

Scientific advice procedures in the EU

– an overview of the regulatory background

Daniela Kenzelmann Broz,
Gabriele Galliverti, Anja Bühler

SFL Regulatory Affairs & Scientific
Communication GmbH, Basel, Switzerland

Correspondence to:

Daniela Kenzelmann Broz
SFL Regulatory Affairs & Scientific
Communication GmbH
Schillerstrasse 7
CH-4053 Basel
+41 61 361 9443
d.kenzelmann-broz@sfl-services.com

Abstract

The prerequisite for obtaining marketing authorisation is an appropriate and robust data package that demonstrates a medicinal product's quality and its efficacy and safety in the proposed indication. Pharmaceutical companies can face regulatory challenges during product development, especially in case of novel treatment modalities, new substances, or rare indications. To support the generation of the appropriate evidence and accelerate patient access to novel treatments, both the EMA and National Competent Authorities offer scientific advice, which allows companies to obtain guidance from a panel of experts regarding quality, non-clinical, clinical, or other aspects of their development strategy. This review provides regulatory background information on the scientific advice procedure in the EU for medical writers, who may become involved in the preparation of the pertaining briefing package.

Background on scientific advice procedures

Legal basis and scope

Developing new medicines is a lengthy and complex process, with an estimated attrition ratio of 10.000:1 and overall costs that can exceed one billion US dollar.^{1,2} One of EMA's tasks is "advising undertakings on the conduct of the various tests and trials necessary to demonstrate the quality, safety, and efficacy of medicinal products" according to Article 57-1 (n) of Regulation (EC) No 726/2004 of the European Parliament and of the Council.³ Accordingly, the EU scientific advice (SA) procedure has been established by the EMA to support the timely and sound development of high-quality, effective, and safe medicines, for the benefit of patients.^{1,4} Since the establishment of the procedure in 1996, the number of SA requests has steadily increased (Figure 1).⁵⁻¹¹

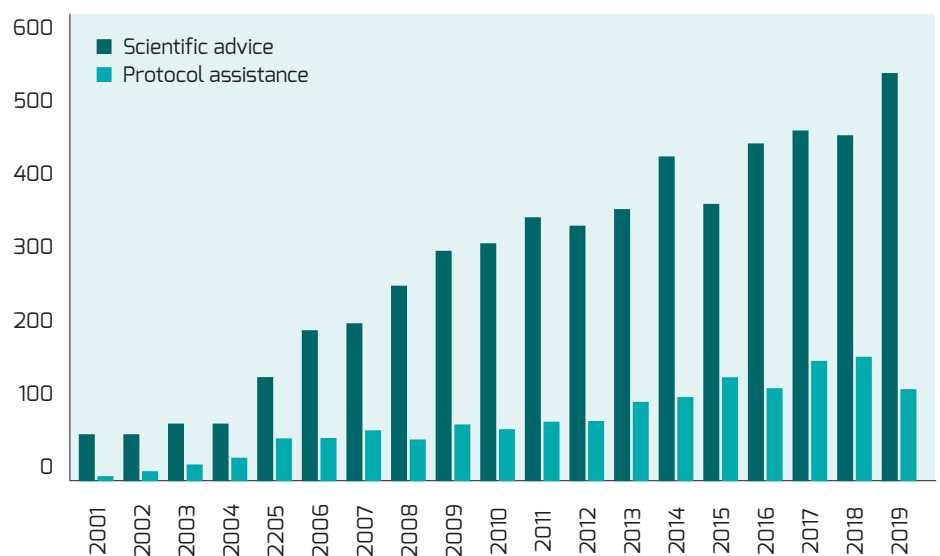


Figure 1. Numbers of scientific advice and protocol assistance requests to the EMA

Source: EMA annual reports 2001, 2004, 2007, 2010, 2013, 2018 and 2019⁵⁻¹¹



SA may be requested for all medicinal products for use in humans, irrespective of their eligibility for the centralised marketing authorisation procedure^{12,20}. While SA is issued by the Committee for Medicinal Products for Human Use (CHMP), it is based on the recommendation of the Scientific Advice Working Party (SAWP), a multidisciplinary expert group that comprises a chairperson and up to 36 members selected based on complimentary scientific expertise. Its combined expertise covers a broad range of therapeutic areas, as well as multiple aspects of the drug development process including manufacturing, preclinical pharmacology and toxicology, clinical pharmacology and pharmacokinetics, gene and cell therapies, clinical trials, and statistics. Furthermore, the SAWP has access to a network of European experts and regularly interacts with the FDA, Health Technology Assessment Bodies (HTABs), the WHO, and patient organisations. The SAWP provides SA based on the applicant's position on the questions asked and on current scientific knowledge, which will be sent as a SA

letter to the applicant following adoption by the CHMP. While SA is not legally binding for either the applicant or the EMA, it is taken into consideration during the review of the marketing authorisation application (MAA), and any deviations from the provided SA needs to be well justified by the applicant. Although applicable throughout the EU, CHMP SA usually does not preclude additional consultations with national competent authorities (NCAs).^{12,13} Importantly, SA is intended to support an efficient MAA evaluation by providing guidance on the requirements and generation of appropriate data for benefit-risk assessment, it is not a pre-evaluation of data to support a planned MAA or evaluate approvability of the product.^{1,14}

Benefits for developers of medicines

The SA procedure is particularly of interest for developers of innovative medicines for rare indications and for products where guidelines are insufficient, or when a developer plans to deviate from the scientific guidelines in their develop-

ment plan. Furthermore, requesting SA is particularly recommended for small and medium enterprises (SMEs) and start-ups, as it gives access to high-level scientific scrutiny at reduced fees. SA promotes a more efficient use of resources during product development by providing feedback on the most suitable study designs and methodologies and reducing the risk of deficiencies in study designs at later stages. Compliance with the obtained SA has a major impact on the probability of a successful MAA outcome. Between 2000 and 2012, the MAA success rate for applicants whose trial design was considered as acceptable at the time of SA, or who modified a trial design to follow the SA recommendation, was 85% compared to 41% of those who had non-compliant trial designs.¹⁵ Furthermore, SA-compliant trial design was also associated with fewer major objections during CHMP review.¹⁵ These benefits for companies are reflected by the continuous strong uptake of the voluntary SA procedure, with 549 SA procedures in 2019, representing a 18% increase from 2018.¹¹

EMA scientific advice procedure

Process and timelines

The initial phase of the SA procedure (Table 1 and Figure 2) requires the submission of a letter of intent (LoI) and/or a draft briefing document to the EMA Secretariat three weeks before the intended start of the procedure, or approximately seven weeks if a pre-submission meeting is requested.¹² Upon forwarding to the SAWP, two coordinators are appointed to manage the SA procedure. As the SAWP meets monthly 11 times per year (no meeting in August), missing a relevant submission deadline delays the procedure at least one month. Although referred to as "draft" in the EMA guidelines, the submitted briefing document must be considered as final by the applicant; however, further changes may be required by the EMA. This initial phase is completed with the validation of the briefing document by the SAWP and the submission of the final briefing package via Eudralink by the applicant. The actual SA procedure (Figure 2) begins with a review of the briefing package by the SAWP coordinators and the preparation of a first report. The SAWP will discuss this report and decide whether the SA can be adopted without meeting the applicant (40 days procedure) or whether the applicant will be invited to

a discussion meeting (70 days procedure). In the latter case, the list of issues raised by the SAWP is addressed during a 90-minute meeting, which takes place at around day 60 and is usually held face-to-face (F2F). Subsequently, the SAWP coordinators will then send their joint report to the Agency Secretariat though currently due to the COVID-19 pandemic all meetings are held virtually until at least the end of 2020. Following peer review by the SAWP, CHMP, and the EMA, the final advice letter is adopted by the CHMP and sent to the applicant. Of note, while confidential in the pre-authorisation phase, SA will be included in the European public assessment report at the time of marketing authorisation after redaction of confidential information.¹³⁻¹⁴ Depending on the scope, the fee for SA currently ranges from 44,400€ to 89,000€, although reductions up to 100% can be granted for certain types of submissions, e.g., if

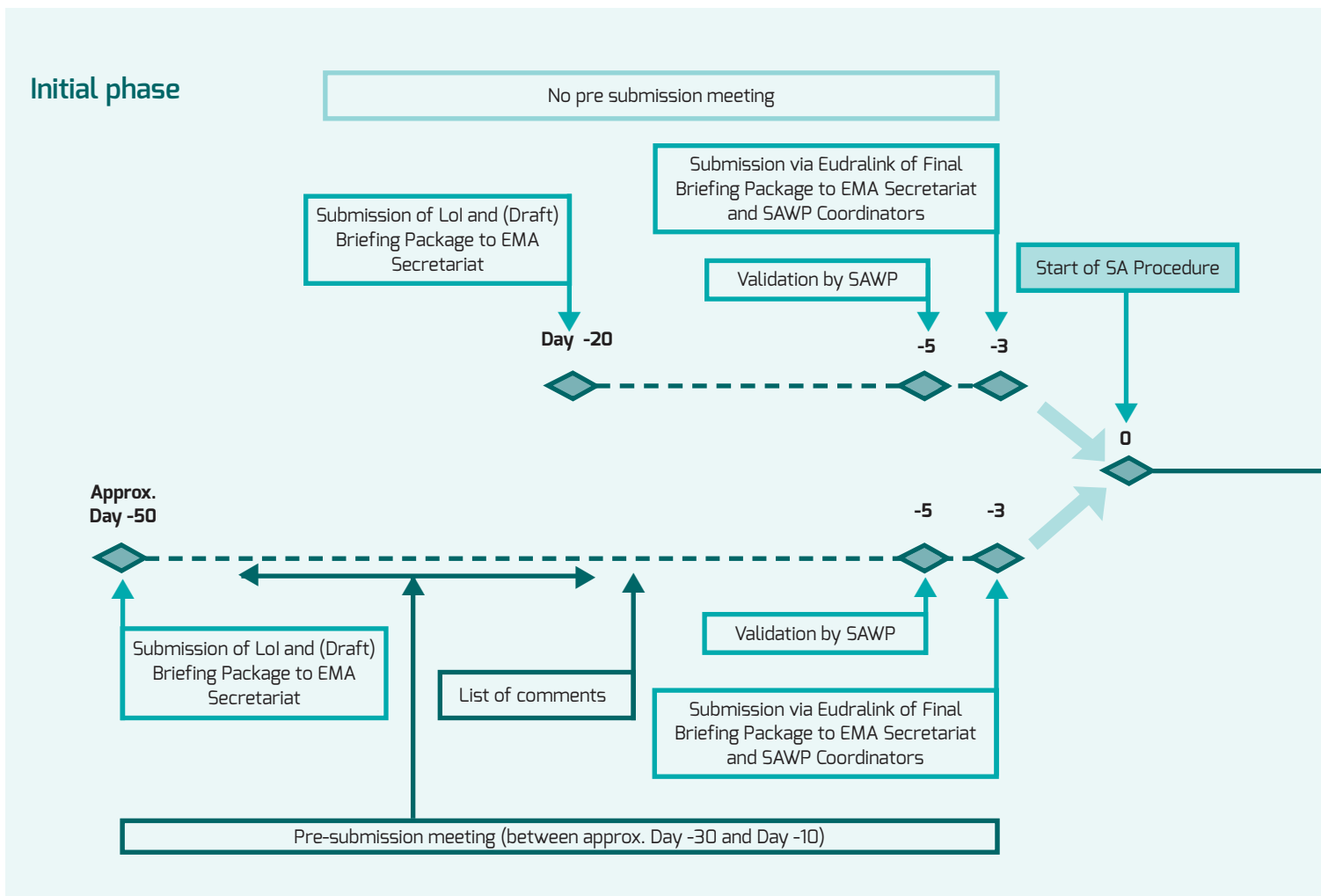
applicant is a SME and/or the developer holds an orphan drug designation (ODD) for the concerned product.^{13,16}

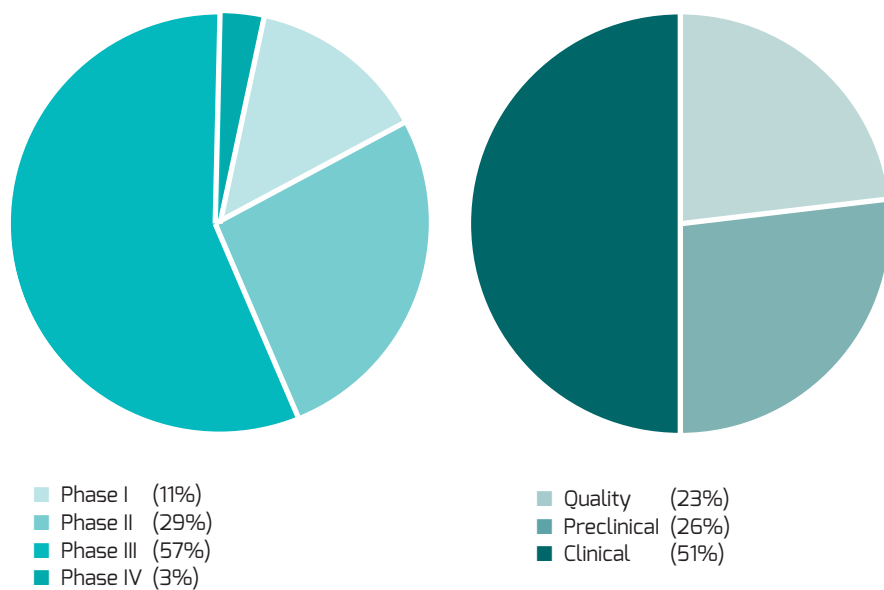
Scope of questions

SA can be requested at any point of product development, including the post-marketing phase. Questions can relate to any part of the development process, including quality, non-clinical, and clinical aspects as well as methodological issues such as statistical tests, data analysis, and modelling and simulation. Further topics in scope of SA include biosimilar development, risk-management plans, paediatric and geriatric development, or orphan drug development (see “protocol assistance for orphan medicines” below). In 2019, the majority of SA requests were related to medicines in phase III of clinical development and to clinical aspects (Figure 3).¹⁰

Document requirements

For both LoI and the briefing document, the use of the templates available on the EMA website is highly encouraged. The briefing document is the core of the SA request and consists of three main parts: I. summary, II. question(s) and applicant’s position(s), and III background information on the product. The summary (part I), which should typically not be longer than three pages, contains background information on the disease to be treated and a brief description of the product including quality, non-clinical and clinical development, its regulatory status, and an explanation of the rationale for seeking SA. The questions (part II) are grouped according to the area of expertise and numbered sequentially. Questions should be phrased carefully, clearly, and unambiguously to obtain a clear and precise answer, and their scope neither too broad nor too narrow to obtain meaningful advice. Typically,





questions are phrased starting with “Does the CHMP agree that/with” followed by the applicant’s proposal, which is detailed and justified in the applicant’s position following each question. The applicant’s position includes a comprehensive justification of the chosen approach, including the context and consideration of alternative options, with a critical discussion of the relative advantages and disadvantages of each approach. With a recommended length of 1–3 pages, each applicant’s position should contain sufficient detail to serve as a “stand-alone” argument, supported by cross-references to relevant parts of the briefing document or annexes supporting the argument, as needed. The background information (part III) provides a comprehensive overview of the medicine’s development programme and presents detailed information on quality, non-clinical, and clinical aspects; though consideration should be

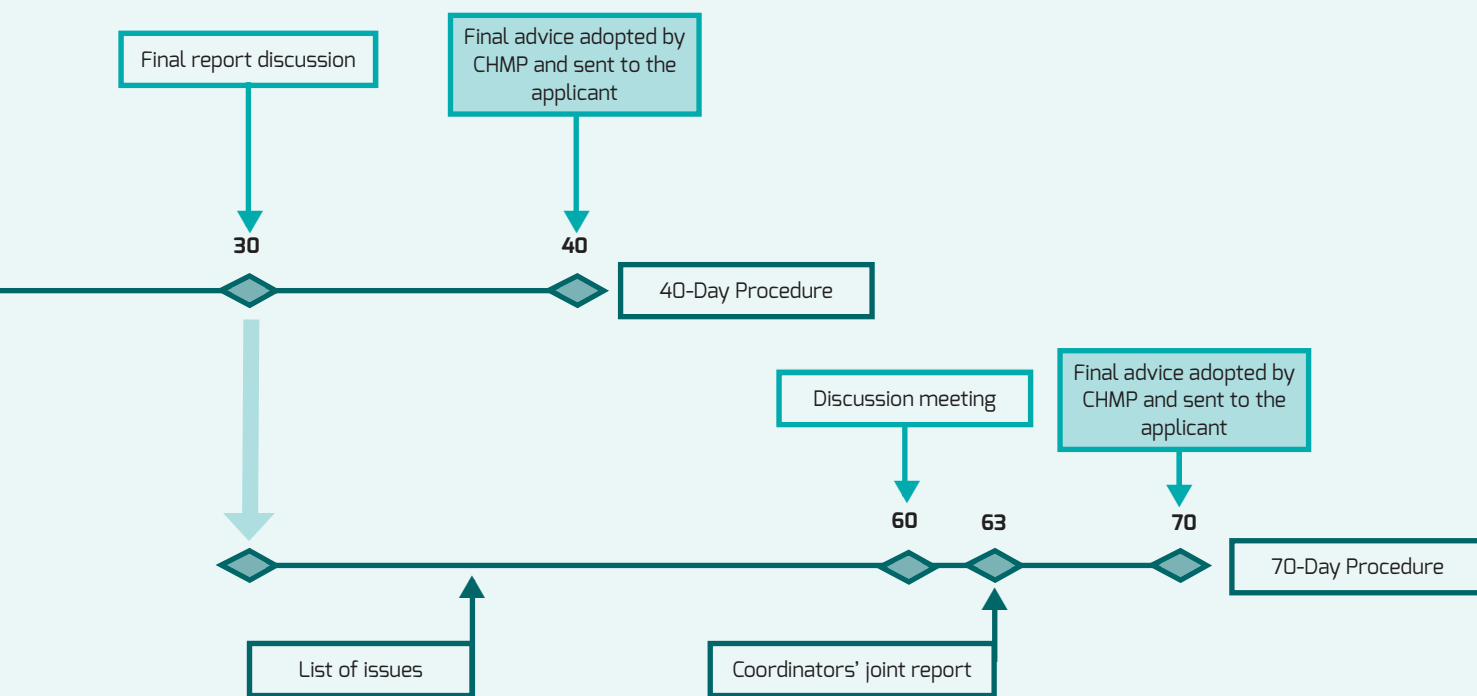
Figure 3. Scope of scientific advice and protocol assistance requests in 2019

Source: EMA annual report 2019.¹¹

SA procedure

Figure 2. European Medicines Agency scientific advice procedure timeline

Abbreviations: CHMP, Committee for Medicinal Products for Human Use; LoI, letter of intent; SA, scientific advice; SAWP, scientific advice working party
Image prepared by SFL Regulatory Affairs & Scientific Communication GmbH.





given to the content and level of detail to keep the overall size of the briefing document reasonable. Tabulated summaries are in the background section and are particularly helpful to keep information comprehensive yet concise. Finally, the final briefing package typically includes relevant annexes, such as the investigator's brochure, clinical study protocols, reports or synopses, previously received SA by the EMA or other regulatory agencies, regulatory documents such as ODDs or agreed paediatric investigation plans and literature references.¹² If the SA procedure includes a discussion meeting, this requires the applicant to prepare a response to issues to be addressed in writing prior to the discussion meeting and slides for a presentation and discussion of issues during the F2F meeting.

Special EMA scientific advice procedures

Protocol assistance for orphan medicines

Protocol assistance (PA) specifically refers to SA for orphan medicines. PA can be requested prior to MAA submission by applicants who have received ODD for the concerned product and follows the same procedure as regular SA (Table 1).¹³ Beyond the typical scope of SA, PA can also include topics specifically relevant for the development of orphan drugs, i.e., the clinical

development strategy to generate the appropriate data for demonstration of significant benefit within the designated orphan indication or in relation to orphan similarity.^{4,13} Between 2000 and 2013, 55% of applicants of orphan MAAs requested advice, compared to 42% for non-orphan MAAs. Similar to SA, the number of PA requests increased over the years (Figure 1) and compliance with PA was associated with a higher MAA success rate, compared to non-compliance (80% vs 36%).²¹

Parallel EMA-FDA scientific advice

The parallel scientific advice (PSA) programme has been established by the EMA and FDA in 2004 with the goal to encourage the dialogue between the agencies (Table 1), though its adoption so far has been limited by significant administrative and logistical resource requirements from the applicants. The PSA may be especially relevant for applicants developing important medicinal products for which no development guidelines exist, or for which existing guidelines differ significantly between the agencies, or for products with significant clinical safety, animal toxicology, or unique manufacturing challenges. Through PSA, the agencies will have the opportunity to discuss the applicant's question with each other and will try

to provide convergent responses; however, each advice is independent and may differ between the agencies. Furthermore, each agency will retain its individual regulatory decision-making authority regarding drug development issues and marketing applications.^{17,18,22}

Parallel consultation with EMA and Health Technology Assessment Bodies

Since July 2017, EMA and the European Network for Health technology Assessment (EUnetHTA) offer a parallel consultation procedure to assist in the generation of the necessary evidence to simultaneously support both the MAA of new medicines and their reimbursement (Table 1). This parallel procedure provides opportunities for mutual discussion, understanding, and problem solving between EMA and HTABs. Additionally, this new procedure facilitates the centralised recruitment of HTABs through the EUnetHTA, avoiding the requirement to contact each HTAB individually.^{19,23}

Qualification of novel methodologies

A dedicated SA procedure called qualification process supports the development of novel methodologies in medicine development (e.g., the use of a novel biomarker or clinical endpoint), resulting in either a CHMP quali-

Table 1. Overview of general and special EMA scientific advice procedures

SA procedure	Duration of the procedure and milestones	Documents required
EMA SA ¹³	<p>Overall duration: 60 to 115 days</p> <ul style="list-style-type: none"> ● Day -45 or -20: LoI and draft briefing document submission ● Day -3: Final briefing package submission ● Day 0: Procedure starts ● Day 40: EMA sends response (if no issues were found by the SAWP that required clarification) ● Day 70: EMA sends response (if SAWP had further issue to be addressed in writing and/or at a discussion meeting) <p>See Figure 2 for detailed timeline</p>	<ul style="list-style-type: none"> ● LoI ● Briefing package including: <ul style="list-style-type: none"> ● Part I: summary ● Part II: list of question and applicant's position ● Part III: background information ● Annexes and References
Protocol Assistance ¹³	<ul style="list-style-type: none"> ● Same as for general EMA SA procedure 	<ul style="list-style-type: none"> ● Same as for general EMA SA procedure
Parallel EMA-FDA ^{17, 18}	<p>Overall duration: 110 to 135 days</p> <ul style="list-style-type: none"> ● Day -45 to -20: LoI and draft meeting package submission + EMA/FDA agreement to PSA request ● Day -5: Final meeting package submission ● Day 0: Procedure starts ● Day 30: EMA-FDA meeting (integrated into the regular SAWP meeting schedule) ● Day 60: EMA-FDA-applicant meeting ● Day 70: EMA sends response ● Day 90: FDA sends response 	<ul style="list-style-type: none"> ● PSA request to both agencies ● EMA only: <ul style="list-style-type: none"> ● LoI ● Briefing package as for EMA SA/PA ● FDA only: <ul style="list-style-type: none"> ● Meeting package
Parallel EMA-HTABs ¹⁹	<p>Overall duration: 150 days</p> <ul style="list-style-type: none"> ● Day -60: LoI submission (with draft briefing package if requesting pre-submission meeting via TC) ● Day -30: Draft briefing package submission (or pre-submission meeting via TC) ● Day -15: Written comments on the draft briefing document sent to the applicant ● Day -2: Revised meeting package submission ● Day 0: Procedure starts ● Day 32: List of issues sent to the applicant ● Day 45: Written responses submission ● Day 56: Presentation and list of participants submission ● Day 60: EMA-HTABs-applicant F2F meeting ● Day 70: EMA sends response upon CHMP adoption ● Day 90: EUnetHTA sends response 	<ul style="list-style-type: none"> ● LoI ● Briefing package following the EMA-EUnetHTA common briefing document template
Qualification of novel methodologies ²⁰	<p>Overall duration: 160 (qualification advice) or 250 days (qualification opinion)</p> <ul style="list-style-type: none"> ● Day -60: LoI and draft briefing document submission ● Day -15: EMA-applicant preparatory meeting (F2F or TC) ● Day -3: Final briefing package submission ● Day 0: procedure starts ● Day 30: List of questions sent to the applicant ● Day 60: Discussion with the applicant (additional interactions are possible via TC) ● Qualification advice: <ul style="list-style-type: none"> ● Day 100: Response sent to the applicant ● Qualification opinion: <ul style="list-style-type: none"> ● Day 130-190: Public consultation ● Day 190: Response sent to the applicant 	<ul style="list-style-type: none"> ● LoI ● Briefing package ● Qualification advice: <ul style="list-style-type: none"> ● Draft protocols ● Development plans for future studies and supportive data ● Qualification opinion: <ul style="list-style-type: none"> ● Protocols ● Study reports and supportive data

Abbreviations: CHMP, Committee for Medicinal Products for Human Use; EUnetHTA, European Network for Health Technology Assessment; F2F, face-to-face; LoI, letter of intent; PA, protocol assistance; HTAB, Health Technology Assessment Bodies; PSA, parallel scientific advice; SA, scientific advice; SAWP, scientific advice working party; TC, teleconference



fication advice or opinion (Table 1). For a qualification advice, the CHMP evaluates the scientific rationale and the submitted preliminary data and issues an advice on protocols and procedures for further development of a method towards qualification. For a qualification opinion, the CHMP evaluates the submitted data and issues a decision on the acceptability of the use of a new method in medicine development. As the scientific knowledge of a new method can evolve over time, the qualification process may involve an ongoing interaction between the applicant and EMA. Additionally, the information is shared with the scientific community prior to the adoption of the qualification opinion to promote scrutiny and discussion. After the qualification process, the EMA may also amend the relevant guidance to implement the newly qualified methodology.^{1,20}

National scientific advice procedures

SA can also be requested from NCAs of EU member states. Although the general purpose of national SA is in line with the EMA SA procedure, some differences may exist in terms of document requirements and timelines (Table 2.)²⁴⁻³¹ Compared to the EMA SA procedure, obtaining SA from an NCA is usually faster and

it may offer more opportunities for discussion meetings to also cover virtual meetings due to COVID-19 (Table 2).

Pilot simultaneous national scientific advice procedure

The simultaneous national scientific advice procedure (SNSA) was introduced to optimise resources and improve regulatory support when an applicant requests SA from different NCAs. The SNSA pilot started on February 1, 2020, and currently allows simultaneous contact with two NCAs. Following an evaluation at the end of 2020 based on the experience from the perspective of the NCAs and the applicants with the SNSA pilot, an optimised best practice approach which will include more than two NCAs will be developed.^{32,33}

Rapid scientific advice for COVID-19 treatments and vaccines

Similar to the response to past public health threats like Ebola,³⁴ the EMA has set up accelerated procedures to speed up development

and approval of medicines and vaccines for the treatment and prevention of COVID-19. These procedures include a rapid SA procedure, which is available for initial MAA of new active substances and indication extension applications for authorised medicines repurposed for the treatment of COVID-19. This rapid SA procedure is free of charge, there are no specific submission deadlines, and its timeline is reduced

to only 20 days from the original 40–70 days, with more flexibility on the type and extent of briefing package based on a case-by-case agreement.³⁵

Role of the medical writer in the scientific advice procedure

Because clear communication is key for applicants to obtain appropriate and useful SA, medical writers play an important role in the preparation of the briefing document, in collaboration with regulatory affairs

and relevant subject matter experts who provide input to the questions and applicant's positions. Importantly, medical writers can support the phrasing of clear, concise questions and drafting

Furthermore, the EMA is constantly updating existing processes and launching new pilot projects to further expand the available options.

Table 2. Overview of document requirements for selected national scientific advice procedures

Country/agency	Timeline for submission of documents	Documents required
Denmark Danish Medicines Agency – Lægemiddelstyrelsen ²⁴	<ul style="list-style-type: none"> Initial documents at least 2-3 months before the proposed meeting date <ul style="list-style-type: none"> Application form List of questions Background to questions (where possible) Final presentation and/or briefing document at least 2-3 weeks before meeting date 	<ul style="list-style-type: none"> Application form (Lægemiddelstyrelsen website) List of questions Background to questions (max. 30 pages) Final presentation and/or briefing document
France National Agency for the Safety of Medicine and Health Products – ANSM ²⁵	<ul style="list-style-type: none"> Meeting request usually 2 months prior to proposed meeting date Briefing document at least 3 weeks before the meeting 	<ul style="list-style-type: none"> Cover letter Briefing document including background information, list of questions with applicant's position and investigator's brochure
Germany BfArM – Federal Institute for Drugs and Medical Devices ²⁶	<ul style="list-style-type: none"> Standard procedure: <ul style="list-style-type: none"> Full package at time of initial application Procedure with supplemental submission: <ul style="list-style-type: none"> List of questions without documentation at time of initial application Documentation at least 4 weeks prior to meeting date 	<ul style="list-style-type: none"> Cover letter (signed pdf) Application form (BfArM website, signed pdf) List of questions (BfArM website “Appendix Questions”, word or pdf format) Briefing document (max. 50 pages, pdf format) List of meeting participants (BfArM website “Appendix Participants”, word or pdf)
Germany Paul-Ehrlich-Institute – Federal Institute for Vaccines and Biomedicines ²⁷	<ul style="list-style-type: none"> Request form 8-12 weeks prior to proposed meeting date Briefing document at least 3 weeks prior to meeting date 	<ul style="list-style-type: none"> Request form (PEI website) Briefing document (max. 40 pages)
Netherlands MEB – Medicines Evaluation Board ²⁸	<ul style="list-style-type: none"> Meeting request (application form with draft list of questions) (usually 1.5-3 months ahead of the planned meeting date) Documentation, presentation, and list of attendees at least 3 weeks prior to meeting date 	<ul style="list-style-type: none"> Application form (MEB website) Briefing document List of participants
Spain AEMPS – Spanish Agency for Medicines and Health Products ²⁹	<ul style="list-style-type: none"> Meeting request (application form, usually 2-3 months ahead of the planned meeting date) After validation of the request, documents should be sent at least 30 days before the meeting 	<ul style="list-style-type: none"> Application form (AEMPS website) LoI List of questions and applicant's position Other relevant documents: Previous SA or reports, guidelines, references
Sweden Läkemedelsverket – Swedish Medical Products Agency ³⁰	<ul style="list-style-type: none"> Application form with well-specified questions (usually 2-3 months ahead of the planned meeting date) Full documentation at least 3 weeks prior to meeting date 	<ul style="list-style-type: none"> Application form (Läkemedelsverket website) Briefing document (max. 100 pages) List of questions (word format) List of meeting participants (word format) Other relevant documents, e.g. references, investigator's brochure
United Kingdom Medicines and Healthcare products Regulatory Agency – MHRA ³¹	<ul style="list-style-type: none"> Meeting request (application form with draft list of questions) (usually 2-3 months ahead of the planned meeting date) Final briefing documents at least 10 days prior to meeting date 	<ul style="list-style-type: none"> Request for scientific advice form (MRHA website) Briefing document: <ul style="list-style-type: none"> Final list of questions and applicant's position Presentation to be given at the meeting (if applicable) Relevant appendices, e.g. background information, previous SA, guidelines

Abbreviations: F2F, face-to-face; LoI, letter of intent; SA, scientific advice; TC, teleconference.

Disclaimer: Regulatory procedures and requirements are subject to change and it is strongly advised to consult the relevant agency's website for current information.

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Author information

Dr Daniela Kenzelmann Broz is Director of Medical Affairs at SFL Regulatory Affairs & Scientific Communication, an interdisciplinary consultancy providing integrated solutions to the pharma and Medtech sectors. She has an extensive scientific background and is experienced in writing of a broad range of regulatory and clinical documents, including scientific advice briefing documents.

Dr Gabriele Galliverti is Medical Affairs Manager at SFL Regulatory Affairs & Scientific Communication. He has an extensive scientific background and is experienced in regulatory writing for pharma and Medtech products.

Anja Bühner is Head of Regulatory Affairs at SFL Regulatory Affairs & Scientific Communication. She has extensive experience in providing strategic regulatory advice for the development and filing of healthcare products and in interacting with Regulatory Authorities.