

Guidance document
MAGHP Procedure

Identification number: ZL000_00_047

Version: 5.0

Valid from: 22.05.2025

List of contents

1	Terms, definitions, abbreviations	3
1.1	Abbreviations.....	3
2	Introduction and objective	4
2.1	Rationale for the MAGHP procedure	4
2.2	Introduction to the procedure.....	4
2.3	MAGHP Light procedure.....	5
3	Collaboration with WHO	5
4	Confidentiality undertaking and conflicts of interest	6
5	Role allocation of the parties involved	6
6	Language and communication with the applicant	6
7	Interaction between Swissmedic and the NRA(s) concerned	7
7.1	Document exchange.....	7
7.2	Meetings and further exchange	7
8	Timelines	9
9	Requests for an MAGHP procedure	9
9.1	Conditions under which an MAGHP procedure can be carried out.....	9
9.2	Required documentation for the request.....	10
9.3	Processing the request and determining the parties involved	10
9.4	Confirmation of submission date.....	11
9.5	Meeting before application submission	11
10	Processing the application for authorisation	12
10.1	Submission and documentation.....	12
10.1.1	Submitting the application to Swissmedic (Day 0).....	12
10.1.2	Validation of initial application (Day 1 to 30)	12
10.2	Evaluation.....	12
10.2.1	Assessment Phase 1 (Day 30 to 150).....	12
10.2.2	List of Questions (Day 150)	13
10.2.3	Assessment Phase 2 (Day 150 to 240).....	13
10.2.4	Preliminary Decision (Day 240)	14
10.2.5	Labelling Phase (Day 240 to 330).....	14
10.2.6	Decision (Day 330).....	14
10.2.7	Sample testing.....	15

11	National decision phase after Swissmedic approval	15
12	PACs management.....	15
13	MAGHP Light procedure	15
13.1	Rationale	15
13.2	Conditions under which an MAGHP Light procedure can be carried out.....	15
13.2.1	Timelines	15
13.2.2	Procedure.....	16
14	Annex	17
14.1	Annex 1: Procedure for Marketing Authorisation for Global Health Products (MAGHP)	17
14.2	Annex 2: Formal Requirements and Relevant Administrative Ordinances	17

1 Terms, definitions, abbreviations

1.1 Abbreviations

API	(New / Known) Active Pharmaceutical Ingredient
ATC	Anatomical Therapeutic Chemical classification
CRP	WHO Collaborative Registration Procedure
CPP	Certificate of a Pharmaceutical Product
CA	Clinical Assessment Division / Clinical Assessor
CT	Case Team
CTD	Common Technical Document
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
MA	Marketing Authorisation
MAGHP	Marketing Authorisation for Global Health Products
MoU	Memorandum of Understanding
NRA	National Regulatory Authority
NCA	Nonclinical Assessment Division / Nonclinical Assessor
PAC	Post Approval Change
PIL	Patient Information Leaflet
QA	Quality Assessment Division / Quality Assessor

RA	Regulatory Assessment Division
RB	Review Board
RA	Regulatory Assessment Division
RM	Regulatory Manager
SHE	Stakeholder Engagement
SMEC	Swissmedic Medicines Expert Committees
WHO PQT	World Health Organisation Prequalification Team

2 Introduction and objective

2.1 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 effective, safe and high-quality medicines for populations living in low- and middle-income countries. The aim is to increase the efficiency of the regulatory assessment and marketing authorisation (MA) process by focusing stakeholders on value-added activities, and to strengthen the regulatory authorities' capacity to protect their citizens' health (capacity building).

In this context, Swissmedic's Marketing Authorisation for Global Health Products (MAGHP) procedure offers a collaborative pathway for the assessment of essential medicines for populations of the global South. The MAGHP focuses on medicinal products targeting a concrete medical need that disproportionately affects the global South. The involvement of National Regulatory Authorities (NRAs) in the assessment process is expected to lead to shortened national MA procedures and earlier access.

2.2 Introduction to the procedure

The MAGHP procedure builds on the existing authorisation processes at Swissmedic. NRAs of targeted countries are actively involved in the assessment process. The MAGHP procedure is open for new marketing authorisation applications and new indications of new and known APIs (for options for variations / life-cycle see chapter 12). The process and timelines follow the regular Swissmedic authorisation procedures.

In case of an approval, the procedure results in a Swiss marketing authorisation. Therefore, criteria applicable to the assessment / benefit-risk assessment and relevant for decision-making refer to the regulatory requirements in Switzerland. 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 assessment process, are the same for both types of marketing authorisation.

The participating NRA will take their own sovereign decision after the applicant has submitted the MA application.

The applicant will submit the application initially to Swissmedic. The applicant must subsequently submit the individual dossier to each of the participating NRAs according to their respective national requirements. Apart from national specifics, the dossier (modules 2 to 5) must be essentially the same. The applicant is encouraged to submit the MA application to the NRA as early as possible in the process.

In order to guarantee an optimal efficient exchange, Swissmedic envisages to accept a maximum number of 10 participating NRAs.

The NRAs participating in a MAGHP procedure will be actively involved in Swissmedic's assessment process. The NRA will provide input and comments to the Swissmedic review as well as add 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. The assessment outcomes are discussed between Swissmedic and the participating NRA to establish consolidated Lists of Questions resp. conditions for approval.

Therefore, the expectation is that the MA authorisation procedure can be shortened for the NRAs because:

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

2.3 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 6.6 of this document.

3 Collaboration with WHO

Under the MAGHP, Swissmedic closely collaborates with the World Health Organisation (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 until the final national decision phase. If the applicants apply for WHO Prequalification (PQ) or for the WHO Collaborative Registration Procedure using Stringent Regulatory Authorities' evaluations (SRA CRP), Swissmedic will share the assessment from the MAGHP procedure with the concerned stakeholders at WHO. The MAGHP and SRA CRP can be seen as complementary. The use of SRA CRP is strongly encouraged for initial authorisation in NRAs that did not participate in the MAGHP, thus increasing access to other countries. SRA CRP also allows for an effective management of the post-approval changes for the applicant and the NRA (see chapter 12).

Products approved through the MAGHP are eligible for the WHO PQ abridged pathway. Further, WHO recognizes Swissmedic MAGHP export registration without any additional assessment for the

alternative listing procedure. For further information on the WHO PQ procedure, please consult the following website: [Welcome to Medicines Prequalification | WHO - Prequalification of Medical Products \(IVDs, Medicines, Vaccines and Immunization Devices, Vector Control\)](#). Products approved under the MAGHP export registration are also eligible for prequalification via a recently introduced [abridged prequalification procedure](#). This procedure allows prequalification (with a WHO reference number) similarly to products approved by Swissmedic for marketing in Switzerland.

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 assessment of the application and is responsible for timelines, LoQ and Decision.
WHO	WHO facilitates the first contact between Swissmedic and the target NRAs. If indicated, WHO experts (i.e. from disease programmes) are consulted to provide scientific expertise on programmatic aspects.
NRA	The NRAs focus on the assessment of the documentation, on providing input and on the peer review of Swissmedic's assessment reports (incl. LoQ). If possible, the NRAs write an assessment report reflecting on the medical need and on regulatory requirements in their country. The NRAs comment on Swissmedic's assessment reports, risk benefit evaluation, preliminary decision, SmPC and PIL and add their 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 by the applicant, the participating NRAs express their intention 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. The applicant specifies the NRAs to be involved and signals the need to include WHO. 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 Language and communication with the applicant

General communication with the applicant (email exchange, calls and meetings) regarding the MAGHP procedure is held in English. 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, French or Italian). Swissmedic reviews the SmPC, PIL and the packaging in the company's correspondence language (German, French or Italian). In addition, Swissmedic provides an English version of the SmPC revisions to the NRAs and WHO.

Communication until the 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. Upon request, Swissmedic facilitates the contact between the applicant and the NRAs concerned.

7 Interaction between Swissmedic and the NRA(s) concerned

7.1 Document exchange

The involved NRAs and WHO will be able to access the following information on an electronic platform

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

Swissmedic manages 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.

7.2 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 call**
Swissmedic sets up a kick-off call with the NRAs and WHO representatives at the beginning of the collaborative procedure. The kick-off call serves to provide general information on the MAGPH procedure, a short introduction to and overview of the application and application timelines.
 - **Case team meetings**
Case team meetings are set up to discuss and align on the outcome of the assessment at defined milestones (at least one in assessment phase 1 and if necessary, at least one in the subsequent assessment phases). After each meeting, Swissmedic updates the ARs based on the discussion and circulates to all participants.
 - **HMEC meetings**
When appropriate, the application is presented and discussed at a HMEC meeting before finalisation of the preliminary decision. Should it take place, representatives from NRA and WHO are invited to attend this meeting.

Participation is organised through web-based conference, i.e. MS Teams).

- b) Further exchange
- Questions arising from the review of the documentation may be discussed with the individual reviewers at any time of the procedure via email.
 - Further clarifications and questions are addressed by email exchange

The prerequisite language for all exchanges between Swissmedic and the NRAs is English.

Therefore, it is required that the appointed assessors have a reasonably proficient level of English to be able to communicate and actively participate in the procedure.

It is not allowed for participants to record a meeting without prior permission from Swissmedic.

8 Timelines

For the MAGH procedure a period of three months prior to submission is needed in order to plan and coordinate the parties involved appropriately. Swissmedic and the applicant commit to a timeline and a deadline for the submission of the application (indicating +/- 2 calendar weeks). The applicant must confirm the definitive submission date for the MAGHP application at the latest 6 weeks before this date. Swissmedic will establish an evaluation plan and communicate it to the applicant and all participating parties.

The timelines follow the [Guidance Document Time limits for authorisation applications](#).

For applications in the Swissmedic fast-track and temporary authorisation procedure only the MAGHP Light procedure is applicable (see chapter 13).

9 Requests for an MAGHP procedure

9.1 Conditions under which an MAGHP procedure can be carried out

The following conditions must be fulfilled in order for an MA application to be accepted as 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 focus is on those diseases that disproportionately affect the region in question, but there is no restriction to any indications
- The clinical and nonclinical trials must be completed at the time of application submission.
- For all applications, including those for export only, the marketing authorisation holder must be a holder of an authorisation to manufacture, import or conduct wholesale trade and have a registered address, registered office or a branch office in Switzerland. However, an applicant does not necessarily need to be based in Switzerland, but can work through a Swiss representative fulfilling the requirements for a MA Holder in accordance with the requirements of art. 10 TPA, e.g. a regulatory office.

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.

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

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.

9.2 Required documentation for the request

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

- Name of active pharmaceutical ingredient (API) / International Non-proprietary Name (INN)
- Name of the medicinal product
- Anatomical Therapeutic Chemical classification (ATC) / Therapeutic Index (IT group)
- Pharmaceutical form and, for injectable solutions, information about the primary container or – if relevant – the administration system (pre-filled syringe, autoinjector)
- Indication(s) and dosage recommendation: SmPC in English
- List of nonclinical 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 meeting before application submission or justification as to why such a meeting is not necessary
- List of preferred 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

9.3 Processing the request and determining the parties involved

Swissmedic confirms receipt of the request for an MAGHP procedure in writing. Swissmedic Stakeholder Engagement (SHE) Division initially informs WHO and invites specific WHO disease programmes (if required by the applicant) to participate in the procedure. WHO supports Swissmedic in establishing contact with the NRAs responsible for the targeted markets (countries) and facilitates the nomination of experts.

Each participating NRA nominates committed experts by indicating their function within the agency, professional background and email address. Where possible, NRAs are asked to designate an expert for each assessment area. One representative shall act as single point 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 4) they are granted access to the electronic platform for the exchange of documentation.

The applicant selects the NRAs to be involved. However, WHO may suggest additional target countries in consultation with the applicant, who takes the final decision.

Within four weeks, Swissmedic decides whether it will be possible to conduct the procedure requested under the conditions stated and taking into account the planned submission date (see 2). The outcome is communicated to the applicant in writing and a draft evaluation plan is provided. In addition, Swissmedic confirms the date of the meeting before application submission (see 9.5).

If it is not possible to start an MAGHP procedure on the submission date proposed by the applicant, Swissmedic 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.

9.4 Confirmation of submission date

If the applicant is informed that an MAGHP procedure is possible within the proposed timeframe, the applicant shall confirm the date on which the application will be submitted to Swissmedic at the latest three months before the planned submission date. The applicant also confirms the date of the meeting before application submission (if applicable).

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.

9.5 Meeting before application submission

The primary aim of a meeting before application 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 involved
- Date of submission of the eCTD test sequence (if an eCTD application is to be submitted)
- Confirming the 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 meeting: e.g. new manufacturing processes, specific statistical analysis and other critical points.

If requested and possible, WHO may already be involved at this stage of the procedure and raise questions or concerns at the meeting. If Swissmedic and the applicant mutually agree that the meeting before application submission is not necessary, it may be omitted.

For further information regarding the meeting before application submission, kindly consult the respective [guidance document *Meetings for applicants held with the Authorisation sector*](#) (chapters 5.1.3 and 6.1.4).

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, nonclinical 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](#) and [Directory Overview of documents to be submitted HMV4](#). The documentation must be in English. 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).

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. If possible, the validation phase should be concluded within 30 days after submission of the application and any formal deficiencies should be communicated and remedied within the 30 days. If deficiencies cannot be remedied within 30 days, the applicant may be granted a 60-day period maximum to remedy the deficiencies.

If the formal requirements are fulfilled, the application is accepted and the applicant is informed accordingly.

If the deficiencies cannot be remedied by the applicant within the given timeframe, Swissmedic will reject the application.

The list of confirmed participating NRAs will be communicated to the applicant in writing at conclusion of the validation period.

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 Regulatory Assessment Division (RA), the regulatory manager (RM) uploads the complete documentation to the MAGHP SharePoint (electronic platform).

10.2 Evaluation

The timelines below apply to new MA applications.

10.2.1 Assessment Phase 1 (Day 30 to 150)

In assessment phase 1 the documentation is reviewed by the regulatory manager and quality, nonclinical, clinical and risk management assessors, resulting in five assessment reports and an LoQ. The assessors follow their respective Standard Operating Procedures.

Within the first two weeks (day 45) of assessment phase 1, SHE together with the RM organises a kick-off meeting with the NRA's and WHO representatives to procedure and timelines and provide an

overview of the submitted documentation. The NRA's and WHO experts are invited to review the documentation, write their own assessment report and form their opinion about the application.

Swissmedic shares the preliminary assessment reports as well as preliminary comments and corrections to the SmPC with the participating NRAs and WHO within 9 weeks after the start of assessment phase 1 (at the latest by day 125). Subsequently, the NRA's experts conduct a peer review of the Swissmedic assessment reports (incl. the drafted LoQ) and the SmPC, consulting the modules (as needed) and add their comments and questions. Inputs provided by the NRAs should include, if necessary, 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 first case team meeting between the Swissmedic assessors and the NRA takes place before the finalisation of the LoQ around day 135. This meeting serves to discuss the NRA's feedback and to consolidate the LoQ. All relevant concerns of the NRAs involved are integrated in the LoQ.

The meetings are organised via MS Teams (see 7.2). 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 LoQ includes preliminary comments and corrections for the SmPC and packaging material. The applicant is granted a 90-day period to respond to the LoQ. The applicant may ask for an extension of this period.

Within two weeks after receipt of the LoQ, the applicant shall inform Swissmedic if the planned date for submissions of the responses to the LoQ differs from the agreed evaluation plan.

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. The RM 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. Any country specific questions shall be reviewed by the concerned NRA.

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).

In assessment phase 2 the assessors 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). Subsequently, the NRA's experts conduct a peer review of the Swissmedic assessment reports and SmPC and 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. If it is deemed appropriate this meeting can be omitted in favour of an email exchange. All relevant concerns of the NRAs involved are added 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.

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)

The responses to the preliminary decision including the texts for the SmPC, PIL and packaging material will be reviewed to determine if all conditions for an approval of the application have been fulfilled.

If any open point remains, an additional round of questions may be required. In this case, the applicant is granted another 60-day period for responding to any open points and/or the reworking of the labelling elements, followed by a 45-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 including approved SmPC, PIL, packaging and public assessment reports. Swissmedic makes available the decision, together with the translation of the approved SmPC 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.

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 by relying on the collaborative assessment and the relative Swissmedic decision. 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 by the applicant, the participating NRAs express their intention 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 shall be made within 90 calendar days after dossier receipt.

12 PACs management

To facilitate and streamline the process of managing Post Approval Changes (PACs), Swissmedic and WHO are aligned in proposing the use of the SRA CRP procedure. Submission under SRA CRP allows NRAs to efficiently manage post-approval changes. If an applicant is interested in the use of SRA CRP, they should consider notify WHO and Swissmedic at the time of initial request for MAGHP in order to ensure a smooth planning and combination of the procedures.

13 MAGHP Light procedure

13.1 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.

13.2 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.

13.2.1 Timelines

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

13.2.2 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](#) or in the form [Variations and extensions](#), 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.

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.

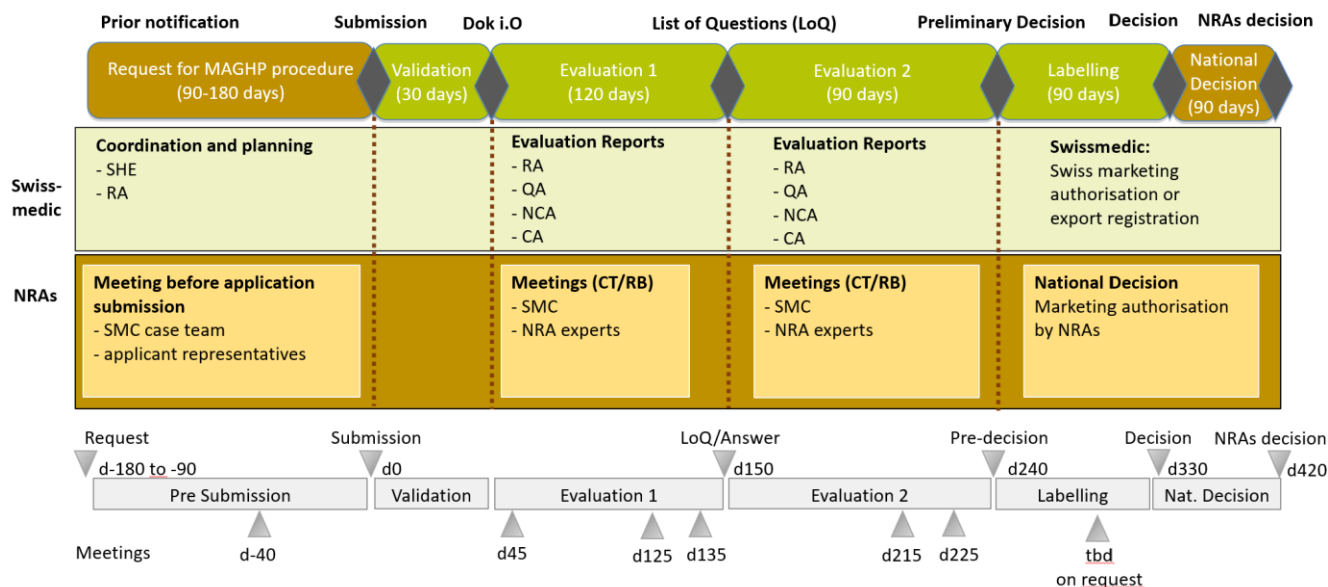
The need to clarify the procedure itself and/or specific questions about the submission from the participating NRAs may be addressed by email exchange.

In contrast to the standard MAGHP procedure, the MAGHP Light procedure does not imply expectations regarding the national decision phase in the targeted countries.

14 Annex

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

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



14.2 Annex 2: Formal Requirements and Relevant Administrative Ordinances

Formal requirements:

- [Guidance Document Formal requirements](#)
- [Directory Overview of documents to be submitted](#)

Relevant Guidance Documents:

- [Guidance Document Time limits for authorisation applications](#)
- [Guidance Document Authorisation of human medicinal product with new active substance](#)
- [Guidance Document Authorisation of human medicinal product with known active pharmaceutical substance](#)
- [Guidance Document Authorisation Biosimilar](#)
- [Guidance Document Variations and Extensions](#)

Change history

Version	Change	sig
5.0	General revision based on lessons learned and exchanges with stakeholders Elimination Suffix HMV4	stb, wec, pal, cho, vy
4.2	New layout, no content adjustments to the previous version.	dei
4.1	Formal adjustments to the header and footer No content adjustments to the previous version.	dei
4.0	Addition chapter 6.6: MAGHP Light Procedure	apl, zeg, ze
3.0	Update based on various clarifications by external stakeholders	apl, zeg, ze
2.0	Complete revision based on the lessons learned from the first projects. Previous version ZL000_00_011 was archived in December 2019.	apl, zeg, ze
1.0	New document, implementation of the MAGHP procedure	net, zl