

Guidance to applicants

Submission of Marketing Authorisation Applications

The purpose of this notice to applicants is to clarify aspects related with the submission to Infarmed – Autoridade Nacional do Medicamento e Produtos de Saúde, I.P., of Marketing Authorisation Applications (MAAs) by national procedure (NP), and by Mutual Recognition and Decentralised procedure (MRP/DCP). It should be used as a supplement to the Decree Law no. 176/2006 of 30 August, in its current wording, that establishes the legal regimen that regulates the marketing authorization of medicinal products for human use.

The Decree Law no. 176/2006 of 30 August, in its current wording lays down the content of the dossier for MAA by NP and by MRP/DCP, and the checklists published by Infarmed in [Página Inicial> Medicamentos Uso Humano> Autorização de Introdução no Mercado> Procedimentos de AIM](#) are supporting documents to the correct submission of applications.

The applicants are advised to carefully read the information provided in the electronic pages of [Infarmed](#) and [CMDh](#) to properly prepare a submission.

Applicants of MAAs by NP and MRP/DCP should submit the dossier to Infarmed only after electronic pre-submission of the application in the portal Medicinal Products for Human Use Management System – MAA (SMUH-AIM).

This document does not cover the simplified registration of homeopathic medicinal products, traditional herbal medicinal products and allergen products.

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1. Electronic pre-submission of MAA and payment of fee

All MAA by NP and by MRP/DCP, including MRP or RUP with Portugal as RMS (for which preparation of the assessment report by the RMS is required previously to the European procedure) must be pre-submitted in the portal [SMUH-AIM](#), available in the Infarmed website, before the submission of the dossier to Infarmed.

The issuing of the payment form with the reference for payment is performed using automatic calculation rules applied to the information in the online form, therefore applicants should consider the need to fill the form appropriately. Applicants should pay the amount discriminated using the indicated payment details.

Applicants are advised to carefully read the Instructions Manual of the portal SMUH-AIM, available in the same area of the Infarmed website, to ensure that applications are properly pre-submitted and to streamline their validation.

1.1. Instructions for payment of the applicable fees

The payment of fees applicable to MAAs is integrated in the new SMUH-AIM portal.

The issuing of the payment form is made by the applicant in the electronic platform after correct filling of the electronic application(s) form(s), and the fee is calculated by automatic calculation rules according to the information in this(ese) online form(s).

After issuing the payment form, the applicant must issue the reference for payment and subsequently pay the amount discriminated using the payment details indicated.

In addition, for applicants paying fees from the national territory, the payment will only be available via "Multibanco" (ATM) reference.

Applicants are advised to carefully read the Instructions Manual of the portal SMUH-AIM, available in the same area of the Infarmed website, to ensure the correct issue of the payment form and of the payment reference.

2. Submission of MAA to Infarmed

The MAA (i.e. the dossier) should only be submitted to Infarmed after electronic pre-submission in the portal SMUH-AIM and validation of payment of fee by Infarmed. The applicant should confirm validation of fee payment in the portal by checking the status "Payment of fee valid", usually between 1-3 working days after paying the fee.

The electronic pre-submission in the portal SMUH-AIM can be made as far ahead as deemed necessary, in order to not to restrict the formal submission of the application to Infarmed in the desired date.

The submission of the application to Infarmed may be made: sent:

- **By post mail**

The documentation should be sent to:

Submission of MAA-NP or Submission of MAA- MRP/DCP (as applicable)
Centro de Comunicação e Atendimento
INFARMED I.P.
Parque da Saúde de Lisboa
Av. do Brasil, n.º 53 – Pavilhão 24
1749-004 Lisboa

- **On-site at Infarmed**

The documentation should be delivered on-site to Infarmed at Pavilhão 24, Parque de Saúde de Lisboa - Avenida do Brasil, 53. The cover letter should mention in the subject *MAA-NP* (for national procedures) or *MAA-MRP/DCP* (for mutual Recognition and decentralised procedures).

In both situations, the submission of the documentation, by itself, does not determine the validation of the application.

The application submitted will be analyzed to verify its compliance with legal, technical and procedural requirements.

The validation of MAA by national procedure is described in [Annex I](#).

3. User registration

For each applicant / proposed MA holder, Infarmed assigns only one user and one password to access SMUH-AIM.

To request access (user and/or password), applicants / proposed MA holders should go to the [User Registration](#) platform at the Infarmed website, accept the terms of use, properly fill in the request form and included mandatory documentation.

The User Registration Manual available in the same area of the Infarmed website should be consulted.

4. Exclusive use of electronic communications

According to article 9 of the Decree Law no. 176/2006 of 30 August, in its current wording, concerning probative value of electronic communications, and with a view to streamlining communications between Infarmed and applicants with regard to validation, starting of the assessment, requests for further information and notification of the end of procedure (if applicable), the Medicinal Product Evaluation Department (DAM) will make communications exclusively by email.

The email addresses used by Infarmed where to applicants should send all correspondence are:

| Procedure Type | Infarmed e-mail addresses |
|--------------------------------------|--|
| MAAs by National procedure (NP) | aim.nacional@infarmed.pt |
| MAAs by MRP/DCP with Portugal as CMS | cms.procedures@infarmed.pt |
| MAAs by MRP/DCP with Portugal as RMS | rms.procedures@infarmed.pt |

The notification of the decision on MAAs with MAA certificate will continue to be sent by post mail.

At the time of electronic pre-submission of MAA, the document *“Declaration form for the use of e-mail communications with Infarmed”* must be attached, identifying the applicant’s e-mail address for Infarmed to send its communications.

The attached form for this declaration ([Annex II](#)) should be filled in, bearing in mind the following:

- Wherever possible, the applicant should indicate a shared e-mail (proxy) for institutional communications with Infarmed.
- The document *“Declaration form for the use of e-mail communications with Infarmed”* should be signed by the applicant / proposed MA holder or a duly authorised representative.

Annex I Provisions applicable only to National Procedure

Validation of the MAAs submitted by national procedure

The validation or invalidation of the application will always be communicated to the applicant within 10 days after the formal submission of the MAA to Infarmed.

Refusal of MAA

The grounds for refusal are:

- No **electronic pre-submission in the portal SMUH-AIM**
- No payment of fee.

Invalidation of MAA

The grounds for invalidation are:

- Non compliance with the provisions of the article 15 of Decree-Law n.º 176/2006 of 30 August, in its current wording.

Infarmed will notify the applicant of the grounds for invalidation and return 90% of the already paid fee. The applicant has 30 days to collect the CD/DVD (if applicable), after which it will be destroyed.

Validation of MAA

The applicant will be notified of the validation of the application.

It is possible to consult the status of a MAA by national procedure in the application [Gestão de Pedidos de AIM](#), using the same username and password assigned for SMUH.

List of questions during the assessment of MAA

In order to harmonize the number of list of questions during the assessment of MAA by national procedure, as well as the target dates for the submission of the responses by applicants, Infarmed inform that:

1. Each assessor can issue two list of questions. The target dates for the submission of the responses are:

- Quality and bioavailability/bioequivalence assessment:
 - 1st List of questions – 60 days
 - 2nd List of questions – 30 days
- Non-Clinical and Clinical assessment:
 - 1st List of questions – 30 days
 - 2nd List of questions – 10 days

2. A third list of question is exceptional and will only be possible after authorization of the Executive Board of Infarmed.

3. Infarmed can authorize an extension of the period for response to a list of questions, at most, equal to the 1st one given to answer. Exceptionally, Infarmed can authorize a 2nd additional extension of the period for response to list of questions not exceeding half the time of the 1st.

4. In preliminary hearings no additional time to response will be allowed.

Annex II Declaration form for the use of e-mail communications with Infarmed

<MA holder> <Authorized representative> <Applicant>, legal entity/taxpayer identification no. <taxpayer identification number>, with its registered office at <address>, represented herein by <name of MA holder representative>, in the capacity of <director, manager, legal representative, etc.> and duly authorised to act, hereby declares, for the purposes of the n.º 3 of article 9 of the Decree Law no. 176/2006 of 30 August, in its current wording, that all of its communications with Infarmed, I.P. relating to applications for MAs, shall be done using the following e-mail addresses:

· <MA holder e-mail address(es)>.

Signature _____

Date _____