## 1 What deadlines apply to an application to convert, extend or waive a temporary authorisation? Revised September 2023

The requirements of the guidance document *Temporary authorisation for human medicinal products* apply. These deadlines have now been harmonised and, in all cases, a **submission deadline of at least 90 calendar days before expiry of the temporary authorisation** applies.

## 2 Temporary authorisation procedure: which application type applies? Revised September 2023

This is an «OT Überführung befr. ZL in reguläre ZL HAM» application The fee is CHF 500 (item 9.3 of FeeO-Swissmedic). This application should be sent to Swissmedic together with the application for and documentation on the fulfilment of conditions at least 90 calendar days before expiry of the temporary authorisation (note in covering letter suffices, see Q&A no. 3 below). As a prerequisite for conversion, it must be possible for all conditions relating to the temporary authorisation to be removed.

## 3 What forms should be submitted to fulfil the conditions/convert a temporary authorisation/extend a temporary authorisation? Revised September 2023

No forms are to be submitted. Fulfilment of the conditions and conversion of the temporary authorisation – or an extension of the temporary authorisation if the conditions cannot fulfilled – should be applied for in the covering letter. The documentation submitted on fulfilment of the conditions must be listed in the covering letter. Please state the specific applications (incl. application IDs) in the subject line of the letter.

A detailed table setting out the individual conditions that have already been fulfilled must be submitted for the application for conversion of a temporary authorisation. This must include the relevant applications (application ID) and the date of the official decision.
When applying to extend a temporary authorisation, the interim reports submitted and other documentation (incl. reason for the extension) must be listed in the covering letter.

## 4 Is it true that the temporary authorisation is extended for the period taken to review the documentation on the fulfilment of conditions? Revised September 2023

Swissmedic may require more than the remaining time until expiry of the temporary authorisation to review the documentation on the fulfilment of conditions. It therefore extends the temporary authorisation as necessary following receipt of the documentation on the fulfilment of conditions. The marketing authorisation holder receives a letter confirming this.

## 5 Fulfilment of conditions and conversion – required modification of the medicinal product information texts: The data on the conditions and the conversion require modification of the medicinal product information texts. Does a type II, C.I.4 *Change in the product information and/or packaging texts due to new quality, preclinical, clinical or pharmacovigilance data* variation application have to be submitted for this in addition?

No. The modification of the medicinal product information texts is taken into account as part of the review of the documentation on fulfilment of conditions and the conversion, and does not require an additional variation application. However, the costs incurred in this regard are charged.

## 6 Can a temporary authorisation be converted to an export licence? New as of September 2023

**No**, this is not possible. Justification:

According to Art. 9*a* para. 1 let. c TPA, a medicinal product can only be temporarily authorised if "*no authorised, alternative or equivalent medicinal product is available in Switzerland*." The legislation therefore requires that there is no equivalent treatment alternative for the patients concerned and focuses here **on Switzerland**.



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**7 Conversion of a temporary authorisation is possible for medicinal product A. What does this mean for the equivalent medicinal products B and C, which also both have temporary authorisation? New as of September 2023**

The initial temporary authorisation granted for medicinal products B and C, which are equivalent to medicinal product A, can no longer be extended on application by the company.



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