



e-form

Scientific Advice Request (SAR) / Protocol Assistance (PA)



Please fill all the predefined fields as accurately as possible.

International Non-proprietary
Name (if available):

Trade name (if available):

Company product code:

Description of the product and
mechanism of action:

Type of product:

Comments:

Intended indication
therapeutic field:

Other ATC code (broad or detailed if
known).

Applicant/ Company:

Address:

Name of contact person:

Telephone:

Fax number:

Email address:

Alternate contact person details:

Telephone:

Fax number:

Email address:

**Name for Invoicing details (if
different from Applicant details):**

Address:

**Name of financial contact person
(if applicable or different from
procedure contact person):**

Telephone:

Fax number:

Email address:

Requirement for pre-submission meeting indicate:

Comments:

Small and Medium Sized Enterprises (SME) status:

For those with marketing approval:

Date of Marketing Authorisation granting:

Route of Marketing Authorisation:

For those with NO Marketing Approval:

Planned date for Marketing Authorisation application:

Planned Route of Marketing Authorisation application:

Additional Scientific Advice planned:

If yes, specify planned date:

At the time of submission of the SAR/PA request the following documents have to be uploaded (please use functions below):

-Questions and company's position (Word format).

-Detailed table of contents:

a. Background information, e.g.: Product Profile Investigators' Brochure.

b. Relevant study protocols or draft study protocols or study outlines.

c. Bibliographical data (references).

d. Content of previous scientific advice received.

e. Relevant guidelines (other than CHMP Guidance documents).

f. Contract agreement if the request is submitted by a consultant/CRO on behalf of the company.

Fee as per L.N. 427 of 2007 published under the EURO ADOPTION ACT, 2006 for scientific advice including pre-Submission Meetings with Malta as Reference Member State in MRP/DCP/national procedure (Scientific advice) Euros 2,300.00.

Appropriate proof of payment should always be attached with the request. Payment of the relevant fee should be made at:

Bank Details: HSBC Malta plc., Gżira Branch, Malta
Account Name: MEDICINES AUTHORITY
Account Number: 039-011176-002
IBAN: MT78 MMEB 44392 0000000 39011176002
Swift Code: MMEBMTMT

When effecting the payment the amount should be remitted in full, net of all bank charges.

Current Fees payable to the Medicines Authority for Clinical Trials are available in Legal Notice 315 of 2006: Marketing Authorisation (Fees) Regulations, 2006 and Pages 194-199 of Legal Notice 427 of 2007 - Fees in Euros.

Regulatory topics may be addressed at pre-submission meetings or in writing separately from the Scientific Advice request.