

GUIDE FOR REGULATORY AND SCIENTIFIC ADVICE (RSA)

1. INTRODUCTION

The purpose of this guide is to give applicants guidance regarding the regulatory and scientific advice – RSA to be provided by Informed through the Regulatory and Scientific Advice Office (GARC).

The Regulatory and Scientific Advice Office has the competence to advise on issues arising with the preparation of documentation for:

- Clinical trial, marketing authorisation, submission of variations, renewals or other subjects related to medicines for human use;
- EC marking or complementary procedures;
- Notification or registration of medical devices and cosmetic products;
- Licensing and good practices procedures;

GARC's final goal is that applications are submitted in accordance with current regulatory and scientific requirements thus allowing for a quicker validation and assessment.

This guide will be regularly updated to reflect the scientific and regulatory evolution, in accordance with new legislation and applicable guidelines. It will also mirror the experience gained in the process.

2. SCOPE

INFARMED, I.P., provides scientific and regulatory advice regarding:

- Development, manufacture and monitoring of medicinal products in the areas of quality, non-clinical and clinical safety, including pharmacovigilance and risk minimisation, efficacy, economic assessment, licensing, inspection and publicity.
- Development and manufacture of medical devices in the areas of quality, non-clinical and clinical safety, including vigilance and risk minimisation, performance and publicity.
- Development and manufacture of cosmetic products in the areas of quality, safety, including vigilance and publicity.

Advice can be sought during initial development stages of medicinal products, medical devices and cosmetic products (pre-submission) and also during post-marketing.

Advice can not be sought after submission of an application for marketing authorisation, clinical trials or request for EC marking.

INFARMED, I.P., will not provide advice whenever the same advice has been requested to EMA's Scientific Advice Working Party (SAWP).

The advice provided by INFARMED, I.P., will only refer to questions to which no clear answer can be found on national regulation or in national or European guidelines, including European and Portuguese Pharmacopoeias.

The advice is provided by experts in different knowledge areas and will not bind Infarmed's final decision on the procedures in which the product will be involved.

3. PROCEDURE

The request for advice will be submitted in the appropriate GARC form. A written reply will be issued or a meeting will be planned upon request by the applicant or by the involved expert(s) to clarify doubts raised during assessment.

The questions shall be clearly stated, identify the main point to be advised on and provide the adequate framework to the problem.

Only five questions per area (i.e. clinical, pre-clinical, regulatory etc.) can be put in the same request and the applicant shall provide its opinion on the subject (one page per question in A4 format) Microsoft Office Word and PDF.

All documentation shall be provided in electronic format (Microsoft Office Word and PDF) and sent with the form to GARC at garc@infarmed.pt.

4. RSA REQUEST

4.1 WRITTEN ADVICE

INFARMED, I.P. advice shall be written and issued no later than 90 days. This time limit shall be suspended while waiting for supplementary information if requested or a planned meeting has been held and the minutes have been submitted for adoption.

The written advice might be replaced by the minutes of a meeting (see point 4.2) this method can be proposed by any of the parts.

The advice adopted will not bind INFARMED, I.P. to future decisions on any authorisation or certification procedures for which RSA has previously been sought.

Whenever the applicant needs additional information on the issued advice, a follow up request has to be submitted to Infarmed with a new set of questions.

The follow up request shall follow the same procedure as the original request.

4.2 MEETING

The meeting (face-to-face or virtual) with the applicant and/or company shall be convened no later than 30 days before the planned closing date.

The participants in the meeting shall be no more than seven and the company shall send a list of participants in the meeting indicating their present position. Should any change occur in the proposed list of participants a new list shall be sent to GARC at least one week before the meeting.

The applicant and/or company, should also submit a brief presentation about the company and the scope of advice.

The meetings will have a maximum duration of two hours.

In the meeting only, aspects related to the submitted request shall be discussed.

If a meeting with a company is convened the applicant shall send to garc@infarmed.pt the minutes of the meeting for comments within 10 days. The template of the minutes is available at GARC.

The minutes will be finalised by GARC and they will constitute the final advice.

ANNEX

REGULATORY AND SCIENTIFIC ADVICE REQUEST

1. COMPLETING THE APPLICATION FORM

In Infarmed's webpage (www.infarmed.pt) the following forms are available:

- Request for Regulatory and Scientific advice – Medicinal Products for Human Use
- Request for Regulatory and Scientific Advice – Medical Devices (Competent Authority)
- Request for Regulatory and Scientific Advice – Cosmetic Products

Mandatory fields to be completed are properly identified as well as those allowing for multiple options. The request for RSA will not be considered valid if the indicated mandatory fields are not completed.

The request form and relevant documentation shall be sent at least one version in word format by e-mail to the following address garc@infarmed.pt. For archival purposes, the subject on the email shall be: Request for Advice + Type (medical device/medicinal product/cosmetic product) + Product Name (if applicable) (i.e. Request for Advice + medicinal product + YWZ)

2. TIMETABLE*

Below is the detailed timetable applicable to Infarmed and RSA applicants.

RSA
INFARMED, I.P.
Validation – 10 days Convening of meeting – no later than 30 days Advice – 60 days Final advice and answer to company - 10 days
Applicant
Payment of Fee, after validation– 5 days Responses to requests – 10 days Submission of meeting minutes – 10 days
*Working days

3. FEES

Regulatory and Scientific Advice requests are subject to the payment of fees in line with the established in no.12 and 13, of the annex to Administrative Rule no. 377/2005, of 4th April.

Five days after receiving confirmation of the validation of the request the applicant shall pay the appropriate fee. The applicant should fill in the payment form available in INFARMED's webpage (only in Portuguese language). (www.infarmed.pt)

The applicant should make an electronic transfer of the sum corresponding to their request and ask his bank for proof of payment.

The applicant should send this proof of payment to the following email address garc@infarmed.pt along with the completed payment form.

An invoice can be given to the applicant by Infarmed, after the payment, only if the applicant requires it.

A duly justified request for fee reduction expressed in the submission form may be granted on grounds of interest for public health and company status, subject to management approval.

4. GARC CONTACT INFORMATION

For further information, please contact:

Regulatory and Scientific Advice Office (GARC).

INFARMED, I.P. – National Authority of Medicines and Health Products, I.P.

Parque de Saúde de Lisboa,

Avenida do Brasil nº 53 – 1700 Lisboa

Portugal

E-mail: garc@infarmed.pt

Phone : +351 21 798 7139/ + 351 21 798 7100

Site : www.infarmed.pt