Temporary Marketing Authorization –
Swissmedic Guidance Revised

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Swiss and EU law both provide a pathway for an accelerated access to market for medicinal products intended to meet unmet medical needs. In Switzerland, this pathway leads to a "temporary authorization" (TempMA), known in the EU as a "conditional marketing authorization." The content of the EU and Swiss provisions regulating the conditions for an accelerated access to the market are similar but not identical. Further, the success of respective applications is highly dependent on interpretation of the legal basis by the competent agencies (i.e., Swissmedic and the European Medicines Agency (EMA)), which may lead to different approaches and decisions.

In this article, we focus on the TempMA and the recent revision by Swissmedic, the Swiss Agency for Therapeutic Products, of its guidance for applicants, explaining the regulatory conditions for a TempMA (TempMA Guidance).[1]

The TempMA Guidance contains important information not only for pharmaceutical companies that intend to submit a respective application but also for all applicants with an innovative product. This is because Swissmedic may issue a TempMA under Article 9a of the Swiss Act on Therapeutic Products (TPA)[2] *ex officio*, that is, without and independent of a specific request, in cases where it considers that an applicant has not succeeded in fully documenting the quality, safety, and efficacy of its product and that a standard marketing authorization therefore cannot be granted but that the conditions of a TempMA may be fulfilled.

1. The Swiss Legal Background

Article 9a, paragraph 1 TPA reads,

> *The Agency may, in accordance with a simplified procedure under Article 14 paragraph 1, temporarily authorise medicinal products for life-threatening or debilitating diseases if:*
> *a. they are compatible with the protection of health;*

[1] The currently applicable TempMA Guidance can be found under this link. At the end of the TempMA Guidance, a change history allows readers to follow the revisions to the TempMA Guidance.
[2] Unofficial translation into English provided by the Swiss Federal Chancellery; official texts are the German, French, and Italian versions.

b. their use is expected to have a major therapeutic benefit; and
c. no authorised, alternative, or equivalent medicinal product is available in Switzerland.

As is usual for Swiss legislation, this principle, which is defined in the formal law, is specified in detail in an ordinance, in this case Article 18 of the Ordinance of the Swiss Agency for Therapeutic Products on the Simplified Authorization of Medicinal Products and the Authorization of Medicinal Products in the Notification Procedure (SAO)[3], which reads:

A medicinal product may be authorized for a limited period if:

a. *it is used for the detection, prevention, or treatment of a disease that can lead to serious disability, severe suffering with possible fatal consequences, or, in the short term, to the death of a patient or an animal;*
b. *no alternative and equivalent medicinal product is authorized or available in Switzerland;*
c. *a major therapeutic benefit is to be expected from its use;*
d. *the applicant is likely to be in a position to provide the necessary data within the meaning of Section 2 or Section 3 of the TPRAO;[4] and*
e. *the collection of all necessary data and the processing and evaluation of the data according to letter d within the framework of the ordinary authorization procedure according to Article 11 TPA would take so long that irreversible damage would occur or be exacerbated, or that this would be associated with severe suffering for the patient.*

Swissmedic published the TempMA Guidance mentioned above and maintains a respective website with Q&As.

2. Recent Revisions of the TempMA Guidance

Swissmedic revised the TempMA Guidance twice within the last six months, on September 15, 2023, and January 15, 2024. With these revisions, Swissmedic introduced clarifications with regard to the following criteria:

The key criterion to be met by an applicant for a TempMA is that there is no ***authorized, alternative***, and ***equivalent*** medicinal product available in Switzerland.[5]

[3] Only available in the official languages of Switzerland: German, French, and Italian; translation into English provided by Sidley.
[4] Ordinance of the Swiss Agency for Therapeutic Products on the Requirements for the Authorization of Medicinal Products (SR: 812.212.22).
[5] TempMA Guidance, Section 5.2, letter b.

A product is to be considered "authorized" according to Article 9a TPA only if it has been authorized based on a full documentation, either in a standard MA procedure or in a TempMA procedure, that has been converted into an ordinary MA based on a completed dossier. As a consequence, a TempMA may be issued even if a competitor with an alternative and equivalent product has already been granted a TempMA by Swissmedic.

Swissmedic assesses the criterion of "equivalence" on the basis of the products' "indication, target population, mechanism of action, ease of use (administration route, pharmaceutical form, dosage recommendation, availability, etc.), and/or the benefit/risk profile."

These updates of the TempMA Guidance may be decisive for applicants and should, therefore, be studied in detail before an application for a TempMA is submitted.

Further, applicants should consider that the maximum initial validity of a TempMA is two years. This is also the standard validity granted by Swissmedic. But Swissmedic is rather strict about prolonging the initial validity. Applicants for and holders of a TempMA should be aware that the initial validity of their TempMA cannot be extended if a competitor succeeds in completing the dossier of its product with a TempMA and having its TempMA converted into a regular MA by the time Swissmedic has to decide on an extension.

Last but by all means not least, there remains the question when these changes in Swissmedic's policy will become applicable. In principle, this will be instantaneous — as of September 15, 2023, and February 15, 2024, respectively. As far as newly issued TempMA are concerned, this is not objectionable. However, should Swissmedic apply these new conditions also to TempMA already issued at the above dates, this could severely infringe existing rights of the respective MA holders, notably with regard to the extension of the initial time limitation. Swissmedic's communication about the revision could lead to the conclusion that the agency intends to apply the new criteria to all existing and future TempMA. This may, however, only be due to the fact that Swissmedic at the time of the communication was not yet aware of the negative consequences for holders of TempMA already issued.

Pharmaceutical companies in the process of or intending to submit products under accelerated procedures for a temporary authorization in Switzerland and/or a conditional marketing authorization in the EU are well advised to be aware of the (new) differences between the Swiss and the EU conditions. Further, holders of TempMA that were issued before September 15, 2023, or February 15, 2024, should ascertain that their rights are not unduly restricted by a change in Swissmedic's policies.