INFORMATION NOTE FOR MA HOLDERS ON COMMUNICATIONS OF SHORTAGE AND TEMPORARY OR DEFINITIVE TERMINATION OF THE MARKETING OF MEDICINAL PRODUCTS

December 2025 update

On 18 December 2025, Law No 182 of 2 December 2025, the 'Simplification Law', published in the Official Gazette, General Series No 281 of 3 December 2025, laying down 'Provisions for the simplification and digitisation of procedures relating to economic activities and services for the benefit of citizens and businesses', entered into force.

Chapter II (Articles 58 to 63) contains Simplification measures in health matters. In particular, Article 61 'Provisions to combat shortages of medicinal products' provides as follows:

1. Legislative Decree No 219 of 24 April 2006 is amended as follows:

a) in Article 34, paragraph 6 is replaced by the following:

«***6. In the event of a temporary or permanent discontinuation of the marketing of a package of the medicinal product in the national territory, the MAH shall notify AIFA thereof. Such notification shall be made at least two months before the discontinuation of the marketing of the product, including in the event of a proven health emergency, and shall be renewed in the event of an extension of the period of discontinuation previously notified, except in the case of discontinuation due to unpredictable circumstances. The time limit does not apply to suspensions of marketing related to product safety reasons. The MA holder, even if the reasons for the interruption are exclusively commercial, shall inform AIFA of the reasons for such action, in accordance with the provisions referred to in paragraph 7»***;

b) in Article 148:

1. in the first sentence of paragraph 1, the words: «paragraphs 6 and» are replaced by: «*paragraph*»;

2. the following shall be inserted after paragraph 1:

«***1-bis. In case of violation of the provisions of article 34, paragraph 6, regarding packages present in a special list published and periodically updated by AIFA, containing the medicinal products for which specific measures have been adopted to prevent or limit shortage or unavailability, even temporary, on the market or in the absence of valid therapeutic alternatives, the MAH is subject to the administrative penalty from six thousand euros to thirty-six thousand euros.***

AIFA, in agreement with the health authorities and trade associations in the pharmaceutical and patient sectors, shall identify the criteria for the inclusion of the packaging of medicinal products in the list referred to in the previous period and for its periodic updating, at least annually»;

3) *omissis*.

Following the enactment of Law No 182/2025 and its recent entry into force, with this 'December 2025 update' of the 'Information note for MA holders on communications of shortage and temporary or definitive termination of the marketing of medicinal products', the Italian Medicines Agency intends to guide MA holders on how to apply the new provisions on notification of the temporary or definitive termination of marketing of a medicinal product in the national territory.[1]

Article 34(6) of Legislative Decree No 219/2006, as amended by Law No 182/2025, provides as follows:
«*6. In the event of a temporary or permanent discontinuation of the marketing of any package of the medicinal product within the national territory, the Marketing Authorisation Holder (MAH) shall notify AIFA accordingly. Such notification must be submitted at least two months prior to the discontinuation, including in cases of a proven health emergency, and must be renewed if the previously notified discontinuation period is extended, except where the discontinuation is due to unpredictable circumstances. This time limit does not apply to marketing suspensions related to product safety concerns. The MAH, even when the reasons for the interruption are solely commercial, shall inform AIFA of the underlying reasons for such action, in accordance with the provisions set out in paragraph 7.* This rule entered into force on 18 December 2025.

As a result of the amendments introduced by Law No 182/2025, notifications by MA holders pursuant to Article 34(6) must be made with at least two months' notice (no more than four months, as provided for in Decree-Law No 35/2019), now explicitly covering individual packages of medicinal products (nine-digit MAs) and not the six-digit MA and the scheme applies '*even in the event of a proven health emergency'.*

Infringement of the abovementioned provisions, in so far as they concern the packaging contained in a special list published and periodically updated by the AIFA, containing the medicinal products for which specific measures have been adopted to prevent or limit shortages or unavailability, even temporary, on the market or in the absence of valid therapeutic alternatives, entails the application of the administrative penalty, pursuant to Article 148(1-bis) of Legislative Decree No 219/2006, introduced by Article 61 of Law No 182/2025, *"from six thousand euros to thirty-six thousand euros".*

Pending the adoption of the list referred to in Article 148(1-bis) of Legislative Decree No 219/2006, MA holders are still required to comply with the reporting obligation referred to in Article 34(6).

INFORMATION FOR MA HOLDERS

In the event of a temporary or permanent discontinuation of the marketing of a medicinal product within the national territory, the MAH must submit to AIFA, at least two months prior to the planned date of discontinuation—or prior to any extension of the previously communicated discontinuation period or the deadline for the planned resumption of marketing—a specific notification. This

---

According to the shared definition set out in the *Guidance on detection and notification of shortages of medicinal products for Marketing Authorisation Holders in the Union (EEA)* adopted by HMA and EMA (EMA/674304/2018 of 1/07/2019), "*a shortage of a medicinal product for human or veterinary use occurs when supply does not meet demand at a national level".* The shortage must allow the identification of a current, impending or anticipated disruption of supply of a medicinal product. Link:
https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guidance-detection-notification-shortages-medicinal-products-marketing-authorisation-holders-mahs_en.pdf

requirement does not apply in cases of interruption due to unpredictable circumstances; however, such cases must still be communicated promptly, providing the information specified below.

Temporary or permanent discontinuation of marketing leads to a shortage of a medicinal product when availability does not meet demand at the national level.

The obligation under Article 105(4) of Legislative Decree No. 219/2006 remains in force for the MAH to supply, within 48 hours and upon request from pharmacies—including hospital pharmacies—or points of sale of medicinal products referred to in Article 5 of Decree-Law No. 223 of 4 July 2006, converted with amendments into Law No. 248 of 4 August 2006, any medicinal product that is unavailable within the regional distribution network. To ensure continuity of treatment, the MAH must adopt appropriate organisational and logistical measures to guarantee compliance with this supply obligation.

I. Methods and content of the communication

To fully comply with the communication obligations and the new notice periods set out in Article 34(6) of Legislative Decree No. 219/2006, as amended by Law No. 182/2025, and to avoid incurring the administrative penalty referred to in Article 148(1-bis) of the same Decree, the MAH must submit, through the channels indicated below, a communication containing all the information specified herein. Incomplete communications—i.e., lacking one or more of the required elements—will be deemed non-compliant and therefore unacceptable, unless they are promptly completed within the prescribed notice periods.
Notices from MA holders concerning the temporary or definitive discontinuation of the marketing of a medicinal product or any other information that may have direct or indirect relevance to current or impending shortages or anticipate the occurrence of a shortage of one of their medicinal products shall mandatorily include the following elements:

a) trade name of the medicinal product, active ingredient, pharmaceutical form and dosage, packaging, marketing authorisation number and trade name of the marketing authorisation holder; (mandatory)

   N.B. The term "medicinal product" refers to a specific package or to the 9-digit MA. In the event of missed or late notification of several packages of the same MA or of different MAs, the PQ-PhCC Office will contest and apply the penalty provided for in Article 148(1-bis) of Legislative Decree No 219/2006 for each package.

b) start date of discontinuation of marketing or of the anticipated shortage; (mandatory)
c) reasons for discontinuing marketing, with a detailed description of the event or reasons (“root cause”). To allow the correct assessment of the "unpredictability" of the circumstances underlying the discontinuation of the marketing of the medicinal product, the MAH shall provide a detailed description of the event or reasons ("root causes"), attaching - where deemed useful - the relevant supporting documentation, which may be available (for example, statements from raw material suppliers); (mandatory)
d) the expected duration and date of the presumed re-marketing (in the case of temporary disruptions); if the marketing authorisation holder is unable to provide a re-marketing date, the marketing authorisation holder is required to communicate, at least indicatively, the period during which the medicinal product will not be available. If the MA holder is unable to provide either of the above information, a statement of reasons must be provided.

e) only after a formal notification has been sent by the MA holder, after verification of the conditions necessary for the effective reinstatement of the marketing of the medicinal product, will AIFA be able to consider that the shortage of the medicinal product has been resolved; (mandatory)

f) any updates (e.g. in the event of a temporary interruption, the extension of the period of non-marketing or the postponement of the expected date of resumption of marketing previously communicated, without prejudice to the obligation to comply with the two-month notice period); (mandatory)

g) where possible, distribution channels affected by the marketing discontinuation; (mandatory)

h) if possible, based on the information in its possession, the MAH must indicate:

i. the existence of equivalent medicinal products; (mandatory)

ii. details of any equivalent medicinal products available; (optional)

iii. in the absence of equivalent medicinal products, the existence of therapeutic alternatives; (optional)

details of any therapeutic alternatives available; (optional)

i) any information on the use of the medicinal product (e.g., off-label use, use in special populations, etc.); (optional)

j) indications regarding any ownership of a similar medicinal product marketed abroad (mandatory); an indication of the countries where the medicinal product is marketed is optional;

k) where possible, indications regarding the possible availability of the MAH to import from abroad; (mandatory)

l) indication of the possible impact of the discontinuation of marketing in other countries (please list the countries concerned); (optional)

m) information on the quantities ('stocks') in stock at the date of the notification; (mandatory)

n) information on the coverage of needs in the period of notice, indicating whether the coverage of that period will be guaranteed by the packages in stock at the date of communication and/or by further supplies planned for the same period; provide details of the dates of any planned supplies; (mandatory)

o) sales data (per month), both for the retail channel and for the hospital channel, relating to the 24 months before the communication; (mandatory)

p) indication of a contact point of the company, with email address (PEC-certified email) and direct telephone number of a contact person (mandatory).

Notices of shortage/ceased marketing of medicinal products marketed in Italy must be sent using one of the following methods:

- through the specific application 'Front End Carenze'(https://www.aifa.gov.it/front-end-carenze-fec-per-i-titolari-di-aic), active since 05/11/2020;
- by certified e-mail to farmacicarenti@pec.aifa.gov.it.

The submission of information via the application "Front End Carenze" or by certified email completely replaces the submission in paper form. The contact persons of the MAH in charge of managing communications relating to shortages and discontinued marketing must register with the AIFA online services portal.

II. Non-compliant or late notifications

Incomplete communications lacking one or more of the elements indicated in paragraph I shall be considered non-compliant and, unless they are promptly integrated, are considered equivalent to missed communications.
Communications submitted after the deadlines provided by the legislation shall be considered late.
In both cases, the penalty provided for in Article 148(1-bis) of Legislative Decree No 219/2006 will be applied for infringement of Article 34(6) (see paragraph IV below).
Communications with general reasons (e.g. production problems, delays in supply) will not allow the application of the unpredictability criteria ("unpredictable circumstances") set out in paragraph III below.

III. Criteria for the definition of unpredictable circumstances

The following table lists, but is not limited to, events classified as 'predictable' and 'unpredictable', which may lead to the discontinuation of marketing:

Event	**Predictable**	**Unpredictable**
Delays in API supplies, excipients and/or packaging materials	Yes, if linked to incorrect programming	Any unexpected event occurring at the supplier's site (e.g., a disruption at the API production plant where the supplier is the sole source) must be documented, even if only through a self-certification by the MAH
Delays/problems in finished product supplies	Yes, if linked to incorrect programming	Any unexpected event occurring at the production site (e.g. a disruption in the production line/equipment – sole manufacturer) must be documented, even if only through a self-certification by the MAH
Revamping/equipment replacement	**Yes**	Yes, if linked to activities necessary for the resolution of deviations found during GMP inspections
Regulatory issues: variations pending (e.g., formulation modifications, manufacturing site modifications, etc.)	**Yes**	Yes, if related to activities necessary for the resolution of deviations found during GMP inspections or to urgent and restrictive measures and/or safety of the Authorities
Quality defects	Not applicable	Yes
Increased demand for the medicinal product caused by a shortage of equivalent or similar medicinal products or for particular contingent situations (e.g., influenza peaks, epidemics)	Not applicable	Yes, to be documented by means of a brief explanatory scheme attesting to the increase in demand.

IV. Administrative penalty

Pursuant to Articles 34(6) and 148(1-bis) of Legislative Decree No. 219/2006, and considering the impact on patients' health caused by shortages of medicinal products within the national territory, any failure to provide communication or any communication that does not comply with the terms and conditions set out above will result in AIFA, following a specific procedure, applying the relevant measures and imposing the administrative penalty provided for under Article 148(1-bis) of Legislative Decree No. 219/2006.

Failure to provide notification will result in the imposition of the maximum penalty set out in Article 148(1-bis) (€36,000). In the case of late notification, the interim penalty (€18,000) will apply, without prejudice in both cases to the provisions on reduced payment pursuant to Article 16 of Law No. 689/1981. Once the deadline for reduced payment has expired, AIFA will issue a payment order against the MAH.

The information communicated to AIFA in the context of this procedure constitutes a self-certification as provided for under Presidential Decree No. 445/2000. Consequently, pursuant to Articles 75 and 76 of the aforementioned Presidential Decree No. 445/2000, any false statements made to the Public Administration constitute a criminal offence and also result in the loss of the benefit obtained (in this case, the exemption from payment of the reduced administrative penalty).