Contents

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Change history

Version	Valid and binding as of:	Description, comments (by author)	Author's initials
4.1	01.03.2021	Formal adjustments to the header and footer No content adjustments to the previous version.	dei
4.0	01.10.2020	Addition chapter 12: MAGHP Light Procedure	pal/zeg/ze
3.0	01.09.2020	Update based on various clarifications by external stakeholders	pal/zeg/ze
2.0	01.08.2020	Complete revision based on the lessons learned from the first projects. Previous version ZL000_00_011 was archived in December 2019.	pal/zeg/ze
1.0	01.01.2016	New document, implementation of the MAGHP procedure	NET/ZL

1 Definitions, terms, abbreviations

1.1 Abbreviations

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
NRA	National Regulatory Authority
PCR	Preclinical Reviewer
PIL	Patient Information Leaflet
QR	Quality Reviewer
RB	Review Board
ROD	Regulatory Operations and Development
SHE	Stakeholder Engagement
SMEC	Swissmedic Medicines Expert Committees
SmPC	Summary of Product Characteristics
TC	Telephone Conference
WHO PQT	World Health Organisation Prequalification Team

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2 Introduction and objective

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 was 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- and middle-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 (capacity building).
Although participation of other regions may be considered, the focus is on supporting regulators in the sub-Saharan region of Africa with the goal of accelerating access to medicinal products – mainly, but not exclusively, 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 the National Regulatory Authorities (hereinafter referred to as NRAs) of the countries concerned. In order to guarantee an optimal exchange, Swissmedic envisages a maximum number of approximately 10 countries.
The NRAs involved in the MAGHP will benefit from being part of the Swissmedic evaluation procedure. This will enable them to acquire knowledge about the product, gain confidence in the scientific evaluation at Swissmedic and, at the same time, provide their own inputs and comments on the evaluation. Therefore, the expectation is that the authorisation procedure can be shortened for the NRAs because

a) knowledge about the product has already been acquired ("well-informed" reliance),
b) access to the Swissmedic assessment and inspection reports is granted and
c) confidence in the scientific process at Swissmedic has been gained.

The MAGHP procedure builds on the existing authorisation processes at Swissmedic. In case of an approval, the procedure results in a marketing authorisation for Switzerland. Therefore, those criteria that are applicable to the assessment and significant for decision-making purposes refer to the medical situation and regulatory requirements in Switzerland.
Nevertheless, the inputs and comments received from participating NRAs are taken into consideration and are included in the exchange with the applicant. These inputs may address country-specific issues, such as special requirements regarding stability data (e.g. climate zone 4), risk management plan or disease programmes, including country-specific treatment guidelines, and will serve as important information for the applicant with regard to the dossier submission.

It is important to note, that, in addition to the application to Swissmedic, the individual dossier will also need to be submitted according to the national requirements to each targeted NRA. Apart from national specifics, the dossier must be essentially the same.
The applicant is encouraged to submit the dossier as early as possible in the process.

The MAGHP procedure is limited to new registrations and new indications of new and established APIs. At present, the lifecycle management of products that have been approved using the MAGHP procedure only affects the Swiss market. As soon as more experience has been gained with the procedure, an extension of the scope will be considered. Nevertheless, it is important to note that the responsibility for the product remains with the NRAs in their respective markets.

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.

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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 NRAs.

MAGHP Light procedure
The MAGHP "Light" procedure, applies to applications in the Fast track and Temporary authorisation procedures. The MAGHP Light procedure foresees a one-directional exchange of documentation with the participating NRAs. For more information on the MAGHP Light procedure, its conditions and scope of applicability please refer to chapter 12 of this document.

3 Collaboration with WHO

The MAGHP will be performed in collaboration with WHO. WHO facilitates the first contact between Swissmedic and the target NRAs and the nomination of experts. If indicated and requested, experts from WHO provide scientific expertise on programmatic aspects. Furthermore, WHO closely follows the process of the MAGHP procedure. Upon request by the applicant for prequalification, as well as for the WHO collaborative procedure, the assessment report generated by Swissmedic under the MAGHP procedure is shared with WHO prequalification and the national regulatory authorities participating in the WHO collaborative procedure to facilitate their regulatory decisions.

4 Confidentiality undertaking and conflicts of interest

To ensure confidentiality and avoid conflicts of interest, each participating representative of the NRAs / WHO must complete and sign the form *Declaration of Interests and Confidentiality Undertaking*. Access to the application dossier is only granted after the signed form has been handed in.

5 Role allocation of the parties involved

Party involved	Activity
Swissmedic	Swissmedic is the leading party for the evaluation of the application and is responsible for timelines, LoQ and Decision sent by day 330. (In case of an approval, the procedure always results in a Swiss authorisation.) Swissmedic makes an independent risk-benefit evaluation but takes into consideration the comments of the NRA's and WHO's experts. All their relevant concerns are integrated in the exchange with the applicant.
WHO	WHO facilitates the first contact, in particular, between Swissmedic and the target NRAs. If indicated, WHO experts (e.g. on disease programmes / Prequalification Team) are consulted to provide scientific expertise on programmatic aspects.
NRA	The NRA evaluates the dossier submitted by the applicant and Swissmedic's assessment reports (incl. LoQ). If possible, the NRA writes an assessment report reflecting the medical need and regulatory requirements in their country. The NRA comments on Swissmedic's assessment reports, risk benefit evaluation, preliminary decision, SmPC and PIL and adds its own questions to the LoQ. Note: Country-specific documents, such as risk management plans, must be evaluated by the respective NRAs. Provided the dossier has been submitted, the NRAs concerned commit to decide on an authorisation within 90 calendar days after completion of the procedure at Swissmedic. If the dossier has not been submitted by the end of the Swissmedic procedure, the decision must be made within 90 calendar days after dossier receipt.
Applicant	The applicant submits the dossier to Swissmedic and conducts dialogue related to the dossier processing. Specifies the NRAs to be involved and signals the need to include WHO.

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	The dossier is submitted to each individual NRA concerned as early in the process as possible. Modules 2 to 5 must be identical to the version submitted to Swissmedic. During the MAGHP process the applicant has the option of switching to the standard Swissmedic processes without the involvement of the NRAs concerned.

6 Interaction between Swissmedic and the NRA(s) concerned

6.1 Language and communication

The documentation for this procedure shall be submitted in English. Assessment reports and Lists of Questions (LoQ) and correspondence are written in English.
The Summary of Product Characteristics (SmPC) and the Patient Information Leaflet (PIL) must be submitted in English and the correspondence language of the applicant (German or French). Swissmedic reviews the SmPC, PIL and the packaging in the correspondence language (German or French). In addition, an English version of Swissmedic's SmPC revisions is made available to the NRAs and the applicant.

Communication until day 330 (decision) during the MAGHP procedure takes place between the applicant and Swissmedic (see overview of the procedure in Appendix 1). Communication in the NRA national decision phase takes place between the NRAs concerned and the applicant directly. On request, Swissmedic facilitates the contact between the applicant and the NRAs concerned.

6.2 Document exchange

Accessing information for the involved NRAs and WHO on an electronic platform

- Full dossier submitted for marketing authorisation by the applicant
- Preliminary and final assessment reports written by Swissmedic
- Swissmedic's List of Questions (LoQ)
- The applicant's answers to the LoQs
- Minutes of case team and Swissmedic Medicines Expert Committee (SMEC) meetings

The Swissmedic Regulatory Operations and Development (ROD) division administers the electronic platform and the documentation uploaded in the context of MAGHP procedures. Best-practice standard operating procedures on how to handle the extranet platform and the confidential information and documentation are introduced to the assigned experts of the NRAs by ROD.

6.3 Meetings and further exchange

The following possibilities for interactions between Swissmedic and the NRAs concerned are envisaged during the review process:

a) Participation in meetings
   - Kick-off and case team meetings
   - Participation in additional review discipline-specific meetings (e.g. Review Board Meeting of the Division Clinical Review)

Participation may be organised through telephone conferences (TC), web-based conferences (e.g. WebEx, Skype) or in person. Swissmedic drafts the minutes and circulates them to the meeting participants for further comments.

b) Further exchange
   - Questions arising from the review of the documentation provided on the electronic platform may be discussed with the individual reviewers.
   - Further clarifications and questions are addressed by email exchange

7 Timelines

Swissmedic and the applicant commit to a timeline and a deadline for the submission of the application (indicating +/- 2 calendar weeks).

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The timelines follow the Guidance Document *Time limits for authorisation applications HMV4*. Hence, in the MAGHP procedure, a period of three months prior to submission is needed in order to plan and coordinate the parties involved appropriately.
For applications in the Swissmedic fast-track and temporary authorisation procedure only the MAGHP Light procedure is applicable (see chapter 12).
Provided the dossier has been submitted, the NRAs concerned commit to decide on an authorisation within 90 calendar days after completion of the procedure at Swissmedic. If the dossier has not been submitted by the end of the Swissmedic procedure, the decision must be made within 90 calendar days after dossier receipt.

8 Requests for an MAGHP procedure

8.1 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 medicinal product with a known active pharmaceutical ingredient (known API) or a new indication for a medicinal product with a new or a known API.
- The clinical and preclinical trials must be completed at the time of application submission. Any results from partner authorities' 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.

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

The focus is on those diseases that disproportionately affect the region in question, but there is no restriction to certain indications.

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 are payable according to the Ordinance on the Fees levied by the Swiss Agency for Therapeutic Products [GebV; SR 812.214.5] and the national fees regulations of the NRAs 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.

8.2 Required documentation

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"

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- 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 as to why such a meeting is not necessary
- List of preferred markets (countries) for which a marketing authorisation is intended
- Whether the involvement of WHO is required (including the desired type of expertise)
- Confirmation that fees will be paid according to the national fee regulations of the NRAs concerned
- Permission to exchange confidential information, including the submitted application dossier, Swissmedic evaluation reports and correspondence with NRAs concerned during the whole process on an electronic platform

8.3 Processing the request and determining the parties involved

Swissmedic confirms receipt of the request for an MAGHP procedure in writing. Within ten weeks, the Swissmedic Stakeholder Engagement (SHE) Division initially contacts the NRAs responsible for the markets (countries) identified in the request and WHO (when required by the applicant), if they are interested in participating in the procedure. If necessary, WHO supports Swissmedic in establishing first contact and facilitates the nomination of experts from targeted NRAs.
Each NRA has to name one or two (at the most) committed experts by indicating their function within the agency, professional background and email address. Those representatives act as single points of contact throughout the whole procedure.
As soon as these experts have signed an agreement on the declaration of conflicts of interest and confidentiality undertaking (see chapter 2) they are granted access to the electronic platform for the exchange of documentation.
Feedback from NRAs or WHO shall be sent to the SHE Division at Swissmedic.
The applicant selects the NRAs to be involved. However, WHO may suggest additional target countries in consultation with the applicant, which takes the final decision.

Within ten 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 2.3). The outcome is communicated to the applicant in writing. This letter contains the list of NRAs to be involved. In addition, it 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 requested, WHO may be involved in the pre-submission meeting.

If it is not possible to start an MAGHP procedure on the submission date proposed by the applicant, Swissmedic, together with the NRAs concerned, examines whether such a procedure is possible within an alternative timeframe, 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 timeframe.

9 Prior notification

9.1 Processing the prior notification

If the applicant is informed that an MAGHP procedure is possible within the proposed timeframe, 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.
In parallel, the applicant should inform the NRAs concerned about the intended dossier submission. This information is important for the planning and resource allocation at the NRAs.

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9.2 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 issues 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.
If requested and possible, WHO may already be involved at this early stage of the procedure and raises questions or concerns at this pre-submission meeting.

If questions about the submission arise during the approval process, the company has the usual meeting options (Clarification Meeting). However, specific questions about the MAGHP Procedure can be discussed with Swissmedic outside of a Clarification Meeting.

10 Processing the application for authorisation

10.1 Submission and documentation

10.1.1 Submitting the application to Swissmedic (Day 0)

The application must include the comprehensive and complete documentation for quality, preclinical and clinical aspects in line with Arts. 3, 4 and 5 of the *Medicinal Products Authorisation Ordinance*.

The requirements are further detailed in the Guidance Document *formal requirements HMV4* and Directory *Overview of documents to be submitted HMV4*. The documentation must be in English. The SmPC/PIL must be in either German or French together with a certified English translated version. The applicant is responsible for certifying the translation.

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

10.1.2 Validation of initial application (Day 1 to 30)

The submitted documentation is evaluated with regard to fulfilment of the formal requirements for the type of application concerned. A validation decision will be made 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.
If the formal requirements are **not** fulfilled, the applicant is informed about the deficiencies in the documentation. The applicant is granted a 60-day period to remedy the deficiencies. If the deficiencies cannot be remedied by the applicant within the given timeframe, Swissmedic will reject the application.

For eCTD submissions, a technical validation precedes the evaluation of the formal correctness of the application. After validation of the documentation is completed by the Swissmedic Case Management Division (CM), ROD makes the application and complete documentation available on the electronic platform to the NRAs concerned.

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10.2 Evaluation

10.2.1 Assessment Phase 1 (Day 30 to 150)

In assessment phase 1 the documentation is reviewed by the case manager (regulatory) and quality, preclinical and clinical reviewers. Each will prepare an LoQ, resulting in four parts of an assessment report. Reviewers follow Standard Operating Procedures.

Within the first two weeks (day 45) of assessment phase 1, a kick-off meeting with the NRA's representatives and Swissmedic's reviewers is held to introduce the dossier and discuss any potential challenges to the review. Next, the NRA's experts are invited to study the dossier submitted by the company, write their own assessment report and form their opinion about the application.

Swissmedic shares the preliminary assessment reports with the NRAs concerned within 9 weeks after the start of assessment phase 1 (at the latest by day 125). At this point, a case team meeting is held to present the outcome of Swissmedic's review. Subsequently, the NRA's experts are expected to study and comment on the Swissmedic assessment reports (incl. the drafted LoQ) and to add their own questions. These inputs provided by the NRAs should address country-specific issues, such as special requirements regarding stability data (e.g. climate zone 4), risk management plan or disease programmes, including country-specific treatment guidelines, and will serve as important information for the applicant with regard to the dossier submission. The NRA's feedback should be in writing.
A third meeting takes place before the finalisation of the LoQ around day 135. This meeting serves to discuss the NRA's feedback and to agree on the final LoQ to be sent to the applicant. All relevant concerns of the NRAs involved are integrated in the LoQ.

The NRAs concerned may participate in the meetings by TC or in person (see 4.3). If the NRA's experts are not able to attend the meeting or give feedback, Swissmedic sends the outcome of the discussion / meeting to the applicant and the experts are informed accordingly, but possible inputs cannot be integrated in the LoQ.

10.2.2 List of Questions (Day 150)

The LoQ 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 LoQ, the applicant shall inform Swissmedic of the planned date of submission of its response to the LoQ.

If requested, a clarification meeting may be held in order to clarify open questions / uncertainties regarding the list of questions and share experiences between the applicant, Swissmedic and WHO.

10.2.3 Assessment Phase 2 (Day 150 to 240)

Assessment phase 2 starts at the end date of the applicant's committed deadline for submission of the response to the LoQ, provided the response is considered complete and formally acceptable. ROD makes the documentation available on the electronic platform.

Swissmedic informs the NRAs concerned about the receipt of the applicant's response document and the timing for the technical review for assessment phase 2. The NRAs are invited to review the applicant's answers and to further process their report prepared in assessment phase 1.

Should the applicant submit additional documentation that is not required to answer the LoQ, Swissmedic decides whether a second assessment phase 1 and a second LoQ 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).

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

Swissmedic shares the (preliminary) assessment reports with the NRAs concerned within 9 weeks after the start of assessment phase 2 (at the latest by day 215). At this point, a case team meeting is held to present the outcome of Swissmedic's review. Subsequently, the NRA's experts are expected to study and comment on the Swissmedic assessment reports and to build their own opinion on the preliminary decision.
This input should be given at the latest by day 225 before a second case team meeting to discuss the outcome. All relevant concerns of the NRAs involved are added as recommendations to the preliminary decision.

When appropriate, the application is presented and discussed at the meeting of the Swissmedic Medicines Expert Committee (SMEC) before finalisation of the preliminary decision.

Summary of Product Characteristics and Patient Information Leaflet

The Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL) must be submitted in English and the correspondence language of the applicant (German or French). Swissmedic reviews and corrects the SmPC, PIL and the packaging material in the correspondence language (German or French). For export registrations, only the SmPC is required.
In addition, Swissmedic translates and transfers the corrections to the English Version of the SmPC. This English version is shared with the NRAs involved and WHO on the electronic platform. The NRA's experts may also comment on the SmPC and the corrections made by Swissmedic.

10.2.4 Preliminary Decision (Day 240)

Swissmedic informs the applicant of the preliminary decision to be made 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 material.
A copy of the letter, including the additional documents, is made available to the NRAs concerned on the electronic platform.
The applicant is granted a 60-day period to submit 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.

10.2.5 Labelling Phase (Day 240 to 330)

During the labelling phase the texts for the SmPC, PIL and packaging material 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 60-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 must be published on the Swissmedic Product Information Publication System by the applicant. Export registrations do not need to be published.

10.2.6 Decision (Day 330)

Swissmedic sends the final decision to the applicant and makes it available, together with the translation of the approved SmPC, PIL and finalized evaluation reports, to the NRAs concerned via the electronic platform. In the case of a positive decision the Swiss marketing authorisation or export registration is granted.
The dispatch of the final decision marks the end of the Swissmedic process.

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10.2.7 Sample testing

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

11 National decision phase after Swissmedic approval

Based on the experience gained by the NRA in the MAGHP procedure, the authorisation procedure should be shortened at national level and the Swissmedic decision should be adopted. Further review activities should focus on country-specific requirements only. For instance, the SmPC may need to be adapted. If required, Swissmedic may provide further support.

Provided the dossier has been submitted, the NRAs decide on an authorisation within 90 calendar days after completion of the procedure at Swissmedic (if possible). If the dossier has not been submitted by the end of the Swissmedic procedure, the decision must be made within 90 calendar days after dossier receipt.

12 MAGHP Light procedure

12.1 Rationale

The MAGHP Light procedure was originally initiated as a response to the global COVID-19 pandemic and the need to accelerate the review processes and global access to life- medicines for the treatment of COVID-19. However, the geographical and medical scope of the MAGHP Light procedure is identical to the standard MAGHP procedure.

12.2 Conditions under which an MAGHP Light procedure can be carried out

The MAGHP Light procedure is applicable to all applications in the fast track and temporary authorisation procedures. No other formal criteria must be fulfilled.

Timelines
The timelines valid for the MAGHP Light procedure depend on the specific timelines set for the type of application and procedure.

Procedure
The MAGHP Light procedure builds on the established MAGHP authorisation process as described above. The applicant indicates the interest in participating in the MAGHP Light procedure by compiling the respective section in the form *New authorisation for human medicinal products HMV4* or in the form *Variations and extensions HMV4*, and specifies the countries/NRAs to be involved in the procedure. Swissmedic evaluates the MAGHP Light request and informs the applicant about the decision.

In this procedure, there are two distinct options for distributing the relevant documentation:

- Option 1: The applicant itself shares the application dossier directly with the targeted NRA. After completion of the procedure, Swissmedic discloses the evaluation reports and correspondence (LoQ, preliminary decision and final decision including the summary of product characteristics) to the involved NRA. At the request of the marketing authorisation holder, Swissmedic will establish contact with the authorities concerned via the WHO.
- Option 2: After completion of the procedure, Swissmedic provides the targeted NRA with both the marketing authorisation dossier as submitted to Swissmedic as well as the evaluation reports and correspondence (LoQ, preliminary decision and final decision including the summary of product characteristics) produced during the Swissmedic assessment procedure.

The official submission of the application to the targeted NRAs remains for both options within the applicant's competence and responsibility.

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In both cases, the applicant grants Swissmedic permission to share confidential information with the targeted NRAs by means of a secured electronic platform.

After having established contact with the target NRAs and having received the signed form *Declaration of Interests and Confidentiality Undertaking*, Swissmedic provides the participating expert with the access credentials to the secured electronic platform.
Due to the shorter timelines set by the accelerated procedures, the MAGHP Light procedure is based on one-way communication with the involved NRAs. This means that the modalities of interaction between Swissmedic and the NRAs are limited to the NRAs accessing the information such as the dossier and evaluation reports. Swissmedic does not provide any type of exchange/interaction with the NRAs during the assessment period.
The need to clarify the procedure itself and/or specific questions about the submission from the participating NRAs may be addressed by email exchange.
In contrast to the standard MAGHP procedure, the MAGHP Light procedure does not imply expectations regarding the national decision phase in the targeted countries.

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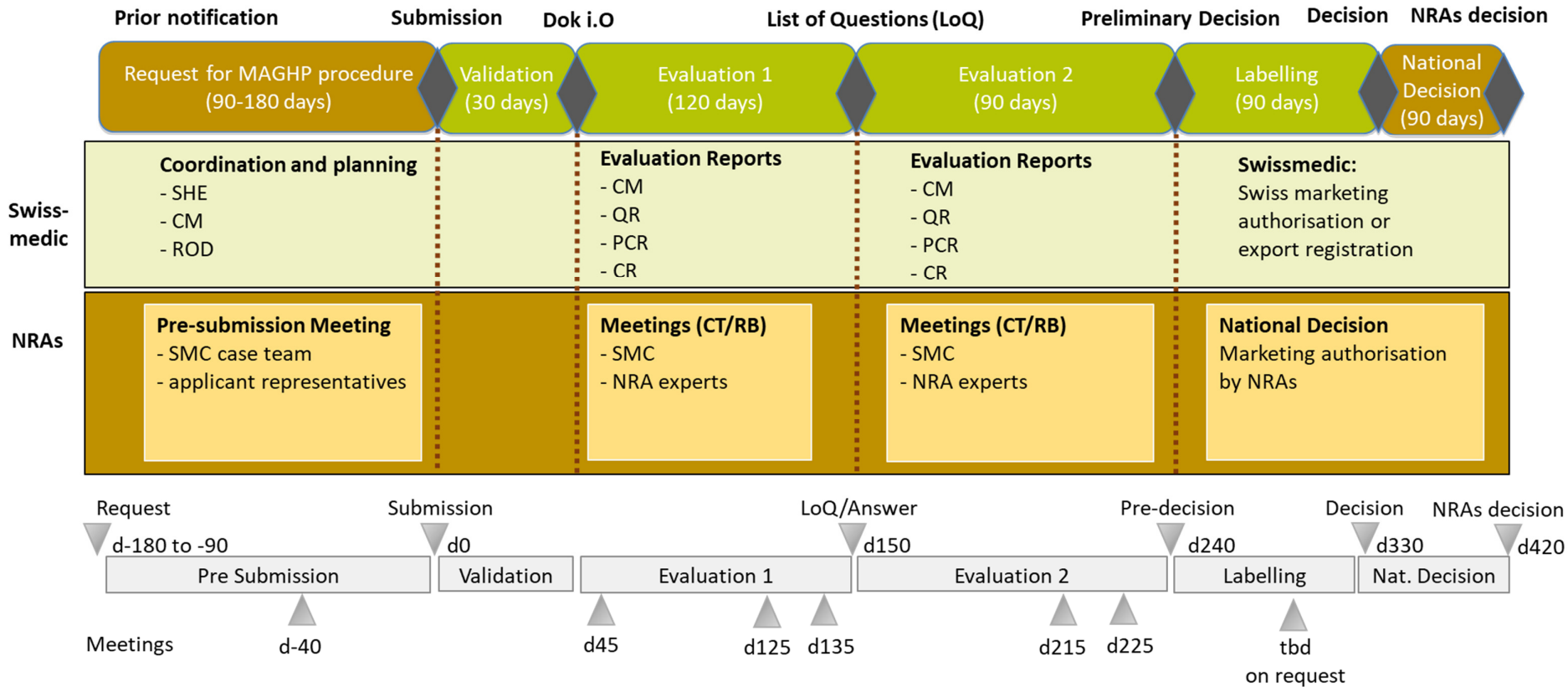
Annex 1: Procedure for Marketing Authorisation for Global Health Products (MAGHP)

The indicated timelines refer to new registrations in the standard procedure.



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Annex 2: Formal Requirements and Relevant Administrative Ordinances

Formal requirements:

- Guidance Document *Formal requirements HMV4*
- Directory *Overview of documents to be submitted HMV4*

Relevant Guidance Documents:

- Guidance Document *Time limits for authorisation applications HMV4*
- Guidance Document *Authorisation of human medicinal product with new active substance HMV4*
- Guidance Document *Authorisation of human medicinal product with known active pharmaceutical substance HMV4*
- Guidance Document *Authorisation Biosimilar HMV4*
- Guidance Document *Variations and Extensions HMV4*

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