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Change history

Version	Valid and binding as of:	Modified without version change	Description, comments (by author)	Author's initials
02	06.06.18		Modification of the chapter 6.1.2 Validation of initial application (Day 1 to 30)	ze
01	04.07.17		New document	sia, ze

1 Abbreviations

AIPS	Product Information Publication System
AMZV	Medicinal Products Authorisation Ordinance (AMZV SR 812.212.22)
API	(New / Known) Active Pharmaceutical Ingredient
ATC	Anatomical Therapeutic Chemical classification
CM	Case Manager
CPP	Certificate of a Pharmaceutical Product
CR	Clinical Reviewer
CT	Case Team
EAC	East African Community
eCTD	Electronic submission in CTD format
EMA	European Medicines Agency
FDA	U.S. Food and Drug Administration
INN	International Non-proprietary Name
IT	Index Therapeuticus
LoQ	List of Questions
MAGHP	Marketing Authorisation for Global Health Products
MoU	Memorandum of Understanding
NMRA	National Medicines Regulatory Authority
PCR	Preclinical Reviewer
PES	Division Process Development and Support
PIL	Patient Information Leaflet
QR	Quality Reviewer
RB	Review Board
SMEC	Swissmedic Medicines Expert Committees
SmPC	Summary of Product Characteristics
WHO PQT	World Health Organisation Pre-Qualification Team

2 Rationale for the MAGHP procedure

In January 2014, a [Memorandum of Understanding](#) (MoU) was signed between the Bill & Melinda Gates Foundation, the Swiss Federal Department of Foreign Affairs and the Federal Department of Home Affairs. Along with the amended mandate that has been approved by the Federal Council in September 2013 this MoU provides the basis for the involvement of Swissmedic in projects in the area of development cooperation.

The overall goal of this partnership is to accelerate and increase access to high-quality, essential medicines for populations living in low-income countries. The aim is to increase the efficiency of the regulatory review and registration process by focusing stakeholders on value-added activities, and to strengthen the regulatory authorities' ability to protect their citizens' health. Although other regions may be involved, the initial focus will be on supporting regulators in the East African countries with the goal of accelerating the access to medicinal products, mainly for those diseases that disproportionately affect the region. In the context of the Marketing Authorisation for Global Health Products (hereinafter referred to as MAGHP) procedure, this should be achieved by involving National Medicines Regulatory Authorities (hereinafter referred to as NMRAs) of the East African Community (EAC). If a listing for WHO prequalification is possible and intended, the WHO Pre-Qualification Team (hereinafter referred to as WHO PQT) will be involved in this marketing authorisation procedure at Swissmedic too. Swissmedic acts as a stringent regulatory authority in this cooperation. For priority global health products with high relevance it is possible to involve NMRAs of countries outside the EAC as observers in the MAGHP procedure (see section [3.4](#)). The expectation is that, if those partners are involved in this first step, the following steps at WHO and at the level of the NMRAs could be abbreviated because

- a) knowledge about the product has already been acquired and
- b) confidence in the scientific process at Swissmedic has been gained.

The MAGHP procedure builds on the existing authorisation process at Swissmedic. The marketing authorisation can be requested for Switzerland or as a so-called export registration, which allows the product to be marketed only outside Switzerland. However, the requirements in terms of the necessary data and documentation, as well as the review process, are the same for both types of marketing authorisation.

The MAGHP procedure will be tested in a pilot phase for about two years with the EAC NMRAs as active participants. After this period, the procedure may be revised to better suit the needs of the involved parties and may be opened up to allow the active participation of other NMRAs.

The benefits and risks of the medicinal products submitted under this procedure are assessed on the basis of the documentation.

The procedure and its timelines follow the regular marketing authorisation procedure at Swissmedic. In addition, applicants are requested to submit a prior-notification around six to three months before the planned submission date in order to allow proper planning of resources and involvement of NMRAs in East African countries as well as the WHO PQT.

3 Requests for an MAGHP procedure

3.1 Conditions under which an MAGHP procedure can be carried out

The following conditions must be fulfilled in order for an authorisation application to be processed within the framework of an MAGHP procedure:

- The authorisation application must concern a medicinal product with a new active pharmaceutical ingredient (new API), a new indication for a medicinal product or for a known active pharmaceutical ingredient (known API).

- The clinical and preclinical trials must be completed at the time of application submission. Any results from foreign assessments available to the applicant, particularly assessment reports from the European Medicines Agency (EMA) or the U.S. Food and Drug Administration (FDA), must be included with the submission.

A request for an MAGHP procedure can be sent to Swissmedic at the earliest six months prior to the expected submission date and must be received at the latest three months prior to the expected date.

For all applications, including those for export only, a Swiss marketing authorisation holder is required. However, an applicant does not necessarily need to be based in Switzerland, but can work through a representative, e.g. a regulatory office.

Fees for the application have to be paid according to the Ordinance on the Fees levied by the Swiss Agency for Therapeutic Products [[HGebV; SR 812.214.5](#)], the [WHO PQT Guidelines \(Prequalification Procedures and Fees\)](#) and national Fees regulations of the NMRAs concerned.

Furthermore, conducting an MAGHP procedure is only possible if the authorisation application is submitted in CTD format, either in electronic form (eCTD application) or as a paper version with CD/DVD (eDok). Submission in electronic form (eCTD) is preferred. Applicants with limited or no experience with eCTD submit a test sequence in good time (at least 3 weeks before submitting the application), in order to avoid exceeding the time limits as a result of technical problems.

The product or indication should be a new one on the Swiss market.

3.2 Language and communication

The documentation for this procedure shall be submitted in English. Also, assessment reports and Lists of Questions (LoQ) and correspondence will be written in English.

The Summary of Product Characteristics (SmPC) and the Patient Information Leaflet (PIL) have to be submitted in English and the correspondence language of the applicant (German or French). Swissmedic will review and correct the SmPC, PIL and the packaging in the correspondence language (German or French). However, the English version of SmPC corrections by Swissmedic will also be made available to the NMRAs, WHO PQT and the applicant.

Communication until day 330 (decision) during the MAGHP procedure will be between the applicant and Swissmedic (see overview of the procedure in [Appendix 1](#)). Communication in the affirmation phase will be between the NMRAs concerned and the applicant directly. Swissmedic will facilitate the contact between the applicant and the NMRAs concerned.

Information regarding the application, including evaluation reports, will be shared on an electronic platform with Swissmedic reviewers and the assigned NMRA and, where applicable, WHO PQT experts involved in the evaluation of the specific application. Confidentiality undertaking and the avoidance of any conflict of interest of participating experts will be assured according to the [WHO PQT Guidelines \(Confidential disclosure agreement, Annex 6 and Consent of WHO prequalification holder for WHO to share information with the national regulatory authority confidentially under the procedure, Annex 2\)](#).

3.3 Documentation required for the request

A written request for an MAGHP procedure shall be sent to Swissmedic and include the following details:

- Product name / International Non-proprietary Name (INN)
- Anatomical Therapeutic Chemical classification (ATC) / Therapeutic Index (IT group)
- Indication(s) and dosage recommendation: SmPC in English
- List of preclinical and clinical trials, in particular with essential information on the pivotal trials

- Completed form: “Status of marketing authorisations abroad”
- Planned submission date of the application and – in the case of submission in eCTD-format - date for submitting the eCTD test sequence (indicating +/- 2 calendar weeks)
- Proposed date for a pre-submission meeting or justification why such a meeting is not necessary
- List of preferred EAC markets for which a marketing authorisation is intended (active participation of NMRAs possible).
- List of preferred markets outside the EAC (participation of NMRAs as observers only, max. 5).
- Confirmation that fees will be paid according to national fees regulations of the NMRA concerned and / or the [WHO PQT Guidelines](#) (if a PQ Listing is intended).
- Permission to exchange confidential information, including submitted application dossier, Swissmedic evaluation reports, correspondence with NMRAs concerned, experts and WHO PQT, during the whole process on an electronic platform

3.4 Processing the request and determining the parties involved

Swissmedic will confirm receipt of the request for an MAGHP procedure in writing. Within six weeks, Swissmedic Networking initially contacts the NMRAs involved in the request as well as WHO PQT to obtain their feedback, i.e.:

- c) If they are interested in actively participating in the procedure. This would include access to confidential information e.g. full documentation of the applicant and evaluation reports on the electronic platform as well as nomination of reviewers/experts to be involved in meetings and/or the provision of (scientific) input into the procedure.
- d) If they are interested in participating as an observer in the procedure. This will include access to the Swissmedic evaluation reports and internal correspondence, excluding the documentation of the applicant on the electronic platform.

NMRAs confirming their interest in an active or passive participation will be referred to as “NMRAs concerned”.

Feedback from NMRAs and WHO PQT shall be sent to the Networking Division at Swissmedic. The Division Process Development and Support (PES) will make the documentation for the request available to the assigned experts of the NMRAs concerned and WHO PQT.

Within six weeks, Swissmedic decides whether it will be possible to conduct the procedure requested under the conditions stated and taking account of the planned submission date (see [3.3](#)). The outcome is communicated to the applicant in writing. This letter also confirms the date of the pre-submission meeting. If Swissmedic and the applicant mutually agree that the pre-submission meeting is not necessary it may be omitted.

If it is not possible to start an MAGHP procedure on the submission date proposed by the applicant, Swissmedic, together with the NMRAs concerned and WHO PQT, examines whether such a procedure is possible within an alternative time frame, and proposes the corresponding alternative to the applicant in its response. If it is not possible for the parties involved to agree on an alternative submission date, the applicant is informed that the MAGHP procedure cannot be carried out within the proposed time frame.

Role allocation of the parties involved:

Party involved	Active participation	Participation as an observer
Swissmedic	Swissmedic is the leading party for the evaluation of the application, responsible for timelines, LoQ and Decision sent by day 330. Concerns of the actively participating NMRAs concerned and WHO PQT may be integrated in the LoQ. Swissmedic makes an independent risk benefit evaluation, but takes into consideration the comments of the experts.	
WHO Pre-Qualification	Feedback to LoQ, risk benefit evaluation, preliminary decision, SmPC and PIL. <i>Commitment of WHO for a prequalification listing within 90 days after a positive decision.*</i>	No feedback or comments. <i>Commitment of WHO for a prequalification listing within 90 days after a positive decision.*</i>
	Confidentiality undertaking and the avoidance of any conflict of interest of participating experts will be assured according the WHO PQT Guidelines (Confidential disclosure agreement, Annex 6 and Consent of WHO prequalification holder for WHO to share information with the national regulatory authority confidentially under the procedure, Annex 2) .	
NMRA	Feedback to LoQ, risk benefit evaluation, preliminary decision, SmPC and PIL. <i>The NMRAs concerned commit to decide on an authorisation within 90 days.*</i>	No feedback or comments. <i>The NMRAs concerned commit to decide on an authorisation within 90 days.*</i>
	Confidentiality undertaking and the avoidance of any conflict of interest of participating experts will be assured according the WHO PQT Guidelines (Confidential disclosure agreement, Annex 6 and Consent of WHO prequalification holder for WHO to share information with the national regulatory authority confidentially under the procedure, Annex 2) .	
Applicant	The applicant commits to provide WHO PQT-conforming data: e.g. stability data 30° / 75% RH, 6 months real time (rolling submission possible) During the MAGHP process the applicant has the possibility to switch to Swissmedic standard processes without the involvement of WHO or NMRAs concerned.	

3.5 Time line

Swissmedic, the NMRA(s) concerned, WHO PQT and the applicant commit to a time line and a deadline for the submission of the application (indicating +/- 2 calendar weeks).

The time lines for new APIs and known APIs follow the ordinance [ZL000_00_006e WL Guidance document Time limits for authorisation applications](#). Hence, in the MAGHP procedure, three months prior to submission are needed in order to plan and coordinate the parties involved appropriately. Therefore the procedure until a Swissmedic decision is issued takes three months longer. *The affirmation phase to require market authorisation in the NMRAs concerned / WHO PQ is expected to last 90 days at the end of the process.*¹ A fast-track procedure is not feasible due to the increased coordination with NMRAs and WHO PQT in the pilot phase.

4 Prior notification

4.1 Prior notification

If the applicant is informed that an MAGHP procedure is possible within the proposed time frame, it shall submit a written prior notification to Swissmedic at the latest three months before the planned submission date. In this notification the applicant confirms to Swissmedic the date on which the application will be submitted (indicating the calendar week). The applicant also confirms the date of the pre-submission meeting.

¹ To be confirmed

After the prior notification is submitted, Swissmedic confirms back to the applicant that the conditions examined within the framework of the request are still fulfilled and that the procedure will be conducted. Swissmedic provides a copy of the correspondence to the NMRAs concerned and WHO PQT on the electronic platform.

4.2 Pre-submission meeting

The primary aim of the pre-submission meeting (approx. six weeks prior to the submission) is to clarify whether all the documentation required to process the application is available.

In particular, this concerns the following aspects of the application to be submitted:

- Index of the scientific documentation and the administrative documents
- Any open questions regarding the documentation
- Information on manufacturers concerned
- Date of submission of the eCTD test sequence (if an eCTD application is to be submitted)
- Volume of the submission
- Establishing the final submission date and the timelines for the marketing authorisation procedure
- Planning of sample testing, if applicable

The applicant may briefly address particular problems that could affect the complexity of the evaluation at this pre-submission meeting: e.g. new manufacturing processes, specific statistical analysis and other critical points.

The NMRAs concerned and WHO PQT may also bring up questions or concerns at this pre-submission meeting.

5 Exchanges and meetings between Swissmedic, the NMRA(s) concerned and WHO PQT

5.1 Interaction during the review process: form and organisation

The following possibilities for interactions between Swissmedic, the NMRAs concerned and WHO PQT are foreseen during the review process:

- a) Participation in meetings
 - Pre-submission meeting (see [4.2](#))
 - Case team meetings 1 and 2 (see [6.2.1](#), [6.2.4](#))
 - Case team meeting prior to finalisation of the preliminary decision (optional; see [6.2.4](#))
 - Participation in additional review-discipline specific meetings (e.g. Review Board Meeting of the Division Clinical Review)

Participation may be organised through telephone conference, web-based conferences (WebEx, Skype) or in person. Furthermore, participation is optional and there is no need to attend all meetings.

- b) Accessing information on an electronic platform
 - Dossier submitted for marketing authorisation
 - Preliminary and final assessment reports
 - List of Questions (LoQs)
 - Answers to LoQs
 - Minutes of Case team and Swissmedic Medicines Expert (SMEC) meetings

The electronic platform is administered and the documentation uploaded in the context of MAGHP procedures by PES. Best-practice standard operating procedures on how to handle the extranet platform and confidential information and documentation will be introduced to the assigned experts of the NMRAs and WHO-PQ with upfront submission by PES.

- c) Chat
- Questions arising from the review of the documentation provided on the electronic platform may be discussed with the individual reviewers

6 Review Procedure

6.1 Submission and documentation

6.1.1 Submitting the application to Swissmedic (Day 0)

The applicant submits an application to Swissmedic.

The application must include the comprehensive and complete documentation for quality, preclinical and clinical aspects in line with art. 3, 4 and 5 of the [Medicinal Products Authorisation Ordinance](#).

The requirements are further detailed in the Guidance Document “Formal Requirements” for the specific type of application ([Guidance document Formal requirements](#) and [VZ Overview of documents to submitted](#)). The documentation must be in English. The SmPC /PIL must be in either German or French together with a certified English version. The applicant is responsible for the certification of the translation.

Accepted submission formats are eCTD and paper version with CD/DVD (eDok).

6.1.2 Validation of initial application (Day 1 to 30)

The submitted documentation is evaluated in regard to fulfilment of the formal requirements for the type of application concerned. A validation decision will be taken and communicated to the applicant within 30 days of the date of the submission of the application.

If the formal requirements are fulfilled, the application is accepted and the applicant is informed accordingly. Swissmedic will also inform the NMRAs concerned and WHO PQT about the acceptance of the application and the timing for the technical review of assessment phase 1.

If the formal requirements are **not** fulfilled, the applicant is informed about the deficiencies in the documentation. Swissmedic sends information about deficiencies and the deadline for re-submission to the NMRAs concerned and WHO PQT. The applicant is granted a 120-day period to remedy the deficiencies. If the deficiencies cannot be remedied by the applicant within the given time frame, Swissmedic will reject the application.

For eCTD submissions a technical validation precedes the evaluation of the formal correctness of the application. After completion of the validation of the documentation, the Swissmedic Case Management Division will make the application and complete documentation available on the electronic platform within one week to the NMRAs concerned and WHO PQT.

6.2 Evaluation

6.2.1 Assessment Phase 1 (Day 30 to 150)

In assessment phase 1 the documentation is reviewed by the case manager (regulatory), quality, preclinical and clinical reviewers. Each will prepare a list of questions resulting in four parts of an assessment report. Reviewers follow Standard Operating Procedures defined for each function while writing the assessment report.

The first case team meeting with the concerned reviewers is held within the first two weeks of the assessment phase 1 (day 45). This meeting is for coordination purposes and to discuss any potential challenges to the review.

The second case team meeting takes place before the finalisation of the list of questions around day 135. This meeting serves to discuss the review outcomes and to agree on the final list of questions to be sent to the applicant.

Swissmedic shares the preliminary assessment reports with the NMRAs concerned and WHO PQT within 9 weeks after the start of assessment phase 1 (at the latest by day 125). The NMRAs concerned and WHO PQT will provide their comments and feedback to the list of questions by day 135 (before the second case team meeting).

The NMRAs concerned and WHO PQT may participate in the case team meetings by phone conference or in person (see [5.1](#)). If the actively participating NMRAs or WHO QP experts are not able to attend the meeting or give feedback, Swissmedic will send the outcome of the discussion / meeting to the applicant. The experts will be informed and eventual inputs cannot be integrated in the LoQ.

6.2.2 List of Questions sent to Applicant (Day 150)

The List of Questions is sent to the applicant on Day 150 of the procedure. The applicant is granted a 90-day period to respond to the LoQ. The applicant may ask for an extension of this period by a maximum of a further 90 days.

Within two weeks after receipt of the list of questions, the applicant shall inform Swissmedic of the planned date of submission of its response to the list of questions.

6.2.3 Applicant's response to the List of Questions

Assessment phase 2 will start at the end date of the applicant's deadline for submission of the response to the list of questions, provided the response is considered complete and formally acceptable. The applicant should submit its response to Swissmedic. PES will make the documentation available on the electronic platform.

The applicant's response to the list of questions is reviewed by the case manager in regard to completeness and fulfilment of the formal requirements.

If the quality of the response documents is not satisfactory, the applicant may be asked to correct and complete the documentation, in general within 30 days. If the applicant has not submitted the response to all questions, the applicant must provide a timeline to Swissmedic for submission of the remaining responses. Under regular conditions, the deadline for submitting the responses to the list of questions may be extended only once by a further 90 days (see [6.2.2](#), List of Questions).

Swissmedic will inform the NMRAs concerned and WHO PQT about the result of the formal evaluation of the applicant's response document and the timing for the technical review for assessment phase 2.

Should the applicant submit additional documentation that is not required to answer to the list of questions, Swissmedic will decide whether a second assessment phase 1 and a second list of questions will be necessary. The time for the second assessment phase 1 is at the expense of the applicant and the time line corresponds with the initial assessment phase 1 (120 days).

6.2.4 Assessment Phase 2 (Day 150 to 240)

In assessment phase 2 the technical reviewers will evaluate the responses of the applicant to the list of questions. In general, assessment phase 2 results in a preliminary decision, which may be positive, partly positive or negative. In exceptional cases, a second list of questions may be issued.

Swissmedic shares the (preliminary) assessment reports with the NMRA concerned within 9 weeks after the start of assessment phase 2 (at the latest by day 215). The NMRAs concerned will have to provide their comments and feedback for the preliminary decision at the latest by day 225 before the

third case team meeting. The NMRAs concerned may participate in the case team meeting by phone conference or in person. If the actively participating NMRAs or WHO QP experts are not able to attend the meeting or give feedback, Swissmedic will send the outcome of the discussion / meeting to the applicant. The experts will be informed and eventual inputs cannot be integrated in the preliminary decision. Where applicable the application will be presented and discussed at the SMEC meeting before finalisation of the preliminary decision.

Summary of Product Characteristics and Patient Information Leaflet

The SmPC and PIL have to be submitted in English and the correspondence language of the applicant (German or French). Swissmedic will review and correct the SmPC, PIL and the packaging in the correspondence language (German or French).

For export registrations, only the SmPC is required. In this case Swissmedic will review and correct the SmPC in the correspondence language (German or French).

The corrections in both languages will be made available to the applicant, WHO PQT and the NMRA partners involved.

6.2.5 Preliminary Decision sent to Applicant (Day 240)

Swissmedic communicates the preliminary decision to be taken and any conditions that would apply to the final decision. With the preliminary decision, the applicant receives the comments and corrections on the SmPC, PIL and the packaging.

A copy of the letter including the additional documents is made available to the NMRAs concerned and WHO PQT on the electronic platform.

6.2.6 Applicant's Response to Preliminary Decision

The applicant is granted a 90-day period for its response to the preliminary decision. The applicant is expected to agree with any obligation linked to the final decision as well as to fulfil all preconditions associated with the final decision.

6.2.7 Labelling Phase (Day 240 to 330)

During the labelling phase the texts for the SmPC, PIL and packaging are finalised. The applicant reviews the SmPC, PIL and packaging elements provided by Swissmedic. If all corrections are accepted by the applicant as demanded by Swissmedic, the final decision will be issued.

If the applicant does not agree with all the comments and corrections, an additional labelling round may be needed. In this case, the applicant is granted another 90-day period for the reworking of the labelling elements, followed by a 90-day review period by Swissmedic. The time for the additional labelling review is at the expense of the applicant.

For new products (i.e. first marketing authorisation) the approved SmPC and PIL have to be published on the Swissmedic Product Information Publication System (AIPS) by the applicant. In the case of an export registration, the publication on AIPS is not required.

6.2.8 Decision (Day 330)

Swissmedic sends the final decision to the applicant and makes it available to the NMRAs concerned and WHO PQT via the electronic platform. In the case of a positive decision the Swiss marketing authorisation or export registration is granted.

6.2.9 Sample testing

Sample testing by Swissmedic takes place in accordance with the instructions that apply generally to the authorisation procedure. Samples and any other documents must then be submitted in accordance with the requirements stated in the LoQ.

6.2.10 WHO Prequalification and decision of the NMRAs concerned (Day 420)

- The NMRAs concerned will decide and confirm their decisions within 90 days of the date on which Swissmedic sent the decision to the applicant. The SmPC may need to be adapted to the specific

requirements by the NMRAs concerned. In the case of a positive decision the marketing authorisation is granted by the NMRAs concerned within three months.*

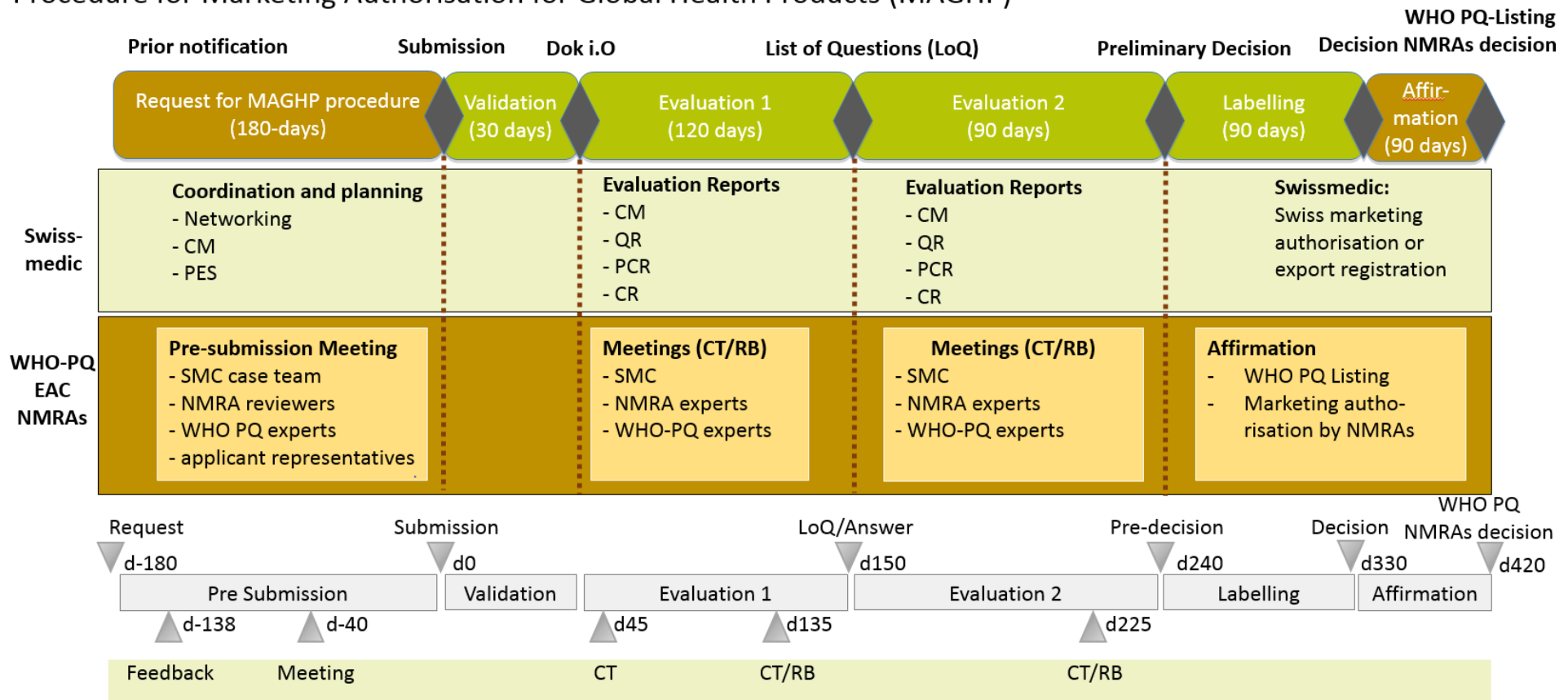
- The WHO Prequalification will be listed within 90 days if WHO PQT was involved in the MAGHP process.²

² To be confirmed

7 Annex

7.1 Annex 1: Procedure for Marketing Authorisation

Procedure for Marketing Authorisation for Global Health Products (MAGHP)



7.2 Annex 2: Time lines

Time lines	Prior notification	Swissmedic: Technical Validation & Formal Control	Applicant: Correction of documents	Swissmedic: Evaluation phase I -> LoQ or prelim. decision	Applicant: Answer to LoQ	Swissmedic: Evaluation phase II -> Prelim. decision	Applicant: Answer to prelim. decision	Swissmedic: Evaluation of the answer to prelim. decision -> Text checking of letter or official decision	Total applicant time	Total SMC time
First authorisation and major variations	Δ-180	Δ30	Δ120	Δ120	Δ90	Δ90	Δ90	Δ90	300	330
Time Points of Meetings	-40	-	-	d45 d135		d225		-		

7.3 Annex 3 Formal Requirements and Relevant Guidance documents

Formal requirements:

<https://www.swissmedic.ch/zulassungen/01520/03957/index.html?lang=en>

Relevant Guidance documents:

- [Guidance document Time limits for authorisation applications](#)
- [Tabular Overview Time limits for authorisation applications](#)
- [Guidance document Authorisation human medicine new active substance and major variation](#)
- [Guidance document Authorisation Biosimilar](#)
- [Guidance document Authorisation of human medicine with known active pharmaceutical ingredient](#)