# New Rules on the Validity of Marketing Authorisations for Medicinal Products

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The proposed new pharmaceutical legislation of the European Union introduces, among several other changes, amendments to the rules governing the validity of marketing authorisations ("MA") for medicinal products.

Pursuant to Article 24 of the current Directive 2001/83/EC, an MA is valid for a period of five years. This rule is subject to two exceptions:

- where the medicinal product is not effectively placed on the market in the Member State that granted the MA within three years of its granting; and
- where a medicinal product that has been authorised and placed on the market in the Member State that granted the MA ceases to be effectively marketed for a period of three consecutive years.

In both cases, the MA lapses upon expiry of the relevant three-year period.

Upon expiry of the five-year validity period, the MA may be renewed and, following such renewal, becomes valid for an unlimited period. This will not be the case only where the competent authority considers that, on pharmacovigilance grounds, the MA should be subject to a further renewal.

The proposed directive removes this initial five-year validity period and, consequently, the requirement for the MA holder to apply for renewal at the end of that period. Indeed, the proposal establishes that, as a general rule, MAs will be granted for an unlimited period. Accordingly, the current rule providing for a five-year validity period is replaced by a regime under which MAs are, in principle, valid indefinitely.

Nevertheless, this principle is subject to certain exceptions:

- where the MA holder has not provided complete data on the efficacy of the medicinal product, the validity of the MA will be limited to an initial renewable period of five years;
- the competent authority of a Member State may, when granting an MA and on medicinal product safety grounds, limit its initial validity to a period of five years.

In these cases, the MA holder may apply for renewal at least nine months before the expiry of the MA. Where the competent authority fails to adopt a decision in due time, namely before the expiry of the MA, the authorisation shall remain valid until completion of the renewal procedure.

Finally, the competent authority may renew the MA based on a reassessment of the medicinal product's benefit-risk balance. Where the MA is renewed following such reassessment, it will thereafter be valid for an unlimited period, unless otherwise decided by the competent authority.

It should also be noted that the proposal seeks to introduce greater flexibility into the mechanism under which an MA lapses if the medicinal product is not effectively placed on the market within a specified period following its granting, or if it ceases to be marketed for a consecutive period of three years. To that end, the wording of the proposed directive grants competent authorities a broader margin of discretion in the application of this mechanism, while maintaining the possibility of derogations on public health grounds.

## Thinking about tomorrow? Let's talk today.

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