)

PRODUCT AUTHORISATION FEES AND OTHER ACTIVITIES

Type of Application	**Fee €**
MUTUAL RECOGNITION PROCEDURE/ DECENTRALISED PROCEDURE/NATIONAL PROCEDURE (Malta Concerned Member State)	
New applications per product	
All applications	250

Type of Application	**€**
MUTUAL RECOGNITION PROCEDURE/ DECENTRALISED PROCEDURE (Malta Reference Member State)	
New Applications per product	
Article 8.3 of Directive 2001/83/EC: New active substance*	140,000
Article 8.3 of Directive 2001/83/EC: Known active substance*	125,000
Article 10 (a) of Directive 2001/83/EC*	35,000
Article 10 (b) of Directive 2001/83/EC*	40,000
Article 10(1) of Directive 2001/83/EC*	26,000
Article 10(3) of Directive 2001/83/EC*	28,000
Article 10(c) of Directive 2001/83/EC*	17,000

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Article 10(4) of Directive 2001/83/EC*	50,000
Article 10(5) of Directive 2001/83/EC*	26,000
Additional strength (applied for at the same time)	3,000
Additional pharmaceutical form (applied for at the same time)	4,000
Line extension	15,000
Parallel application (same timetable as lead procedure)	10,000
Mutual Recognition Procedure	10,000
Duplicate application (different timetable from lead procedure)	15,000
Application withdrawn during validation	90% of relevant fee is refunded
Change from Malta Concerned Member State to Reference Member State	5,000
Zero Day procedure (per product included in procedure)	500

*A discount of 30% shall be given on fees for Micro Enterprises as defined in Commission Recommendation 2003/361/EC

Malta Reference Member State in a Mutual Recognition Procedure/ Decentralised Procedure – Other activities	**€**
Renewal of Marketing Authorisation	1,000
Annual Maintenance fee (for each form and strength) †	900

† Activities covered include pharmacovigilance;

Type of Application	**€**
OTHER ACTIVITIES	
Renewal application per product (where applicable)	
National procedure	450
Mutual Recognition Procedure/Decentralised Procedure (Malta Concerned Member State)	450
Annual fee (for each form and strength) (All Authorisations) †	275
Transfer of Marketing Authorisation Holder (change in legal entity)	150

† Activities covered include variations (all types) and pharmacovigilance

Type of Application	**€**
Traditional Herbal Medicinal Products (Article 16 of Directive 2001/83/EC) (National/MT Reference Member State)	
Registration for Traditional Herbal Medicinal Product	10,000
Variations:	

Administrative	115
Technical	500
Renewal	800

Type of Application

Authorisation in accordance with regulation 4(2) of the Medicines (Marketing Authorisation) Regulations (S.L. 456.34)	**€**
New application	1,000
Annual fee†	500
† Activities covered include pharmacovigilance and notifications of variations	
Homeopathic Product	**€**
New Product (single stock)	250
New Product (for two (2) or more stocks)	500
Variations:	
Administrative	40
Technical	100
Renewal	100
Parallel importation licence (per strength/form/source country))	**€**
New parallel import licence application/renewal# of Parallel Import Licence	1,000
Annual fee†	500
# Renewal application shall be submitted 6 months before the expiration of the licence (every 5 years) † Activities covered include pharmacovigilance and notifications of variation	
Request for Authorisation under of the Clinical Trial Regulations (S.L. 458.43)	
Phase I, II, III or IV of Clinical Trials	**€**
Investigational medicinal product containing an established active substance	1,500
Investigational medicinal product containing a new active substance	2,000
Amendments to Clinical Trials	**€**
Notice of Amendment under the Clinical Trial Regulations (S.L. 458.43)	410
Amendments to include a new investigational medicinal product dossier	880
Application for clinical trial authorisation [under Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use and repealing Directive 2001/20/EC	
Applications with Investigational Medicinal Product Dossier (IMPD)	**€**
Mono National	3,170
MT – Reporting Member State	7,950
MT – Concerned Member State	2,000
Supplement – where MT subsequently becomes the Reporting Member State	4,780
Reporting Member State – 2nd & subsequent phases	500
Non Commercial/Academic Clinical Trials	300
Applications without Investigational Medicinal Product Dossier or with simplified Investigational Medicinal Product Dossier or a low intervention trial	**€**

Mono National	2,155
MT – Reporting Member State	6,750
MT – Concerned Member State	1,500
Supplement - where MT subsequently becomes the Reporting Member State	4,595
Reporting Member State - 2nd & subsequent phases	500
Non Commercial/Academic Clinical Trials	300
Substantial Modifications (Part one only) - with the addition of a new Investigational Medicinal Product Dossier (IMPD)	**€**
Mono National	1,230
MT - Reporting Member State	1,450
MT - Concerned Member State	1,175
Non Commercial/Academic Clinical Trials	100
Substantial Modifications – other	**€**
Mono National	760
MT - Reporting Member State	1,060
MT - Concerned Member State	300
Non Commercial/Academic Clinical Trials	100
Classification Committee	**€**
Classification Committee per product	50
Scientific advice/pre-submission meetings	**€**
Malta Reference Member State/Rapporteur in European procedures or for national procedures	2,300

[1] The fees in brackets are for applications for academic research without any financial support from industry. The decision shall be at the sole discretion of the Licensing Authority.

Exemption in line with Article 20 of the Medicines Act (Cap. 458)	**€**
New application for medicinal products sourced from within the EU (per specific product details)	550 and 50* processing fee
New application for medicinal products sourced from third countries (per specific product details)	1,500 and 50* processing fee
Exemption in accordance with Delegated Regulation EU 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use	**€**
New application (per specific product details)	150 and 50* processing fee
Non-resolution of alerts breach	400 and 50* processing fee

*The processing fee is not refundable if the application is withdrawn or rejected.".

Substitutes Schedule 2 to the principal regulations.

8. Schedule 2 to the principal regulations shall be substituted

by the following new Schedule:

"**SCHEDULE 2**

(regulation 3)

VARIATION FEES PER PRODUCT

Variation Type (for national procedures* and procedures where Malta is the Reference Member State in the Mutual Recognition Procedure and Decentralised Procedure)	**Fee €**
Type I	
Type IA	115
Batch specific exemption request	115
Type IB	350
Type II	
Type II Simple	1000
Type II Complex	4,000
* Where an application is not accompanied by an acceptable EU approval For grouped variations (in accordance with the Communication from the Commission – Guideline on the details of the various categories of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products) fees shall be charged for each variation included in the group for the first marketing authorisation (Marketing Authorisation number/Procedure number) but not for additional strengths which are included in the group and subject of the same variations.	
Specific exemption request for a batch (applicable to all registration routes)	150

Other post-authorisation activities (Malta Rapporteur/Reference Member State)	**€**
Assessment of PSUR/DSURs/ASR	2,300
Assessment of Post Authorisation Safety Studies (PASS) protocol	800 (400) [1]
Assessment of Post Authorisation Efficacy Studies (PAES) protocol	800 (400) [1]
Assessment of PASS Results	1,000
Assessment of PAES Results	1,000
Assessment of safety annual reports for coordinated safety member state procedure in accordance with Commission Implementing Regulation (EU) 2022/20 of 7 January 2022 laying down rules for the application of Regulation (EU) No 536/2014 of the European Parliament and of the Council as regards setting up the rules and procedures for the cooperation of the Member States in safety assessment of clinical trials	6,000

[1] The fees in brackets are for applications for academic research without any financial support from industry. The decision shall be at the sole discretion of the Licensing Authority.

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9. Schedule 3 to the principal regulations shall be substituted

Substitutes Schedule 3 to the principal regulations.

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by the following new Schedule:

"**SCHEDULE 3**

(regulation 3)

INSPECTORATE FEES

Activity (involving an inspection in Malta or within the European Union/European Economic Area)	Fee for type of Licence €	
	Issue of new licence and, or major initial inspection[1]	Annual renewal of licence[2]
GOOD MANUFACTURING PRACTICE[3] Issue of licence and annual renewal		
Full manufacture		
Small (less than 15 employees[4])	4,700	1,000
Medium (15 to 75 employees[4])	7,000	1,500
Large (76 to 200 employees[4])	9,350	2,000
Super (more than 200 employees[4])	14,000	3,000
Partial manufacturing	1,400	300

Activity (involving an inspection in Malta or within the European Union/European Economic Area)	Fee per type of Licence €	
	Issue of new licence and, or major initial Inspection[1]	Annual renewal of licence[2]
IMPORTATION, WHOLESALE DEALING		
Issue of licence and annual renewal		
Import[5]	950	500
Wholesale	500	250
PHARMACY		
Issue of pharmacy licence and inspection every year (includes all follow up and other inspections)	400	In accordance with the Licensing Fees for Private Medical Premises Regulations (S.L. 458.26)

Variation to pharmacy licence		
Administrative variation		80*
Non-administrative variation including an inspection		150*
*Fast-track service is offered at double the original fee		
OTHER ACTIVITIES (Frequency as required and involving an inspection in Malta or within the European Union)	Initial inspection	Follow-up and routine inspections
Good Clinical Practice (clinical trials) / centre / trial	1,100	250
Pharmacovigilance inspections	600	250

Activity (involving an inspection in a third country[6,9])	Fee for type of Certificate/ Inspection €

GOOD MANUFACTURING PRACTICE Issue of licence and annual renewal	Issue of new certificate and, or major initial inspection[1]	Annual renewal of certificate[2]
Full manufacture	25,000 and 600 per day per inspector[7]	7,500 and 600 per day per inspector[7]
Partial manufacturing	15,000 and 600 per day per inspector[7]	5,000 and 600 per day per inspector[7]
OTHER ACTIVITIES (Frequency as required and involving an inspection in a third country[6, 9])	Initial Inspection	Follow up and routine Inspections
Good Clinical Practice (clinical trials) / centre / trial	20,000 and 600 per day per inspector[7]	5,000 and 600 per day per inspector[7]
Pharmacovigilance inspections	20,000 and 600 per day per inspector[7]	5,000 and 600 per day per inspector[7]

ADMINISTRATIVE ACTIVITIES	**Fee €**	
Variations (not requiring an inspection)	80	
Issue of Certificate of a Pharmaceutical Product	100	
Issue of Certificate of a Pharmaceutical Product (fast-track)[8]	150	
Issue of Good Manufacturing Practice Certificates (not requiring an inspection)	80	
Supervision of destruction of pharmaceutical waste	50	

[1] Includes issue of licence and first time inspection.

[2] Includes inspections for licence renewal, routine inspections and other inspections. Fees also apply to variation applications that involve an inspection.

[3] Includes manufacture of finished dosage forms, Active Pharmaceutical Ingredients and Investigational Medicinal Products. When a company additionally manufactures Investigational Medicinal Products and a separate inspection is required the fee for this service shall be charged at 25% of that for initial inspections.

[4] Includes all the personnel employed within the company. It is the responsibility of the company to inform the Regulatory Authority of any changes in the number of its employees.

[5] Applications for an import authorisation by a company already in possession of a manufacturing or wholesale dealer licence shall be charged at 50% of the normal applicable rates for import activities.

[6] For applications involving an inspection in a third country the applicant has to additionally cover the flight and all accommodation and subsistence expenses allowance of the inspectors together with an additional €500 per inspector for other additional and sundry expenses.

[7] Includes days spent for actual inspection and for travel.

[8] This fee applies for the issue of Certificate of a Pharmaceutical Product within 48 hours.

[9] If a mutually agreed-upon scheduled inspection is cancelled 30 calendar days or less before the first day of inspection due to reasons attributable to the applicant, all applicable fees for third country inspections shall apply, including any costs related to flights and accommodation cancellations, if the cancellation occurs more than 30 calendar days before the first day of the inspection for reasons attributable to the applicant, a charge of €3,000 shall apply in addition to any costs associated with flights and accommodation cancellations.

Brokers of medicinal products and importers or distributors of active pharmaceutical ingredients shall be subject to all fees applicable for wholesale dealers.

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Substitutes Schedule 4 to the principal regulations.

10. Schedule 4 to the principal regulations shall be substituted by the following new Schedule:

"**SCHEDULE 4**
(regulation 3)

GENERAL

Activity	**Fee €**
Consultation (per man hour)	40
Issue of original copies of licences/certificates	20
Appeals	40
Appeals to Medicines Review Board*	11,650

(*Fee for appeals shall be fully refunded if appeal is successful)

Adds new Schedules to the principal regulations.

11. Immediately after Schedule 4 to the principal regulations, as substituted, there shall be added the following new Schedules:

"**SCHEDULE 5**
(regulation 3)

Fees related to Medical Devices and *In Vitro* Diagnostic Medical Devices

Standard service for the processing of an application is within a 30 working day timeframe from date of submission of the application and supporting documentation, unless otherwise specified with respective application fee details, below. Fast-track service is available for selected applications (marked with an asterisk*), for the processing of the application to be completed within a 10 working day timeframe. If the Authority requires any further information and, or clarification, this shall be communicated to the applicant and the time period shall be interrupted and the time period shall recommence to run, accordingly, upon receipt of the applicant's response.

All fees under Schedule 5 are non-refundable.

Distributor / Importer	**€**
Initial Application for Organisation Registration of Distributor/Importer	500*
Annual Registration of Distributor / Importer (renewable annually)	500*
Change in Organisation Registration Application details	100*
Initial Application for Notification of device per manufacturer	100
Annual Notification per device (renewable annually per group)	15*
Amending Notification of Medical Device	100*
Initial Application for Medical Device Registered Person (MDRP)	100*
Annual Registration of Medical Device Registered Person (MDRP) (renewable annually)	100*
Amending Medical Device Registered Person (MDRP) details	50*

*Fast-track service is offered at double the original fee

Manufacturer based in Malta	**€**
Initial Application for Organisation Registration application of Manufacturer	2,500*
Annual Organisation Registration for Manufacturer:	
> 150 employees[1]	25,000
100 – 150 employees[1]	18,000
50 – 99 employees[1]	12,000
16 – 49 employees[1]	5,000

5 – 15 employees[1]	1,250
< 5 employees[1]	250
Change in Organisation Registration application for Manufacturer	100*

*Fast-track service is offered at double the original fee

[1] Includes all the personnel employed within the company. It is the responsibility of the company to inform the Regulatory Authority of any changes in the number of its employees

Manufacturer (Non-EU) whose Authorised Representative is based in Malta	**€**
Initial Application fee for Manufacturer (Non-EU) with Authorised Representative is based in Malta	2,500*
Annual Organisation Registration of Manufacturer (Non-EU) whose Authorised Representative is based in Malta Annual Fee	2,500
Change in Organisation Registration of Manufacturer (Non-EU) whose Authorised Representative is based in Malta	100*

*Fast-track service is offered at double the original fee

Authorised Representative	**€**
Initial Application for Organisation Registration of Authorised Representative	500*
Annual Organisation Registration of Authorised Representative (maximum €50,000)	1,000
Change in Organisation Registration for Authorised Representatives	100*

*Fast-track service is offered at double the original fee

Notified Body	**€**
Notified Body Designation application – Initial Setup of Notified Body	30,000
Notified Body Designation application – Extension of Scope	10,000
Annual Application for Notified Body Designation	20,000

Application timeframe is according to EU legislation and Guidance document timelines.

Certificate of Free Sale	**€**
Certificate of Free Sale application (per DoC)	250*

*Fast-track service is offered at double the original fee

Device Registration in the European Market	**€**
Device Registration – placing a medical device on the European market application (per DoC)	100*
Device Registration – placing a medical device on the European market application – Amending Registration of Medical Device (Revised) Withdrawal incurs no charge	100*

*Fast-track service is offered at double the original fee

Derogations	**€**
Derogation application in terms of Article 59 of Regulation (EU) 2017/745 of the European Parliament and Council and Article 54 of Regulation (EU) 2017/746 of the European Parliament and Council	1,000
Derogation application in terms of Article 97 of Regulation (EU) 2017/745 of the European Parliament and Council and Article 92 of Regulation (EU) 2017/746 of the European Parliament and Council	1,000

MDR Derogation (Regulation (EU) 2017/745 on medical devices) Article 59 and IVDR (Regulation (EU) 2017/746 on in vitro diagnostic medical devices) Article 54, and MDR (Regulation (EU) 2017/745 on medical devices) Article 97 and IVDR (Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices) Article 92 (Renewal)	750

Timeline for the processing of an application is within a 90 working day timeframe from date of submission of the application and supporting documentation.

Clinical Investigation/ Performance Study	**€**
Pre-Submission Meeting Request application	1,000
Application/notification for clinical investigation in accordance with Articles 62 and 74(1) of EU Regulation 2017/745 of the European Parliament and Council	5,000
Application/notification for clinical investigation in accordance with Article 82 of the EU Regulation 2017/745 of the European Parliament and Council	1,000
Application/notification for performance study in accordance with EU Regulation 2017/746 of the European Parliament and Council	5,000
Modification to Clinical Investigation/ Performance Study application	500

Application timeframe is according to EU legislation and Guidance document timelines.

Applications related to Point-of-Care Covid-19 Testing	**€**
Initial Application for a designated premises for the performing of Point-of-Care Covid-19 Tests application	350*
Annual renewal application for a designated premises for the performing of Point-of-Care Covid-19 Tests	350*
Amending details for Designated Premises for the performing of Point-of-Care Covid-19 Tests application (to revise premises details within approved premises)	175*
Amending details for Designated Premises for the performing of Point-of-Care Covid-19 Tests application (to revise details of owner/manager and/or details of the responsible healthcare professional)	50*
Application for Initial Notification of Point-of-Care Covid-19 Test or Device for Self-Testing for Covid-19 to be placed on the local market	200*
Renewal of Annual Notification of Point-of-Care Covid-19 Test or Device for Self-Testing for Covid-19 to be placed on the local market	200
Amending details of Notification of Point-of-Care Covid-19 Test or Device for Self-Testing for Covid-19 to be placed on the local market –Withdrawal notification incurs no charge	100*

*Fast-track service is offered at double the original fee

Application for use of a Non-CE marked medical device in Malta	**€**
Application for use of a Non-CE marked medical device in Malta	500

Request for advice on Making Available Medical Device / *In Vitro* Diagnostic Products in Malta	**€**
Request Form for Advice on Making Available Medical Device / *In Vitro* Diagnostic Products in Malta	500
Request Form for Medical Device / *In Vitro* Diagnostic confirmation of risk classification	1,000

Timeline for the processing of an application is within a 90 working day timeframe from date of submission of the application and supporting documentation

Audit / Inspection fees - If the activity is of 8 hours, that is a whole working day, the 'per day' fee is applicable. Otherwise, 'per hour' fee applies. The fees below refer to the unannounced or 'for-cause' local reviews, addressing a particular issue or to verify compliance; which may include but are not limited, to inspections intended for clinical investigations/performance studies and notified bodies.

Audit/Inspection Fees	**€**
Per day, per member of the surveillance team	1,500
Per hour, per member of the surveillance team	200
Inspection Letter for Good Practice for Manufacturer (every 3 years)	500
Inspection Letter for Good Practice for Authorised Representative (every 3 years)	500
Inspection Letter for Distributor/Importer (every 3 years)	300
Clinical investigations/performance study initial inspection	1,500
Clinical investigations/performance study follow up inspection	500

Other Activities	**€**
Search Function fee of national medical devices database	50
Scientific Advice request	2,300

SCHEDULE 6
(regulation 3)

Fees related to Apostille of documents

Apostille Fees	**€**
Apostille handling fee (per document, excluding third-party expenses)	200

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VERŻJONI ELETTRONIKA

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