EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Scientific Advice and Protocol Assistance procedure		
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1. Purpose

To describe the procedure for the validation and evaluation of applications for scientific advice or protocol assistance in accordance with Regulations (EC) 726/2004 and (EC) 141/2000.

2. Scope

This SOP applies to the Scientific Advice office in the Scientific Evidence Generation Department.

3. Responsibilities

It is the responsibility of the European Medicines Agency to adhere to the processes described in this document .

4. Changes since last revision

Major revision.

5. Documents needed for this SOP

European Medicines Agency Guidance for Applicants seeking scientific advice and protocol assistance

CHMP protocol assistance scientific advice briefing document template

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6. Related information

0101 SOP - Conducting checks for CoI of Agency employees assigned duties relating to medicinal products for human or veterinary use (europa.eu)

0040 SOP - Evaluation of conflicts of interests of experts for involvement in Agency activities (europa.eu)

7. Definitions

CHMP	Committee for Human Medicinal Products
COMP	Committee for Orphan Medicinal Products
SAG	Scientific Advisory Group
SAWP	Scientific Advice Working Party
PR	Patient Representative
WP	Working party of the Committee for Human Medicinal Products

8. Records

Records produced from the procedure described in this document are stored in the European Medicines Agency customer relationship management and document repository systems.

9. Procedure

Step	Action
1	Receive submission for an application for scientific advice or protocol assistance
2	Hold preparatory meeting, if required.
3	Validate submission and involve identified WPs/SAGs/committees and PRs
4	Nominate coordinators
5	Start evaluation by drafting the first report
5	Discuss first report and decide outcome
6	Co-ordinate SAWP assessment - Outcome 1: list of issues to applicant - go to step 7 - Outcome 2: final advice letter – go to step 9
7	Send list of issues to applicant and receive written response to list of issues, if applicable
8	Hold discussion meeting

Step	Action
9	Draft joint report and incorporate comments from WPs/SAGs/committees and PRs involved
10	Conduct peer review
11	Draft final advice letter
12	Send to CHMP for adoption (and COMP when significant benefit questions are raised)
13	Send adopted final advice letter to applicant - END
14	Post-advice issues raised by the applicant
15	Respond to post-advice issues - END

10. Process Flow Chart