1 How does Swissmedic deal with new applications relating to essentially identical medicinal products (KAS without innovation) during the period in which document protection does not yet exist for a time-limited authorisation?

Essentially identical medicinal products (KAS without innovation) can be authorised only with referencing to a medicinal product with complete documentation (in the procedure according to Art. 11 TPA). Since the documentation for a time-limited authorised product cannot (yet) be considered as complete, an application for a KAS without innovation based on this product cannot be submitted. In other words, Swissmedic would not consider such an application.

2 Is document protection granted when a time-limited authorisation transitions to a regular authorisation?

The condition for the transition to a regular authorisation is the submission of a complete dossier. Consequently, this dossier is also granted document protection. This presupposes, however, that the same active substance for the same indication, based on an independent complete dossier of a third party, has not been authorised in the meantime.

3 How is document protection handled if company A undertakes a combination study with an active substance from company B? Does the document protection apply with respect to company B, or can company B incorporate the new indication in the medicinal product information?

If an active substance is covered by document protection, then this is asserted in all cases unless the corresponding marketing authorisation holder explicitly waives the protection.

4 Is document protection granted to medicinal products authorised according to Art. 13 TPA?

Yes. Document protection is always granted when a medicinal product is authorised in the procedure according to Art. 11 TPA. Since Art. 13 TPA constitutes a simplification in the authorisation process rather than an independent application procedure, this simplification does not prevent document protection.

5 A new authorisation application for an essentially identical medicinal product can now be submitted as early as two years before the document protection for the reference product expires. So does the review of the essentially identical medicinal product also start at this point, and is this product authorised on the day the document protection expires?

When an application for the authorisation of an essentially identical medicinal product is submitted two years before the document protection of the reference product expires, the review is not delayed, but starts immediately after submission. The official decision is issued in accordance with the Swissmedic time limits, potentially before the document protection expires. In this case, the authorisation is granted with a date in the future (= at the earliest the first day after the document protection expires).

6 If the document protection is granted retrospectively, what happens to dossiers on essentially identical medicinal products that have already referred to the reference dossier?

New authorisation applications for essentially identical medicinal products which were submitted or approved before the retrospective granting of document protection for the reference product are processed independently of the document protection. Under no circumstances are corresponding new authorisations cancelled.

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7 Can the newly extended 10-year document protection period also be requested for indications approved in 2018?

No. An extension of the document protection for an innovative indication to 10 years is only possible for new indications that were requested on or after 01.01.2019.

An extension of the document protection for indications that were approved in 2018 can only be requested according to the old legislation (i.e. extension to 5 years).

8 Can the applicant for a biosimilar make reference to the documentation of an earlier biosimilar after the document protection expires?

Biosimilars can be authorised only with referencing to a medicinal product with complete documentation (in the procedure according to Art. 11 TPA), i.e. biosimilars themselves cannot be authorised as reference products.

9 Does the document protection for 15 years still apply if a non-orphan indication is added and authorised during the 15-year period?

Although the addition of a non-orphan indication would result in the withdrawal of the Orphan Drug/MUMS status of the medicinal product, the corresponding document protection period of 15 years would still apply.

10 Is it correct to state that document protection should be requested already at the time of submission?

Yes. Swissmedic recommends that the request for extended document protection for innovative indications (10 years), for medicinal products with Orphan Drug/MUMS status (15 years) and for medicinal products for purely paediatric use (10 years) be submitted at the same time as the application. This has the advantage of dispensing with the need to submit a separate (chargeable) application and avoiding the premature expiration of the document protection.

Incidentally, the 10-year document protection for new active substances and the 3-year document protection for authorisation extensions and for additional indications/new dosage recommendations apply ex officio and do not need to be requested explicitly.

11 Does the document protection for an additional indication apply only to the new indication or to the whole medicinal product?

Only those documents that formed the basis for the additional indication are protected.

12 Can the document protection be requested retrospectively in order to obtain 15 years of document protection from authorisation for medicinal products with Orphan Drug status that are already authorised?

Yes. However, the document protection period of 15 years can be granted only for medicinal products with Orphan Drug / MUMS status if their new authorisation application is received on or after 01.01.2019.

13 Can a marketing authorisation holder voluntarily waive document protection during the ongoing authorisation application process, or is this protection always necessarily granted and thus published ex officio?

The document protection for new active substances (10 years), authorisation extensions (3 years) and new indications/dosage recommendations (3 years) is granted ex officio. It is not possible to waive document protection in this situation. Nor can its publication be prevented.

However, the authorisation holder has the option, at any time, of waiving document protection with respect to a third party. Specifically, this means that the authorisation holder explicitly permits a third party to refer to its still protected documents for the new authorisation of a medicinal product with known active substance. However, the document protection as such, and thus its publication as well, still applies.

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The document protection for innovative indications (10 years), medicinal products for purely paediatric use (10 years) and medicinal products with Orphan Drug / MUMS status (15 years) does not apply ex officio, but must be applied for. If a corresponding application is not submitted, then document protection is not granted.

14 A new authorisation application for an essentially identical medicinal product can now be submitted as early as two years before the document protection for the reference product expires. Does this ruling apply only to reference products that were submitted after 01.01.2019?

No. The authorisation date of the reference product is not relevant. In this case, only the expiry date of the document protection for the reference product and the submission date for the essentially identical medicinal product (i.e. on or after 01.01.2019) are decisive.

15 Should extended document protection (for innovative additional indications, medicinal products with Orphan Drug / MUMS status and medicinal products for purely paediatric use) be applied for with the cover letter, or is a specific form available?

Ideally, document protection that does not apply ex officio (for innovative additional indications, medicinal products with Orphan Drug / MUMS status and medicinal products for purely paediatric use) should be requested directly using the new authorisation application/variation application. In this case a corresponding mention in the cover letter is sufficient.

If document protection is applied for retrospectively, the specifically designated types of variation application must be used (using the Variations and authorisation extensions form):

C.I.102 Extension of document protection for additional indications (Type II)

C.I.103 Document protection for purely paediatric use (Type IB)

C.I.104 Document protection for important medicinal products for rare diseases (ODS/MUMS) (Type IB)

16 What is an innovative additional indication?

An innovative additional indication exists if it can be shown, on the basis of clinical data, that the benefit-risk ratio for an indication is significantly better than the available therapeutic options.

17 Is document protection granted for new combinations of known active substances? If so, for how long? Does this document protection apply ex officio?

The 10-year document protection for fixed combinations of medicinal products is granted only if the combination contains at least one new active substance. It is issued ex officio.

18 Can a new authorisation application for a medicinal product with Orphan Drug / MUMS status which was already submitted in December 2018 according to the new regulations include the request for 15 years of document protection?

Yes, this is possible. For all applications submitted in December 2018 according to the new legislation, the official submission date is considered to be 03.01.2019. The new ruling introduced with TPA 2 applies universally from this key date.

19 What does document protection protect?

Document protection protects documents, i.e. prevents any referencing to these documents. But document protection is not synonymous with market exclusivity. So if a new complete and independent dossier is submitted in relation to an active substance that is itself document-protected, authorisation may result – as no referencing is necessary.

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20 Do the requirements relating to the extension of document protection for an innovative indication to 10 years differ from the previous requirements that had to be satisfied for an extension of the first applicant protection to 5 years?

No, the requirements remain essentially the same. The innovation must be demonstrated on the basis of corresponding clinical data both according to the new (applicable since 01.01.2019) and "old" legislation.

21 From what point may a generic whose authorisation was granted before the document protection for the reference product expired (i.e. the authorisation became valid from the first day after the document protection expired) be imported into Switzerland?

Although an existing document protection does not, per se, preclude importation, the TPA specifies that only those medicinal products authorised in Switzerland (or those not subject to authorisation) may be imported (Art. 20 para. 1 TPA). Consequently, the generic may be imported into Switzerland only from the date on which its authorisation becomes legally valid, i.e. at the earliest on the first day after the document protection for the reference product expires.

22 By law, a document protection period of 15 years is granted, on application, for medicinal products with Orphan Drug / MUMS status. Does this apply only in connection with an authorisation application?

The 15-year document protection period for a medicinal product with Orphan Drug / MUMS status is granted (on application) when it is newly authorised. If the application is submitted separately only after new authorisation, the granted protection is backdated to the authorisation date.

23 Can document protection be granted for a medicinal product with Orphan Drug / MUMS status that is authorised according to Art. 14 para. 1 letter a^{bis}, a^{ter} or a^{quater} TPA?

No. Document protection is designed to protect company know-how, i.e. it rewards the company for its investment and research. No corresponding documentation requiring protection is submitted with applications according to Art. 14 para. 1 letter a^{bis}, a^{ter} or a^{quater} TPA. Any Orphan Drug / MUMS status is irrelevant in this situation.

24 It is possible that two or more companies apply for the new authorisation of a new active substance at the same time or separated by a short interval (i.e. before authorisation of the first submitted product). Which dossier receives the 10-year document protection in this scenario?

The dossier that was submitted first and can also be authorised first within the specified time limits is granted document protection. However, if the review of the first submitted dossier involves additional work/complications (incomplete dossier, incomplete answers to questions, documents submitted spontaneously at a later date, difficult-to-reconcile labelling discrepancies, etc.), the authorisation of the second submitted product may not be delayed because of that, i.e. the product submitted in second place can therefore be authorised first and granted document protection accordingly.

It should be noted, however, that in this case the document protection for both products is only of limited value. Since only one dossier can be protected, a third company would be free to reference the dossier of the other product and thus open up the market for itself as well.

25 Can the inclusion of an indication that is still protected on authorisation of a generic also be requested two years before the corresponding document protection expires?

No. The inclusion of an indication that is still protected on authorisation of a generic can be applied for, at the earliest, on the first day after the document protection expires

(if the wording is identical using the type IAIN variation application / if the wording is not identical using the type IB variation application).

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26 The document protection for new active substances (NAS) lasts 10 years. To what extent does the protection period of 10 years for medicinal products for purely paediatric use offer added value?

The product for purely paediatric use can also be an essentially identical medicinal product (known active substance / biosimilar / medicinal product according to Art. 12 para. 5 TPLO).

Moreover, if all the conditions set out in the paediatric investigation plan (PIP) are fulfilled, and if the knowledge obtained on paediatric use is fully incorporated in the Information for healthcare professionals, then Swissmedic will confirm this on request. On receipt of this confirmation from Swissmedic, the applicant can apply to the Federal Institute of Intellectual Property (IIP) for a 6-month extension of an existing supplementary protection certificate (SPC) or apply for a new paediatric SPC.

27 10 years of data protection for a paediatric indication: What does this mean? That the indication is exclusively for paediatric use? Does this mean that it cannot have an adult indication?

This type of document protection is granted only for medicinal products that are intended specifically and exclusively for paediatric use. The medicinal product may not have an additional indication for adults.

If a company wishes to use the same active substance in adults, it must do so with a separate medicinal product (separate product name, separate authorisation number).

28 Can 20 years of data protection be obtained for a paediatric use only product?

No. For medicinal products that are specifically and exclusively intended for paediatric use, Swissmedic grants a document protection period of 10 years. It is granted only if the submitted studies / investigations correspond with the paediatric investigation plan (PIP) according to article 54a TPA.

If all the conditions set out in the PIP are fulfilled, and if the knowledge obtained on paediatric use is fully incorporated in the Information for healthcare professionals, then Swissmedic will confirm this on request. On receipt of this confirmation from Swissmedic, the applicant can apply to the Federal Institute of Intellectual Property (IIP) for a 6-month extension of an existing supplementary protection certificate (SPC) or apply for a new paediatric SPC.

29 Is the 10-year document protection period for purely paediatric use granted only for new active substances?

No. The only condition is that the medicinal product is intended specifically and exclusively for paediatric use. This can involve not just a new active substance, but also a known active substance (incl. biosimilar or medicinal product according to Art. 12 para. 5 TPLO).

If you intend to apply for a purely paediatric indication for an existing medicinal product, you will need to do so in the form of a separate product. The document protection for this medicinal product might be granted for the paediatric use, provided the submitted studies correspond with the paediatric investigation plan according to Art. 54a TPA and all the measures specified in the PIP relating to the target population are fulfilled.

30 Where exactly is the document protection published on the Swissmedic website, and what specific information is presented? Does this involve a list in Excel format?

The document protection list has been available in Excel format on the Swissmedic website since February 2019, in the Services and lists section, then Lists and directories (List no. 8) and includes the following information: Authorisation number, medicinal product name, active substance, authorisation status, type of document protection (category and more detailed description), date granted, expiry date and authorisation holder.

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