

Veterinary Medicines Products Shortages state of play and management in France

HMA/EMA multi-stakeholder workshop on shortages - veterinary break-out session

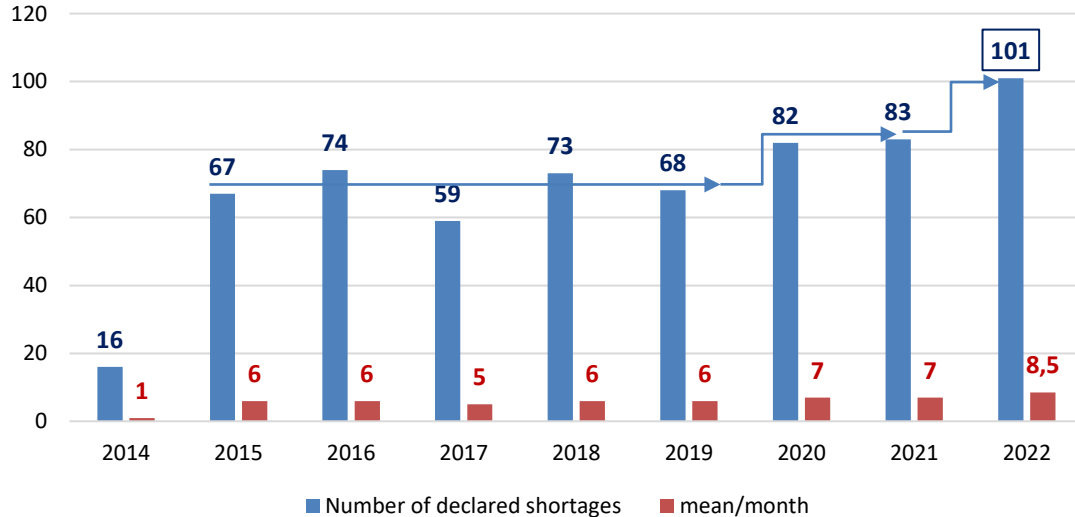
ANMV - Paule Carnat-Gautier

1. Data and shortages trends



Evolution of declared shortages

Declared shortages 2014-2022

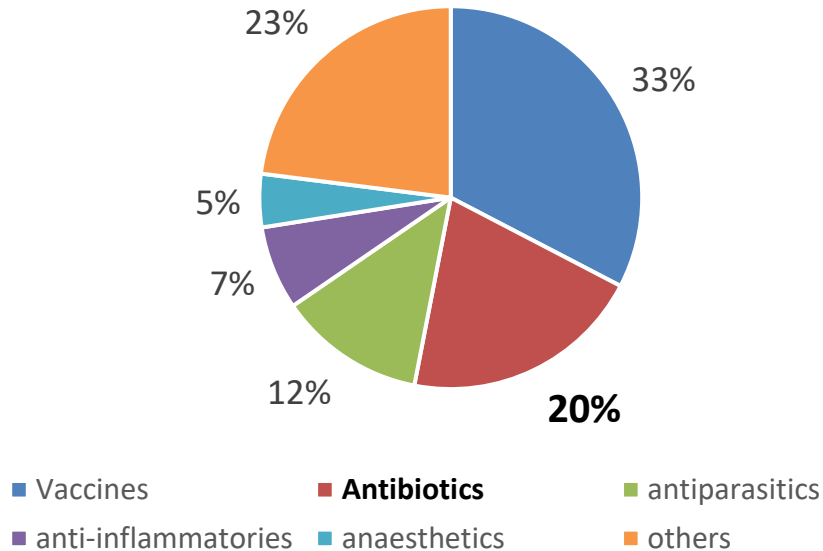


Effective shortage : no units of VMPs available in the distribution channel

An increase is noted in 2020 / 2022 whereas the declarations were relatively stable before.

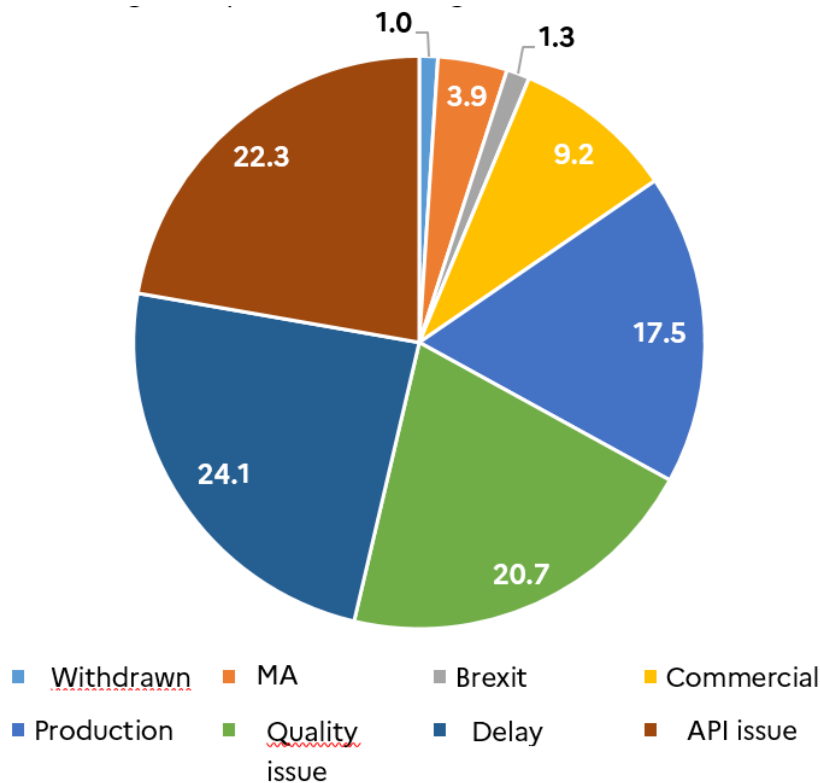
Shortages and therapeutics classes

Categories of VMPs 2014-2022 (622 cases)



The declarations of antibiotic shortages (20%) come just after those of vaccines, but are generally not considered as critical so far because alternatives are usually still available

Origine of shortages



1. Delay

API supply, manufacturing, sub-contractors

2. API supply

GMP certificates, export restrictions, lack of suppliers

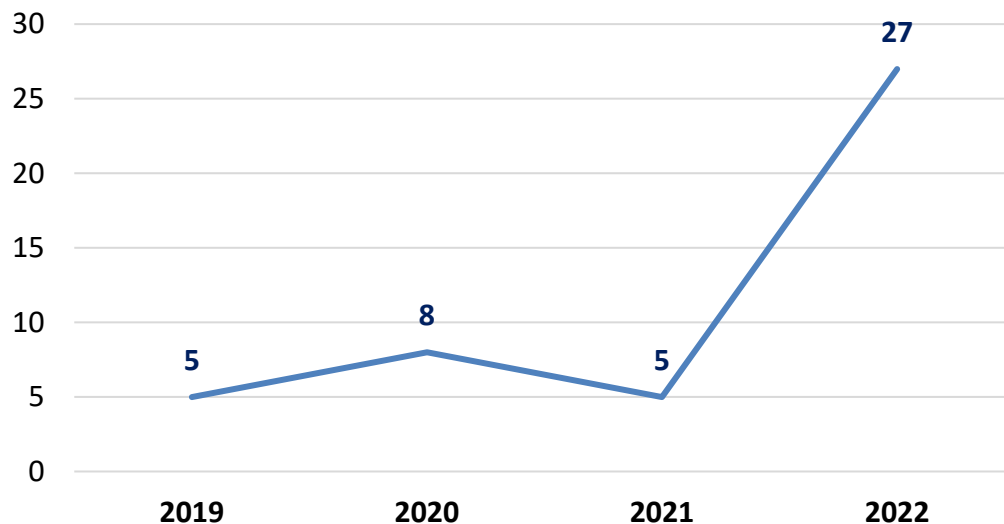
1. Quality issue

Impact on batch release



Evolution of critical shortages

Number of critical shortages communications published in the Anses website

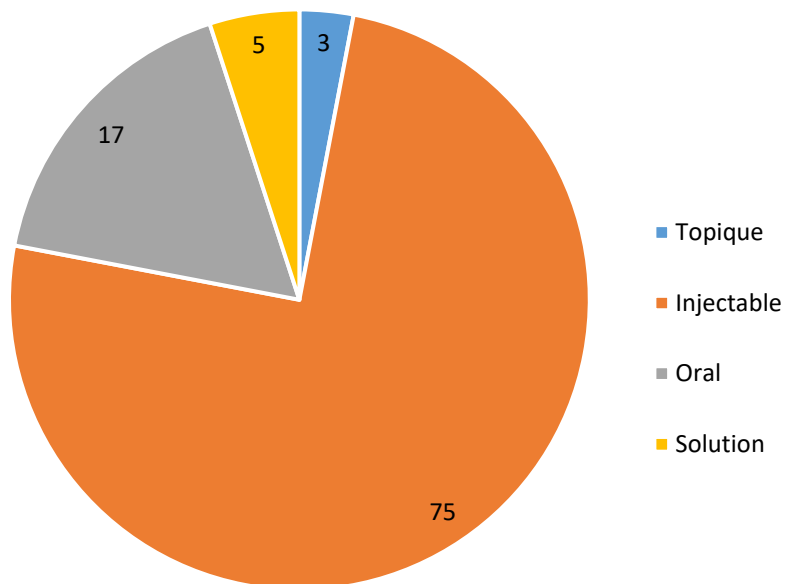


Critical shortage : potential risk for public health or animal health

A great increase is observed in 2022, essentially due to critical shortages of vaccines.



Critical shortages



Injectable pharmaceutical form has the most important critical shortages.

- Vaccines : 53%

Critical as few alternative available

- Antiparasitics : 9%

- Antibiotics : 5%



2 Shortages management



Shortages management

Working group

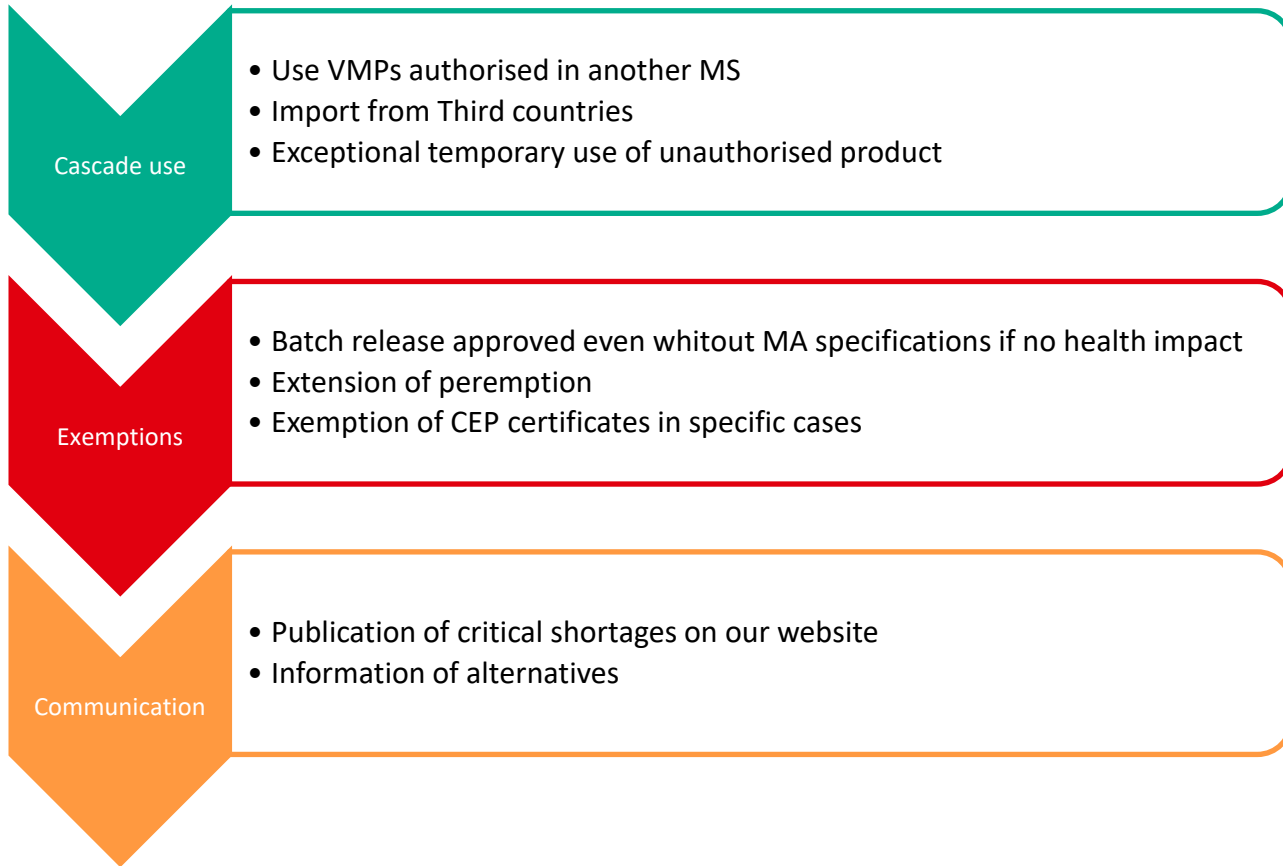
- Octobre 2017
- multiskateholders : veterinarians, wholesalers, MAHs

Legal obligation

- Declaration of effective and potential shortage by MAHs : online application
- Assessment by the competent authority, search of alternatives
- Publication of critical shortages on the agency website

Pilot phase

- 2018-2021
- Good practices in 2018 :
 - definition of a critical VMP shortage
 - roles of each actor (Agency, pharmaceutical company, wholesale distributor, veterinarians)



Thank you