Guideline for fees payable to the Malta Medicines Authority in relation to medicinal products in accordance with Legal Notice 315 of 2006 (Subsidiary Legislation S.L.458.46) – Medicines Authority Fees

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Abbreviations

AA – Authorisation in accordance with article 126(a)

CMS – Concerned Member State

DCP – Decentralised Procedure

EMA – European Medicines Agency

MA – Marketing Authorisation

MRP- Mutual Recognition Procedure

PI – Parallel import

PAES – Post Authorisation Efficacy Studies

PASS – Post-Authorisation Safety Studies

PSUR – Periodic Safety Update Report

RMS – Reference Member State

THMP – Traditional Herbal Medicinal Products

1. Introduction

This guideline is intended to assist applicants and marketing authorisation holders in identifying the correct fees to be paid for applications for registration of medicinal products for human use, post-authorisation procedures and other medicinal product related fees. Proof of payment is to be submitted with all applications sent to the Licensing Directorate.

The applicable fees and any related agreements and invoices are governed by Maltese law, with any disputes subject to the exclusive jurisdiction of Malta's courts.

2. Registration of medicinal products to be placed on the market in Malta

2.1 European procedure applications for a marketing authorisation where Malta is Reference Member State (RMS) and national procedures

Fees for new applications through the decentralised (DCP) and mutual recognition procedures (MRP) where Malta is Reference Member State (RMS) and for national procedure are included in the table below:

Type of Application	**€**
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 (Bibliographic/well established use) application) *	26,000
Article 10 (b) of Directive 2001/83/EC (Fixed combination) *	26,000
Article 10(1) of Directive 2001/83/EC (Generic application) *	23,000
Article 10(3) of Directive 2001/83/EC (Hybrid application) *	23,000
Article 10(c) of Directive 2001/83/EC (Informed consent application) *	17,000
Article 10(4) of Directive 2001/83/EC (Similar biological medicinal product) *	40,000
Article 10(5) of Directive 2001/83/EC (Additional indication) *	26,000
Additional strength (applied for at the same time)	2,000
Additional pharmaceutical form (applied for at the same time)	2,000
Line extension applied for after grant of Marketing Authorisation*	10,000
Parallel application (applied for at the same time) *	10,000
MRP/Repeat use MRP *	10,000
Application withdrawn during validation	Refund of 90% of fees paid
Duplicate application/National Duplicate *	10,000
Change from Malta Concerned Member State to Reference Member State	4,000
Zero Day MRP	500

Table 1

Duplicate applications:

Duplicate applications submitted at the same time or later after submission of the lead procedure must be identical to the lead except for the product name and marketing authorisation holder (and relevant RMP and PSMF). If during the assessment phase new data is encountered, this may require the payment of the full (lead) fee.

The fee for each additional strength/s (including new strength/s introduced in initiation pack/s) and forms applied for at the same time (irrespective of the legal basis of the application) is €2,000.

Example: For an application for one pharmaceutical form in two strengths with legal basis article 10(1) of Directive 2001/83/EC the fee to be paid is:

	€
For first product – 25mg tablets	23,000
For the additional strength – 50mg tablets	2,000
For the additional form – oral solution 25mg/5ml)	2,000
	27,000

A parallel application applied for at the same time incurs a fee of €10,000 with an additional €2,000 for each additional form and strength.

A duplicate* application applied for after the start of the first procedure incurs a fee of €10,000 with an additional €2,000 for each additional form and strength.

Applicable discounts:

If the same applicant submits 3 new lead marketing authorisation applications nationally or through the decentralised procedure within a 12-month period (dates of submission should be within 12 months from the submission of the first application), the applicant is eligible for 30% discount on the total due for the 3 procedures. This discount is given when submitting the third lead application. Calculations should be made as per below example i.e. additional strengths or forms are not to be taken into consideration. These discounts only apply for marketing authorisation applications submitted through the national and Mutual Recognition and Decentralised Procedures with Malta as RMS.

The applicant who is eligible for the 30% discount is to kindly submit the form (Appendix 1) as per Annex 5.1 with the third application.

Example:	Fee for Initial Strength €	Amount to be paid €
First application (legal basis article 10(1))	23,000	23,000
Second application (legal basis article 10(3))	23,000	23,000
Third application (legal basis article 10(b))	26,000	
Total	**72,000**	
Less 30% discount	21,600	
Total amount to be paid for the 3 lead applications submitted within 12 months	**50,400**	
Amount to be paid with the third application, assuming first 2 applications were paid in full		
(€50,400 - €23,000 - €23,000)		4,400 *
Total		**50,400**

**This amount does not include the fee for additional strengths/forms hence these need to be included.*

Discount for Micro Enterprises

A 30% discount applies for applicants falling under the definition of a micro enterprise given in Commission Recommendation 2003/361/EC of May 2003 for new applications. This discount is only applicable for companies submitting marketing authorisation applications through the MRP, DCP with Malta as Reference Member State or through the national route only (marked by * in the above table).

To be able to avail of the discount applicable to micro-enterprises, applicants must provide documentation confirming that the company falls within the definition of a microenterprise, that is, that the company employs fewer than 10 employees and that your annual turnover and/or balance sheet total does not exceed €2 million (Commission Recommendation 2003/361/EC of 6 May 2003). A copy of the audited financial statements for the previous financial year or a letter from the auditors confirming the above would suffice.

The discounts above cannot be availed of at the same time.

A refund of 90% of the fees paid under section 2.1 is given for applications that are withdrawn by the applicant during the validation period or are invalid.

However, no refund will be made by the Malta Medicines Authority if the application proceeds after the validation period and is withdrawn by the applicant any time between Day 0 and the end of the procedure or the procedure has a negative outcome.

2.2 European procedure applications for a marketing authorisation where Malta is a Concerned Member State (CMS)

The fee for each product included in the same procedure is €250 (per form or strength included in the procedure including new strength/s introduced in initiation pack/s). This fee also applies for line extensions and Zero Day administrative procedures.

2.3 Registration of medicinal products to be placed on the market in Malta – other types of applications

2.3.1 Application for a new authorisation in accordance with article 126(a) of Directive 2001/83/EC (regulation 4(2) of the Medicines (Marketing Authorisation) Regulations)

	€
New application	450[1]
Fast track application for authorisation (10 working days)[2]	1,000[3]

Table 2

The fee for a new registration is €450 per product and per source country. Where in the source country, a different registration number is granted for different vial sizes (for injectable product only), these are considered as different products. Therefore, a fee per product is applicable. In these cases, one application form can be submitted to include all the vial sizes required. This is not relevant for different pack sizes/types, where only one fee is applicable for all sizes.

The possibility of a fast-track application has been introduced for authorisations in accordance with article 126(a). The authorisation will be issued within 10 working days of submission of payment and a valid application form (i.e. the timeline excludes the validation period in which the applicant must submit the correct/missing information/updated application form and clock-stops). If information is requested from the source country National Competent Authority, the time elapsed to receive such information is not included in the internal processing timelines of the Malta Medicines Authority.

If this option is chosen, please mark the tick-box on the first page of the application when filling in the form. This option is only considered for critical products and is

[1] 25% of the fee is to be paid upon submission of application and in case of positive outcome, the outstanding balance of 75% of the fee will be requested before issuing of final authorisation.
[2] 10 working days from valid application and exclude clock-stops.
[3] 25% of the fee is to be paid upon submission of application and in case of positive outcome, the outstanding balance of 75% of the fee will be requested before issuing of final authorisation.

accepted at the discretion of the Malta Medicines Authority.

2.3.2 Parallel import applications with reference products with a national marketing authorisation (granted through the national, MRP or DCP) and renewals

	€
New parallel import licence application/renewal	450

Table 3

The fee for a new registration and for the 5-yearly renewal is €450 per product and per source country.

2.3.3 Line extensions of products authorised in the transitional period

The fees for line extensions of national products authorised during the transitional period are €250 per product. Fees for line extensions of purely nationally authorised products incur fees as per table 1.

2.3.4 Traditional Herbal Medicinal Products (THMP) (Chapter 2a of Directive 2001/83/EC)

	€
National simplified registration (Traditional Herbal Medicinal Product Regulations) in accordance with article 16a of Directive 2001/83/EC	582.34
Administrative variations	34.95
Technical variations	69.88

Table 4

2.3.5 Homeopathic product registrations (Chapter 2 of Directive 2001/83/EC)

	€
New product (single stock)	232.94
New product (2 or more stocks)	465.87
Administrative variations	34.94
Technical variations	69.88

Table 5

3. Post-authorisation Procedures

3.1 Variations

3.1.1 Fees for variations for purely national products (those products not authorised through the transitional arrangements and their line extensions)

Type I	**€**
Type IA	115
Type IB	350
Type II	
Type II Simple	800
Type II Complex	4,000

Table 6

Products authorised through the transitional arrangements and their line extensions do not incur any fees if the submission is a variation:

- Accompanied by an approval letter from another EU National Competent Authority (to be provided in English and covering the scope/s of the variation applied for). For type IA variations proof of submission in another Member State is sufficient. and/or
- Resulting from paediatric worksharing (Article 45/46 of the Paediatric Regulation) not requiring further assessment and/or
- Resulting from a referral on the basis of an article 30 or article 31 of Directive 2001/83/EC and/or
- Following a PSUR worksharing procedure and/or
- Resulting from a referral on the basis of article 107(i) of Directive 2001/83/EC and/or
- Concerning a CEP update classified as a type IA variation
- Resulting from PSUSA, PRAC Recommendation, CMDh outcome impacting product information classified as a type IA variation.

If the variation is the result of any of the above, please indicate this clearly in the cover letter.

All variations where Malta is acting as RMS include a fee, as per the table above. The footnotes exempting fees do not apply for RMS variations. The above exemptions are not applicable for procedures where Malta is the RMS.

The definition of complex variations is given in detail in the Fees Legal Notice.

Grouping of variations:

Article 7(2)(a) of the Variations Regulation sets out the possibility for a MAH to group

several Type IA/IAIN variations under a single notification to the same relevant authority, or to group them with other types of variations.

Several Type IA and/or IAIN affecting several medicinal products from the same MAH provided that those variations are the same for all medicinal products and are submitted to the same relevant authority.

Type IA/IAIN can also be grouped with other variations (e.g. Type IB, Type II, extension application, as listed in Annex III of Commission Regulation 1234/2008. Groupings not included in the aforesaid Annex should be discussed and agreed with the Agency prior to submission.
Such grouped submissions will follow the review procedure of the highest variation in the group. Only one application needs to be submitted for a grouped variation and the cover letter should indicate that the application is for a grouped variation, as this will have an impact on the fees due. No grouping is necessary for products falling under the same global marketing authorisation undergoing an identical variation. In this case the fee for the single variation applies.

Variations can be grouped in line with the respective legislation and grouping guidelines.

Examples for Grouped (G) variations:

1. **Grouping of different variations for a number of products**

For grouped variations, a fee applies for each variation included in the group. However, no fee will apply for the additional strengths/products/procedures applied for at the same time which are the subject of the same variation.

Example 1

2 x Type IA and 1 x Type IB for 3

strengths 2 x Type IA (€115 + €

115) + € 350 (IB)

2. **Grouping of products/procedures undergoing the same variation**

Example 2

Grouping of the same variation for a number of products is also possible. In this case the fee to be paid is the fee for the single variation.

1 type IA variation (identical variation) for 20 products – the fee to be paid is

Euros 115. 1 type IB variation (identical variation) for 5 products – the fee to be

paid is Euros 350.

Example 3

*Worksharing/Grouping procedure where Malta is not Lead Member State, but which includes procedures where Malta is RMS and/or include products authorized in Malta through the National procedure ((***NOT authorised through the transitional arrangements and their line extensions)**

E.g. NL/xxxxWS/NN

a) Type IA variation – Euros 115^ (irrespective of the number of procedures involved)

b) Type IA variation and Type IB variation – Euros 115^ + Euro 350^ (irrespective of the number of procedures involved)

^The same fee for variations as per table 6, depending on the type of variation.

Example 4

Worksharing/Grouping procedure where Malta is the Lead Member State and includes different EU procedures.

E.g. MT/H/xxxx

a) Type IA variation – Euros 115 (irrespective of the number of procedures involved)
b) Type IA variation and Type IB variation – Euros 115 + Euro 350 (irrespective of the number of procedures involved)

The same fee for variations as per table 6, depending on the type of variation.

Example 5

Worksharing/Grouping procedure where Malta is the Lead Member State and includes different EU procedures including products authorized in Malta through the National procedure **(irrespective of whether national products are authorized through the transitional arrangements and their line extensions or not).**

E.g. MT/H/xxxx/

a) Type IA variation – Euros 115^ (irrespective of the number of procedures involved)
*b) Type IA variation and Type IB variation – Euros 115^ + Euro 350^*

(irrespective of the number of procedures involved)

^ The same fee for variations as per table 6, depending on the type of variation.

Example 6

Worksharing/Grouping procedure where Malta is the Lead Member State and includes products authorized in Malta through the National procedure (**(irrespective of whether national products are authorized through the transitional arrangements and their line extensions or not)** and in different Member States

E.g. MT/H/xxxx

a) Type IA variation – Euros 115^ (irrespective of the number of products involved)
b) Type IA variation and Type IB variation – Euros 115^ + Euro 350^ (irrespective of the number of products involved)

^ The same fee for variations as per table 6, depending on the type of variation.

3.1.2 Variations for procedures where Malta is CMS

Variations where Malta is CMS are covered by the annual fee and do not incur a processing fee.

3.1.3 Batch specific exemption requests (nationally or via DCP/MRP)

Batch specific variations incur the fee for a type IA variation.

3.1.4 Notifications for variations to products authorised in accordance with article 126(a)/ Variations for Parallel Imported products

The above notifications are included in the annual fee and do not incur a processing fee.

3.1.5 Changes in the legal status (prescription only to non-prescription in Malta).

A change in legal status (prescription only to non-prescription) is a national decision and the data for this change requires assessment. This change should be submitted as a type II variation, irrespective of the registration route.

A type II complex fee applies unless evidence is provided that product has already been assessed in another Member State as non-prescription medicinal product.

3.2 Annual maintenance fees and renewal fees

3.2.1 Malta Reference Member State and National Procedure

Annual fees for products authorised nationally (excludes the products that were part of the transitional list and their line extensions), and for products authorised with Malta as Reference Member State:

	€
Annual maintenance fee/product	800

Table 7

If annual fees are not paid, the Malta Medicines Authority reserves the right to suspend the Marketing Authorisations and cease processing of any post-authorisation procedures for product/s until they are paid.

Renewal for each marketing authorization number (one-time renewal, except in cases where the Malta Medicines Authority decides that additional renewals are required), is €1,000

3.2.2 Malta Concerned Member State and national products authorised during the transition period and their line extensions:

The renewal fee for each marketing authorization number is €450.

For injectable medicinal products, where more than one MA number is given to a number of presentations (vial sizes), a single fee of €450 will apply and will cover all presentations.

	€
Annual maintenance fee	275

Table 8

If annual fees are not paid, the Malta Medicines Authority reserves the right to suspend the Marketing Authorisations and cease processing of any post-authorisation procedures for product/s until they are paid.

3.2.3 Annual maintenance fees for other types of registrations – marketing authorisations granted in the transitional period and their line extensions, authorisations in accordance with article 126a and parallel import licences

	€
Annual maintenance fee (per authorisation/licence)	275

Table 9

If annual fees are not paid, the Malta Medicines Authority reserves the right to suspend the Marketing Authorisations and cease processing of any post-authorisation procedures for product/s until they are paid.

3.3 Transfer applications for marketing authorisations

A change in legal entity of the holder of a marketing authorisation incurs a fee of €150 irrespective of route of registration. This application applies for products authorised through the transitional arrangements and their line extensions, CMS and RMS.

3.4 Withdrawal applications

Withdrawal applications following the granting of a marketing authorisation do not incur any fees.

4. Clinical Trial applications

	€
Phase 1,2 or 3 patient trial with a known product	1,500
Phase 1,2 or 3 patient trial with a new product	2,000
Phase 4 patient trial	1,500
Amendment/s	150

Table 10

Fees for academic research without support from industry benefit from a fee exemption of 70% of full fee. Decisions on discounts are at the discretion of the Malta Medicines Authority.

5. Scientific Advice

	€
Scientific advice related to registration of medicinal products/application	2,300

Table 11

6. Assessment of PSURs, PAES and PASS

Other post-authorisation activities (Malta rapporteur/Reference Member State)	€
Assessment of PSURs	2,300
Assessment of Post Authorisation Safety Studies (PASS)	800 (400)
Assessment of Post Authorisation Efficacy Studies (PAES)	800 (400)

Table 12

Fees in brackets are for applications for academic research without financial support from the pharmaceutical industry. Decision will be at the discretion of the Licensing Authority.

The above fees are not applicable if the procedures are also levied a fee at the EMA.

7. Direct Healthcare Professional Communications

A fee of €2,300 is applicable for the Malta Medicines Authority to distribute DHPC communications. This fee covers all products (and companies) which are the subject of the communication.

8. Borderline Classification Committee

	€
Classification Committee per product	46.59

9. Reprints of Licenses

A fee of €11.65 per MA is applicable for the Malta Medicines Authority to reprint a license.

Appendices

Appendix 1 (Annex 5.1) Discount form

Signatures on File