

1 Under the new law, do authorisations still have to be renewed every five years?

Medicinal products are initially authorised for a period of five years (Art. 16 para. 2 TPA). Five years after first authorisation, a once-only application for extension of authorisation must be made. Renewal is subject to ongoing fulfilment of the conditions for authorisation. Once renewed, authorisation is generally valid for an unlimited period (Art. 16b paras. 1 and 2 TPA).

However, this does not apply to medicinal products authorised under a notification procedure. Such products are deemed to be authorised for an unlimited period right from the time new authorisation is granted.

2 Does “renewal due” refer to the expiry date of the current authorisation or the time at which the renewal application is submitted?

“Renewal due” generally refers to the expiry date of the current authorisation. Renewal applications can be submitted no sooner than one year and no later than six months before the authorisation expires.

3 When should notification of discontinuation of authorisation be submitted? Is it possible to specify a particular date on which authorisation will be revoked?

Notifications of discontinuation must be submitted no later than two months before the date on which distribution is definitively discontinued. If the medicinal product is intended solely for paediatric use, notification must be given no later than three months before distribution is discontinued.

Notification of discontinuation can be combined with an application for a revocation order effective from a particular date (delayed revocation). The maximum delay that can be requested is one year. If the medicinal product’s authorisation expires in less than one year, the maximum delay in revocation is the expiry date of the authorisation.

4 From Swissmedic's perspective, what would be the correct procedure if a company decides to cease distribution of a medicinal product in, say, May 2019, but the last distributed batch does not expire until January 2022? According to the guidance document “Renewal and discontinuation of authorisation”, Swissmedic should be notified of discontinuation two months before distribution ceases. Is there a form for this? When should applications for a (delayed) revocation order be submitted?

Notification of discontinuation must be submitted two months before distribution ceases. There is no form. Applicants should simply submit a covering letter setting out the reasons for discontinuation. It is the marketing authorisation holder's decision whether it makes sense to apply for a revocation order effective from a particular date (delayed revocation). In the example given above (last distributed batch expires in 2022), this appears to be the case. However, revocation cannot be delayed for more than one year (in other words until May 2020 in the example above).

5 Will confirmation of authorisation still be sent when authorisation is renewed?

No. Swissmedic stopped automatically sending confirmation of authorisation on 1 January 2019. However, portal users can download an up-to-date confirmation at any time. Non-portal users can order the authorisation confirmation in return for payment of a fee.