

Below you can find the Fees Tables for:

- 1- Initial Marketing Authorisation Application – Spain & Portugal
- 2- Variations and Extensions – Spain & Portugal
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## Fees for Initial MAAs

Country	Modality of payment	DCP	MRP	National	Comments
Spain	<p>Proof of payment. Fees are to be paid preferably electronically. Filling of payment form model 317 by the applicant. Justification of payment is requested for validating of the application. A fee of 780,46* € is to be paid to reserve a slot for ES to act as RMS for a Decentralized or Mutual Recognition Procedure. it is discounted later when you pay the fees for submission.</p>	<p><b>Full dossier or hybrid</b> 21,362.73* €  <b>Generic</b> 8,689.78* €                      25% when acting as RMS in DCP</p>	<p><b>Full dossier or hybrid</b> 21,362.73* €  <b>Generic</b> 8,689.78* €                      One third of the amount to be paid when acting as RMS in MRP</p>	<p><b>Full dossier or hybrid</b> 21,362.73* €  <b>Generic</b> 8,689.78* €</p>	<p>No reduction for additional strengths.</p> <p>Annual maintenance fee for authorized medicines (385,03* €). Centralized products are exempt. It must be paid in December.</p> <p>MRP &amp; DCP: The fee expires 3 months from the payment date (notice to the applicant ref. SG, 1/2014).                      NP: The fee expires 10 days from the payment date (notice to the applicant ref. SG, 3/2013)</p> <p>*Fees from AEMPS website - Last update 20/01/2021</p>

## Fees for Initial MAAs

Country	Modality of payment	DCP	MRP	National	Comments
Portugal	<p>Proof of payment The application must be electronically pre-submitted in SMUH-AIM (local portal) and the fee should be validated by Infarmed. The validated proof of payment of fee is to be attached to the final submission.</p>	<p><b>PT is RMS:</b> 7,672.50* €; each supplementary dosage: 1,759.66* € <b>PT is CMS:</b> 3,069.00* €; each supplementary dosage: 613.80* €</p>	<p><b>PT is RMS:</b> 5,115.00* €; each supplementary dosage: 1,314.56* € <b>PT is CMS:</b> 3,069.00* €; each supplementary dosage: 613.80* €</p>	<p><b>Full dossier</b> 2,915.55* €; each supplementary dosage: 588.23* € <b>Generic or Hybrid</b> 1,759.56* €; each supplementary dosage: 291.56* €</p>	<p>Applicants / proposed MA holders should request access to SMUH-AIM. For each applicant / proposed MA holder, Infarmed assigns only one user and one password to access SMUH-AIM. Reduction for additional strengths * Fees from Infarmed website, 2021 - Tabela a que se refere o n.º 1.º da Portaria n.º 377/2005, de 4 de Abril</p>

## Fees for Variations & Extension

Country	Modality of payment	Type IA	Type IB	Type II	Extension of marketing authorisation	MA Transfer	Comments
Spain	Proof of payment Fees are to be paid preferably electronically. Filling of payment form model 317 by the applicant. Justification of payment is requested for validating of the application.	746,37* € 25% when acting as RMS	1287,07* € 25% when acting as RMS	7338,06* € 25% when acting as RMS	70% of the first product authorization or parallel submission (RD 1/2015 - art 123.2). 25% when acting as RMS	For MAH transfer or addition of Local Responsible: 725,90* € per MA, No reduction for additional strengths.	Reduction for additional strengths, each supplementary dosage: 377.59* € (RD 1/2015 -art 123.6) *Fees from AEMPS website - Last update 20/01/2021.

## Fees for Variations & Extension

Country	Modality of payment	Type IA	Type IB	Type II	Extension of marketing authorisation	MA Transfer	Comments
Portugal	The application must be electronically pre-submitted in SMUH-ALTER (local portal) and the fee should be validated by Infarmed. The validated proof of payment of fee is to be attached to the final submission.	DCP & MRP: 797,94* €, each supplementary dosage: 271,10* € If only company name or address MAH: 10 medicines - 383,63* € Each 5 more up 50 - 204,60*€ Each 5 more up 120 - 179,03* €, Each 5 more - 153,45* € NP: 40% fee reduction 478,76* €, each supplementary dosage: 162,66* € If only company name or address of MAH: 184,14* €	DCP & MRP: 797,94* €, each supplementary dosage: 271,10* € NP: 40% fee reduction 478,76* €, each supplementary dosage: 162,66* €	DCP & MRP: 1585,65* €, each supplementary dosage: 511,50* € NP: 40% fee reduction 951,39* €, each supplementary dosage: 306,90* €	3166,19* €, each supplementary dosage: 368,28* € NP: 40% fee reduction	291,56* €, each supplementary dosage: 102,30* €	* Fees from Infarmed website, 2021 - Tabela a que se refere o n.º 1.º da Portaria n.º 377/2005, de 4 de Abril

## Fees for Renewals

Country	Modality of payment	DCP	MRP	National	Comments
Spain	Proof of payment Fees are to be paid preferably electronically. Filling of payment form model 317 by the applicant. Justification of payment is requested for validating of the application.	2413,70* € 25% when acting as RMS in DCP	2413,70* € 25% when acting as RMS in MRP	2413,70* €	No reduction for additional strengths  MRP & DCP: The fee expires 3 months from the payment date (notice to the applicant ref. SG, 1/2014). NP: The fee expires 10 days from the payment date (notice to the applicant ref. SG, 3/2013)  *Fees from AEMPS website - Last update 20/01/2021
Portugal	The application must be electronically pre-submitted in SMUH-ALTER (local portal) and the fee should be validated by Infarmed. The validated proof of payment of fee is to be attached to the final submission.	PT is RMS 2404,05* €, each supplementary dosage: 291,56* € PT is CMS 1759,56* €, each supplementary dosage: 291,56* €	PT is RMS 2404,05* €, each supplementary dosage: 291,56* € PT is CMS 1759,56* €, each supplementary dosage: 291,56* €	1759,56* €, each supplementary dosage: 291,56* €	* Fees from Infarmed website, 2021 - Tabela a que se refere o n.º 1.º da Portaria n.º 377/2005, de 4 de Abril