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Post-MA surveillance of veterinary medicinal products

2018 Annual report

October 2019 - Scientific Edition

Authors: French Agency for Food, Environmental and Occupational Health & Safety (ANSES) - French Agency for Veterinary Medicinal Products (ANMV)
Jean-Pierre ORAND, Mickaëlle SACHET, Sylviane LAURENTIE, Gregory VERDIER, Flore DEMAY, Nathalie LEGRAND, Delphine BARBOT

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POST-MA SURVEILLANCE OF VETERINARY MEDICINAL PRODUCTS
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A/ Introduction

The French Agency for Veterinary Medicinal Products (ANSES-ANMV), part of ANSES, is the competent authority for the assessment and management of risks associated with veterinary medicinal products in France. Its missions are structured around three themes: assessment, authorisation and surveillance. Its task is to ensure that prescribers and animal owners are provided with veterinary medicinal products that are **safe, effective and of good quality**.

To do this, it assesses national or European marketing authorisation applications for veterinary medicinal products and takes part in the assessment of European dossiers on maximum residue limits (MRLs) of veterinary medicinal products in foods of animal origin.

It grants marketing authorisations for medicinal products, and authorises clinical trials of these products and the opening of pharmaceutical establishments (operators, wholesalers, manufacturers, exporters and/or importers of veterinary medicinal products). It certifies imports and exports of veterinary medicinal products.

It monitors the risk of adverse effects resulting from the use of veterinary medicinal products, as well as problems of availability on the French market. It controls quality through testing, assessments of quality defect reports and advertising of veterinary medicinal products. The Agency also monitors the operation of veterinary pharmaceutical establishments.

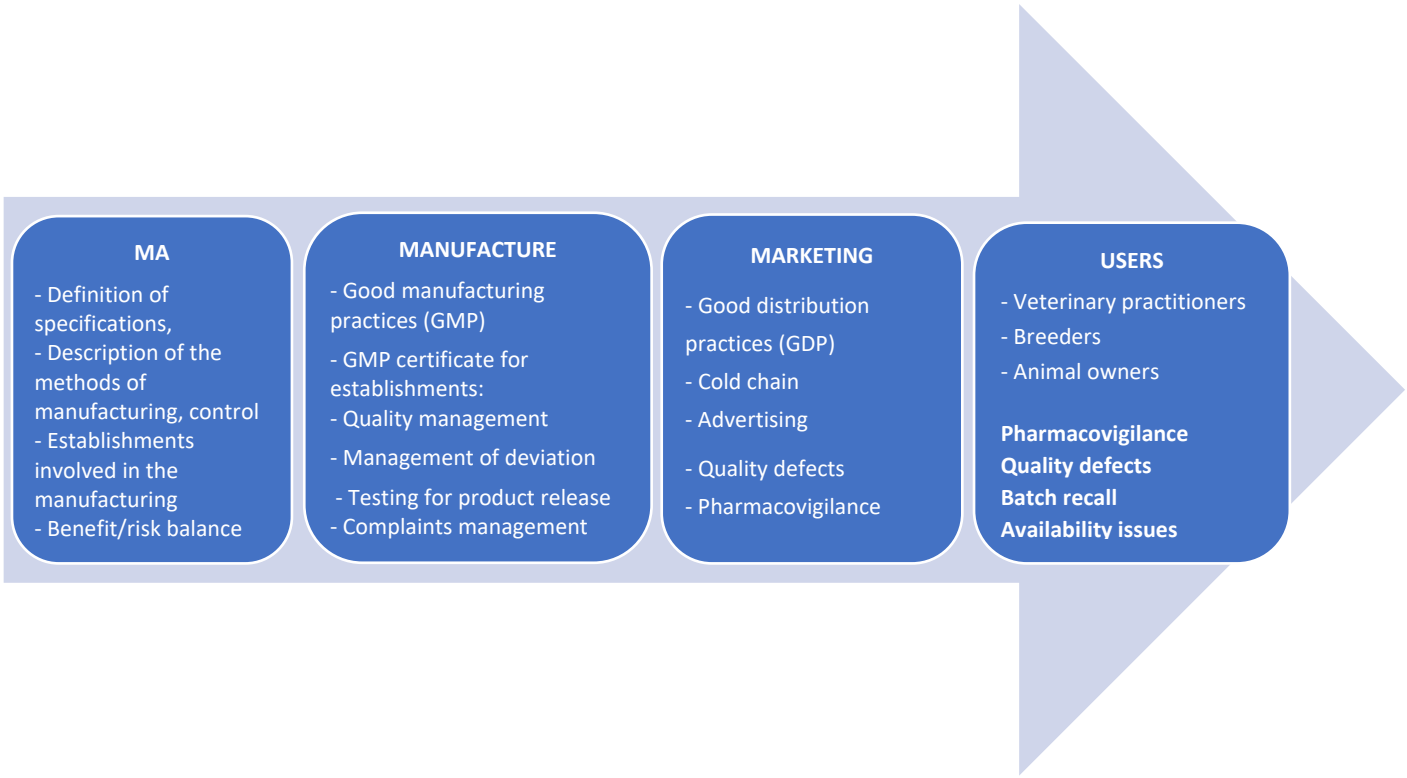


Figure 1: The veterinary medicinal product lifecycle

Surveillance of veterinary medicinal products once they have been granted authorisation involves:

- Inspecting veterinary pharmaceutical establishments to ensure they manufacture good quality medicinal products;
- Monitoring the quality of veterinary medicinal products through expert appraisals and management of quality defects, analytical control of veterinary drugs, and verification of labelling and advertising;
- Monitoring of adverse effects through veterinary pharmacovigilance.

This report covers all the results for 2018 related to the surveillance of medicinal products.

B/ Inspection of veterinary pharmaceutical establishments

As of 31 December 2018, 507 veterinary pharmaceutical establishments possessed an "authorisation to open" for one or more activities. Apart from establishments in charge of medicated feedingstuffs, whose numbers fell by about fifteen, an increase in the number of "operator" establishments was noted in 2018. Numbers of the other categories of establishments were stable compared to 2017.

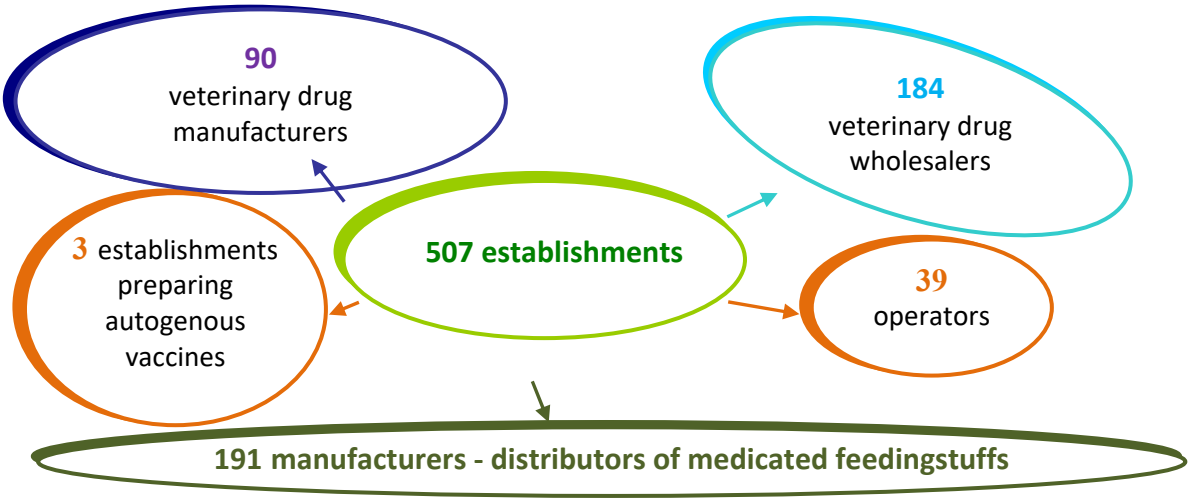


Figure 2: Breakdown of veterinary pharmaceutical establishments authorised in France in 2018, according to their main activity

To guarantee the quality of veterinary medicinal products, the surveillance scheme relies on inspections by ANSES of veterinary pharmaceutical establishments, which ensures compliance with the good practices inherent in their activity and enables them to maintain their certification.

With regard to the administrative management of establishments, the key figures were as follows:

- 22 opening authorisation applications,
- 70 amendment applications,
- 9 transfer applications,
- 22 closures,
- 2678 certificates for export of veterinary medicinal products.

In 2018, 71 establishments of all categories were inspected, compared to 63 in 2017. This inspection rate ensures compliance with regulatory inspection frequencies and means that the validity of certifications issued for veterinary pharmaceutical establishments is kept up to date. It also includes missions designed to meet unexpected requests for urgent health inspections or investigations: eight such inspections were carried out in 2018. Lastly, five inspections were carried out in Third Countries at the request of the EMA or French manufacturers.

As part of veterinary drug research and development, 32 establishments are enrolled in the "Testing Facility" programme. Nine of them underwent a good laboratory practice (GLP) inspection. The purpose of these inspections is to verify the good practices followed when carrying out laboratory tests. These tests primarily help guarantee the safety of the veterinary medicinal products tested.

No formal notice was served in 2018 for establishments inspected by ANSES-ANMV inspectors.

The 2018 inspection report showed some deviations among manufacturers, mainly with regard to the writing of subcontracting contracts, the validation of cleaning processes and the control of cross-contamination. Regarding operators and wholesalers, there has been a clear improvement in cold-chain control and quality risk management. However, efforts need to continue. Management of complaints in these categories of establishment still requires vigilance.

During 2018, as part of implementation of the inspection plan, work continued to train and accredit four inspectors after a period of supervision. In 2019, this supervision will be continued, particularly for a recently recruited inspector.

From 5 to 9 November 2018, the French Agency for Veterinary Medicinal Products hosted a team of three inspectors within the framework of the Heads of Medicines Agencies (HMA) Joint Audit Programme (JAP). This is a European audit between competent authorities within the network of human and veterinary agencies covering the fields of inspection, quality control of veterinary medicinal products (including quality defect management and batch recalls) and export certification. The audit team consisted of two assessors working in human medicine agencies (Greek and British) and one from the Hungarian veterinary agency. The audit programme is designed to ensure an adequate level of inspection systems in the various Member States and to renew confidence in the equivalence of inspections between Member States of the European Union.
In addition, three inspectors from the Food and Drug Administration of the United States of America (US-FDA) attended this audit as observers, as part of implementation of the mutual recognition agreement between the European Union and the United States of America, the scope of which is expected to be extended to chemical veterinary drugs in late 2019.
This major agreement between the European Union and the US-FDA updates the historic 1998 text and strengthens relations on both sides of the Atlantic, with a view to better streamlining the resources devoted to inspections and deploying more resources to other regions of the world where active substances and medicines are produced. It will enable recognition of inspection missions and authorisations of pharmaceutical establishments manufacturing veterinary medicinal products between the countries of the European Union and the United States. It will increase access to high-quality, safe and effective medicines regardless of where they are manufactured and will make it easier to prioritise inspections of the highest risk sites.

This exercise was carried out in two parts, beginning with a review of the 78 European indicators by two European auditors and two FDA observers. This review took place on the Agency's premises and required an intense preparatory phase to complete a questionnaire. Then, the second part involved an on-site industrial inspection, with a team of two inspectors from the Agency, a European auditor and an FDA observer. The results of this audit were very positive since no critical deviations were mentioned, although some areas for improvement were proposed. This audit highlighted the quality of the Agency's work and the robustness of our system.

C/ Market surveillance

C1 – Quality defects

In 2018, 88 quality defects were recorded. This number is similar to that reported in previous years. As in previous years, the primary cause of the reported quality defects related to administrative measures (31%). These concerned medicinal products that were on the market but whose labelling no longer complied with their marketing authorisations following changes to their dossier information (for instance, an amendment to specifications such as withdrawal time or shelf life). Problems with level of active ingredient, package label and leaflet errors, and non-compliances concerning physico-chemical specifications other than those concerning the active ingredient were the other three main causes of quality defects and covered nearly 90% of them. The breakdown of quality defects is shown in the figure below:

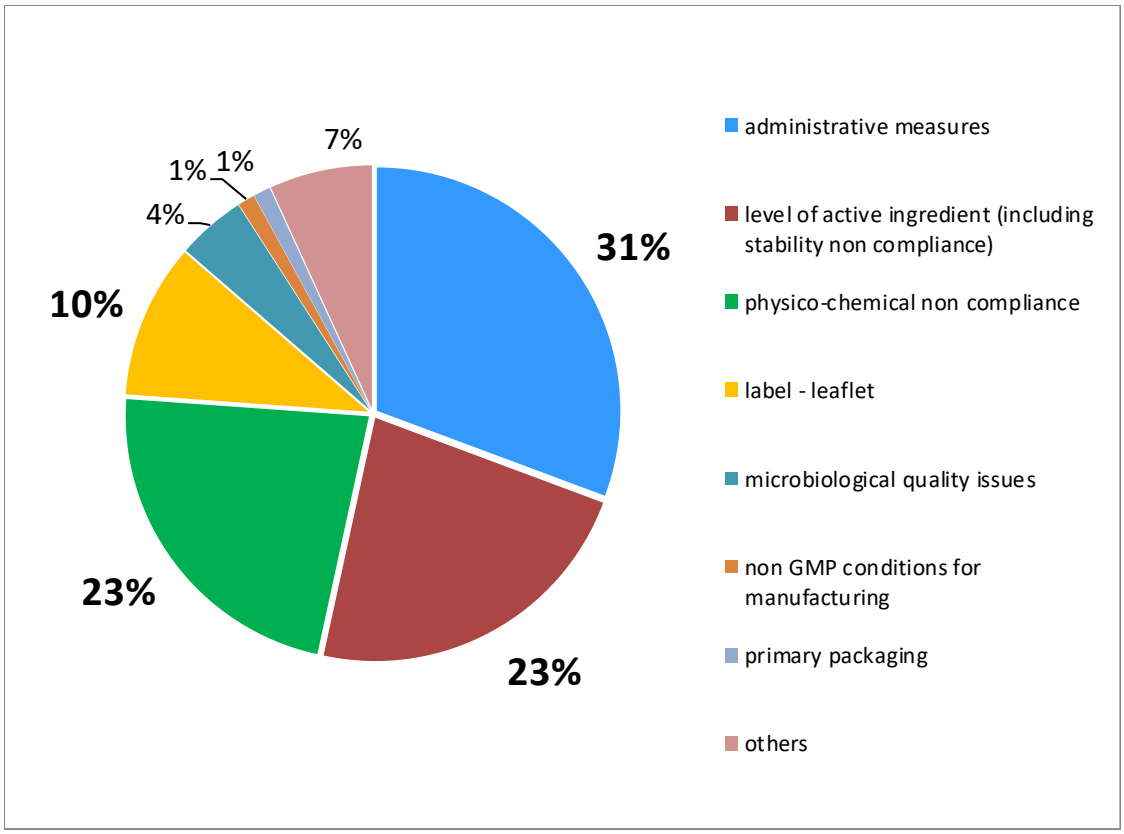


Figure 3: Breakdown of quality defects monitored in 2018 (n=88) by non-compliance type

The quality defects recorded in 2018 led to 34 batch recalls, an equivalent number to that of 2017 (26 recalls) and 2016 (32 recalls). Seventeen batch recalls took place at the manufacturer-depositary level, 14 at the wholesaler level and three at the retail level.

In 2017, ANSES-ANMV was an active participant in the European working group aimed at harmonising quality defect management and batch recall practices in the various Member States. This work continued in 2018 with the implementation of a shared quality defect rating tool largely inspired by the system already in place in France for the past few years. The ANSES-ANMV Market Surveillance Unit (USM) was also actively involved in the documentary review for the guideline on quality defect management and the early warning system.
Quality defect management was also included in the scope of the JAP audit that took place in the Inspection Unit in November 2018. No specific comments were made on the management of quality defects, and suggestions for improvement were made.

C2 – Analytical control of veterinary medicinal products

Quality control of veterinary medicinal products involves analytical control of selected drugs according to an annual programme.
A rating grid for veterinary medicinal products is now available in Europe for classifying these products in terms of risk level. This rating grid is currently being tested for drugs with a centralised MA.
At the Agency, the tool has been adapted to classify all veterinary medicinal products marketed in France. Six parameters were initially selected for assessing the risk level of the drug in question. The six rating criteria, leading to a unit increment in the score, are as follows:

- route of administration (parenteral or ocular);
- chronic use (≥ 1 month);
- low dose or concentration (≤ 2 mg or 2%);

- complex formulation (more than one active ingredient or "emulsion" or "suspension");
- product sensitivity regarding its stability (shelf life of 1 year or less or storage below 15°C);
- product intended for livestock.

The drugs identified as most at risk were given priority by ANSES-ANMV's analytical laboratory in the annual veterinary drug control programme.

In 2018, 74 veterinary medicinal products sampled from the French market were tested, representing a total of 248 analyses. Eight non-compliances with the MA specifications were detected, accounting for 12.9% of the drugs in the programme. The non-compliances were mainly related to the concentration of the active ingredient, tablet breakability, re-suspension and uniformity of mass with oral pastes. There was an increase in non-compliances compared to 2017, linked to a multiplicity of dosage forms introduced in the 2018 programme.
The implementation rate for the annual programme was 98%.
The laboratory is part of the European network of Official Medicines Control Laboratories (OMCL network). In 2018, it was not asked to analyse medicines taken from other European markets at the request of other OMCLs.

C3 – Verification of labelling

Control of the sampled veterinary medicinal products also involves verifying their labelling.
In addition to the veterinary medicinal products verified in the laboratory, 54 controls were performed following specific sampling: monitoring of minor changes to the MA, follow-up of non-conformities from 2017, and/or controls at the request of the MA Department. These tested labels were found to be compliant. Only three labelling non-compliances were detected when checking veterinary medicinal products analysed in the laboratory, and none on products taken from distribution sites.
Changes demanded during the previous year were effectively implemented by the laboratories within six months of notification.

C4 – Control of advertising

The advertising of veterinary medicinal products is regulated by the French Public Health Code (CSP)[1]. It can only relate to authorised veterinary medicinal products. Advertising to the public is only permitted for non-prescription medicinal products.
In 2018, 589 advertising applications led to 1229 advertising tools needing to be verified.

[1] CSP Article R. 5141-82 *et seq.*

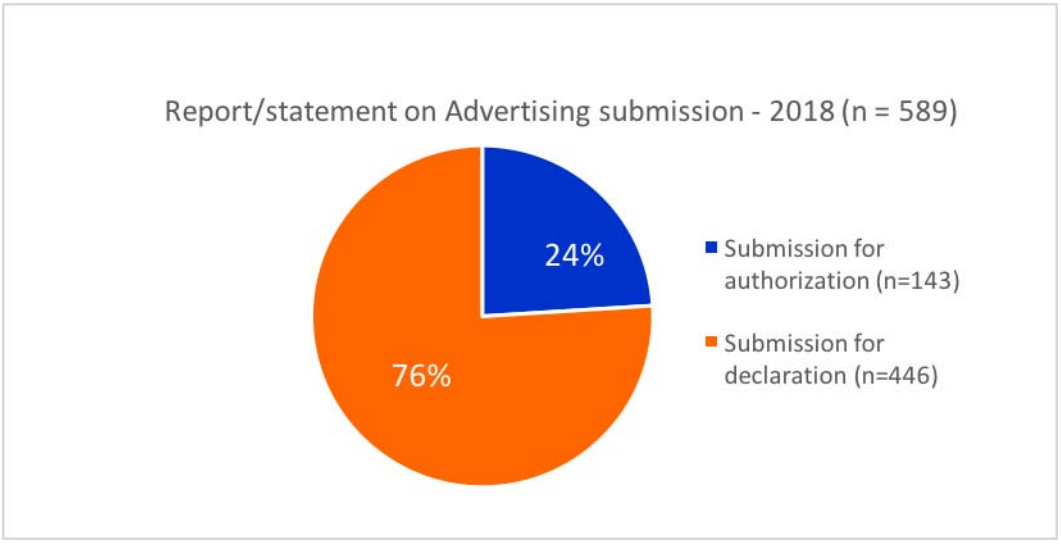


Figure 4: Breakdown of advertising applications in 2018 (589) by type: authorisation/declaration

Of the 143 applications submitted for authorisation, three were abandoned. Of the 446 applications subject only to reporting, 23 were abandoned and 12 were classified as not applicable.
As can be seen in the figure below, the vast majority of applications submitted for authorisation concerned medicinal products intended for the general public or antimicrobials.

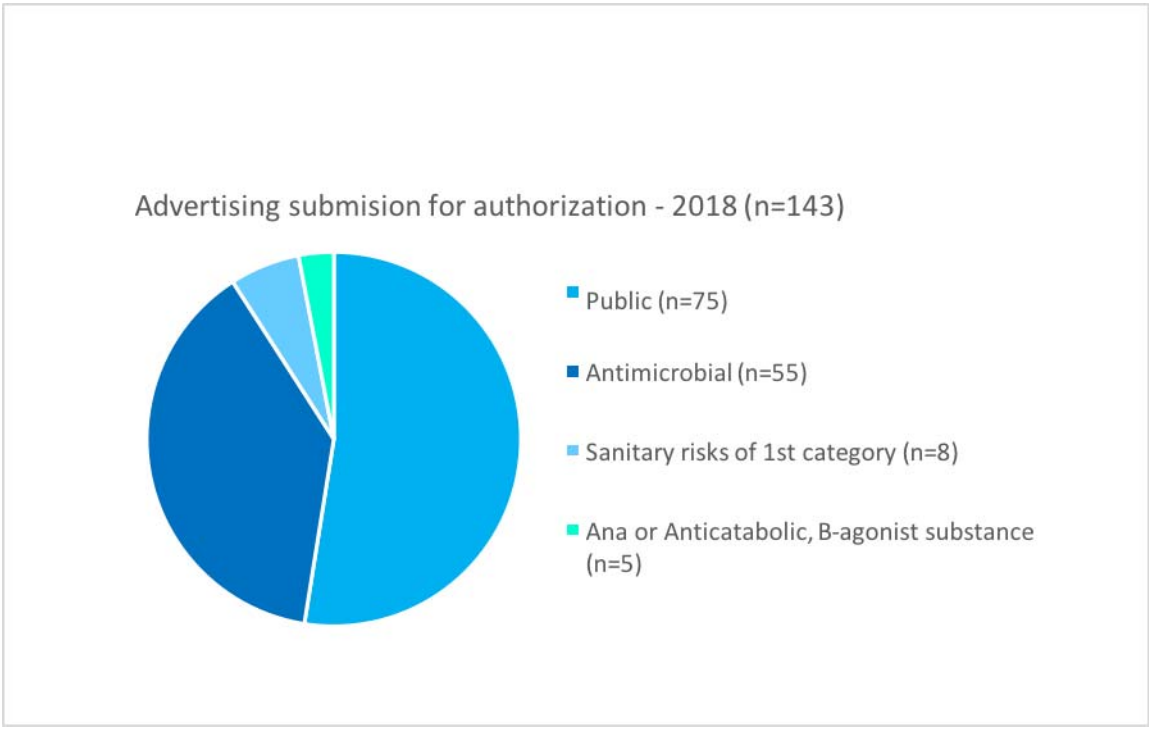


Figure 5: Breakdown of advertising applications submitted for authorisation in 2018

In April 2018, version 4 of the guide to good advertising practices was published. This update included the addition of new recommendations on mandatory statements, procedures for applying for advertising authorisation, terminological clarifications, related data, the offering of gifts and other items, and the promotion of offers and services.

C5 – Classification of so-called borderline products

When examining advertising dossiers or in the event of complaints made to ANSES-ANMV, the Agency carries out classification of so-called borderline products. Given the presentations and claims made, the aim is to determine whether or not the products in question have the legal status of veterinary medicinal products. In many cases, this concerns products on the boundary with biocides or food additives. This activity has been structured within the Market Surveillance Unit, and mainly involves use of a generic assessment grid.
In 2018, ANSES-ANMV received 80 requests concerning around 450 products (a 12% increase compared with the previous year).

These requests included nine reports from industrial companies and 37 from other ANSES entities or various government departments. The remaining 34 were requests from industrial companies for regulatory opinions (before their products were placed on the market, for example).

Following these reports, in most cases, a simple reminder of the regulations in force was sufficient for the manufacturers to comply with them (removal of the product from the promotional material, changes to product claims, etc.). Nevertheless, in 2018, 13 letters of formal notice were written, concerning one or more products.

The majority of these formal notice letters (7 out of 13) concerned a sector that has been problematic for the classification activity since 2016: the issue of bee products. Work will continue in 2019, particularly on products to combat nosemosis.

Some twenty reports also highlighted the problem of natural herbal products (herbs, essential oils, etc.), sometimes with therapeutic claims.

In 2018, there were no reports of any marketing suspension of products classified as medicinal products, by presentation or function.

Lastly, the position paper on the legal classification of borderline products was reviewed and presented to the various national entities for their opinions and comments. It was published on the ANSES website in 2019.

C6 – Management of stock shortages – availability of veterinary medicinal products

Just like quality defects, stock shortages must be reported to ANSES-ANMV. Helped by these reports, the challenge is to reduce the number, duration, frequency and impact of proven disruptions for practitioners and animal owners by implementing palliative solutions as quickly as possible. In 2018, 73 cases of shortages were reported. The breakdown by drug type is shown in the figure below:

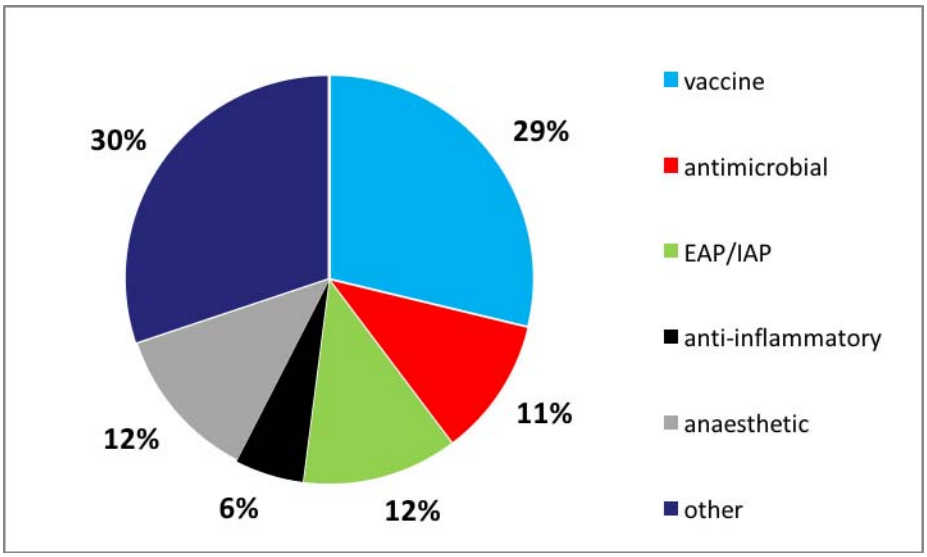


Figure 6: Breakdown of shortages monitored in 2018 by medicinal product type

This breakdown is similar to that of previous years. The reports of shortages mainly concerned vaccines and antimicrobials. As in 2017, the poultry-rabbit (38%) and cattle-sheep-goat (24%) sectors were the most affected.

Some twenty specific measures were initiated to deal with shortages in 2018 (30% of cases):

- Exchanges with other laboratories to anticipate possible cascade risks;
- Import authorisations;
- Release of specific batches;
- Preparation of autogenous vaccines;
- Extending batch shelf life;
- Information for veterinarians.

These measures are in line with the commitments made following the findings of the working group on good practices for managing interruptions in veterinary drug supplies.
These good practices specify the measures to be taken by each professional to ensure the best possible management of stocks of veterinary drugs of in the event of a shortage. They also deal with exchanges of information between the various players in the veterinary medicinal product chain. One section specifies that critical stock shortages should be communicated on the ANSES-ANMV website.
These good practices were submitted for approval to the Veterinary Association National Council, as well as to the various industry, wholesale distribution and veterinary associations and unions, and were published on the ANSES website (November 2018).

In the European Medicines Agency (EMA), the ANSES-ANMV Market Surveillance Unit takes part in working groups on the themes of "Shortages" and "Availability", which have begun writing European procedures for harmonised management of shortages and implementing "Good practice guidance for communication to the public on medicines' availability issues" to improve inter-agency communication on shortages.

Availability and therapeutic gaps

Tables listing therapeutic gaps by sector were first drawn up in 2013. In 2018, these were updated by ANSES-ANMV with the help of the MA Department and through the organisation of three meetings for the poultry (January 2018), equine (July 2018) and small ruminants (November 2018) sectors. Action tables were drawn up following these meetings.
Meetings with the beekeeping, fish, cattle and pig sectors are scheduled for 2019.

C7 – Work initiated in 2018

Sale of veterinary drugs on the internet

The USM is increasingly consulted about cases involving the sale of veterinary drugs on the Internet. The unit has therefore begun monitoring these sales.

At national level, meetings were organised to bring together the various French public entities (OCLAESP/BNEVP/DGAL/DGS/DGCCRF[2]/Customs) interested in the sale of veterinary drugs on the Internet. These meetings were designed to review each entity's actions to address these sales and the interactions to be set up between them to optimise their response to illegal sales sites.
At European level, the USM participates in a Working Group of Enforcement Officers (WGEO) set up by the HMA. The themes tackled by the group are Internet drug sales, and trafficking of animals and veterinary drugs. Its main objective is to pool the information and actions of several Member States in order to improve their response to these websites, which usually have a European or even international reach.

D/ Pharmacovigilance

- ### D1 – 2018 review

- Change in the total number of reports of adverse events

In 2018, 4750 pharmacovigilance reports were notified to ANSES-ANMV, representing a 14% increase in the total number of reports compared to 2017. These data correspond to the number of reports of adverse events occurring in animals or humans following administration of/contact with a veterinary medicinal product or, in the framework of the "cascade" approach, adverse events occurring in animals following administration of a medicinal product designed for human use.

[2] OCLAESP: Central Office for Combating Damage to the Environment and Public Health, BNEVP: National Brigade for Veterinary and Phytosanitary Investigation, DGAL: Directorate General for Food, DGS: Directorate General for Health, DGCCRF: Directorate General for Competition, Consumer Affairs and Fraud Control

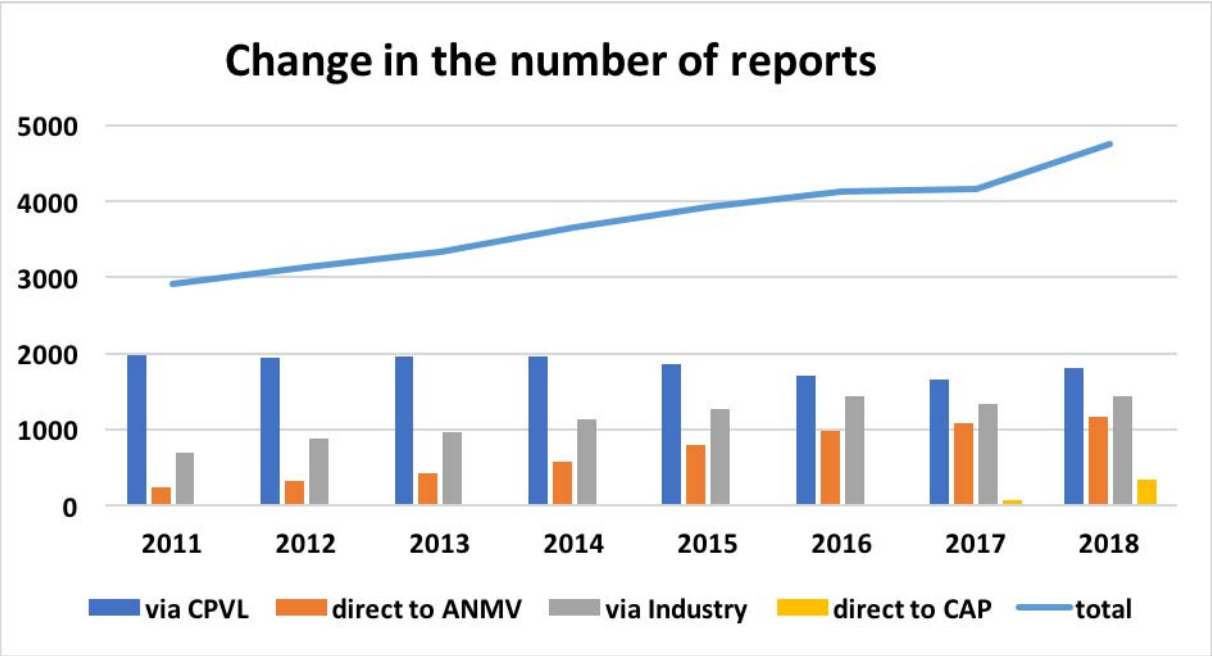


Figure 7: Change in the number of reports from 2011 to 2018

The greatest increase concerns cases in humans following the use of veterinary drugs (+45% compared to 2017) but this is related to a change in procedures and not a sudden increase in the number of adverse effects in humans in 2018. Indeed, since the end of 2017, adverse effects in humans recorded by human poison control centres (CAPs) have been forwarded to the veterinary pharmacovigilance network via the Veterinary Pharmacovigilance Centre in Lyon (CPVL), making 2018 the first full year in which these cases were received. An assessment of the human cases recorded in 2018 following the use of veterinary drugs will be the subject of a separate specific publication.
In animals, although to a lesser degree, the total number of cases also increased compared to 2017 (+8%), regardless of the reporting channel (ANSES-ANMV, CPVL or industry).

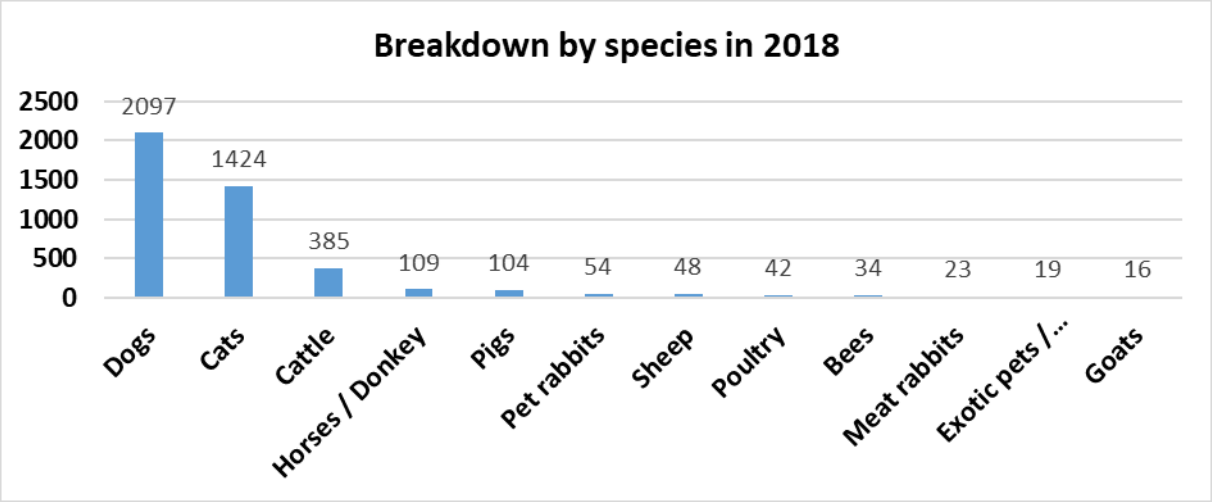
Although the number of reports of suspected lack of efficacy increased for most species in 2018, the typology of reports was generally similar (apart from the human cases: see above) to that observed in previous years: in animals, 88-90% of reports concerned adverse effects in the strict sense of the term, while 8-10% concerned a suspected lack of efficacy:

Typology of reports	
Adverse reactions in animals	3822
Lack of efficacy	519
Residue issues	14
Environmental issues	0
Adverse events in humans	395
Total	**4750**

Figure 8: Typology of reports in 2018

- Reports by species and therapeutic class

Since a single report may concern several medicinal products, a total of 5599 drugs were involved in the 4750 reports.
As shown in the graph below, domestic carnivores were still involved in more than 80% of all reports.



Vaccines remained the main products involved in an adverse event in most species, except for cats and bees, for which ectoparasiticides were the most frequently cited.

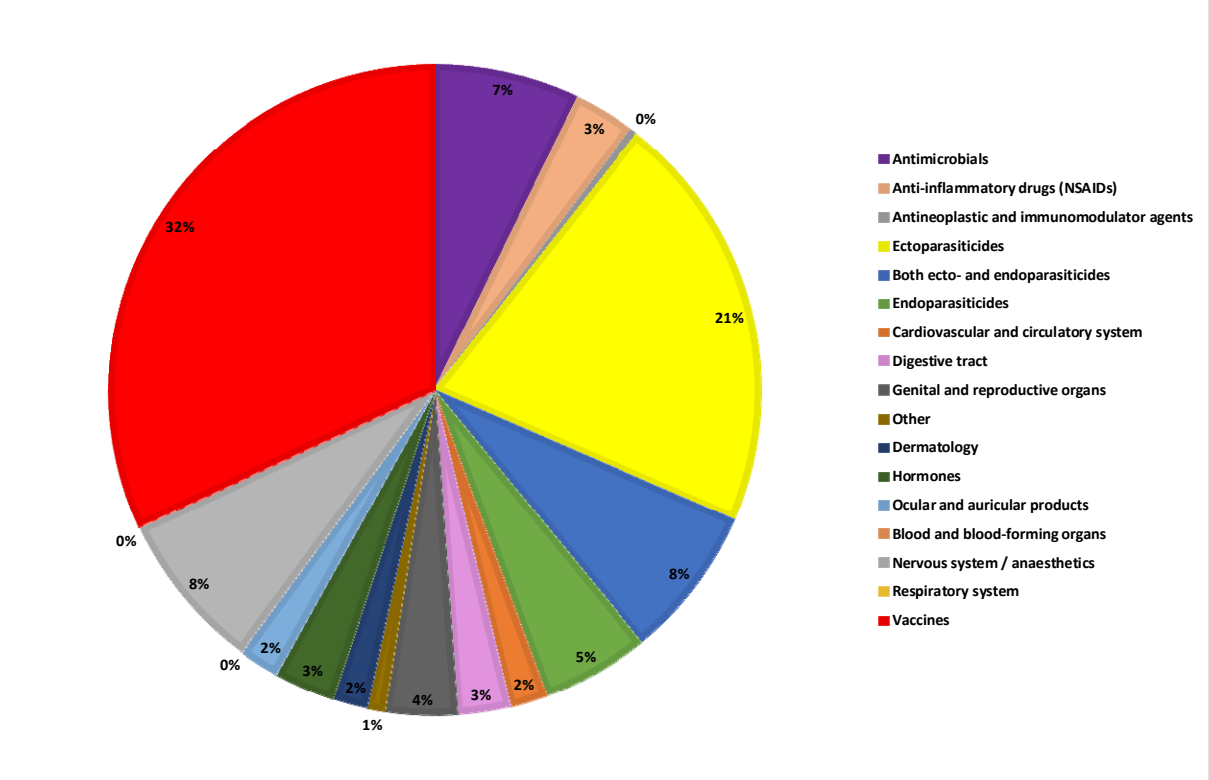


Figure 10: Overall breakdown of reports by therapeutic class

Figure 11: Breakdown by therapeutic class of the number of reports according to species in 2018

	Dogs	Cats	Cattle	Horses/Donkeys	Pigs	Pet rabbits	Sheep	Poultry	Bees	Meat rabbits	Exotic pets/Wildlife	Goats	General total
Vaccines	944	289	264	50	122	28	24	32	0	23	1	10	1787
Ectoparasiticides	590	510	7	3	1	18	4	0	34	0	3	1	1171
Both ecto- and endoparasiticides	129	249	19	4	0	4	10	0	0	0	4	6	425
Endoparasiticides	121	108	34	4	3	2	12	10	0	0	3	0	297
Nervous system/Anaesthetics	229	146	16	41	5	2	1	0	0	0	2	0	442
Antimicrobials	145	82	122	28	4	2	5	8	0	0	3	2	401
Anti-inflammatory drugs (NSAIDs)	118	31	10	9	2	2	0	0	0	0	0	0	172
Digestive tract	72	45	20	7	1	2	0	0	0	0	0	0	147
Cardiovascular and circulatory system	60	41	2	1	0	0	0	0	0	0	0	0	104
Hormones	93	70	1	1	0	0	0	0	0	0	3	0	168
Genital and reproductive organs	78	36	83	2	0	0	0	0	0	0	0	0	199
Ocular and auricular products	69	38	0	2	0	1	0	0	0	0	0	0	110
Dermatology	71	23	0	2	0	0	0	0	0	0	0	0	96
Antineoplastic and immunomodulator agents	6	15	0	0	0	0	0	0	0	0	0	0	21
Blood and blood-forming organs	0	2	2	0	0	0	0	0	0	0	0	0	4
Respiratory system	2	1	2	0	0	0	0	0	0	0	0	0	5
Other*	38	12	0	0	0	0	0	0	0	0	0	0	50
General total	**2765**	**1698**	**582**	**154**	**138**	**61**	**56**	**50**	**34**	**23**	**19**	**19**	**5599**

* The drug category "Other" includes allergy products, homeopathic drugs and medicinal products for human use.

- MA amendments

The reports and their analysis, at either national or European level, enable the summaries of product characteristics (SPCs) to be amended to take account of this new information obtained through pharmacovigilance. These amendments concerned 71 drugs in 2018, compared to 43 in 2017. This assessment of the pharmacovigilance data mainly led to the "Adverse events" section of the SPCs being completed, with the addition of new adverse effects or changes to their incidence of occurrence, but also enabled warnings/contraindications and precautions for use to be added.

D2 – Work carried out in communication on veterinary pharmacovigilance

ANSES-ANMV regularly communicates on different themes related to the promotion of pharmacovigilance. Topics include a summary of the reports recorded, related to a specific drug, therapeutic category and/or species, as well as position papers on ways to facilitate reporting and improve report quality.

This information is disseminated via different media, such as the ANSES website, the newsletter of the French Veterinary Statutory Body, the professional press, and congresses. In addition, ANSES-ANMV promotes research and thesis work in the field of veterinary pharmacovigilance by providing access to the data in the national pharmacovigilance database.

Articles published on pharmacovigilance in 2018 included a dossier on serious adverse effects following vaccination in dogs:

- *Effets indésirables graves des vaccins chez le chien : réalité chiffrée* [Serious adverse reactions to vaccines in dogs: a numerical reality];
- *Vaccination : mise en place de la réponse immunitaire protectrice et risque d'effets indésirables* [Vaccination: implementation of the protective immune response and risk of adverse effects];
- *Les bonnes pratiques de la vaccination et la prise en charge des effets indésirables chez le chien* [Good vaccination practices and the management of adverse effects in dogs];

as well as an article on the contribution of pharmacovigilance to drug surveillance, with the example of antiparasitic drugs for livestock.

Monthly publication of clinical cases
Moreover, to improve understanding of the analytical work carried out on each report by the veterinary experts of ANSES-ANMV and the CPVL, the study of an individual case of a reported adverse effect has been published in *La Dépêche Vétérinaire* each month since last summer.
Selected for its potential interest to the profession, the description of each clinical case is followed by the pharmacovigilance specialist's analysis of the possible relationship between the administered drug(s) and the clinical sign(s) observed subsequently, as well as the resulting causality score.

Definition of serious cases in the beekeeping sector
Under the regulations, the obligations of the different veterinary pharmacovigilance stakeholders vary according to the severity of the adverse effects. Reporters (veterinarians and health professionals) are required to report serious adverse effects. For marketing authorisation holders and institutional organisations (ANSES-ANMV and the CPVL), serious cases must be reported electronically within 15 days in the European network.

The definition from the French Public Health Code applies clearly to an individual medicine, but less so to a collective treatment, where the veterinarian is alerted more by an increase in the mortality rate or

a deterioration in zootechnical performance. An initial study launched in autumn 2014 with the correspondent/sentinel veterinarians for the rabbit, poultry and pig sectors at the French National Society of Veterinary Technical Groups (SNGTV) helped define for each sector the alert thresholds above which an event should be regarded as serious and therefore notifiable.

SERIOUS CASE IN AN ANIMAL

Regulatory definition

When occurring in an animal, a serious adverse effect is an adverse effect which results in death, is life-threatening, results in significant disability or incapacity, is a congenital anomaly/birth defect, or which results in permanent or prolonged signs in the animals treated.

This work continued in 2018 with the beekeeping sector and an updated note is available on the ANSES website: https://www.anses.fr/fr/system/files/Cas%20grave%20indus%20ANSES-ANMV%20aout%202018.pdf

Direct communication with livestock farmers

As veterinarians are the source of more than 90% of all reports, they are the priority target for ANSES-ANMV when promoting pharmacovigilance. However, pharmacovigilance data can also be used to raise awareness among farmers about the importance of proper drug use. For example, an article based on individual cases of adverse effects in pigs reminded farmers of the importance of good injection practices[3]. Articles for other production sectors are expected to be published in 2019.

E/ Outlook for 2019

New European regulations:

In January 2019, after four years of discussion, the following regulations were published:

- Regulation (EU) 2019/6 on veterinary medicinal products
- Regulation (EU) 2019/4 on medicated feed
- Regulation (EU) 2019/5 amending Regulation (EC) No 726/2004

These texts entered into force on 28 January 2019 and will be applied from 28 January 2022.
These regulations provide for the publication of 27 secondary acts (nine delegated and 18 implementing acts) for Regulation No 2019/6 on veterinary medicinal products, and four secondary acts (two delegated and two implementing acts) for Regulation No 2019/4 on medicated feed. The European Commission has given the European Medicines Agency a mandate to draw up technical proposals for the drafting of this secondary legislation. ANSES-ANMV experts are involved in this work and will be proposing new ideas for the preparation of the secondary legislation.

At the same time, an in-house study was initiated in March 2018, to identify each of the measures having an impact on ANSES-ANMV's activities. Each theme is being reviewed by the Agency's specialist departments and support units in order to determine specific action plans to be implemented. This process concerns the scope of ANSES-ANMV's missions, the adaptation of its organisation and internal procedures, and the role of its expertise in negotiations on secondary legislation with the relevant European bodies. For example, a study on authorisation of websites engaging in distance selling of veterinary medicinal products was initiated within the USM. This will continue in 2019. ANSES-ANMV will also be involved in work on the revision of French law to bring the French Public Health Code and French Rural and Maritime Fishing Code into line with European Union law.

[3] X. Sauzea, E. Fresnay, S. Laurentie – *Mieux utiliser les médicaments avec la pharmacovigilance* [Better use of drugs with pharmacovigilance] – *Réussir Porc* issue 261 – September 2018

Official batch release

ANSES-ANMV is the competent authority in France for issuing certificates allowing the official release of immunological products, in accordance with a procedure recognised by all Member States. Previously, ANSES-ANMV only issued official batch release certificates (OCABR certificates) for rabies vaccines following analytical controls conducted by ANSES's Nancy Laboratory. In 2019, in the context of the United Kingdom's exit from the European Union, ANSES-ANMV will also start issuing official batch release certificates based on a documentary review of the protocol (OBPR).

F/ CONCLUSION

The main prospects for 2019 in the monitoring of veterinary medicinal products are fully in line with ANSES-ANMV's general activity programme and concern two subjects in particular.

The first relates to the Agency's European positioning, with the revision of European legislation in the field of veterinary medicinal products (as mentioned in the previous section), but also activity relating to Brexit, for which ANSES-ANMV will continue to monitor the United Kingdom's exit conditions.

The second priority concerns communication, which is key to the success and recognition of the work of ANSES-ANMV. In this context, ANSES-ANMV's actions will be structured around several themes: increasing the number of publications in specialised journals, improving the information available on the website, and ensuring a greater and more visible presence for ANSES-ANMV at congresses, exhibitions and seminars.

Promotion of pharmacovigilance also remains a priority for ANSES-ANMV. In this context, after the simplification of reporting procedures, efforts will focus on communication relating to pharmacovigilance data and its diversification (target audience, data type, species concerned, etc.).

Lastly, the organisation in late 2019 of a second ”information day” for stakeholders dedicated to the work of ANSES-ANMV is also part of this desire for greater openness and sharing.

Once again, the quantitative results presented in this fourth annual report highlight the year-to-year stability of post-MA drug surveillance activities. Concerning market surveillance, controls of sales of veterinary medicinal products (unauthorised sales or promotions, or sales of counterfeit products) will be watched carefully over the coming year. The same will apply to monitoring of the availability of veterinary medicinal products, which was already a major focus in 2018, and to communication in the event of a critical shortage. This approach reflects the will of all the players in the veterinary medicinal product chain to be proactive and provide the best possible solutions in critical situations of shortages, including the sharing of any alternatives that may be available at European level.

Agence nationale de sécurité sanitaire
de l'alimentation, de l'environnement et du travail
14 rue Pierre et Marie Curie
F94701 Maisons-Alfort cedex
www.anses.fr
@Anses_fr

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