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Change history

Version	Valid and binding as of	Description, comments (by author)	Author's initials
6.0	01.01.2023	New section 5.7 *Document protection when converting from temporary to regular authorisation* due to expansion of scope of temporary authorisations/temporary additional indications. Previous section 5.7 is now 5.8. Section 5.4 Explanation of the requirements for extended DP for a new indication.	stb/ru/fg/nma/hv
5.0	28.01.2022	Adaptation of guidance document due to new structure of VMP variations (early revision of VMP regulations)	fg/ps
4.2	01.08.2021	Clarification/addition to section 6: These DP applications do not have to be submitted separately if they are submitted with the NA, AI (type II) or extension NDF.	stb
4.1	01.03.2021	Formal adjustments to the header and footer No content adjustments to the previous version.	dei
4.0	01.08.2020	Explanation of simultaneous authorisation of an NAS and associated authorisation extension (section 5.2). Explanation of the conditions to be fulfilled to obtain an extension of document protection for innovative indications (section 5.4).	ze
3.0	01.12.2019	Explanation regarding the procedure when processing of an application for an essentially identical medicinal product is completed before the document protection expires.	ze
2.0	13.02.2019	Explanation regarding the duration of document protection requested subsequently (innovative indication, purely paediatric application, Orphan Drug / MUMS status)	ze
1.0	01.01.2019	New document for HMV4	ze

1 Definitions, terms, abbreviations

1.1 Definitions and terms

Document protection (DP)
Documents for human medicinal products submitted by the first applicant in connection with an authorisation application or an application for an authorisation extension or variation of the indications or dosage recommendations, particularly the pharmacological, toxicological and clinical trial data, are protected from use by third parties (document protection). Documents for veterinary medicinal products are accordingly protected to the same extent (regardless of whether they have been submitted with an authorisation extension or variation). Documents regarding a new target animal species are also protected in the case of veterinary medicinal products.

1.2 Abbreviations

DP	Document protection
FeeO-Swissmedic	Ordinance of 14 September 2018 on the Fees charged by the Swiss Agency for Therapeutic Products (FeeO-Swissmedic; SR 812.214.5)
HMP	Human medicinal product
KAS	Medicine with known active substance
MUMS	Minor Use Minor Species
NAS	New Active Substance
rAI	Regular additional indication

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temp.auth.	Temporary authorisation
TPA	Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (Therapeutic Products Act, SR 812.21)
TPO	Ordinance of 21 September 2018 on Therapeutic Products (Therapeutic Products Ordinance; SR 812.212.21)
TPLO	Ordinance of the Swiss Agency for Therapeutic Products of 22 June 2006 on the Simplified Licensing of Therapeutic Products and the Authorisation of Therapeutic Products by the Notification Procedure (TPLO; SR 812.212.23)
VMP	Veterinary medicinal product

2 Introduction and objective

The guidance document describes the rules for granting and managing DP, as well as the associated rights and obligations for the marketing authorisation holder. As this is a guidance document aimed at administrative bodies, it does not directly specify the rights and obligations of private individuals. Swissmedic uses this document first and foremost as a resource for applying the legal provisions on authorisation in a uniform and equitable manner. The publication of the guidance document is designed to make it clear to third parties what requirements must be fulfilled according to the practice of Swissmedic.

3 Scope

Within the context of authorisation at Swissmedic, the guidance document applies to applications for new authorisation, for authorisation extension and for variation of the indications and dosage recommendations for human and veterinary medicinal products which are received by Swissmedic from 1 January 2019.

4 Legal foundations

The rules for granting and managing DP as well as the marketing authorisation holder's associated rights and obligations are based on the following legal provisions:

TPA

- Art. 9a *Temporary authorisation*
- Art. 11a *Document protection in general*
- Art. 11b *Document protection in special cases*
- Art. 12 *Authorisation of essentially identical medicinal products*
- Art. 16a *Revocation and transfer of the authorisation*, para. 4 and 5
- Art. 54a *Paediatric investigation plan*

TPO

- Art. 11 *Notification in case of no marketing and cessation of distribution*, para. 3 and 5
- Art. 30
- Art. 68, para. 1 d
- Art. 86

5 Managing document protection

5.1 General

An application for the authorisation of a medicinal product that is essentially the same as a medicinal product whose documents are protected by DP can be based on the results of its pharmacological, toxicological and clinical trials only if either the protection for the corresponding documents has expired or the marketing authorisation holder of the medicinal product with DP provides the corresponding written permission (Art. 12, para. 1 TPA).

If the authorisation holder does not consent to reference being made to its protected documents, an application for authorisation of an essentially identical medicinal product based on the protected data may be submitted, at the earliest, two years before the protection period expires (Art. 12, para. 2

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TPA). If a corresponding application is submitted sooner, Swissmedic will not consider the application (Art. 30, para. 6 TPO).

The first authorisation of an essentially identical medicinal product is granted, at the earliest, on the first day after the protection period expires. If Swissmedic finishes processing the application before the protection period ends, the decision will be issued immediately after the assessment has been completed but the authorisation will be granted with effect from the first day after the protection period has ended. This regulation applies equally to first authorisations of medicinal products with documents protected in accordance with Art. 11a and 11b TPA.

If, for an essentially identical medicinal product, authorisation is requested at the same time for indications that are (still) protected, any authorisation can only be granted with effect from the time the protection period for the indication with the longest protection expires. In order to obtain authorisation restricted to individual indications at an earlier time, the applicant must not include an application for authorisation of the indications that are still protected. Requests relating to the relevant applications of the reference medicinal product for an existing authorised medicinal product cannot be submitted until the first day after expiring of the protection period for the essentially identical medicinal product. If the product information under the headings of relevance to the respective application is identical to that of the reference medicinal product, a type IA_{IN} (C.I.2 a) variation report must be submitted for the subsequent authorisation of a further application for human medicinal products or a variation without assessment (C.3) for veterinary medicinal products. If the wording in the relevant passages differs from that for the reference medicinal product, it is classified as a type IB variation (C.I.2 a) in the case of human medicinal products or a variation with assessment and “reduced” time limit (G.I.2) in the case of veterinary medicinal products (cf. Guidance document *Variations and extensions HMP HMV4 /* Guidance document *Variations VMP HMV4*).

Variation applications relating to essentially identical medicinal products can be submitted as soon as the new authorisation decision is issued and will be processed by Swissmedic accordingly, even if the entry into force of the new authorisation decision is deferred (cf. Guidance document *Variations and extensions HMP HMV4 /* Guidance document *Variations VMP HMV4*).

An application for a co-marketing medicinal product relating to an essentially identical medicinal product cannot be submitted until the authorisation of the basic product has become valid (Art. 34 TPLO).

For the granting of DP in Switzerland, it is immaterial whether the product to be protected is already authorised in another country or whether it has already received DP in that country.

DP is ordered and published by Swissmedic (Art. 30 para. 5 TPO) and applies regardless of any patent protection that may exist.

5.2 New active substances

According to Art. 11a TPA, Swissmedic grants a document protection period of 10 years for a medicinal product containing at least one new active substance (NAS). However, a 10-year document protection period of this kind can only be granted to medicinal products which have been approved with a complete dossier in accordance with Art. 11 TPA. No such protection is afforded for medicinal products approved in a simplified authorisation procedure in accordance with Art. 14 TPA or granted time-limited authorisation as per Art. 9a TPA. A second medicinal product containing the same active substance cannot be granted DP according to Art. 11a TPA, even if a complete dossier according to Art. 11 TPA is submitted. The only instance in which this does not apply is if an active substance previously used only in veterinary medicinal products is used for the first time in a human medicinal product and vice versa. If an NAS and associated authorisation extension (e.g. new pharmaceutical form) are submitted simultaneously for a human medicinal product, or an NAS and a variation with assessment for a veterinary medicinal product, DP is only granted to the NAS. Because the medicinal product authorised as an authorisation extension or variation with assessment is reliant on the documentation for the NAS, it is therefore indirectly protected along with the NAS, but does not qualify for separate protection of its own.

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The 10-year DP for fixed combinations of medicinal products is granted only if the combination contains at least one NAS.

The DP is ordered with the authorisation (Art. 30, para. 5 TPO). The authorisation holder is informed in advance, via the preliminary decision, that DP will be granted. However, the DP for a medicinal product with an NAS applies by law, i.e. the DP applies even if not explicitly ordered at the time of authorisation. Moreover, the DP remains in place even after an authorisation has been revoked or discontinued, or the product is transferred to another authorisation holder.

5.3 Extensions or variations of the authorisation

According to Art. 11b, para. 1 TPA, a document protection period of 3 years is granted for the following authorisation extensions or variations:

- new indication
- new administration route
- new dosage form
- new dosage strength
- new dosage recommendation
- application in new target animal species

The 3-year DP is granted both for medicinal products with NAS and with known active substances (KAS). In the case of new applications for a KAS with innovation, the documents that record the added value compared with medicinal products containing the same active substance(s) that have already been authorised by Swissmedic can be protected accordingly.

For a 3-year DP to be granted, it is immaterial whether another DP for the same medicinal product exists at the time the decision is issued (e.g. DP as per Art. 11a TPA). For any medicinal product, different documents can be protected at the same time and independently of each other. In other words, various rights to protection can exist sequentially and/or in parallel next to each other. For example, if a 10-year DP exists for an NAS and if, 5 years after first authorisation, an additional 3-year DP is issued for a new dosage form, both rights to protection are active in parallel for three years; after the 3-year protection expires, the 10-year protection continues for a further two years.

The order for DP is issued together with authorisation (Art. 30, para. 5 TPO[21]). The authorisation holder is informed in advance, via the preliminary decision, that DP will be granted. However, the DP for the above-mentioned authorisation extensions or variations applies by law, i.e. the DP applies even if this has not been explicitly ordered at the time of authorisation. Moreover, the DP remains in place even after an authorisation is revoked or discontinued, or the product is transferred to another authorisation holder.

5.4 Extension of the DP for a new indication

According to Art. 11b, para. 2 TPA, a 10-year DP can be granted for a new indication if a significant clinical benefit (i.e. improved risk-benefit ratio) over existing, standard-of-care treatments has been demonstrated for it and the new indication is supported by comprehensive clinical trials. All medicinal products for the same indication that are available at the time the application for extended DP is submitted are deemed to be standard-of-care treatments. If Swissmedic is processing several applications for extensions in the same indication at the same time, all are equally entitled to evaluation for extended DP.

The requirements for extended DP are fulfilled if:

- substantially improved efficacy compared to standard of care valid at the time the application was submitted has been documented in (a) randomised controlled study/studies with a clinically significant endpoint. In the event of a change in the standard of care during the study, the comparison must be shown against the standard of care valid at the time the application was submitted.

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- Should it not be possible to submit a randomised, controlled study, applicants must explain why the new treatment option they are submitting fulfils the therapeutic benefit requirement and should be granted extended DP. They should support their explanation with a table of historical data referring to the standard of care. If there are several standard-of-care treatments, the comparison must cover all of them.

Or if

- a clinically significant improvement in the safety of the existing treatment/diagnosis can be documented in a study/studies in a large proportion of the treated population.

Approval of an application for a fast-track authorisation procedure (FTP) submitted beforehand for the indication being assessed for DP does not in any way pre-empt the decision on the DP applied for in the indication in question. Whereas an assessment of probability with no detailed evaluation is adequate for the FTP appraisal of high therapeutic benefit, determining significant clinical benefit for the purpose of DP extension involves a detailed evaluation. As a result, the outcomes of both procedures may differ.

The DP is granted regardless of whether the medicinal product contains an NAS or a KAS.

A protection period of 10 years is granted only on application. A corresponding application should be submitted together with the application for a new indication. In exceptional cases, Swissmedic will accept the submission of an application of this type for up to a maximum of one year after the new indication is authorised. However, the starting point for the 10-year period of DP is still the date on which the new indication application was approved.

An extension of the DP from 3 to 10 years can only be granted for new indications for which an authorisation application is submitted to Swissmedic after 1 January 2019 (Art. 86 TPO).

5.5 Medicinal products for paediatric use

According to Art. 11b para. 3 TPA, a medicinal product intended specifically and exclusively for paediatric use is granted DP lasting 10 years.

The DP is granted regardless of whether the medicinal product contains an NAS or a KAS.

DP is granted only if the submitted studies correspond with the paediatric investigation plan according to Article 54a TPA that was approved during authorisation, and if all measures for the proposed paediatric population from the investigation plan were carried out.

The requirements pertaining to the paediatric investigation plan are set out in the guidance document *Paediatric Investigation Plan HMV4*.

DP for purely paediatric use is granted only on application. A corresponding application should be submitted together with the authorisation application. In exceptional cases, Swissmedic will accept the submission of an application of this type for up to a maximum of one year after the first authorisation of the medicinal product intended purely for paediatric use. However, the starting point for the 10-year period of DP is still the date on which the medicinal product intended purely for paediatric use was approved.

The DP is only granted for medicinal products intended purely for paediatric use for which authorisation is requested from Swissmedic after 1 January 2019 (Art. 86 TPO).

If a marketing authorisation holder intends to discontinue the distribution of a medicinal product authorised specifically and exclusively for paediatric use and for which DP in accordance with Art. 11b para. 3 TPA or patent protection in accordance with Article 140n or 140t of the Federal Act on Patents for Inventions (PatA; SR 232.14) has been granted, it must inform Swissmedic of this intention at least three months in advance so that it can be announced publicly (Art. 16a para. 4 TPA). Conversion of a main authorisation to an export licence is also considered to represent discontinuation of distribution under this regulation.

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Swissmedic publishes the notifications it receives and at the same time also points out that the authorisation documents required for paediatric use are also provided at no cost to third parties in order to permit them to obtain their own authorisation (Art. 16a para. 4 and 5 TPA in conjunction with Art. 11 para. 3 and 5 TPO). The obligation to release the relevant authorisation documentation exists regardless of whether a granted DP is still active or not. The discontinuation of the authorisation or conversion of a main authorisation into an export licence will be published in the Swissmedic Journal. A reference to the free availability of the documents will also be added to the internet list on DP (see p. 5, section 5.7).

This legal ruling is designed to ensure that – in the overriding interest of public health – the medicinal products authorised in Switzerland for paediatric use remain available on the market even after their DP and/or supplementary protection certificates have expired.

5.6 Important medicinal products for rare diseases

According to Art. 11b, para. 4 TPA, an important medicinal product for rare diseases (i.e. one with Orphan Drug Status) is granted DP for 15 years. By analogy, a 15-year DP is also granted for veterinary medicinal products with MUMS status.

Both medicinal products containing an NAS and those with a KAS are eligible for protection. In addition, the DP is granted regardless of whether the authorisation of the indication results in the authorisation of a new medicinal product at the same time or whether this is a new indication for a medicinal product that has already been authorised.

The DP for an important medicinal product for rare diseases is granted only on application. A corresponding application should be submitted together with the authorisation application. In exceptional cases Swissmedic will accept the submission of an application of this type for up to a maximum of one year after the first authorisation of the medicinal product for rare diseases. However, the starting point for the 15-year period of DP is still the date on which the medicinal product for rare diseases was approved.

The DP is granted only for important medicinal products for which authorisation is requested from Swissmedic after 1 January 2019 (Art. 86 TPO).

5.7 Document protection with conversion of temporary to regular authorisation

No document protection is granted for temporary authorisations (temporary new authorisations or temporary additional indications).

Relevant document protection is granted or the ex officio period of protection starts on the date of conversion from a temporary to a regular authorisation. In particular, this means:

a) 10 years of protection for new authorisation of a medicinal product with a new active substance according to Art. 11*a* HMG

b) 10 years of protection for new authorisation of a medicinal product with a known active substance specifically and exclusively for paediatric use according to Art. 11*b* para. 3 TPA (on request)

c) 15 years of protection for new authorisation of an important medicinal product for rare diseases (orphan drug status, ODS) according to Art. 11*b* para. 4 TPA (on request)

d) 3 years of protection for new authorisation of a medicinal product with known active substance with innovation according to Art. 11*b* para. 1 TPA

e) 3 years of protection for additional indications according to Art. 11*b* para. 1 TPA

f) 10 years of protection for additional indications according to Art. 11*b* para. 2 TPA (on request)

Special case:

Granting of document protection for a regularly authorised additional indication for temporarily authorised medicinal products.

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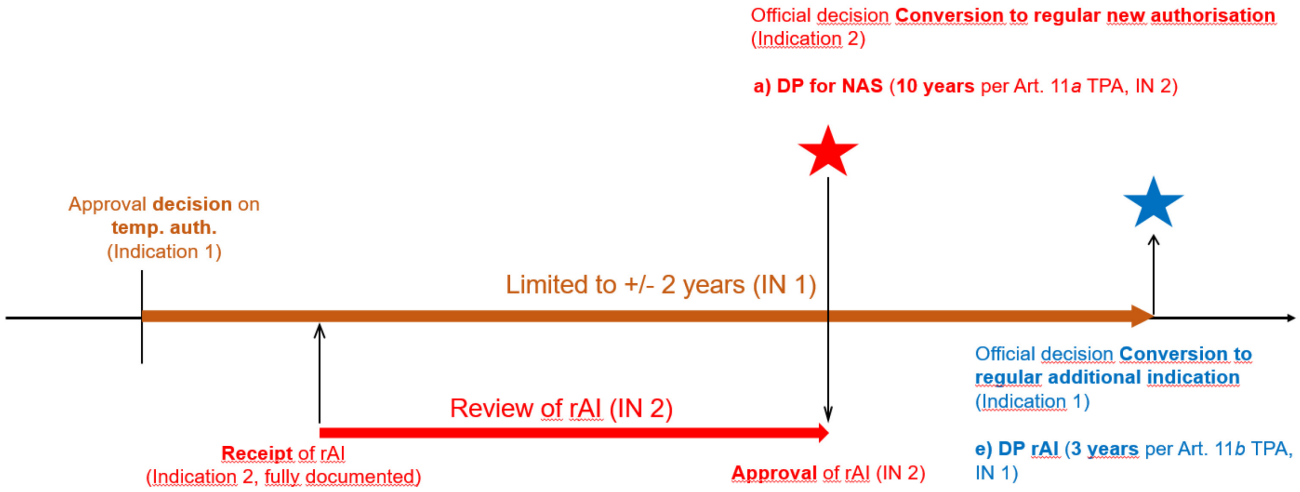
A medicinal product with at least one regularly authorised indication is considered to have a regular authorisation. If an application for additional indication (rAI) with a complete data record (Indication 2) is concluded before the temporary authorisation on the medicinal product (with Indication 1) expires, document protection for the new authorisation is granted with the authorisation of the AI (see red star in following figure). On completion and conversion re. Indication 1, document protection for this indication is granted (see blue star in following figure).



5.8 Publication of the DP

The nature and duration of the DP for a particular medicinal product is published by Swissmedic (Art. 68, para. 1 d TPO). The corresponding list is publicly accessible on the Swissmedic website

6 Applications for a variation of the DP

The application for the extension of DP for a new indication is processed as a major variation (type II) (Art. 23 TPO) in the case of human medicinal products or as a variation with assessment and time limit “Standard” (Art 25b TPO) in the case of veterinary medicinal products (see C.I.102 and G.I. 102 *Extension of the document protection for additional indications*).

Applications for DP to be granted for purely paediatric use or for important medicinal products for rare diseases are handled as minor variations that must be notified in advance (type IB; Art. 22 TPO) in the case of human medicinal products (see *C.I.103 Document protection for purely paediatric use* and *C.I.104 Document protection for important medicinal products for rare diseases (ODS/MUMS)*). In the case of veterinary medicinal products, the application for DP is classified as a variation with assessment and time limit “Reduced” (Art. 25b TPO; see G.I.103 *Document protection for important medicinal products for rare diseases (MUMS)*).

If these applications for extension or granting of the DP are submitted together with the related new authorisation, authorisation extension or variation applications, no separate variation application is required and no additional fees are due.

The requirements and the process for processing applications are based on the guidance documents *Variations and authorisation extensions HMP HMV4 / Variations VMP HMV4*.

6.1 Formal requirements

The formal requirements are based on the guidance documents *Variations and extensions HMV4* and *Formal requirements HMP HMV4 / Variations VMP HMV4* in conjunction with the *Overview of documents to be submitted HMV4*.

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6.2 Time limits

The time limits are based on the guidance document *Time limits for authorisation applications HMV4*.

6.3 Fees

The fees are charged in accordance with the *Ordinance on Fees Levied by the Swiss Agency for Therapeutic Products (FeeO-Swissmedic)*.

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