|  |
| --- |
| **Form** |
| **New authorisation of human medicinal products** |
| **Identification number:** | ZL100\_00\_001 |
| **Version:** | 8.3 |
| **Valid from:** | 15.04.2024 |

# Basic information

|  |
| --- |
| **External reference (Company Reference):** …… |
| **Name of medicinal product:** …… |
| **Active substance(s):** ……*(Published on receipt of the application)* |
| **Dosage form:** …… |
| **Medical application:** ……*(Published on receipt of the application)* |
| **Basic company dossier no.: ……***(mandatory for teas in the notification procedure and for cough and throat sweets and pastilles in the notification procedure)* |
| **Pharmaco-therapeutic group** | **ATC Code[[1]](#footnote-1):** …… | **IT No.:** …… |
| **Dosage strength(s)** | **Primary container***(e.g. blister pack)* | **Secondary container***(All pack sizes including hospital packs)* |
| …… | …… | …… |
| …… | …… | …… |
| …… | …… | …… |
| …… | …… | …… |
|  |
| **Product category**Select an option.For antivenins please use only the form *New authorisation variation antivenin*  |
| **Dispensing category**Select an option. |

**To be completed additionally for known active substances and biosimilars**

|  |
| --- |
| **Information on the Swiss reference medicinal product**  |
| Name of the Swiss reference medicinal product: | …… |
| Swissmedic authorisation no.: | …… |
|  | yes | no |  |
| Used in bioequivalence study (KAS) or comparability study (biosimilar) | [ ]  | [ ]  |  |

|  |
| --- |
| **Information on the foreign comparator product**  |
| Name of the foreign comparator product: | …… |
| Name and address of the authorisation holder abroad: | …… |
| Country of authorisation: | …… |
| Authorisation no.:  | …… |
| LOT: | …… |
| EXP: | …… |
| Reference country / Reference source / Address:(wholesale / pharmacy) | …… |

|  |
| --- |
| ***KAS without innovation***Is inclusion as a generic in the FOPH's list of pharmaceutical specialities being sought? yes [ ]  no [ ]  n/a [ ] Remark: …… |

# Addresses

## Marketing authorisation holder

|  |  |
| --- | --- |
| Company name: | …… |
| Addition: | …… |
| Street / no.: | …… |
| Postcode, town/city: | …… |
| Canton: | ……  |
| Telephone: | …… |
| E-mail | …… |

## Address for correspondence (if not the same as 2.1)

|  |  |
| --- | --- |
| Company name: | …… |
| Addition: | …… |
| Street / no.: | …… |
| P.O. Box: | …… |
| Postcode, town/city: | …… |
| Telephone: | …… |
| E-mail | …… |

## Legal representative (if not the same as 2.1)

|  |  |
| --- | --- |
| Name: | …… |
| Addition: | …… |
| Street / no.: | …… |
| P.O. Box: | …… |
| Postcode, town/city: | …… |
| Telephone: | …… |
| **Does Swissmedic already possess the power of attorney?**[ ]  yes [ ]  no, the power of attorney is enclosed with this application (incl. original signature) |

# Application type

## Medicinal product with indication

|  |  |
| --- | --- |
| **Application type** | **Code***(SMC internal)* |
| [ ]  | New active substance |  |
| [ ]  | Known active substance with innovation (incl. new combination according to Art. 6 TPLRO) |  |
| [ ]  | Known active substance without innovation |  |
| [ ]  | Known active substance herbal medicinal products (incl. new combination according to Art. 6 TPLRO) |  |
| [ ]  | Complementary medicine with indication |  |
| [ ]  | Known active substance for which simplified authorisation is not possible according to Art. 12 para. 5 TPLO |  |
| [ ]  | Biosimilar |  |
| [ ] [ ]  | Teas in the notification procedure *(Art. 12 KPTPO)🡪* A precondition for the application is an approved basic company dossier according to Art. 37 KPTPO, see for*m New authorisation variation in notification procedure KPTPO*  |  |
| [ ]  | Cough and throat sweets and pastilles in the notification procedure *(Art. 13 KPTPO)**🡪* A precondition for the application is an approved basic company dossier according to Art. 37 KPTPO, see for*m New application for variation in notification procedure KPTPO*  |  |
| [ ]  | Co-marketing *(Art. 32 ff. TPLO)🡪* Submit only the form *New authorisation co-marketing of a medicinal product*. |  |
| [ ]  | Parallel import *(Art. 14 para. 2 and 3 TPA)🡪* Submit only the form *Import of a medicinal product Art. 14 para. 2 and 3 TPA (parallel import).* |  |
| [ ]  | Allergen product *(Art. 5 AllergO)* |  |
| [ ]  | Related product *(Art. 6 AllergO)* |  |

## Compleme**n**tary medicinal product without indication

|  |  |  |
| --- | --- | --- |
| [ ]  | Complementary medicinal product without indication according to Art. 25 para. 2 and Art. 30 KPTPO |  |
| [ ]  | Complementary medicinal product without indication with reduced dossier according to Art. 25 para. 1 KPTPO |  |
| [ ]  | Complementary medicinal product without indication in the notification procedure and submission of the corresponding documentation (e.g. basic company dossier, master dossier, sample quality documentation)🡪 Submit only the form *New authorisation variation in notification procedure KPTPO*. |  |

# Special procedures / Status

|  |  |  |
| --- | --- | --- |
| [ ]  | Use of fast-track authorisation procedure1 | Official decision on: …… |
| [ ]  | Use of procedure with prior notification1 | Notified on: …… |
| [ ]  | Use of temporary authorisation1 | Official decision on: …… |
| [ ]  | Application for use of procedure according to Art. 13 TPA[ ] The form *Information for application Art.13 TPA* is enclosed (compulsory). |  |
| [ ]  | Herbal medicinal product with traditional use |  |
| [ ]  | Herbal medicinal product with Well Established Use |  |
| [ ]  | Application for use of procedure according to Art. 14 para. 1 letter abis TPAEU/EFTA country with authorisation for at least 10 years for the active substance: …… EU/EFTA country from which medicinal product information is taken over: …… |
| [ ]  | Application for use of procedure according to Art. 14 para. 1 letter ater TPACountries with at least 30 years' experience of use in medical applications: ……EU/EFTA countries with at least 15 years' experience of med. use: …… |
| [ ]  | Application for use of procedure according to Art. 14 para. 1 letter aquater TPASwiss canton on which authorisation application is based: …… |
| [ ]  | Orphan Drug Status | Granted on: …… |
| *1Prior approval / granting by Swissmedic required.* |

# Additional forms to be submitted

The list is not exhaustive. Please also consult the *directory Overview of documents to be submitted*.

|  |
| --- |
| [ ]  The form *Manufacturer information* is enclosed (must be submitted)*A "Declaration by the Responsible Person " form should be submitted for each proposed foreign manufacturer*🡪 Guidance document *GMP compliance by foreign manufacturers* **Exception:** A *Manufacturer information* form is not needed for teas in the notification procedure (Art. 12 KPTPO) or for cough and throat sweets and pastilles in the notification procedure (Art. 13 KPTPO). |

|  |
| --- |
| [ ]  The form *Full declaration* is enclosed (must be submitted) |

|  |
| --- |
| Is a paediatric investigation plan required for this application according to the guidance document *Paediatric investigation plan*?[ ]  yes, the *Paediatric investigation plan* form is enclosed[ ]  no |

|  |
| --- |
| * Is any TSE risk material used for the manufacture of the medicinal product?
* Are other materials of animal origin used for the manufacture of the medicinal product?
* Is human material used for the manufacture of the medicinal product?

[ ]  yes, TSE risk material and/or animal and/or human material is used; the form *Substances of animal and human origin* is enclosed[ ]  no |

|  |
| --- |
| Does the medicinal product contain genetically-modified organisms (GMO) per se or substances that may have been derived from GMO?[ ]  yes; GMO per se 🡪 the declaration is based on Art. 27 para. 2 TPO[ ]  yes, substances that may have been derived from GMO; the form *Confirmation regarding substances from GMO* is enclosed.[ ]  no |

|  |
| --- |
| Does a decision of a foreign authority exist for this application, or has the application been submitted to a foreign authority?[ ]  yes, the *Status of authorisation applications abroad* form is enclosed[ ]  no[ ]  According to the *Overview of documents to be submitted*, the form need not be submitted for this application |

|  |
| --- |
| Is the medicinal product a radiopharmaceutical?[ ]  yes, the *Declaration of radiopharmaceuticals* form is enclosed[ ]  no |

|  |
| --- |
| Is a Drug Master File used?[ ]  yes, the form *DMF for first authorisations* is enclosed[ ]  no |

|  |
| --- |
| Are clinical trials (including bioequivalence trials) enclosed with the application?[ ]  yes, the completed EMA "GCP inspections template" is enclosed[ ]  no |
|  |
| Is a QR code being added to the medicinal product information and/or the packaging? [ ]  yes, the *Mobile Technologies* form is enclosed.[ ]  no |

# Further information

## Placing on the market

|  |  |
| --- | --- |
| [ ]  | Intended for placing on the Swiss market |
| [ ]  | Intended for export only |

## Company meetings

|  |
| --- |
| Was a company meeting conducted for this application? |
| Presubmission meeting | [ ]  no | yes, date: ……Application ID: …… |
| Scientific Advice Meeting | [ ]  no | yes, date: ……Application ID: …… |

## Advanced document protection

|  |  |  |  |
| --- | --- | --- | --- |
| Do you wish to request 15-year document protection for important medicinal products for rare diseases (Art. 11b para. 4 TPA) as part of the new authorisation? | [ ]  yes | [ ]  no | [ ]  n.a. |
| Do you wish to request 10-year document protection for purely paediatric use (Art. 11b para. 3 TPA and Art. 30 para. 4 TPO) as part of the new authorisation? | [ ]  yes | [ ]  no | [ ]  n.a. |

## Real world evidence

|  |  |  |
| --- | --- | --- |
| Does the application include real world evidence (RWE) in support of the proof of safety and efficacy? | [ ]  yes | [ ]  no |

If so:

Study design (please check all appropriate boxes):

|  |  |
| --- | --- |
| [ ]  | Randomised controlled study with pragmatic elements  |
| [ ]  | Study designs that use real world data (RWD) to supplement the control arm |
| [ ]  | Single-arm study that uses RWD in an external control arm |
| [ ]  | Non-interventional (observational) study |
| [ ]  | Other study design (please provide details): …… |

Other comments on the study design: ……

RWD sources (please check all appropriate boxes):

|  |  |
| --- | --- |
| [ ]  | Data from electronic patient records |
| [ ]  | Data from medical service logging |
| [ ]  | Data from patient registers (e.g. disease and product registers) |
| [ ]  | Data from digital healthcare technologies in non-research environments (e.g. wearables) |
| [ ]  | Other data sources (e.g. questionnaires) which could provide information on state of health (please provide details): …… |

Other comments on the RWD sources: ……

## Nanoparticles

|  |  |  |
| --- | --- | --- |
| Does the medicinal product contain synthetic nanoparticles1? | [ ]  yes | [ ]  no |
| If so, which component(s) of the medicinal product is/are involved? |
| Active substance(s): | …… | see Module(s): | …… |
| Excipient(s): | …… | see Module(s): | …… |
| Others: | …… | see Module(s): | …… |

*1 The particles have at least one dimension on the nanoscale (1-1000nm) plus a function and/or mode of action based on nanotechnology characteristics.*

## Blood or blood components

|  |  |  |
| --- | --- | --- |
| Are blood or blood components used for the manufacture of the medicinal product? | [ ]  yes | [ ]  no |

## Narcotics

|  |  |  |
| --- | --- | --- |
| Does the medicinal product contain a narcotic substance? | [ ]  yes | [ ]  no |
| 🡪 If yes, the narcotic substance is classified as list | Select an option. |

## Combination products

|  |  |  |
| --- | --- | --- |
| Is the product in question a combination product (medicinal product with medical device component)? | [ ]  yes*🡪 Question a) to c)* | [ ]  no |
| 1. Is it an **integral** combination product and is the medical device component an integral part of the combination (physically inseparable, *integral*)? [ ]  yes [ ]  no
 |
| 1. Is it an **integral** combination product with the medical device component enclosed in the packaging (use-specific non-separability, *co-packaged*)? [ ]  yes [ ]  no
 |
| 1. Is it a **non-integral** combination product with the medical device component **not** enclosed in the packaging, but referred to for combined use (*referenced*)? [ ]  yes [ ]  no
 |

# Confirmations and consents

## Completeness of scientific documentation and compliance with formal requirements

|  |
| --- |
| The applicant confirms having submitted all available data that are relevant for assessing the quality, safety and efficacy of the medicinal product and that the application documentation conforms to the Guidance document *Formal Requirements* and the *Overview of documents* to be submitted. [ ]  yes |

## eDok confirmation of identity (paper-based applications with eDok copy)

|  |
| --- |
| The applicant confirms that the electronic copy and the paper documentation are complete and identical. The applicant hereby consents to the review being conducted by Swissmedic exclusively on the basis of the electronic documents. [ ]  yes [ ]  n.a. |

## Confirmation of identity for the bioavailability study

|  |
| --- |
| The applicant confirms that the test medicinal product used in the bioavailability study is identical to the medicinal product notified to Swissmedic.[ ]  yes *(No additional documents need to be submitted).*[ ]  no, a description and an evaluation of the differences between the test medicinal product and the medicinal product submitted for authorisation are attached *(see under Module 1 Additional information)* and mentioned in the cover letter*.*[ ]  n.a. |

## Confirmation of procedure according to Art. 14 para. 1 let. abis TPA

|  |
| --- |
| The applicant confirms that it is able, throughout the period in which its medicinal product is authorised, to spontaneously and promptly present all internationally recorded safety signals on the foreign reference medicinal product (Art. 14a para. 2 para. 1 TPA). [ ]  yes [ ]  n.a. |

## Conformity of the Information for healthcare professionals and Patient information with reference medicinal product for KAS without innovation and biosimilar

|  |
| --- |
| The applicant confirms that the medicinal product information conforms to the currently published text of the Information for healthcare professionals and Patient information for the reference medicinal product (name of reference medicinal product) dated (month/year), apart from any deviations permitted by TPLRO. [ ]  yes [ ]  n.a. |

## Packaging material / laser colour prints

|  |
| --- |
| The applicant confirms that the enclosed laser colour prints for the above-mentioned product are completely identical to the original print of the packaging materials in terms of both text and graphic design. [ ]  yes [ ]  n.a. |

## Sharing information with partner authorities of the Consortium

|  |
| --- |
| The applicant permits Swissmedic and, where necessary, the Federal Expert Commission for Radiopharmaceuticals (ECRP) to share the assessment reports that it draws up on this medicinal product within the framework of collaboration with partner authorities of the International Regulators Consortium (Therapeutic Goods Administration of Australia, Health Products and Food Branch of Canada and Health Sciences Authority of Singapore and Medicines and Healthcare Products Regulatory Authority of the UK), based on existing agreements ([https://www.swissmedic.ch/swissmedic/information-exchange](https://www.swissmedic.ch/swissmedic/en/home/about-us/international-collaboration/bilateral-collaboration-with-partner-authorities/agreements-on-information-exchange.html)) for the purpose of sharing information and as support for forming opinions. Swissmedic is thus authorised to provide its assessment reports to partner authorities on request1. The decision regarding an authorisation is made independently of any information sharing with Swissmedic. [ ]  yes [ ]  no1 *These assessment reports may contain confidential data, such as personal data, business secrets and both positive and negative evaluations with regard to the assessment of an authorisation.* |

## Exchange of information with partner authorities, international organisations and Swiss federal offices for medicinal products with COVID-19 indications

|  |
| --- |
| In the case of new authorisations of medicinal products with COVID-19 indications, the applicant consents to Swissmedic exchanging information on the application documentation and assessment results, in compliance with the usual confidentiality rules, in the context of its cooperation with Swiss federal offices (e.g. FOPH), with international partner authorities (e.g. EMA and FDA) and with international organisations (e.g. WHO). [ ]  yes [ ]  no [ ]  n.a.The applicant acknowledges that, under Art. 24e of Ordinance 3 on Measures to Combat the Coronavirus (COVID-19 Ordinance 3; SR 818.101.24), Swissmedic is authorised to notify such information to the federal agencies named in Art. 12 para. 1 COVID-19 Ordinance 3. [ ]  yes [ ]  n.a. |

## Exchanging information within Project Orbis

|  |
| --- |
| The applicant consents to Swissmedic and, where necessary, the Federal Expert Commission for Radiopharmaceuticals (ECRP) exchanging information on application documentation and assessment results with its partner authorities the *U.S. Food and Drug Administration* (U.S. FDA), the *Therapeutic Goods Administration of Australia* (TGA), the *Health Products and Food Branch of Canada* (Health Canada), the *Health Sciences Authority of Singapore* (HSA), the UK *Medicines and Healthcare Products Regulatory Agency* (MHRA), the Brazilian *Agência Nacional de Vigilância Sanitária* (ANVISA) and the Israeli *Ministry of Health – Pharmaceutical Division* (MOH) in order to evaluate new authorisation applications that are assessed within Project Orbis (see guidance document *Project Orbis*). [ ]  yes [ ]  No [ ]  n.a. |

## Disclosure of documentation as part of the MAGHP Light procedure

|  |
| --- |
| The applicant wishes to share the application documentation with the following authorities1 as part of the MAGHP Light procedure:……Option 1: The applicant itself provides the authorisation dossier to the specified authorities directly. Swissmedic will disclose the assessment reports and correspondence (including information for healthcare professionals)2 after the procedure has been completed. At the authorisation holder's request, Swissmedic will establish contact with the authorities in question. [ ]  yes [ ]  no [ ]  n.a.Option 2: Swissmedic will provide both the application dossier submitted and the assessment reports and correspondence (including information for healthcare professionals)2 to the specified authorities after the procedure has been completed. [ ]  yes [ ]  no [ ]  n.a.For information on the conditions and the process, please see the [*MAGHP Procedure*](https://www.swissmedic.ch/dam/swissmedic/de/dokumente/stab/networking/maghp_procedure.pdf.download.pdf/maghp_procedure.pdf) guidance document.*1 The focus is on countries in sub-Saharan Africa.**2 The Swissmedic documents may contain confidential data such as personal data, business secrets and both positive and negative evaluations with regard to the assessment of an authorisation. Note that other requirements may apply to the handling of confidential data in other countries than in Switzerland.**Internal: [yes] report to Stakeholder Engagement* |

## Evidence of notification of the use of a genetic resource or related traditional knowledge in accordance with the Nagoya Ordinance

|  |
| --- |
| According to Art. 3 para. 2 TPO, a new application for authorisation of a medicinal product whose development is based on the utilisation of genetic resources or related traditional knowledge must include the registration number pursuant to Art. 4 para. 3 or 8 para. 5 of the Nagoya Ordinance (NagO, SR 451.61). The registration number serves as evidence that the obligation to notify pursuant to Articles 4, 5 or 8 of the NagO is satisfied, and is a prerequisite for authorisation according to Art. 9 para. 2 TPO. The obligation to notify according to Art. 4 NagO must be complied with if access to the genetic resource was gained after 12 October 2014 (see Art. 25*d* of the Federal Act on the Protection of Nature and Cultural Heritage (NCHA]; SR 451). If the use of traditional knowledge relating to genetic resources pursuant to Article 23*p* NCHA is involved, the obligation to notify according to Art. 4 NagO is similarly applicable. If the use of a genetic resource from Switzerland pursuant to Art. 8 NagO is involved, evidence that the obligation to notify has been met is to be provided once Art. 8 NagO has taken effect from 1 January 2017. |
| Is the new application for authorisation subject to the obligation to notify pursuant to Art. 4, 5 or 8 of the NagO? | [ ]  yes | [ ]  no | [ ]  n.a. |
| If yes, the registration number issued by the FOEN as evidence that the obligation to notify has been met is as follows: | …… |

## Dispatch of Assessment Report for Applicants (ARA)

|  |  |  |
| --- | --- | --- |
| Will a request to view the Assessment Report for Applicants when the decision is opened be submitted simultaneously with this application?No Assessment Reports for Applicants are issued for medicinal products authorised in the notification procedure. | [ ]  yes | [ ]  no |

## Letter elements / texts in English

|  |  |  |
| --- | --- | --- |
| The applicant agrees that some parts of Swissmedic’s correspondence (e.g. in the List of Questions) may be written in English. If the response is “no”, all texts will be sent in the correspondence language. | [ ]  yes | [ ]  no |

## Sharing information relating to risk assessments for nitrosamine impurities

|  |
| --- |
| The applicant consents to Swissmedic sharing evaluations drawn up by Swissmedic on nitrosamine impurities for a medicinal product with international partner authorities for the purpose of sharing information and as support for forming opinions as part of its collaboration in the Nitrosamine Strategic Group (NISG) and Nitrosamine Technical Working Group (NITWG). This exchange is based on the existing agreements ([https://www.swissmedic.ch/swissmedic/information-exchange](https://www.swissmedic.ch/swissmedic/en/home/about-us/international-collaboration/bilateral-collaboration-with-partner-authorities/agreements-on-information-exchange.html)). Swissmedic is thus authorised to provide its evaluations1. The decision regarding an authorisation is made independently of any information sharing with Swissmedic.Authorisation Holder's consent [ ]  yes [ ]  noDMF Holder’s consent (cf. FO *DMF*, part B)1 *These evaluations may contain confidential data, such as personal data, business secrets and both positive and negative evaluations with regard to the assessment of an authorisation.* |

# Signature

|  |
| --- |
| **All the entries made in this form and in additional forms enclosed with the application are certified to be complete and accurate:***(company stamp of the applicant, optional)*……………… |
| *Authorised signatory*  | *Other responsibilities (Optional signature)* |
| Place, date: ……Signature: …………………………….. | Place, date: ……Signature: …………………………….. |
| Last name: | …… | Last name: | …… |
| First name: | …… | First name: | …… |
| Position: | …… | Position: | …… |
| Telephone: | …… |  |
| E-mail: | …… |
|  |
| **The application must be sent to** | **For enquiries contact** |
| SwissmedicSwiss Agency for Therapeutic ProductsOperational Support ServicesHallerstrasse 73012 Bern | Telephone +41 58 462 02 11Fax +41 58 462 02 12E-mail Anfragen@swissmedic.ch |

Change history

| **Version** | **Change** | **sig** |
| --- | --- | --- |
| 8.3 | Sections 7, 7.3 and 7.8: Corrections | stb |
| 8.2 | Revision of section 3.1 Parallel import due to amendment of Art. 14 para. 3 TPA | ski |
| 8.1 | New layout, no content adjustments to the previous version. | dei |
| 8.0 | New section 6.4 “Real world evidence”: Details on RWE must now be entered in application submissions | dts |
| 7.3 | Section 5: Possibility of adding a QR code to medicinal product information and/or packaging | ski, sab, zsa |
| 7.2 | Section 4: Clarification of wording, previously: “Approved on:”, now: “Official decision on” or “Notified on: …”Section 6.7: Combination products: Clarification of concepts.Previous term “evaluation report” replaced with “assessment report”.Section 7.7: Deletion of the sentence *Swissmedic informs the applicant in writing if evaluation reports are shared.* | stb, spb, wph, nma, na |
| 7.1 | Clarification in section 7.14 (DMF Holder issues consent, cf. FO *DMF HMV4*, part B) | stb |
| 7.0 | Inclusion of a new section 7.14 “Sharing information relating to risk assessments for nitrosamine impurities” for the purpose of obtaining the applicant's consent.“n.a.” deleted in section 7.7. | stb, zsa, ber |
| 6.0 | Inclusion of allergen product and related product in accordance with Art. 5 and 6 AllergO as possible application types under section 3.1. | stb |
| 5.0 | Mention of the Federal Expert Commission for Radiopharmaceuticals (ECRP) in Access Consortium and Orbis applications (sections 7.7 and 7.9) and naming of the Israeli Ministry of Health (MOH) – Pharmaceutical Division (section 7.9) for the purpose of obtaining consent to sharing information. | ski, stb |
| 4.1 | Clarification in section 6.7 Combination products and 7.9 Exchanging information within Project Orbis | stb, ski |
| 4.0 | Section 4: Clarification of the text in the application for use of procedure according to Art. 14 para. 1 abis TPAAddition in section 6.7 (Combination products) with new requirement for a Notified Body Opinion for integral combination products in certain classes that do not have a CE mark.Section 7.8: Clarifications in text on exchange of information for medicinal products with COVID-19 indications. | mag, stb |
| 3.0 | Section 1: New footnote on the ATC code New section 7.9: Exchanging information within Project OrbisNew section 7.13: Declaration of consent that parts of the correspondence may be in English. | dts, stb |
| 2.2 | Inclusion of MHRA as a new Access Consortium Partner (section 6.8, page 6) | stb |
| 2.1 | New section 7.8 inserted: Declaration of consent re. COVID-19 MP | dts |
| 2.0 | Addition to section 7.8: Disclosure of documentation as part of the MAGHP Light procedure | ze |
| 1.8 | Author in system synchronised with author in change history. Approval by a person in the VM team, as the document is not shown in the VMS search. | tsj |
| 1.7 | Correction in wording from old: “public ER” to new: “Evaluation Report for Applicants” in chapter 7.9 | stb |
| 1.6 | Section 5: Addition of information regarding clinical trialsSection 6.3: Addition regarding document protection | stb, ze |
| 1.5 | Section 7.3: Clarification of confirmation of identity for the bioavailability studySection 7.4: Clarification of confirmation of procedure according to Art. 14 para. 1 let. abis TPA | fg, nmadts |
| 1.4 | Basic information: Deletion of the eCTD sequence no. | dts |
| 1.3 | Chapter 5: Explanation regarding the list of forms to be submitted in addition. | ze |
| 1.2 | Addition of medicinal product categories in the drop-down menu. | dts |
| 1.1 | Addition to Chapter 7.4. “Confirmation of procedure according to Art. 14 para. 1 let. abis TPA”. | dts |
| 1.0 | Implementation of TPO4 | dts |

1. If the WHO has not yet issued a valid ATC code, or a new ATC code has only just been applied for, the ATC code applied for must be specified (with a note to that effect) stating the level up to which the code is already clear. [↑](#footnote-ref-1)