Contents

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1 Definitions, terms and abbreviations

1.1 Definitions and terms

1.1.1 Evaluation Report for Applicants (ERA)

The Evaluation Report that is made available to the applicant. The ERAs document the evaluation results of an application, from receipt until the official decision, and are produced by the specialist departments Case Management, Quality Review, Preclinical Review, Clinical Review and Safety of Medicines.

1.1.2 Swiss Public Assessment Report (SwissPAR)

The SwissPAR is a summary, public evaluation report drafted by Swissmedic that relates to an authorisation procedure. The SwissPAR is produced for all human medicinal products with a new active substance and transplant products for which a new authorisation application has been approved or rejected by Swissmedic. Swissmedic produces a supplementary report for additional indications for which a SwissPAR has already been published in connection with the new authorisation application. A SwissPAR is not published if an authorisation procedure is abandoned due to a withdrawal of the application. The SwissPAR only includes content from the ERA, i.e. the evaluation results of the application for new authorisation or additional indication of a human medicinal product, but excluding the applicant's commercial or manufacturing secrets and personal data (see section 5.2.4).

1.1.3 Public Summary SwissPAR

The Public Summary SwissPAR is a layperson's summary of the SwissPAR. It is based entirely on the published SwissPAR and the officially approved medicinal product information texts. The Public Summary SwissPAR does not contain any business or production secrets belonging to the company in question, nor does it contain personal data.

1.1.4 Confidential information of the applicant or third parties, Commercially Confidential Information (CCI)

Any manufacturing or commercial secrets of the applicant or third parties contained in the documentation that are not publicly accessible because they satisfy the criteria for exemption are referred to as CCI in this guidance document (see section 5.2.3).

1.2 Abbreviations

Art.	Article
ASMF	Active Substance Master File
CCI	Commercially Confidential Information
CopA	Federal Act of 9 October 1992 on Copyright and Neighbouring Rights (SR 231.1)

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DMF	Drug Master File
ERA	Evaluation Report for Applicants
FoIA	Federal Act on Freedom of Information in the Administration of 17 December 2004 (SR 152.3)
HMP	human medicinal products
Let.	letter
Para.	paragraph
PatA	Federal Act of 25 June 1954 on Patents for Inventions (SR 232.14)
Public Summary SwissPAR	Summary of the SwissPAR
SwissPAR	Swiss Public Assessment Report
TPA	Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (Therapeutic Products Act, SR 812.21)
TpA	Federal Act of 9 October 1992 on the Transplantation of Organs, Tissues and Cells (SR 810.21)
TPO	Ordinance of 21 September 2018 on Therapeutic Products (Therapeutic Products Ordinance, TPO) (SR 812.212.21)

2 Introduction and objective

Following the entry into force of the revised Therapeutic Products Act (revision dated 18.03.2016), Swissmedic publishes additional information of general interest relating to therapeutic products, specifically summary evaluation reports (SwissPAR) relating to approvals and rejections of applications for the new authorisation of human medicinal products with a new active substance and transplant products and to their additional indications. The publication of SwissPARs and Public Summary SwissPARs reveals the logic underpinning the evaluations and decisions of Swissmedic.

This guidance document is aimed primarily at administrative bodies and is used by Swissmedic first and foremost as a resource for applying the legal provisions in a uniform and equitable manner. It does not justify any rights or obligations of private individuals.

The publication of this guidance document is designed to demonstrate the principles on the basis of which Swissmedic creates and publishes SwissPARs. This guidance document serves to:

- establish a consistent practice relating to procedures and the creation and publication of SwissPARs and Public Summary SwissPARs.
- minimise any potential risk of the publication by Swissmedic of confidential information of the applicant, confidential information of third parties or personal data that should not be disclosed.

3 Scope

This guidance document is valid for Swissmedic for the creation of SwissPARs and Public Summary SwissPARs concerning decisions on:

- new authorisation applications for human medicinal products with a new active substance according to Art. 4 para. 1 let. h., Art. 9 para. 1, Arts. 10 and 11 TPA
- new authorisation applications for human medicinal products according to Art. 13 TPA with a new active substance
- new authorisation applications for human medicinal products according to Art. 14 TPA para. 1 with a new active substance
- new authorisation applications for the granting of a temporary authorisation according to Art. 9a TPA with a new active substance
- additional indications for human medicinal products with a new active substance, for which a SwissPAR has already been created
- new authorisation applications for transplant products according to Art. 49 para. 1 TpA in conjunction with Art. 9 para. 1, Art. 10 and 11 TPA

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This guidance document is **not** applicable to:

- new authorisation applications for human medicinal products with known active substances
- new authorisation applications for biosimilars
- new authorisation applications for medicinal products in the notification procedure according to Art. 15 TPA in conjunction with Art. 32 para. 1 TPLO
- major variations (type II), excluding additional indications for which a SwissPAR was published in connection with the new authorisation
- minor variations (types IA/IA_{IN} and IB)
- Applications for extensions
- new authorisation applications for veterinary medicinal products

The SwissPAR is intended particularly for healthcare professionals, industry representatives and other national and international authorities. Swissmedic produces layperson's summaries of SwissPARs – Public Summary SwissPARs – for interested members of the public.

4 Legal basis

The procedure for the creation of SwissPARs is based, in particular, on the following legislative texts:

FoIA

- Art. 5, para. 1 — Official documents
- Art. 6 para. 3 — Freedom of information
- Art. 7 para. 1 let. g and h
- and para. 2 — Exceptions
- Art. 8, para. 2 — Legally binding administrative procedure

TPA

- Art. 62 — Data confidentiality
- Art. 67 para. 1 and 9 — Informing the general public, secrecy interests

TpA

- Art. 49 para. 1 — Handling of transplant products

CopA

- Art. 2 — Concept of the work
- Art. 5 para. 1 let. c — Unprotected works
- Art. 10 para. 1 — Use of the work by the author
- Art. 25 — Quotations

TPO

- Art. 68 para. 1 let. e no. 1 — Summary reports on authorisation procedures for the public

5 General principles and content

5.1 Principle on the publication of the SwissPAR and Public Summary SwissPAR

On the basis of Art. 67 para. 1 TPA and the implementing provisions of Art. 68 para. 1 let. e TPO, Swissmedic produces a SwissPAR and Public Summary SwissPAR for all human medicinal products with a new active substance and transplant products for which a decision to approve or reject authorisation has been issued. These summary evaluation reports are published on the Swissmedic website. Swissmedic produces and publishes a supplementary report for approved or rejected applications for an additional indication for a human medicinal product for which a SwissPAR or Public Summary SwissPAR has been published following the new authorisation.

If authorisation applications for human medicinal products are withdrawn, Swissmedic does not draft a SwissPAR or Public Summary SwissPAR.

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5.2 Structure and content of the SwissPAR

The ERAs form the basis for the production of SwissPARs. The evaluation results are summarised in the SwissPAR. The report focuses on the transparent presentation of the benefit-risk profile of the human medicinal product.

Swissmedic produces the SwissPAR in English technical language. It contains the following specific sections:

- Terms, definitions, abbreviations
- Background Information on the Procedure
- Quality Aspects
- Nonclinical Aspects
- Clinical and Clinical Pharmacology Aspects
- Risk Management Plan Summary
- Appendix

5.2.1 Risk Management Plan Summary

Swissmedic publishes Risk Management Plan Summaries for authorised human medicinal products and transplant products drafted by the marketing authorisation holders on its website. The SwissPAR refers to these documents.

5.2.2 Appendix

The Swiss Information for healthcare professionals, translated into English, is attached as an appendix to the SwissPAR. The authorisation holder is responsible for the correct translation of the text. Only the Information for healthcare professionals issued in an official Swiss language is binding and legally valid.

5.2.3 Commercially Confidential Information CCI

Procedure for CCI

In publishing the SwissPAR, Swissmedic discloses important information on new human medicinal products[1] and transplant products. Information from the application documentation is not published if publication would disclose commercial or manufacturing secrets.

Swissmedic produces the SwissPAR based on the content of the ERA. In connection with the legal hearing after the draft version of the ERA is issued, and which is opened together with the preliminary decision on the authorisation application, the applicant is requested to apply to Swissmedic to keep secret information which it considers to be CCI and which should not be published (see section 6). If the applicant believes that text passages in the ERA should not be used in the SwissPAR, these should be specified and the corresponding reasons stated. A blanket reference to the existence of such secrets is not sufficient. Swissmedic would point out that applications are not simply accepted automatically, but are reviewed in the context of the legal provisions. Whether commercial or manufacturing secrets exist in a document in an individual case is decided according to the following preconditions.

In principle, the secrecy interest can only relate to individual facts, hence the need for evidence that the preconditions for secrecy are met for each individual commercial or manufacturing secret. Documents can be declared as integral to commercial secrets only in exceptional cases. If protected data of third parties are included in the ERA (e.g. data concerning the active substance manufacturer), the applicant must seek clarification from the third company regarding the information that it believes should not be published. This should also be justified.

Required precondition for the existence of CCI

[1] Art. 67 para. 1 TPA in conjunction with Art. 68 para. 1, let. e TPO; Art. 5 para. 1 in conjunction with Art. 6 para. 3 FoIA

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In order for company information to be considered as a secret to be protected, four cumulative preconditions should be fulfilled:

a) **A relationship exists between the information and the company.** The protection of the information relates only to information that is connected with a company, i.e. it involves the secrecy interests of a particular company. This is no longer the case if the relationship to the company is lacking from the outset, or has become loosened to such an extent that the relevant fact can be attributed to general market situations or (also) to other companies.

b) **The information is relatively unknown.** This applies if only a small group of individuals is familiar with the information. In particular, the information should not be publicly accessible (e.g. via published annual reports, the press, Internet sites, etc.). Whether the owner of the information keeps this group of people under control is a crucial factor in the individual case.

c) **The owner of the information wishes to keep it secret (subjective secrecy interest).** The wish for secrecy must be explicitly expressed by the owner of the information or must be recognisable from the circumstances as a result of implied behaviour.

d) **Objective secrecy interest.** This is assumed only if the information to be kept secret can influence the outcome of business operations. Important data are considered to be secret only if their disclosure by the competition would lead to market distortions or cause the affected company to lose a significant competitive advantage or result in a competitive disadvantage. *Therefore, the competitive relevance of the information concerned is a crucial factor*. An objective secrecy interest exists provided that

   - the fact in question has *economic value* for the company and is thus important for its commercial success, and
   - the fact relates to an *individual company* (i.e. not to a group of competing companies), and can be traced back to this individual company.

e) For a manufacturing or commercial secret to be considered secret it must concern either a manufacturing process or commercially relevant information.

   - A *manufacturing secret* essentially constitutes technical knowledge, i.e. any knowledge that includes instructions relating to technical action (e.g. manufacturing instructions, research results, manufacturing processes, manufacturing resources, Restricted Part of the DMF/ ASMF, content of the Plasma Master File, quantitative composition of all constituents, information on the qualitative and quantitative composition of flavours).
   - A *commercial secret* can be considered to involve any facts that primarily concern commercial knowledge, for example sources of supply, market strategies, planned or ongoing research projects and information which, if published, might significantly influence the share price of companies.

The EMA evaluation criteria in respect of CCI apply accordingly to the information to be published in the SwissPAR.

https://www.ema.europa.eu/en/about-us/how-we-work/transparency

Further information on the procedure for the EMA European public assessment report (EPAR) can be found here:

https://www.ema.europa.eu/en/about-us/how-we-work/what-we-publish/european-public-assessment-reports

5.2.4 Personal data

No personal data are published in the SwissPAR with the exception of the applying company (name) (Art. 67 para. 9 TPA).

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5.2.5 Data protected by copyright

Since little room for manoeuvre exists for a SwissPAR, because of the standardised structure and assessment, its character as a copyrightable work is doubtful. Individual elements of the SwissPAR originating from the authorisation documentation may be protected by copyright (see Art. 2 CopA). Such elements may be published only with the consent and naming of the applicant (Art. 9 ff. CopA).

Possible elements that might be protected by copyright:

- Graphical illustrations
- Scientific or technical drawings
- Tables
- Photographs

Since they are official reports, the published SwissPARs and the elements contained therein are not protected by copyright (Art. 5 para. 1 let. c CopA).

If the applicant believes that copyright protected elements occur in parts of the authorisation documentation, it must explain to Swissmedic in connection with a legal hearing why, in each individual case, a work can be considered to be copyrightable and whether it will consent to publication or not (see section 6).

If Swissmedic integrates content from external sources (e.g. scientific publications) in the SwissPAR, the relevant statements are referenced accordingly[2].

5.2.6 Patent law

If, for reasons of patent law, a medicinal product cannot be placed on the market immediately after authorisation, even publication of the medicinal product information (MPI), and thus publication of the SwissPAR, can be considered to be a patent infringement. Swissmedic therefore accepts exemptions from the publication of the SwissPAR if the medicinal product cannot be placed on the market immediately after authorisation for reasons of patent law. However, the MPI and SwissPAR must be published, at the latest, when the product is first placed on the market. The authorisation holder is obliged to inform Swissmedic at an early stage about any future first placing on the market so that the SwissPAR can be prepared and published.

5.3 Structure and content of the Public Summary SwissPAR

Swissmedic produces a Public Summary SwissPAR in addition to the SwissPAR. The Public Summary SwissPAR is compiled entirely on the basis of the published SwissPAR and the medicinal product information texts officially approved by Swissmedic. It summarises the content of the SwissPAR in layperson's language and focuses on providing an easy-to-understand description of the risks and benefits of the human medicinal product. The document is published on Swissmedic's website in all official Swiss languages and in English.

Specifically, the Public Summary SwissPAR contains the following information:

- Name and brief description of the characteristics of the medicinal product
- Publication date of the Public Summary SwissPAR
- Brief description of mode of action, use and precautions
- Comparison of the risks and benefits
- Rationale for authorisation decision
- Links to further information, e.g. patient information

When preparing Public Summary SwissPARs, Swissmedic takes due account of rights that may prevent publication, as listed for SwissPARs in sections 5.2.3 to 5.2.6.

[2] Art. 25 CopA

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6 Process

6.1 Editing process at Swissmedic

6.1.1 Preparation of the ERA during the review process for the authorisation application

As part of the reviewing of an application for the new authorisation of a human medicinal product with a new active substance or an application for an additional indication, the specialist departments Case Management, Quality Review, Preclinical Review, Clinical Review and Safety of Medicines produce ERAs. These evaluation reports document the material result of the scientific evaluation, from receipt of the application through to the official decision.

6.1.2 Opening a draft ERA with preliminary decision on authorisation / rejection, granting of a legal hearing

Together with the preliminary decision on approval or rejection of the authorisation application, Swissmedic provides the applicant with the draft version of the ERA prepared up to this point. At the time the preliminary decision is issued, the intended SwissPAR texts are available for the Regulatory Review, Quality Review and Preclinical Review disciplines, but not for Clinical Review (see explanations below); there is no draft text for the Public Summary SwissPAR. In addition to its statement on the circumstances, the applicant is given the opportunity to express its opinion on the draft of the ERA:

- The applicant informs Swissmedic about those specific parts of the ERA which it believes should be considered to be CCI (per section 5.2.3) and therefore not suitable for publication in either the SwissPAR or Public Summary SwissPAR.
- The applicant specifies those elements in the ERA for which it claims patent or copyright protection (per section 5.2.5 and 5.2.6 respectively).
- The texts intended for publication in the SwissPAR are available in the ERA drafts for the Regulatory Review, Quality Review and Preclinical Review disciplines at the time the preliminary decision on authorisation is made. In these review disciplines, applicants must present objections of legal obstacles to the planned publication in the SwissPAR only in those chapters that contain the draft text for the SwissPAR. No separate SwissPAR text is available in the Clinical Review discipline at the preliminary decision on authorisation stage because the preconditions that Swissmedic opens and sets out in its preliminary decision on the authorisation process have to be resolved through the response to the preliminary decision under the right to a legal hearing. Applications therefore have to present objections of legal obstacles to planned publication for the entire ERA draft, with the exception of part 3, which is not a component of the SwissPAR.
- The objections of legal obstacles to the publication of parts of the ERA should be identified and justified by the applicant for each individual text element (see sections 5.2.3 – 5.2.6).
- If the applicant submits additional documents to Swissmedic after the preliminary decision on authorisation has been issued, the confidential information in these documents must also be identified and the applicant’s objections to publication in the SwissPAR or Public Summary SwissPAR should be individually justified.

6.1.3 Review and decision on applications by the applicant relating to the ERA in the official decision on authorisation

As part of the evaluation of the reply to the preliminary decision in the authorisation procedure, Swissmedic assesses the applications in respect of the applicant's CCI, CopA and PatA. Swissmedic approves justified applications by not publishing the relevant information or documents in the SwissPAR or Public Summary SwissPAR. For applications that it does not accept, Swissmedic rejects them individually in the ruling of the official decision on authorisation or rejection. The ERA forms an integral part of the official decision on authorisation or rejection and is enclosed with the official decision. This final ERA includes the material content for producing the SwissPAR.

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If the new authorisation application is approved, the authorisation holder is asked to submit the Swiss Information for healthcare professionals for the medicinal product in English to Swissmedic within 10 calendar days of receipt of the official decision.

6.1.4 Preparation of the SwissPAR by Swissmedic and publication

The SwissPAR only includes content from the issued ERA. During the preparation of the SwissPAR, Swissmedic considers all the accepted applications from the applicant concerning CCI and copyright and patent legislation. The Information for healthcare professionals translated into English is enclosed with the SwissPAR as an appendix.

If no appeal against the official decision on authorisation or rejection has been lodged within the permitted time limit of 30 days, Swissmedic publishes the SwissPAR on its website within 60 days of the official decision on authorisation.

If an appeal is lodged against the ERA or against an official decision of rejection, the SwissPAR is published after the decision acquires legal force.

Swissmedic produces a supplementary report for additional indications for human medicinal products for which a SwissPAR was published in connection with the new authorisation. The process for producing and publishing the supplementary SwissPAR is similar to that for new authorisation applications.

6.1.5 Preparation of the Public Summary SwissPAR by Swissmedic and publication

Once the SwissPAR has been published, Swissmedic compiles the Public Summary SwissPAR. The Public Summary SwissPAR consists entirely of content from the published SwissPAR and the officially approved medicinal product information texts. Swissmedic publishes the Public Summary SwissPAR no later than 60 days after publication of the SwissPAR on its website.

6.2 Authorisations under Art. 13 or 14 TPA or temporary authorisation according to Art. 9a TPA

6.2.1 Publication of SwissPAR

If the review of the application for authorisation of a human medicinal product with a new active substance or applications for additional indications for such a product is conducted according to Art. 13 TPA or Art. 14 para. 1 TPA, Swissmedic only publishes those results obtained from the independent scientific (partial) review in the SwissPAR. In these cases, Swissmedic reserves the right to refer, in the SwissPAR, wholly or partly to evaluation reports published by the foreign reference authority.

- If Swissmedic carries out the assessment independently, the SwissPAR consists entirely of content from the ERA produced for the application procedure. Where Swissmedic adopts decisions from reviews conducted by foreign reference authorities, Swissmedic will publish the SwissPAR as a reference to the foreign reference authority's public assessment report for this section.

- If Swissmedic does not carry out its own scientific review of the application and adopts the outcome of the foreign reference authority's review in full, the SwissPAR will be published as a reference to the foreign reference authority's public assessment report.

The procedure for processing the applicant's requests to keep data from the ERA confidential is in accordance with section 6.1.

For applications for the temporary authorisation of human medicinal products with a new active substance according to Art. 9a TPA and corresponding additional indications, the SwissPAR is produced and published accordingly.

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6.2.2 Publication of Public Summary SwissPAR

Where Swissmedic adopts the outcome of the foreign reference authority's review in full, Swissmedic publishes the Public Summary SwissPAR as a reference to the summary report published by the foreign reference authority.

6.3 Processing times

The processing time for producing the SwissPAR or Public Summary SwissPAR is based on the relevant figures in section 6. Otherwise, the time limits for processing new authorisation applications or additional indications are based on the guidance document *Time limits for authorisation applications HMV4*.

6.4 Fees

The costs for producing and publishing the SwissPAR and Public Summary SwissPAR are covered by the respective flat fees charged for procedures for new authorisation or additional indications.

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