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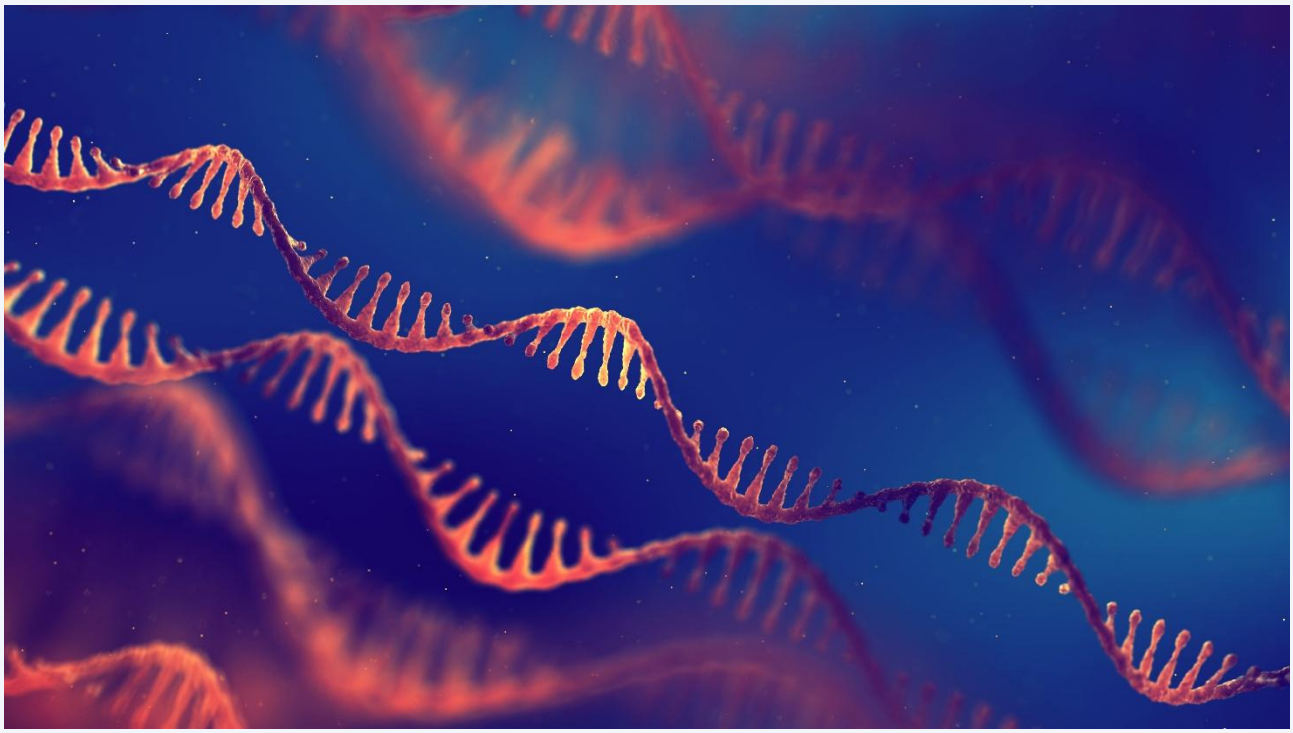

Progressing EMA's PRIority Medicines scheme through new pilot features

Report on the experience with the new PRIME features following the 5-year review of the scheme to support the development of medicines targeting unmet needs

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Executive Summary

The European Medicines Agency's (EMA) PRIME scheme, established in 2016, provides early and enhanced regulatory support to accelerate the development of medicines addressing unmet medical needs. Building on insights from the Agency's five-year analysis of PRIME, EMA launched three new pilot features - the regulatory roadmap and product development tracker, expedited scientific advice, and the submission readiness meeting - to strengthen regulatory agility, continuity of interactions, and preparedness for marketing authorisation applications (MAAs).

This report presents the findings from a two-year pilot (April 2023–March 2025) to assess the effectiveness of the new features in supporting PRIME product development, and to understand the experiences and perceptions of regulators and PRIME developers as support tools. The report integrates quantitative analyses of submissions and feedback from PRIME developers and regulatory assessors from the European medicines regulatory network (EMRN).

The **regulatory roadmap and product development tracker** was designed to provide a structured, dynamic framework for monitoring product development, replacing the annual update with more targeted, issue-focused information. It aims to support continuous dialogue, increase transparency around development progression, facilitate early identification of risks, and improve predictability for developers as well as Rapporteurs and their assessment teams.

Feedback on the tool highlighted it to be effective for tracking critical development issues and preparing for PRIME meetings whilst usability challenges and administrative burden were noted. Generally emphasised was the need for more detailed guidance and predictable update expectations. Developers also highlighted the importance of systematic EMA feedback to enhance the tracker's value as a two-way communication tool.

Key recommendations from the pilot focus on:

- **Refining the structure and formatting** to enhance usability for developers and streamline interpretation for assessors.
- **Strengthened guidance** on update frequency, level of detail, and impact categorisation.
- **Establishing systematic EMA/Rapporteur feedback** on submitted trackers to promote continuous dialogue.
- Progressing toward a **future integrated digital solution** enabling real-time tracking of development progress and associated regulatory interactions.

The **expedited scientific advice procedure** aims to deliver timely regulatory input on well-defined, critical development questions, particularly those requiring rapid clarification to maintain programme momentum. It sought to improve flexibility, ensure continuity of scientific support, and enable more agile responses to urgent issues.

The average expedited advice procedure time was reduced compared to standard scientific advice. PRIME developers valued the flexibility and timeliness of the process but sought more

agility and broader access criteria, while regulators stressed the importance of maintaining a focused scope. The process remained limited by reliance on Scientific Advice Working Party (SAWP) plenary cycles, constraining further acceleration.

Key recommendations for a refined implementation of the procedure include:

- **Updated guidance** detailing topics suitable for expedited advice based on pilot experience.
- **Expansion of scenarios where** the expedited procedure **can be sought**, including issues arising from kick-off and submission readiness meetings.
- Explore mechanisms to further **shorten procedure duration** and **increase flexibility outside SAWP plenary cycles**.

The **Submission Readiness Meeting** was introduced as an additional key milestone meeting between the PRIME developer, Rapporteur and EMA/EMRN experts. It is held approximately 9–12 months before MAA submission, to assess implementation of scientific advice, the maturity of datasets, submission strategy, and eligibility for accelerated assessment. It aims to reduce delays, facilitate accelerated assessment timelines, and ensure knowledge transfer and continuity through pre-submission activities.

Both developers and Rapporteur teams viewed the meetings positively, noting clear objectives, appropriate expertise, effective identification of MAA risks, and discussion of data maturity, and accelerated assessment considerations. Developers requested greater flexibility in timing, while regulators noted variability in discussions of critical operational topics such as orphan designation maintenance, inspection readiness, and PIP compliance. Early outcomes suggest a positive influence on MAA preparedness and maintenance of accelerated assessment, though sample size remains limited.

Key recommendations arising from the pilot experience include:

- Reinforced focus on **scientific advice implementation, dossier maturity,** and **accelerated assessment**.
- Allowing **more flexible timing** tailored to product-specific development considerations.
- Strengthened follow-up pathways for outstanding issues impacting the MAA assessment, including **targeted use of expedited scientific advice**.

As PRIME reaches 10 years of operation, the scheme remains a cornerstone of EMA's strategy to accelerate the development and assessment of innovative medicines addressing unmet medical needs. While its core objectives have remained consistent since 2016, PRIME has evolved through continuous learning and refinement of its support tools. The confirmation of the new features as standard PRIME support tools represents a significant milestone, strengthening early and sustained dialogue between developers, EMA, and Rapporteur teams, and fostering a continuum of knowledge that supports robust dossier preparation and efficient assessment. As we prepare for a future operation under the forthcoming EU pharmaceutical legislation, the features reaffirm EMA's commitment to the continuous evolution of PRIME, strengthening its operation and enhancing its ability to accelerate the availability of innovative medicines for patients with unmet medical needs.

1. Introduction

PRIME is a scheme launched by the European Medicines Agency (EMA) in 2016 to accelerate the development and availability of medicines addressing unmet medical needs, offering early and enhanced regulatory support to developers. Through this support the scheme aims to optimise the generation of robust data on a medicine's benefits and risks and enable accelerated assessment of marketing authorisation applications (MAA). Following the EMA analysis of the first 5 years' experience with the PRIME scheme, three new pilot features were launched to fulfil recommendations for further refinement and enhancement of the support features.

In March 2022, EMA published the analysis of the first five years' experience with the PRIME scheme, which confirmed the scheme's positive contribution to the authorisation of medicines addressing conditions with no current or limited treatment options. The analysis also highlighted areas for improvement, including the need for greater flexibility in scientific advice provision, enhanced continuity of regulatory interactions, and better preparedness for marketing authorisation application (MAA) submissions, and assessments. These findings informed the design of three new features — a product development tracker and regulatory roadmap, expedited scientific advice, and submission readiness meetings — aimed at addressing the recommendations, expanding the regulatory tools to communicate and monitor the development programme, and thereby strengthening PRIME's operational framework and optimising support for innovative medicines. The introduction of three new features reflects EMA's commitment to the continuous improvement of the PRIME scheme, ensuring that regulatory support remains agile, transparent, and tailored to the needs of innovative medicines.

1.1. Aims of the new PRIME features

1.1.1. Regulatory roadmap and product development tracker

The PRIME regulatory roadmap and product development tracker introduces a structured development tracking format to monitor the development progress of PRIME products. Replacing the previous annual update submission, it is designed to facilitate continued dialogue between PRIME product developers, EMA and the assigned Rapporteur. This tool provides a pragmatic, action-oriented framework to monitor progress and critical milestones throughout development. PRIME developers maintain ownership of the tracker, updating it via EMA's IRIS platform whenever significant changes occur, such as new data availability or regulatory interactions. The regulatory roadmap outlines the planned and completed regulatory interactions, encompassing key steps such as Kick-off Meetings (KOM), Scientific Advice (SA), Paediatric Investigation Plans (PIP), Orphan Designation (OD), and ultimately the Submission Readiness Meeting (SRM).

This structured format aims at enhancing transparency, enabling early identification of potential hurdles and fostering proactive risk mitigation. Overall, the regulatory roadmap and development tracker aims to improve knowledge building to support accelerated assessment (AA), to facilitate Rapporteur participation in regulatory procedures through the PRIME

development by increasing predictability of submissions, and to support the Rapporteur team in their assessment work.

1.1.2. Expedited Scientific Advice

Expedited Scientific Advice introduces a flexible and accelerated scientific advice (SA) procedure for PRIME developments for development issues linked to previously discussed development programmes (previously defined as follow-up scientific advice), provided the scope is clearly defined and the advice is required more urgently than the standard timelines allow. Under this agile framework, EMA consults with the Rapporteur to determine whether the query can be resolved through direct clarification, and if not, whether the criteria for expedited advice are met.

This expedited procedure aims to employ a flexible approach to address PRIME developer queries, increase the ability of developers to address emerging challenges and urgent issues promptly, and ensure continuity of regulatory support through strengthened involvement of the Rapporteur team in the advice through the SAWP Coordinator.

1.1.3. Submission Readiness Meeting

The PRIME 5-year analysis found that although PRIME products are highly likely to obtain accelerated assessment, more than half of PRIME MAAs that initially targeted accelerated assessment reverted to standard timelines, often due to incomplete implementation of scientific advice or immature data packages. The SRM aims to address this finding by providing an opportunity at a time point closer to the MAA filing date to discuss with the Rapporteur's team and EMA the status of the development, including the implementation of previous regulatory advice for key development areas and the resulting data package intended to support the MAA.

The SRM differs from pre-submission interactions as it takes place 9-12 months prior to the MAA and aims to facilitate earlier, open dialogue on the development status and MAA preparedness. The SRM mirrors the multidisciplinary format of the KOM, involving the Rapporteur team, CHMP/CAT leadership, EMA committee and SAWP representatives, and the EMA product team. By fostering earlier discussion on implementation of scientific advice, and aligning on submission strategy and data maturity, the SRM aims to reduce major objections (MOs) during validation and accelerate the assessment process. Discussions also cover potential regulatory challenges such as PIP compliance, GCP and GMP inspection readiness, and maintenance of orphan designation, and post-marketing evidence generation.

2. New PRIME features: pilot objectives and methodology

2.1. Objectives of the Pilot

The main objectives of the pilot of feature are outlined in the following sections.

2.1.1. Pilot Objectives: Regulatory roadmap and product development tracker

To assess the uptake and use of the regulatory roadmap and development tracker in terms of the number of trackers submitted, frequency of updates.

To assess the role of the regulatory roadmap and development tracker in facilitating the continuous dialogue between regulators and developers as the development programme progresses.

To obtain and assess PRIME developers' experience in populating/maintaining the development tracker, its user-friendliness, its effectiveness to support internal processes, and planning for regulatory interactions.

To obtain and assess regulators' experience in using the development tracker, its effectiveness in tracking critical issues and planned regulatory submissions.

To understand what changes to the regulatory roadmap and development tracker format would promote effective tracking and oversight of development issues.

2.1.2. Pilot Objectives: Expedited Scientific Advice

To assess the use of expedited scientific advice procedure in terms of the number of expedited SA requests received, scope, and duration compared to standard scientific advice.

To identify the scope (quality/non-clinical/clinical/multidisciplinary) and specific questions that were considered suitable for the expedited scientific advice.

To obtain and assess PRIME developers' and regulator's experience with the procedure and its effectiveness as a tool for provision of dynamic, flexible and iterative scientific support.

2.1.3. Pilot Objectives: Submission Readiness Meeting

To assess the SRM in terms of meeting scope, impact on the timing of the MAA submission, and impact on subsequent pre-submission interactions.

To assess the impact on obtaining and maintaining accelerated assessment for those products subsequently reaching and concluding the MAA.

To obtain and assess PRIME developers' and regulator's experience with the meeting and their perception of its effectiveness as a tool for strengthened engagement, identification of outstanding risk to the MAA, AA/MAA preparedness.

2.2. Methodology

The three new features were piloted for 2 years, with data collected in the period April 2023-March 2025. The report is based on data available to EMA through IRIS submissions covering scientific advice procedures, PRIME periodic updates, and KOM/SRM requests.

The parameters for the analysis were pre-specified, covering key indicators of their uptake and effectiveness:

- The number and frequency of product development trackers, context of submission, and product/developer profile.
- The number of expedited scientific advice requests, expedited request outcome, scientific advice scope and specific topics, procedure duration, Rapporteur assessment team's participation.
- The number of SRMs held, product/developer profile, meeting topics discussed, post-meeting interactions (scientific advice, pre-submission meetings), MAA submission and outcome.

In addition to the data analysis, three surveys were developed to obtain feedback from developers and regulators on their experience and perceptions of the new features.

EMA launched a survey to all developers with an active PRIME designation during the pilot period (referred to as the PRIME developer survey in this document), and to Rapporteurs, their assessment teams and regulators involved in PRIME.

The EMA surveys consisted of statements to which respondents specified the level of agreement (strongly agree (5), agree (4), neutral (3), disagree (2), strongly disagree (1)) and free-text fields to describe experiences with the pilot features and suggestions for further improvements. The surveys ran for a 6-week period from March to May 2025.

A cross-Trade Association Industry survey (referred to as the all-Industry survey in this document) was launched in parallel to the EMA surveys. The all-Industry survey was launched to developers, irrespective of experience with PRIME. The survey consisted of binary statements (yes, no) and statements seeking an opinion on a 5-point scale.

2.2.1. EMA Survey to regulators involved in PRIME products

The scope of the regulators' survey was to gather feedback on experience with the new features and perceptions of their effectiveness in supporting continued dialogue and preparation for the future assessment. A questionnaire was sent to all CHMP, CAT and SAWP members, representing 30 EEA national competent authorities (NCA). 20 responses were received representing 12 different NCAs (40% response rate).

Of the 20 responses, 6 (25%) had stated experience with assessing the development tracker, 5 (25%) had experience with expedited scientific advice and 6 (30%) had experience with the SRM. However, since Rapporteurs are assigned to multiple PRIME products, the responses

constitute Rapporteur team feedback for 30 of the 73 (41%) development trackers submitted, 8 of the 12 (67%) expedited scientific advice procedures completed, and 8 of the 10 (80%) SRMs held during the pilot.

2.2.2. EMA Survey to PRIME product developers

The scope of the PRIME developer survey was to gather feedback on experience with the new features and perceptions of their effectiveness in providing enhanced regulatory and scientific development support.

The survey was sent to the contact points for 78 products that were in the PRIME scheme (existing and newly granted) between April 2023 and March 2025. One survey was requested per PRIME product, which was identified through the EMA Research Product Identifier (RPI). Responses were received for 36 products (46% response rate). Since multiple development trackers and expedited scientific advice requests were submitted for some PRIME products, the responses comprise developer's feedback for 43 of the 73 (59%) development trackers submitted, 8 of the 12 (67%) expedited scientific advice procedures, and 8 of the 10 (80%) SRMs held during the pilot.

10 responders were SMEs (28%), 3 responders were Academic developers (8%), and 23 were non-SME Industry developers (64%).

2.2.3. Industry Survey to developers

The scope of the all-Industry survey was to collect feedback on Industry experience with the new features, and to gather Industry's general views on PRIME, irrespective of actual experience with the scheme. 25 Industry responses were received, of which 16 companies had products in the PRIME scheme. Of the 25 respondents, 82% were aware of the new features, and 64% considered these new features adding value to PRIME scheme. Of the 25 respondents, 11 (44%) responded to the pilot questions, of which 6 had experience with the new features.

3. Key findings and discussion

This section of the report presents the key findings for the three pilot features, results of the EMA network and PRIME developer surveys, and discussion of the main themes emerging from analyses. Feedback from respondents to the all-Industry survey (see 2.2.3) is referenced in the text, as appropriate. Overviews of the PRIME developer and regulator survey results are presented as the mean response score (out of a maximum of 5) and further contextualised by percentage agreement (combined agree and strongly agree) and disagreement (combined disagree and strongly disagree). Selected responses are discussed in the context of key findings, and the full EMA questionnaires are described in annex 1.

3.1. Regulatory roadmap and product development tracker

3.1.1. Submissions and key figures

During the pilot period, 73 regulatory roadmap and development tracker submissions were received by EMA. Of the 73 submissions, 17 (23.3%) were by SME developers, 3 (4.1%) by Academic developers and 53 (72.6%) by non-SME Industry developers. While the PRIME developers' survey highlighted the administrative burden associated with populating and maintaining the tracker, this was not specified as a barrier to submitting but reasonably can be expected to impact SME applicants more acutely than non-SME companies.

In terms of product type, 32 submissions were for advanced therapy medicinal products (ATMPs), 27 submissions were for biological medicinal products and 14 submissions were for chemical medicinal products (Figure 1).

Most development trackers were submitted either as a supporting document for the KOM (29), or as a periodic development update (34). A further 10 development trackers were submitted as a supporting document for all SRMs held during the pilot (Figure 1). The pilot experience indicates the development tracker served two key purposes for regulators; as an effective tool for tracking critical development issues and planning regulatory interactions (83.3% survey agreement) and for supporting KOM/SRM discussions (81.8% survey agreement).

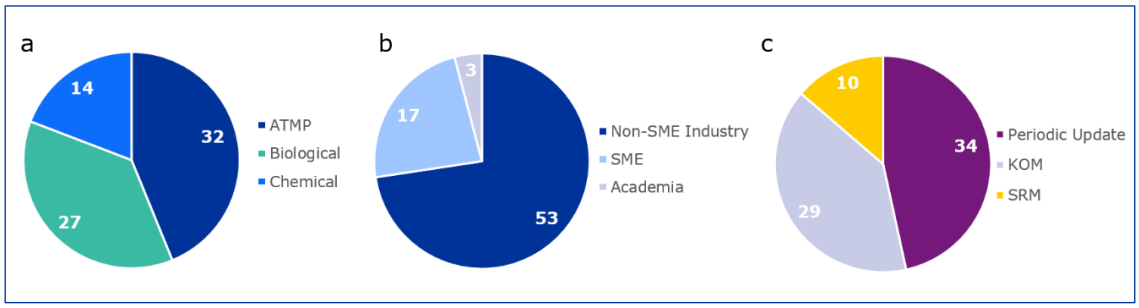


Figure 1. *Product development tracker submissions per product type, Developer type, and process*

73 product development tracker submissions were received by EMA, representing 57 PRIME products. Iterative submissions were received for the 14 products; 12 products submitted 2 development trackers and a further 2 products submitted 3 development trackers (Figure 2a). For the remaining 43 PRIME products one development tracker was submitted to EMA during the pilot.

For the 14 products for which more than one tracker was submitted, the interval between updates ranged from 4 to 15 months, with an average of 8.9 months (Figure 2b). The average interval was largely consistent, whether the development tracker was received as a periodic development update (7.8 months) or in the context of the SRM (10.5 months).

For the pilot implementation, an annual development tracker submission was not required; developers are recommended to submit an update whenever there are updates critical to development or with high impact on evidence generation. While the intention is to promote flexibility and reduce unnecessary administrative burden, feedback from both regulators and PRIME developers indicated that a specified timeline for periodic tracker updates would promote continued engagement and predictability.

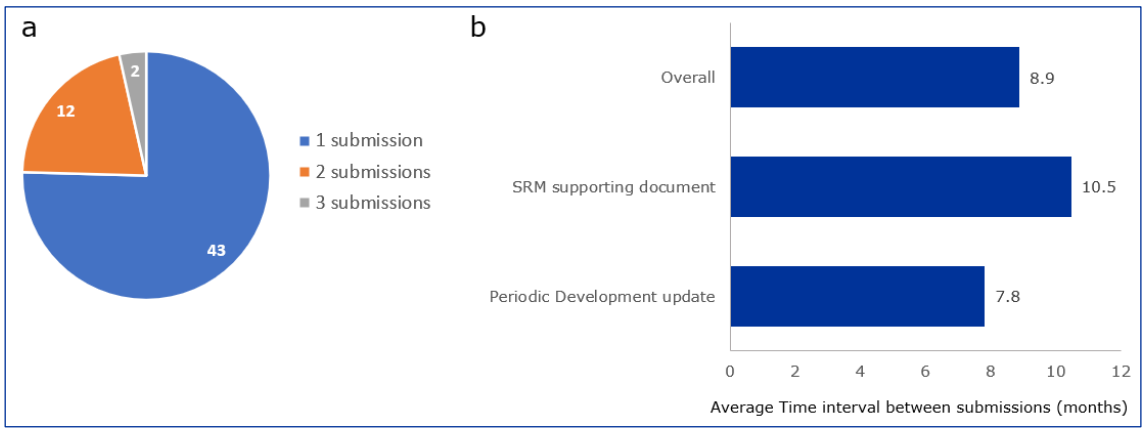


Figure 2. *Frequency of development tracker submissions per product and average time interval between submissions*

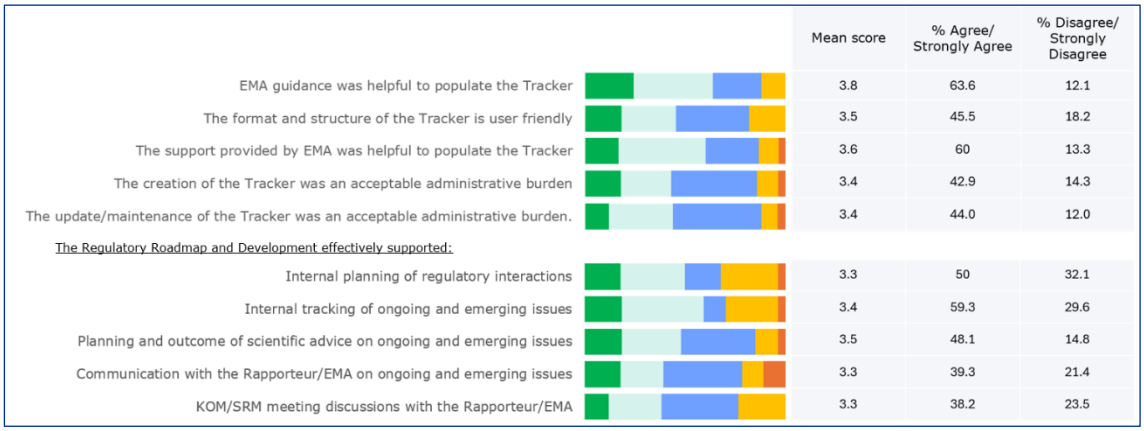
3.1.2. Preparation and submission of the development tracker

PRIME developers' experience with preparing and maintaining the development tracker was evaluated through the survey to understand its ease of use and its utility, both as an internal tool for tracking issues and regulatory submissions, and as a tool for communicating with EMA and the Rapporteurs.

Although the majority of respondents found the EMA support and the published guidance helpful for populating the tracker, just under half the respondents found the format and structure of the tracker to be user friendly (45.5% agreement), and the population and maintenance of the tracker to be an acceptable administrative burden (42.9-44% agreement) (Figure 3). This may be particularly relevant for SME developers with more limited resources; although SME developers did not see the effort required to populate and maintain the tracker as a barrier to submission, SME developers were under-represented in terms of submissions (23%) relative to their overall participation in the scheme (47%).

Feedback from the PRIME developer survey as well as the all-Industry survey included suggestions to improve ease of use, including more detailed guidance on populating the tracker. Experience indicated that clearer guidance on the application of the impact categorisation, with appropriate examples, could support more consistent and meaningful use of the tracker. For the purpose of the pilot, the development tracker was implemented as a word document which is submitted through IRIS for broader dissemination to the Rapporteur and the EMA product team. Although any improved technical implementation will be dependent on the IT and knowledge management tools available to the Agency, the tracker could be improved with a dynamic tracking solution that integrates development issues and planned interactions with the relevant regulatory procedures and submitted scientific documentation.

While the product development tracker's primary purpose is to document development issues and interactions with regulators, the survey also sought to evaluate how the tracker could support PRIME developers' internal processes. Experience also varied; while a majority of developers found that the tracker effectively supported their internal tracking of development issues, only half of respondents considered that it effectively supported planning of scientific advice to address the issues. The experience reinforces the importance of future evolution toward greater interoperability and aggregation of existing regulatory information, supporting a continuous knowledge-building process across development and assessment phases.



	Mean score	% Agree/ Strongly Agree	% Disagree/ Strongly Disagree
EMA guidance was helpful to populate the Tracker	3.8	63.6	12.1
The format and structure of the Tracker is user friendly	3.5	45.5	18.2
The support provided by EMA was helpful to populate the Tracker	3.6	60	13.3
The creation of the Tracker was an acceptable administrative burden	3.4	42.9	14.3
The update/maintenance of the Tracker was an acceptable administrative burden.	3.4	44.0	12.0
The Regulatory Roadmap and Development effectively supported:			
Internal planning of regulatory interactions	3.3	50	32.1
Internal tracking of ongoing and emerging issues	3.4	59.3	29.6
Planning and outcome of scientific advice on ongoing and emerging issues	3.5	48.1	14.8
Communication with the Rapporteur/EMA on ongoing and emerging issues	3.3	39.3	21.4
KOM/SRM meeting discussions with the Rapporteur/EMA	3.3	38.2	23.5

***Figure 3**. PRIME developers' survey key findings: regulatory roadmap and development tracker*

3.1.3. Monitoring product development issues and promoting dialogue

As a key objective of the development tracker is to support the knowledge building through improved tracking of critical issues and serve as a guidance for discussion through relevant procedures and dedicated PRIME meetings, the surveys also evaluated the effectiveness of the tracker to support communication with the Rapporteur team and PRIME KOM/SRM discussions.

The regulators' survey clearly indicates that the development tracker facilitated effective tracking of critical issues and planning for the associated regulatory submissions (4.0, 83.3% agreement) (Figure 4). However, PRIME developers considered the product development tracker less effective in supporting communication on ongoing and emerging issues (3.3, 39.3% agreement). Pilot experience highlighted the importance of EMA/Rapporteur feedback on the submitted development tracker for effective two-way communication. Thus, the

disparity in perceived effectiveness between regulators and developers may be addressed by establishing a process for systematic feedback from EMA and Rapporteurs on (for example) the developer's assessment of the issues, their assigned criticality, planned mitigation, and discussion through the appropriate regulatory interaction. This process would further promote ongoing two-way communication and assure alignment on the approach to address issues through timely regulatory interactions.

Similarly, while the regulators' survey shows clearly that the development tracker was helpful to support KOM/SRM discussions (3.8, 81.8% agreement), agreement was lower with PRIME developers (3.3., 38.2% agreement). The development tracker was used primarily by EMA/Rapporteur teams in preparation for the KOM/SRM to review the development status and identify discussion topics, and after the meeting to ensure discussions are adequately reflected. Thus, while the development tracker was not intended to be used as the primary document during the KOM/SRM, its role in the preparation for the meeting and documentation of its outcome can be further clarified to PRIME developers in the meeting guidance. More generally, the surveys emphasised the potential value as a primary tool to promote knowledge building and to provide a central link between these milestone meetings and the broader PRIME scientific and regulatory support.

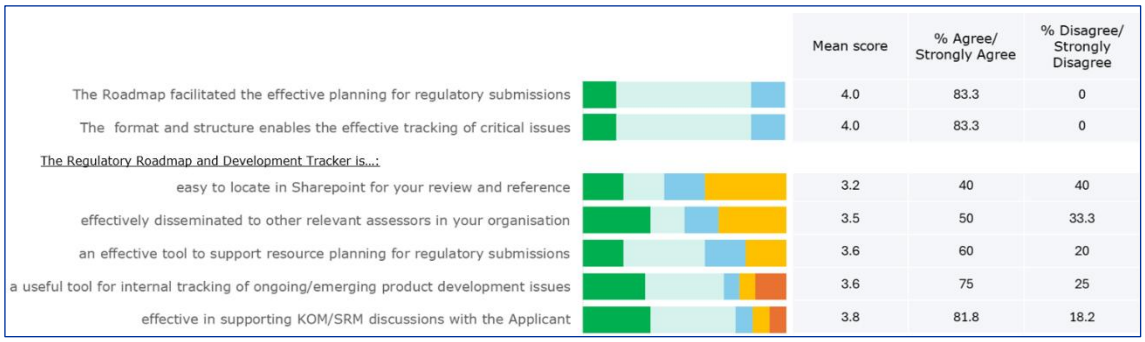


Figure 4. *Regulators' survey key findings: regulatory roadmap and development tracker*

3.2. Expedited Scientific Advice

3.2.1. Overview of expedited scientific advice requests

During the pilot, 12 requests for expedited scientific advice, with justification for meeting the criteria for the expedited process, were submitted. 5 of the 12 requests were for orphan designated products (41.6%), and 4 of the 12 requests were from SME developers (33%). (Figure 5).

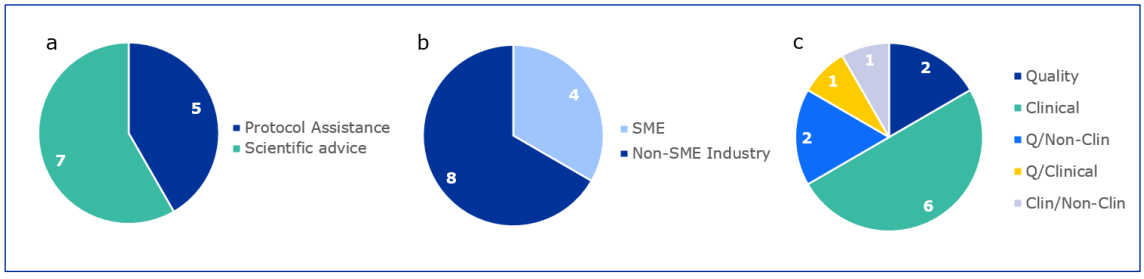


Figure 5. *Expedited scientific advice per process (A), Developer type (B) and advice area (C)*

The 12 requests comprise 10 different PRIME products; expedited advice was sought once for 8 products and twice for 2 products. The area of each expedited advice request (quality/non-clinical/clinical), specific scope of each request, and outcome of the request is presented in Table 1. The criteria for the pilot were topics with a limited, well-defined scope, but did not preclude multi-disciplinary topics. Although the majority of requests concerned a single area of advice (6 clinical advice, 2 quality advice), 4 requests were submitted covering multi-disciplinary scope (quality/non-clinical, quality/clinical and non-clinical/clinical). The majority of clinical topics related to specific aspects of a previously discussed clinical study design (e.g. the statistical analysis plan, study population, choice of primary and secondary endpoints) and were justified as urgent to facilitate the planned clinical trial application/modification. Quality advices covered a range of topics (comparability, potency assay, process validation) justified as urgent for a planned clinical trial application or the MAA. Although multidisciplinary advices usually cover a single topic (e.g. comparability programme), one multidisciplinary advice on disparate non-clinical and quality topics was accepted on the basis that each topic met the criteria.

#	Therapeutic area	Area of Advice	Advice scope	Questions (no.)	ExpSA agreed?	ExpSA timeline completed
1	ONC	Clinical	Statistical approach	3	Yes	Yes
2	HAEM	Clinical	Statistical approach	1	Yes	Yes
3	Vaccines	Quality/ Non-Clinical	Comparability programme	2	No	N/A
4	HAEM	Quality	Potency Assay	1	Yes	Yes
5	ECV	Clinical	Conditional MA, Statistical aspects	2	Yes	Yes
6	DERM	Quality	Manufacturing process validation	3	Yes	Yes
7	ECV	Quality/ Clinical	Comparability programme	2	Yes	Yes
8	DERM	Clinical	Pivotal study interim analysis	2	Yes	No – DM required
9	ECV	Non-Clinical/ Clinical	Choice of endpoints, Conditional MA	6	Yes	Yes
10	Vaccines	Clinical	Choice of endpoints	2	Yes	Yes
11	Vaccines	Quality/ Non-Clinical	Analytical methods, comparability, non-clin package	6	Yes	Yes
12	Vaccines	Clinical	Choice of endpoints; Study population	2	Yes	No – DM required

PA: Protocol Assistance; SA: Scientific Advice; DM: Discussion Meeting; ONC: Oncology; HAEM: Haematology/Haemostaseology; ECV: Endocrinology, cardiovascular; DERM: Dermatology

Table 1. Overview of expedited scientific advice submissions and outcomes

The eligibility of each expedited scientific advice request was discussed by EMA, the Rapporteur and relevant SAWP coordinators of the previous scientific advice(s), based on the published criteria. All 12 of the submitted requests for expedited scientific advice were considered to meet the criteria for expedited scientific advice. 11 of the 12 requests (91.7%) were accepted under the expedited timeline; one request did not proceed due to the immediate unavailability of Rapporteur team. Thus, the procedure started under the standard timelines in the following procedure cycle. The piloted expedited advice procedure does not include the option for a discussion meeting within the procedure, but should SAWP decide a discussion meeting is required, the procedure reverts to standard timelines at the time of the initial SAWP discussion. Of the 11 expedited procedures, 9 were completed on the expedited timeline, while 2 procedures reverted to standard timelines to facilitate a discussion meeting.

The high acceptance rate indicates that the requests were appropriately scoped, and the criteria were applied flexibly by EMA and the Rapporteur. The acceptance rate also aligns with the regulators' survey which considered that the qualifying criteria identify suitable issues for an expedited assessment (100% agreement) (Figure 7). The majority of PRIME developers agreed that the criteria were clear (65.7% agreement) and sufficiently broad to avail of the procedure for their development programme (56% agreement) (Figure 6). However, feedback from the PRIME developer survey as well as the all-Industry survey on the procedure also requests broader criteria to cover more topics and scenarios. While the regulators' survey does not agree with significantly widened criteria (i.e. to all initial advice requests, or to broad, non-critical issues), the surveys do suggest that the procedure can be used more systematically in scenarios where the issues have been identified through the PRIME dialogue. For example, topics identified in PRIME KOM and SRMs should be suitable for expedited scientific advice since the discussions advance understanding of the issue and can facilitate an efficient expedited SAWP report. As discussed in section 3.3.3, expedited mechanisms are particularly relevant for addressing essential outstanding issues within compressed pre-submission timelines following the SRM, where the practical feasibility of standard scientific advice may be constrained. Updated guidance specifying the type of topics that may be eligible for expedited advice should also promote more systematic use by PRIME developers.

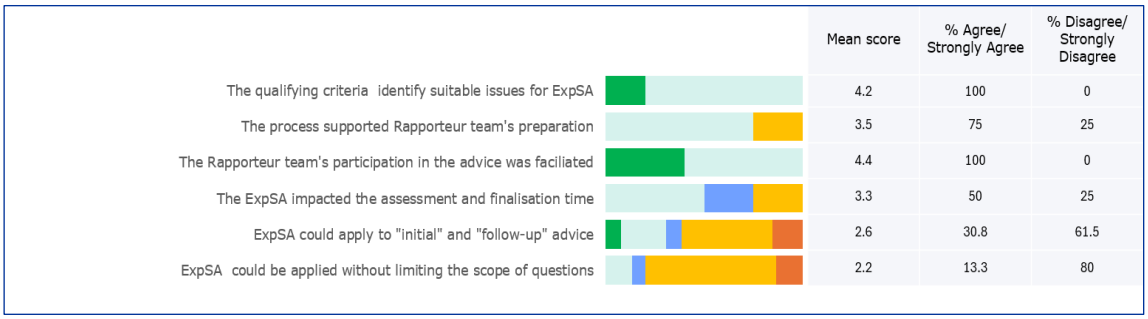


***Figure 6**. Regulators' survey key findings: expedited scientific advice*

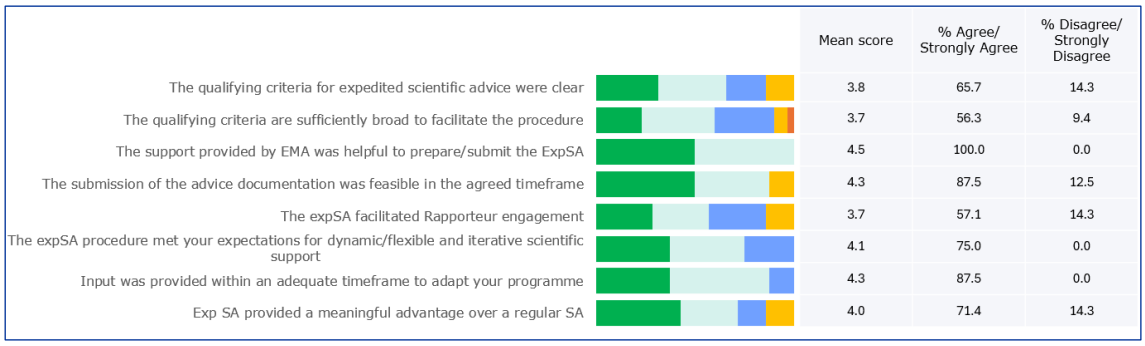


***Figure 7**. PRIME Developers' survey key findings: expedited scientific advice*

3.2.2. Rapporteur's team participation in the scientific advice

Rapporteurs found that the prior agreement to accept the expedited procedure facilitated their subsequent preparation and participation. This is clearly reflected in the pilot results, where all 12 of the subsequent scientific advices proceeded with the Rapporteur's team participation through the relevant SAWP coordinator. The majority of respondents to the survey agreed that the procedure facilitates engagement between the PRIME developers and Rapporteurs (100% of regulators and 57.1% of PRIME developers agree). The lower agreement by developers may be related to the broader preference for direct dialogue with the regulators outside of the advice as well as during the procedure. Dialogue during the standard scientific advice is facilitated by a discussion meeting, which is not foreseen in the expedited procedure. Potential future adaptations to the procedure are further discussed in section 3.2.3.

3.2.3. Impact of Expedited scientific advice on procedure duration

To assess the impact of the expedited process on the overall scientific advice procedure timelines, the expedited procedure duration (validation and evaluation) was compared to the average procedure duration for standard scientific advice (i.e. SA/PA procedures without preparatory meetings and/or discussion meetings) in the same 2-year pilot period. As a key aspect of the expedited procedure is flexible submission of the scientific briefing document and rapid validation, duration was measured from the submission of the briefing document to the completion of the SAWP joint report. Given the low number of expedited procedures, results are presented descriptively and procedure days as calendar days.

The average time from the submission of the briefing document to the SAWP joint report finalisation was 50 calendar days for the expedited procedure, compared to 79.6 calendar days for the standard procedure. This corresponds to 35.7 procedure days, compared to 56.9 procedure days for standard scientific advice.

To assess where the saving in procedure time was gained, validation and evaluation phases were compared between expedited and standard procedures. The decreased duration was obtained through a shortened validation phase (6.5 versus 24.9 days) whereas the evaluation phase was comparable between the expedited and standard procedure (29.2 days versus 32 evaluation days) (Figure 8).

The substantially decreased validation phase was achieved through highly flexible submission deadlines for the scientific documentation and prioritised validation review. In this regard, PRIME developers considered the support provided by EMA helpful to prepare and submit the advice (4.5, 100% agreement), and the submission of the documentation was feasible within the agreed timeframe (4.3, 87.5% agreement). To maximise flexibility, the submission timeline was agreed for each procedure on a case-by-case basis with the EMA scientific officer. However, PRIME developers' feedback on the procedure also suggested improving the predictability of the procedure through published timelines for submission and finalisation of the advice. Further consideration should be given to formal timelines for expedited scientific advice, to ensure the correct balance is struck between procedural agility and predictability for developers and regulators.

The comparable evaluation phase duration can be attributed to the implementation in which the advice was still scheduled for discussion in a regular SAWP plenary meeting, and in which consultation with the appropriate committees/working parties was maintained. When combined with the preference for assessors to preserve the assessment time (day 0 to day 30 of the standard scientific advice procedure), these factors limited the potential for decreasing the evaluation phase.

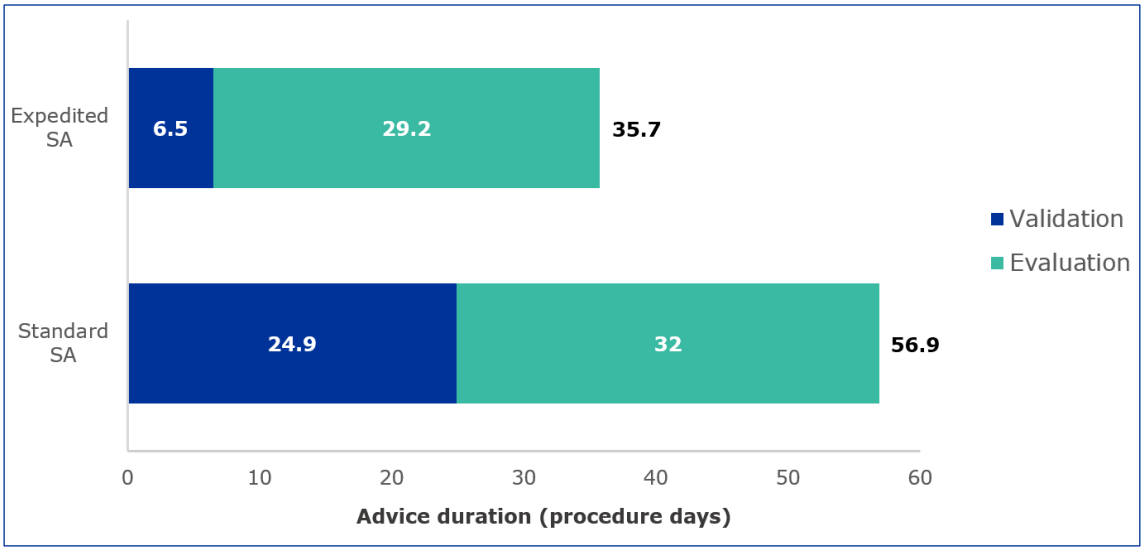


***Figure 8**. Expedited and standard scientific advice procedure duration*

Overall, the piloted expedited procedure decreased the time for delivery of the advice, and the majority of the surveyed PRIME developers considered expedited scientific advice met their expectation for dynamic, flexible and iterative scientific support (4.1, 75% agreement), delivered the required input within an adequate timeframe to timely adapt their programme (4.3, 87.5% agreement), and provided a meaningful advantage over the standard procedure (4.0, 71.4%). However, the decreased average procedure time of 50 calendar days was modest, mostly attributable to the validation phase, and the observed procedure duration exceeded the ~4 weeks target for completion of the expedited advice at the outset of the pilot. For the integration of expedited scientific advice as a permanent feature of PRIME, consideration will be given to further decreasing the procedure duration and increasing the agility of the procedure beyond the established SAWP plenary meetings and timelines for discussion.

3.3. Submission Readiness Meeting

3.3.1. Planning and operation of the submission readiness meeting

During the pilot, 10 SRMs were held for PRIME products approaching the MAA submission. 3 of the 10 meetings were for ATMPs, 4 were for biological products, and 3 were for chemical products. One of the 10 product developers held SME status, and 7 of the 10 products held orphan designations in the PRIME indication (Figure 9).

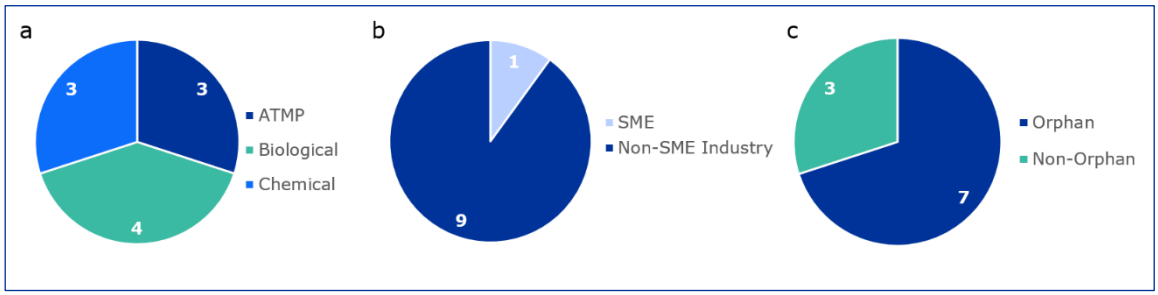


Figure 9. *Submission readiness meetings per product type (a), Developer type (b) and Orphan status (c)*

The SRM is held 9-12 months prior to the MAA submission, with the exact timing of the meeting agreed with the PRIME developer, EMA and Rapporteur on a case-by-case basis. For the 5 products that reached MAA submission following the SRM, the submission ranged from 7 to 13 months after the SRM, with an average of 9.5 months after the SRM. The timing of the meeting was considered appropriate by most Rapporteurs (4.0, 83.3% agreement) and PRIME developers (3.9, 66.7% agreement) (Figure 12 and 13). However, feedback from the PRIME developers' survey and the all-Industry survey suggested further flexibility in the timing of the SRM. This may be closer to the planned MAA (when more relevant data will be available to inform the discussion on MAA readiness, facilitating participation of Co- and PRAC Rapporteur) or earlier (to provide time to implement recommended actions) depending on the specific programme.

In terms of guidance and support, PRIME developers found that the SRM preparation was facilitated by the dedicated meeting guidance (4.3, 90% agreement) and support provided by EMA (4.6, 100% agreement). Participating regulators also found the applicant's documentation was adequate to prepare for the SRM (4.2, 83.3% agreement).

3.3.2. Submission readiness meeting: experience and topics covered

The SRM was generally well-received by developers and regulators; surveyed PRIME developers considered the meeting scope and objectives were clear (4.4, 93.9% agreement), the meeting participants provided the appropriate expertise for the discussion (4.3, 83% agreement) and that overall met their expectations and objectives for the meeting (4.4, 100% agreement). Most Rapporteur respondents considered the meeting would benefit their preparation and the MAA assessment (3.8, 60% agreement).

The SRM scope for the pilot implementation focused on the implementation of scientific advice, identification of potential critical issues for the MAA assessment, the MAA submission strategy and the expected data package, and the potential for accelerated assessment. Analysis shows

that these key scientific and regulatory topics were actively discussed in all 10 SRMs, thereby addressing the overarching meeting objectives (Figure 10).

This finding is also reflected in the PRIME developers' survey responses; the SRM was considered to identify outstanding risks to the planned MAA (4.2, 90% agreement) and expectations for accelerated assessment (4.2, 80% agreement). The regulators' experience was aligned with respect to identifying outstanding risks to the planned MAA (4.3, 83.3% agreement) and expectations for accelerated assessment (4.0, 83.3% agreement). While fewer Network and developer respondents survey found the meeting facilitated discussion on the potential for CMA (66.7% and 30% agreement, respectively), this requires further contextualisation; CMA was proposed for only a minority of products (3 of 10) and either a full MA (6) or MA under exceptional circumstances (1) was proposed in the other cases. Thus, while CMA remains an important pathway for facilitating patient's early access to PRIME medicines, it may not be appropriate, or otherwise not align with the regulatory strategy for a given development programme.

Although PRIME developers agreed the SRM facilitated discussion on the level of data maturity (4.3, 80% agreement), Rapporteur teams did not perceive the SRM to facilitate agreement on the level of data and timing of the MAA (2.8, 20% agreement). This is also reflected by Rapporteur feedback requesting a stronger focus on the maturity and the content of the dossier. Given that the Applicant's decision to proceed to MAA submission is dependent on subsequent availability of the clinical data, and pre-assessment of data is not in scope of the SRM, a final agreement on the MAA timing may not be possible during the SRM. This finding may also reflect the assessors' broader concerns for premature submission and the resulting complexity for the benefit/risk assessment. However, the finding highlights that there is further scope for alignment on the expectations for the MAA dossier through enhanced dialogue during the evidence generation phase and in the SRM.

Despite the 7 of 10 SRM products holding orphan drug designations, the approach for maintenance of orphan drug designation or orphan similarity issues was discussed in only 5 SRMs. GCP/GMP inspection readiness and PIP compliance were discussed in 6 of 10 SRMs and 4 of 10 meetings, respectively. As these topics were considered important to discuss in the SRM by respondents to all surveys, the SRM could benefit from more systematic discussion for relevant products, with the participation of relevant experts from PDCO, COMP and EMA Inspections. Exploring opportunities to also engage other decision makers, such as HTAs, in the submission readiness discussions was also highlighted as a topic for consideration by PRIME developer and all-Industry survey respondents.

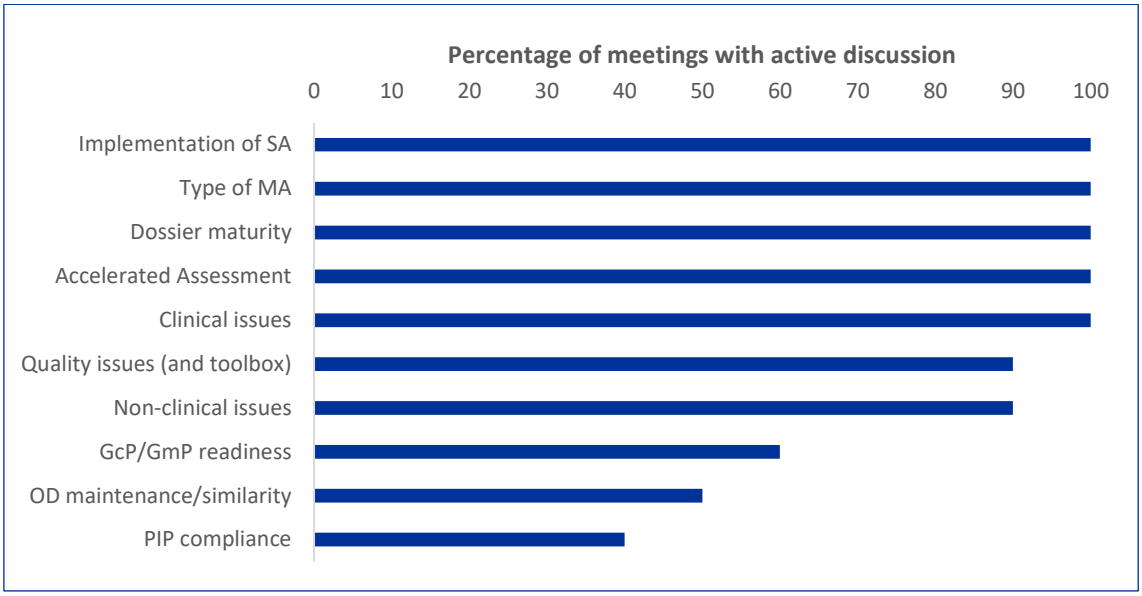


Figure 10. *Submission readiness meetings discussion topics*

3.3.3. SRM outcomes and impact on MAA preparation

Given that the time between the SRM and MAA submission is limited and crucial for the MAA preparedness, feedback from PRIME developers and regulators focussed on establishing the appropriate course of action to address outstanding issues in a timely manner. The actions included the submission of supporting data or justification in the MAA, direct follow-up with the appropriate EMA function (e.g. EMA regulatory affairs, Inspections), and in 3 out of 10 SRMs, a recommendation for scientific advice prior to the MAA. The SRM was considered to provide clear proposals to mitigate the identified risks by the majority of PRIME developers (3.8, 70% agreement) and Rapporteurs (3.6, 60% agreement). To facilitate the formal scientific advice in the limited available timeframe, respondents to the PRIME developer survey as well as the all-Industry survey proposed systematic use of expedited scientific advice, to mitigate the impact on the MAA preparation. Given that scientific advice was recommended in the minority of SRMs, broadening the expedited advice criteria to include SRM topics appears feasible, and it would represent a practical, impactful use of the expedited procedure during the pre-submission phase. This is particularly relevant for PRIME products in the context of potential parallel regulatory submissions in a global expedited development programme.

While all PRIME MAA applicants are encouraged to make full use of the pre-submission interactions with the Agency, the SRM may in some cases replace the Rapporteur pre-submission meeting (PSM), following discussion with the Rapporteur. For those products that reached submission, no Rapporteur PSM was held in 4 out of 5 cases. Although the available data indicate the SRM was usually effective in discussing the regulatory and scientific issues to the extent that the PSM could be foregone, Rapporteur and developer feedback indicates the distinction between the SRM and PSM was not always clear, and the SRM scope should be further clarified and delineated from that of the PSM.

3.3.4. SRM impact on MAA submission and accelerated assessment

At the time of the analysis, 5 of the 10 products are still in active development/MAA pre-submission, while 5 products proceeded to MAA submission (Figure 11).

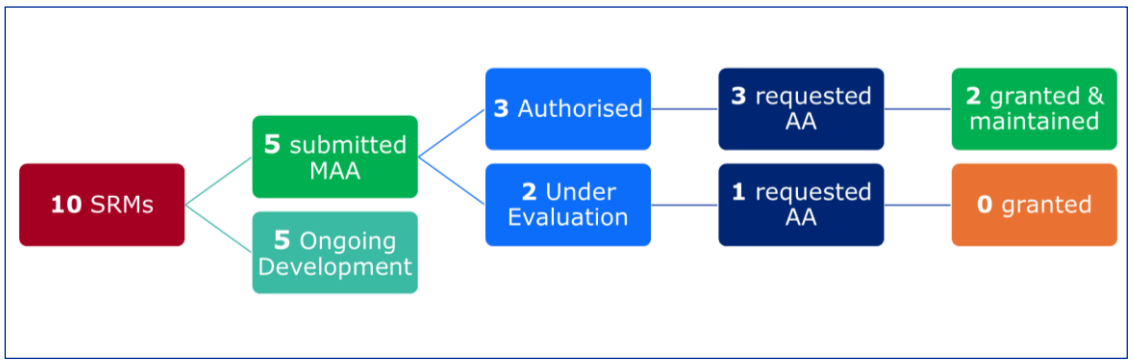
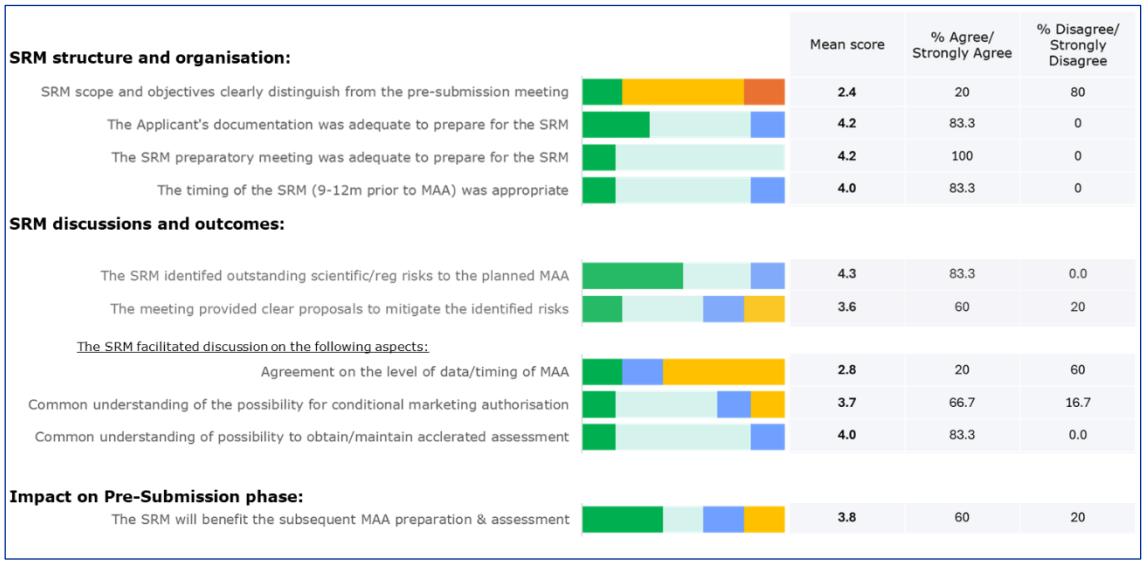


Figure 11. *Submission readiness meeting MAA status and accelerated assessment outcome*

Of the 5 MAAs, 3 products (Brinsupri, Kygevi and Vimkunya) received a recommendation for marketing authorisation (Kygevi was recommended to grant under exceptional circumstances). Two of those products (Brinsupri, and Vimkunya) were completed following AA. The 2 products still under evaluation both started the MAA under standard timelines. Although the dataset is currently too small to draw firm conclusions on the impact of the SRM discussion on the AA, the finding is consistent with the PRIME 5-year analysis which found that PRIME products are more likely to obtain and maintain AA. This is also reflected by the surveyed PRIME developers and Rapporteur teams who perceived that the SRM facilitated discussion of the AA request.

	Mean score	% Agree/ Strongly Agree	% Disagree/ Strongly Disagree
SRM structure and organisation:			
Based on the guidance, the SRM scope and objectives are clear	4.4	93.9	0.0
The timing of the meeting (9-12 months prior to MAA) is appropriate	3.9	66.7	12.1
The written guidance was helpful to prepare the SRM briefing documentation	4.3	90	0
The support provided by EMA was helpful to prepare for the meeting	4.6	100	0
SRM preparation benefitted subsequent pre-submission activities	4.6	100	0
The meeting participants provided appropriate expertise for the discussion topics	4.3	80	0
SRM discussions and outcomes:			
The SRM identified outstanding scientific/reg risks to the planned MAA	4.2	90	0
The meeting provided clear proposals to mitigate the identified risks	3.8	70	20
The SRM met your objectives and expectations	4.4	100	0.0
The SRM facilitated discussion on the following aspects:			
The required level of data maturity to support MAA submission	4.3	80	0
The required quality data package (EMA toolbox guidance)	4.3	80	0
The request for conditional marketing authorisation	3.4	30	0
The maintenance of Orphan Designation (+ sign benefit)	3.5	30	0
The expectations for the assessment of Orphan similarity	3.5	30	0
The expectations for obtaining/maintaining accelerated assessment	4.2	80	10
Impact on Pre-Submission phase:			
Continuity of support through PSI activities was maintained	4.2	88.9	11.1
SRM faciliated a decision on the need Rapp pre-submission meeting	4.0	66.7	0.0

***Figure 12**. PRIME Developers' survey key findings: submission readiness meeting*



	Mean score	% Agree/ Strongly Agree	% Disagree/ Strongly Disagree
SRM structure and organisation:			
SRM scope and objectives clearly distinguish from the pre-submission meeting	**2.4**	20	80
The Applicant's documentation was adequate to prepare for the SRM	**4.2**	83.3	0
The SRM preparatory meeting was adequate to prepare for the SRM	**4.2**	100	0
The timing of the SRM (9-12m prior to MAA) was appropriate	**4.0**	83.3	0
SRM discussions and outcomes:			
The SRM identifed outstanding scientific/reg risks to the planned MAA	**4.3**	83.3	0.0
The meeting provided clear proposals to mitigate the identified risks	**3.6**	60	20
The SRM facilitated discussion on the following aspects:			
Agreement on the level of data/timing of MAA	**2.8**	20	60
Common understanding of the possibility for conditional marketing authorisation	**3.7**	66.7	16.7
Common understanding of possibility to obtain/maintain acclerated assessment	**4.0**	83.3	0.0
Impact on Pre-Submission phase:			
The SRM will benefit the subsequent MAA preparation & assessment	**3.8**	60	20

***Figure 13.** Regulators' survey key findings: submission readiness meeting*

4. Overall Recommendations

The analysis considers the experience, perspectives and procedural learnings based on the two-year pilot of the new PRIME features. On this basis, key recommendations on each feature have been identified to refine their operation, and to further promote the scheme's intended objective for strengthened scientific support and oversight through regular, flexible, efficient engagement between PRIME developers, the Agency and Rapporteurs.

4.1. Regulatory roadmap and product development tracker

Based on experience in the pilot with the population, submission and review of the regulatory roadmap and product development tracker, EMA will:

- **Refine the structure and formatting** of the product development tracker, with the aim to **improve user-friendliness** for the PRIME developers populating and maintaining the tracker, and promoting ease of **review and interpretation** by EMA, Rapporteur teams, and relevant experts.
- **Update the published guidance** and development tracker **template**, providing more detailed instructions on the timing of periodic updates topics for inclusion, the required level of detail, and the assigned impact category, with examples based on the experience gained through the pilot.

To further promote two-way communication on emerging and ongoing product issues, EMA should:

- **Enhance the process for regular EMA/Rapporteur feedback** on periodic product development tracker following submission to promote dialogue on the identified issues, to align on the proposed plans for their mitigation and to agree on any resulting regulatory interactions (reflected in the regulatory roadmap).

Experience and feedback from the pilot emphasised the potential for the product development tracker as the central tool connecting all aspects of PRIME support from the KOM, through iterative scientific advice, to preparation for MAA submission. To further utilise the tool through all PRIME activities, EMA should:

- **Further promote** the development tracker as a core support tool for iterative scientific advice through the evidence generation phase, preparing a mature dossier to facilitate submission readiness, and obtaining accelerated assessment.

EMA will, in the short-term, refine the structure and formatting of the product development tracker document. However, in future, technical solutions should be considered that could more effectively integrate submitted product information with planned/completed regulatory procedures. Such a solution will aim to provide dynamic, real-time tracking of product development issues and the associated regulatory interactions to address them. Therefore:

- EMA will **consider future opportunities for enhanced use** (also considering IT and knowledge management tools) for the tracking of planned regulatory interactions,

identified product development issues and risks, proposed mitigation, and the resulting impact on the development milestones.

4.2. Expedited scientific advice

To provide further clarity on the qualifying criteria and to promote access to the expedited scientific advice procedure for critical development issues, EMA will:

- provide **additional guidance** on the specific questions/topics where expedited scientific advice can be sought, based on the experience gained during the pilot procedures
- **broaden the specific scenarios in which expedited advice can be sought**, including for key issues identified in the PRIME kick-off and submission readiness meetings for agreed follow-up, thereby streamlining their discussion and resolution
- clarify **timelines for submission of documentation and receipt of written advice** for the expedited procedure, to increase predictability for PRIME developers and assessment teams.

Although the expedited process reduced the overall procedure duration, the reduction should be progressed further as the current process still relies on the established SAWP evaluation time and discussion in plenary meetings. Scope remains for further expediting the procedure for PRIME products, which aligns with ongoing discussions on increasing the agility of expedited advice more broadly. Therefore, EMA will consider, together with the network, mechanisms for:

- further decreasing the expedited scientific advice **procedure duration** and further increasing the **agility of advice and developer interactions** outside of the established scientific advice timelines and SAWP plenary meetings.

4.3. Submission Readiness Meeting

The SRM analysis and survey feedback indicates that the meeting is delivering on its goal as a platform for discussion of the development programme, outstanding scientific issues and associated risks to the MAA, and the potential to obtain accelerated assessment. Elevating these aspects as pillars of PRIME dialogue – both during the evidence generation phase, driven by the revised development tracker, and in the SRM through targeted agenda points and supporting documents – can further the utility of the SRM discussions. Therefore:

- For efficient and meaningful discussion on aspects critical for the submission and assessment of the MAA, the **meeting should be further focussed** on implementation of scientific advice, MAA data maturity, the MAA basis, and the approach to obtain and maintain accelerated assessment.

The SRM is milestone in an iterative preparatory process for developers and assessors, and it serves as the pivot between the scientific evidence generation and MAA pre-submission phases. Engagement of the EMA product team across the lifecycle will enable knowledge transfer and experience gained to support an efficient MAA process.

- To facilitate knowledge sharing, **strengthened EMA product team involvement** in submission readiness is recommended to support efficient pre-submission activities.

Feedback on SRM emphasises the need for fast, structured and predictable channels to discuss and mitigate issues identified in the meeting which may impact the MAA and potential for accelerated assessment. Utilising the product development tracker and expedited advice to track and address outstanding topics, EMA will:

- **Establish clear routes for timely follow-up of outstanding risks**, including expedited scientific advice for scientific issues requiring formal feedback (monitoring through development tracker).

The SRM is timed to take place 9-12 months prior to the MAA to facilitate earlier, open dialogue on the MAA preparedness when there is greater scope to meaningfully inform the dossier content and timing of the submission. Based on PRIME developer feedback highlighting the potential benefit of discussions closer to the MAA when more data are available to inform planning, and with a range of experts with key roles in the MAA assessment:

- EMA, with the Network, will give consideration to **more flexible timing of the SRM** to support discussion on the MAA data package, and to facilitate broader participation of network experts.

5. Conclusions and reflections

PRIME launched in 2016 to provide early and enhanced support to medicines that have the potential to significantly address patients' unmet medical needs. Through optimised generation of robust data on a medicine's benefits and risks, PRIME aims to streamline the MAA assessment, enable accelerated assessment of applications and ultimately deliver promising new medicines to patients as early as possible. As PRIME reaches 10 years of operation, it is timely to consider how the scheme has evolved in a rapidly changing scientific and regulatory landscape. While the core aims of PRIME remain constant throughout its lifetime, the tools for delivering support have been refined through an ongoing process of review and learning from the accrued experience.

The implementation of the new PRIME features, and the recommendations for their further refinement following the pilot phase, reflect the next significant step in the scheme's evolution and future operation. Each feature will serve as a key tool to build continuous dialogue between developers, EMA and Rapporteur teams. This dialogue in turn facilitates a continuum of knowledge building which supports the generation of a robust dossier in preparation for the MAA submission and further supports the Rapporteur team in their assessment work during development.

While PRIME specifically targets medicines with the potential to significantly address unmet medical needs, the scheme is central to EMA's broader vision for supporting innovative medicines and may be seen as a vehicle for piloting new development support approaches. In fact, the new features also offer synergies with other EMA and EMRN initiatives aiming at increasing agility and efficiency of our product support:

- Successful implementation of the features will be supported by the new **Product Development Coordinator (PDC)** role, launched in parallel as a pilot for a subset of PRIME products. The PDC will utilise the product development tracker to promote efficient communication between EMA, Rapporteurs and PRIME developers, facilitate expedited scientific advice through their scientific and procedural expertise, and ensure effective knowledge transfer to the EMA product lead across the product life-cycle.
- Considerations for further **agility of PRIME expedited scientific advice** outside of the standard timelines aligns similar initiatives in specific therapeutic areas (e.g. for ETF rapid scientific advice for products addressing public health threats) and can inform ongoing discussions between EMA and developers in a focus group for increasing the agility of the standard scientific advice procedure.
- The experience and learning from the SRM will inform considerations for broader revision of the **EMA pre-submission interactions**, which are under discussion through the EMA pre-submission interactions group (Pre-SIG).
- The product development tracker, especially if evolved into a dynamic tool automatically integrating incoming information, will serve as the backbone to **efficient two-way communication between PRIME developers and EMA**. Such tool can in principle apply

to non-PRIME products, and future consideration will be given to a wider roll-out to strengthen EMA's product development support.

- Finally, all these converging initiatives will inform the implementation work on **strengthening EMA's development support offering overall**, triggered by the new EU pharmaceutical legislation.

The integration of the new pilot features as standard PRIME tools marks a waypoint on the path that started with the scheme's launch in 2016, through 10 years of experience and learnings, and continues towards a strengthened operation under the future EU legal framework for pharmaceuticals. The new features reconfirm EMA's commitment to continuous evolution of PRIME in order to better deliver on its objective to accelerate the availability of innovative medicines to patients with unmet medical needs.

Glossary

AA Accelerated Assessment

ATMP Advanced Therapy Medicinal Product

CAT The Committee for Advanced Therapies

CMA Conditional Marketing Authorisation

CHMP Committee for Medicinal Products for Human Use

COMP Committee for Orphan Medicinal Products

EEA European Economic Area

EMA European Medicines Agency

EMRN European medicines regulatory network

GCP Good Clinical Practice

GMP Good Manufacturing Practice

KOM Kick-off Meeting

MA Marketing Authorisation

MAA Marketing Authorisation Application

MO Major objection

NCA National competent Authorities

OD Orphan Designation

PA Protocol Assistance

PDCO Paediatric Committee

PIP Paediatric Investigation Plan

PRAC Pharmacovigilance Risk Assessment Committee

PRIME Priority Medicines

SA Scientific Advice

SAWP Scientific Advice Working Party

SME Small and medium sized enterprises

SRM Submission readiness meeting

UMN Unmet medical need

Annexes

Annex 1: Survey questions

EMA PRIME Pilot features survey: PRIME product developers

PRIME Pilot Network Survey.pdf

EMA PRIME Pilot features survey: Regulators

PRIME Pilot Developers Survey.p

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