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Good Practices for early management of a marketing suspension and/or a withdrawal of marketing authorisation for a veterinary medicinal product

1. Regulatory bases:

European Regulation 2019/06, Article 58-13, responsibilities of Marketing Authorisation Holder (MAH):
The MAH shall without delay inform the competent authority which has granted the Marketing Authorisation or the Commission, as applicable, of any action which he intends to take in order to cease the marketing of a veterinary medicinal product prior to taking such action, together with the reasons for such action.

Article L. 5141-5-2 of the French Public Health Code:
The MAH shall inform the French Agency Anses-ANMV, in advance or in an emergency at the same time, of any action it takes to suspend marketing, to withdraw from the market or recall a specific batch as well as of any risk of shortage of a veterinary medicinal product, which could lead to a risk to human health, animal health or animal welfare.
The procedure for making the declarations provided for in Article 58 of Regulation (EU) 2019/6 of 11 December 2018, is laid down by decision of the General Director of the Anses.

2. Definition and context:

A marketing authorisation withdrawal is defined as the decision of the MAH, to no longer maintain the marketing authorisation for a veterinary medicinal product (VMP) and consequently to no longer market it in France. A marketing suspension preceded generally the proposed withdrawal of marketing authorisation.

A marketing suspension is defined as a voluntary and sustainable shutdown of the distribution of the VMP on the national market, which distinguishes it from a supply disruption/shortage.

In both cases, the consequence is the cessation of the availability of a VMP in France.

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The MAH or his representative in France (Responsible of the Marketing in France) must therefore inform the Anses-ANMV before ceasing to market its veterinary medicinal product, whether or not it ultimately leads to the withdrawal of the MA, and specify the reasons for doing so.
This declaration will help to anticipate, and if possible prevent, major problems of availability on the market, i.e. a potential therapeutic gap and/or periods of cascading shortages of other veterinary medicinal products.
The recommended notice period is 12 to 24 months before any marketing discontinuation, whether or not it precedes a future withdrawal of marketing authorisation.
For this information, the MAH/RMF will use the "declaration of suspension of marketing and/or withdrawal of marketing authorisation for a VMP" form, drawn up in partnership between Anses-ANMV and SIMV (union of the French veterinary medicine industry).

The criticity of a proposed withdrawal of marketing authorisation and/or suspension of marketing for the veterinary therapeutic arsenal will be based on a risk analysis to be carried out by the MAH/RMF and then to be evaluated by the Anses-ANMV. It will be based in particular on the following criteria:
- market share of the medicinal product, quantity of product sold at the time of the notification ;
- other VMPs available on the French market for the indications and species concerned (as well as their respective market shares and quantities sold at the time of the notification if necessary);
- reasons for the suspension of marketing or withdrawal of the marketing authorisation;
- frequency and severity of diseases treated or prevented by the VMP... ;
- economic importance for the animal sector concerned.

These Good Practices (GP) do not concern disruptions in market supply/shortages, of any length, as long as it is not a voluntary and sustainable cessation of market supply.
They have been drawn up in conjunction with the SIMV with the general aim of promoting the maintenance and availability of VMPs on the French market, in compliance with regulation 2019/06.

These GPs therefore define the roles to be played by each of the actors in order to anticipate and prevent as far as possible the consequences of a marketing suspension and/or a proposed withdrawal of marketing authorisation.

They therefore mainly concern the research and implementation by the MAH and the Anses-ANMV of solutions designed to avoid or limit the potential consequences of the discontinuation of the marketing of the VMP in the field.

They therefore specify the actions to be taken by each party in order to:
- know and correctly assess all the consequences of the suspension of marketing and/or the withdrawal of marketing authorisation on national territory, and identify alternatives,

- define the minimum deadlines and supplies that should be guaranteed before marketing suspension or withdrawal of marketing authorisation, in order to avoid the consequences of excessively abrupt cessation.

2. Actions to be taken by the various stakeholders

2.1. *MAH and/or RMF*

- Notify the Anses-ANMV of the planned suspension of marketing or withdrawal the marketing authorisation as far in advance as possible, possibly 12 to 24 months before the last batches are no longer marketed. This declaration use the corresponding declaration template available on the Anses website, sent to defauts.qualite@anses.fr and enreg@anses.fr in copy for information.

- Assess beforehand all the direct and indirect impacts of the abrupt marketing cessation of the VMP on the French market (indications, species).

Where a significant impact on the market is identified* :
- Seek all possible alternatives and propose them to the Anses-ANMV.
- Define a gradual cessation of the production and the distribution of the VMP as necessary, in order to limit the consequences of discontinuation if it is deemed unavoidable.

NB: The information examined and provided to Anses-ANMV in the MAH's declaration is proportional to the potential impact of discontinuing the product, linked primarily to its market share for the target species and indication(s).

**Other than estimated low on the declaration form*

These advance declarations do not replace the official notification to the ANMV (enreg@anses.fr) of the withdrawal of marketing authorisation, which must then be made in the month preceding the exact date of withdrawal.

2.2. The Anses-ANMV

- Review the notification and validate the potential impact indicated by the MAH and, if necessary, confirm the critical/impacting nature of the suspension of the marketing or the withdrawal of marketing authorisation.
  Where a significant impact on the market is identified* :
  o Continue to work with the notifying pharmaceutical laboratory to search alternative solutions.
  o Evaluate the transitional period for the making available of the last batches on the market, before stopping marketing and/or introducing an alternative VMP.
  o Evaluate without delay any requests for Temporary Use Authorisation and import which may constitute a transitional measure, as well as any requests for a specific batch release made by the MAH before the product is discontinued.

  *Other than low on the declaration form

- In the event of an abandonment project of the MA, forward the information to the SIMV in order to facilitate a possible transfer of the MA.

2.3. The SIMV

Implement a platform for the MA transfer from the MA holder to another holder interested in acquiring it.

3. Communication

The projects to discontinue marketing authorisations will be communicated to the SIMV after approval by the TAMM/RMA.

The most significant/critical marketing discontinuations will ultimately also be communicated on the Anses-ANMV website, in the same way as critical shortages.

Previously, each party undertakes to maintain the confidentiality of the data exchanged.