

## Scope

Under Art. 21 para. 1 of COVID-19 Ordinance 3 (SR 818.101.24), Swissmedic can, during the process of reviewing authorisation applications and on the basis of a risk/benefit analysis, authorise deviations from the applicable legal requirements for medicinal products that are intended to prevent or combat COVID-19. The FAQs below are based on this provision of COVID-19 Ordinance 3 and apply generally to medicinal products intended to prevent or combat COVID-19.

**1. Is it possible to dispense with patient information on the basis of Art. 14 para. 2 TPLRO and only produce information for healthcare professionals instead?**

Yes, patient information can be omitted on the basis of Art. 14 para. 2 TPLRO. Information for healthcare professionals is sufficient.

**2. Will Swissmedic accept information for healthcare professionals that is entirely in English and in SmPC format?**

Yes, provided the medicinal product is only administered in hospitals or administration centres such as regional vaccination centres, neither additional translations in the official Swiss languages and TPLRO-compliant format nor structure are required.

**3. Will Swissmedic accept international versions (EU packaging) of English-language primary packaging?**

Yes.

**4. Will Swissmedic accept international versions (EU packaging) of English-language secondary packaging? Amended 19.11.2020**

Yes. However, within one year of Swissmedic's authorisation decision an additional sticker must be affixed to secondary packaging for Switzerland that states the authorisation number, the authorisation holder in Switzerland and the dispensing category.

**5. Will Swissmedic accept package leaflets with a QR code that takes users to the current approved version of the information for healthcare professionals?**

Yes. However, the QR code must be designed so that it leads users to the information for healthcare professionals approved by Swissmedic. Where electronic solutions such as these are used, information for healthcare professionals should ideally be available in all the official Swiss languages required by Art. 26 para. 2 TPO.

The information for healthcare professionals approved by Swissmedic should always (also) be published on <https://www.swissmedicin.ch>.

**6. Does Swissmedic insist on information for healthcare professionals being provided as a package leaflet with a QR code, or is it sufficient to have a QR code on the secondary packaging (e.g. folding carton), for example?**

A QR code on the folding carton is sufficient. See the answer to question 5 for further details of how QR codes should be implemented.

**7. Will Swissmedic accept patient information that is entirely in English and in SmPC format? New since 16 September 2021**

No, the patient information of medicinal products which are also dispensed to patients to take/use must be written in one of the three Swiss official languages according to Art. 26 para. 2 of the Therapeutic Products Ordinance (TPO SR 812.212.21) and comply with the format as stated in the Therapeutic Products Licensing Requirements Ordinance (TPLRO, SR 812.212.22). Exceptions are only possible in the exceptional situation of a pandemic when the medicinal

product will be administered exclusively by a doctor and adequate information for the patient is therefore ensured.

**8. Will Swissmedic accept the EU label?**

No, Swissmedic always carries out its own independent assessment. Accordingly, labels that deviate from EMA requirements are possible. However, Swissmedic is conducting a close scientific dialogue with its partner authorities, including the EMA, and will take appropriate account of the exceptional situation created by the pandemic in its decisions and in issues relating to labelling.

**9. For COVID-19 vaccines, does Swissmedic accept a QR code (with an appropriately registered and currently valid expiry date) instead of printed expiry dates on the folding carton or label? **New since 22 December 2020****

Yes. Since stability data are being obtained on an ongoing basis, Swissmedic accepts the registering of the (variable) expiry date on the folding carton or label by way of a QR code.