anses
French agency for food, environmental and occupational health & safety

Investigate, evaluate, protect

2018 ANNUAL REPORT

FRENCH AGENCY FOR VETERINARY MEDICINAL PRODUCTS

The French Agency for Veterinary Medicinal Products (ANMV), part of ANSES, is the competent authority for the assessment and management of risks associated with veterinary medicinal products in France. It assesses national and European marketing authorisation (MA) applications for veterinary medicinal products, as well as European dossiers on acceptable maximum residue limits (MRLs) in foods of animal origin. It issues MAs for veterinary medicinal products, authorises clinical trials, imports, temporary use and the opening of establishments for pharmaceutical manufacturing, operation, wholesale distribution and export, and also certifies exports of veterinary medicinal products.

It monitors the risk of adverse effects and problems of availability on the market of veterinary medicinal products, verifies product quality and advertising, and inspects veterinary pharmaceutical establishments. Lastly, it is a collaborating centre for the World Organisation for Animal Health (OIE).

CONTEXT

Last year was very much shaped by advancements in two European dossiers:

- the finalisation of negotiations for the legislative package relating to veterinary medicinal products, with the adoption of three European regulations. The ANMV's teams were closely involved in finalising the tripartite negotiation process between the Council of the European Union, the European Parliament and the European Commission;

- preparation for Brexit, for which no agreement has yet been signed between the United Kingdom and the European Union as of 1 January 2019, meaning that the preparation process has had to take into account a worst-case scenario, i.e. an exit without a deal. In these conditions, the ANMV rolled out its roadmap and conducted an impact assessment on the consequences of Brexit, especially in terms of the availability of veterinary medicinal products. In particular, it strengthened its teams by recruiting six experts in order to be able to cope with the increase in workload in light of the upcoming withdrawal of British expertise.

MARKETING AUTHORISATION

- **150** MAs issued in 2018
- **2017** procedures for amending MAs notified
- **119** MA renewals
- **146** MA transfers (**19** transfers between holders)
- **618** import authorisations issued
- **20** submissions for clinical trials
- **1** application for a temporary authorisation for use
- **45** batch release authorisations

INSPECTION AND MARKET SURVEILLANCE

- **71** inspections of pharmaceutical establishments
- **22** opening authorisation applications for veterinary pharmaceutical establishments **71** amendment applications and **9** transfer applications
- **2678** export certificates for veterinary medicinal products
- **36** official batch release certificates
- **248** quality control tests performed on **73** veterinary medicinal products
- **80** requests for qualification on the legal status of a product, representing 420 products to be assessed
- **73** notifications of shortage
- **88** notifications of quality defects leading to **34** batch recalls
- **588** advertising applications, representing **1189** documents

PHARMACOVIGILANCE

- **4767** adverse effect reports assessed, of which **2347** were considered serious

WORK UNDERTAKEN AND KEY EVENTS

WORK ON VETERINARY PHARMACOVIGILANCE

Serious cases in the beekeeping sector

Reports of adverse effects are processed differently (lead times, obligations for reporting and transmission channels) depending on whether or not the observed adverse effect is serious. In the past few years, the ANMV has published various documents to help veterinarians and manufacturers determine this degree of severity. In this context, a new annex concerning the definition of serious cases in the beekeeping sector was published in August 2018 (https://www.anses.fr/fr/system/files/Cas%20grave%20indus%20 ANMV%20aout%202018.pdf).

Monthly publication of a pharmacovigilance case

Since June 2018, based on an adverse effect reported to the ANMV or the Veterinary Pharmacovigilance Centre in Lyon (CPVL), a pharmacovigilance case has been published every month, along with commentary, in *La Dépêche Vétérinaire*. The goal is to explain, based on real events, the assessment of this case as it is undertaken by ANMV or CPVL pharmacovigilance specialists, according to the assessment method in force in the European Union.

WORK ON ANTIMICROBIAL RESISTANCE

The ANMV continued to collaborate with various sectors in this respect. In particular, it published the initial results of the observatory for the use of antibiotics in veal calves, in partnership with the French Livestock Institute (IDELE). As part of the mandatory reporting of sales of antibiotics by beneficiaries of veterinary medicinal products, the ANMV published its sales survey of veterinary medicinal products containing antimicrobials, which highlighted the progress made in terms of the prudent use of antibiotics. A pilot phase was launched for the reporting of antibiotic sales by manufacturers/distributors of medicated feedingstuffs. Its initial results are expected in the first half of 2019. Moreover, with a view to providing necessary reference data on veterinary medicinal products, the ANMV initiated a partnership with the Adelie association, in charge of managing exchanges between veterinarians and the

KEY DATES

authorities regarding data on reported antibiotic sales. The ANMV also actively participated in numerous European and international meetings on the topic of antimicrobial resistance. In particular, it contributed to the Second OIE Global Conference on Antimicrobial Resistance and Prudent Use of Antimicrobial Agents.

A BUSY YEAR IN TERMS OF INTERNATIONAL ACTIVITIES

The ANMV provided support on topics dealing mainly with antibiotics (assessment, sales monitoring and alternatives), whether at the Agency (hosting of experts from the Ukraine and Thailand) or within the relevant institutes (Morocco, China). Two training courses on veterinary medicinal product quality and residues were organised at ONSSA (Morocco). The ANMV also participated in the training of control officials for veterinary medicinal products in the countries benefiting from the Regional Sahel Pastoralism Support Project (Mali, Niger, Burkina Faso, Senegal, Mauritania, Chad) as well as in Dakar (Senegal) in October. Lastly, it actively contributed to three training sessions for OIE National Focal Points for veterinary products, including one in Abidjan (Côte d'Ivoire) for French-speaking Africa in January, another in Bangkok (Thailand) for Asia in March, and the last in Lyon (France) for Europe in October.

CONTINUATION OF THE ANMV'S COMMUNICATION ACTIONS

Every year, the ANMV continues to participate in annual congresses for veterinary professionals (meetings of Veterinary Technical Groups, the French Association of Veterinarians for Pets, and the French Equine Veterinary Association). These provide it with opportunities to directly communicate to veterinarians regarding the latest developments in the areas of veterinary pharmacovigilance and antimicrobial resistance, as well as changes in the regulations on veterinary medicinal products.

The ANMV was present at the International Exhibition for Animal Production (SPACE), where it gave a talk on the use of essential oils in veterinary medicine, with a special focus on the risks related to their use.

Hosting of a Thai delegation at the ANMV for a training for monitoring sales of antibiotics

5 TO 9 NOVEMBER

European audit (JAP) of the ANMV's inspection system, in the presence of experts from the US Food and Drug Administration (US FDA)

5 DECEMBER

Publication of good practices for managing shortages for a veterinary medicinal product

This presentation was given in the current context of combating antimicrobial resistance and searching for alternatives to antibiotics, and in light of increasing demand from veterinarians and breeders regarding the legal use of essential oils.

Similarly, as part of the *Fête de la Science* and the 2018 Festival of Science, the ANMV organised a talk for the general public entitled "*La résistance aux antibiotiques, une affaire de tous*" (Antimicrobial resistance is everyone's business). The presentation was followed by a discussion on the following questions: "What is antimicrobial resistance?",

"Why and to what extent is antimicrobial resistance a threat?", and "How can the phenomenon of antimicrobial resistance be combated?"

Lastly, a survey of veterinary professionals on the ANMV's communication highlighted a need for information on the Agency's various communication channels as well as demand for a communication medium such as a newsletter. In September 2018, the ANMV therefore developed a new design for its newsletter, which includes a list of the decisions published in the previous month and now features news items in addition to links to the pages of the ANSES website most frequently consulted by veterinarians.

GOOD PRACTICES FOR THE MANAGEMENT OF SHORTAGES

A workshop on the theme of "shortages of veterinary medicinal products" was organised on "ANMV Day", on 21 September 2017. This workshop was followed by the creation of a working group, whose members represent veterinarians, manufacturers, wholesalers and the French Agency for Veterinary Medicinal Products.

In 2018, this group's work led to the drafting of good practices for the management of shortages of veterinary medicinal products. These good practices specify actions to be taken by each category of professional to ensure the best possible management of stocks in the event of a shortage. They also deal with exchanges of information between the various players in the veterinary medicinal product chain. One of the sections specifies that critical shortages will be communicated on the Agency's website.

These good practices have been submitted for approval to the Veterinary Association Council, as well as to industry, wholesale distribution and veterinary trade unions. 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.

OUTLOOK AND PROJECTS INITIATED

FOUNDATION STONE AND CONSTRUCTION OF THE ANMV BUILDING

On 15 January 2018, in the presence of the Chairman of the Brittany Regional Council and the Chairman of the Ille-et-Vilaine Departmental Council, the Director General of ANSES and the ANMV Director laid the foundation stone for the new building of the French Agency for Veterinary Medicinal Products, at the heart of the BioAgroPolis centre of excellence in Fougères.
This relocation, scheduled for April 2019, is intended to group all of the ANMV's departments together in the same building and facilitate the overall functioning of the Agency.

IMPLEMENTATION OF THE NEW EUROPEAN REGULATIONS

The European regulations on veterinary pharmaceuticals have been fully revised with the publication, at the beginning of 2019, of two new regulations, applicable in 2022, dealing respectively with veterinary medicinal products and medicated feedingstuffs. A study was initiated in March 2018, with the aim of identifying each of the measures having an impact on the ANMV's activities. Each theme will be reviewed by the Agency's technical departments and support units, in order to determine specific action plans to be implemented. This process covers the scope of the ANMV's missions, the adaptation of its organisation and internal procedures, and the role of its expertise in negotiations on secondary procedures with the relevant European bodies. The ANMV will also be involved in work on the revision of French national law to bring the French Public Health Code and Rural and Maritime Fishing Code into line with European Union law.

PREPARING FOR BREXIT

In the context of Brexit, the ANMV adopted an action plan in order to strengthen its position within European bodies and the network of agencies, mainly through a plan to reinforce its teams. In 2018, the ANMV thus became the Reference Member State for 96 mutual recognition and decentralised procedures previously managed by the United Kingdom, i.e. for 15% of them.
Regarding the availability of veterinary medicinal products in France, the ANMV launched a survey in February 2018 to identify the plans of holders of MAs for veterinary medicinal products registered through the national procedure in France. This survey, undertaken in parallel with a survey of European MA holders, led to the establishment of a list of veterinary medicinal products risking stock shortages after Brexit.

PARTICIPATION IN THE SPRING COURSE ON ANTIMICROBIAL RESISTANCE

The ANMV, a collaborating centre for the World Organisation for Animal Health (OIE) in the field of veterinary medicinal products, actively participated in the development of a spring course on antimicrobial resistance organised by the National School of Veterinary Services (ENSV), an OIE collaborating centre for the training of official veterinarians. This seminar was held from 26 to 30 March in Lyon, at the ENSV, with the participation of veterinary service representatives from 13 countries: Algeria, Brazil, Egypt, Hong Kong, Japan, Jordan, Malaysia, Morocco, the Philippines, Thailand, Tunisia, Vietnam and Zambia. The objective was focused on the development of national action plans for combating antimicrobial resistance as part of a "One Health" approach, with a presentation of the strategies of the World Health Organization, the OIE and the United Nations Food and Agriculture Organisation, as well as a presentation on the French Ecoantibio plan and the work undertaken by ANSES in terms of monitoring both the resistance of pathogenic bacteria (RESAPATH) and antibiotic sales and uses. A technical visit to a farm in the Lyon region was organised as part of the seminar in order to provide an example of a veterinary medicinal product inspection in animal husbandry.

The session ended with a round table led by the ANMV which took place at the OIE headquarters office in Paris.

A YEAR MARKED BY AUDITS

Three audits took place in 2018, including two at European level.

From 20 to 22 March 2018, the ANMV welcomed three auditors from Croatian, English and German agencies mandated to undertake the benchmarking audit, which refers to the peer assessment of European agencies for human and/or veterinary medicinal products. These audits examine around 40 points covering all of these agencies' activities, and rely on the ISO 9001 standard. For all of these items, the ANMV obtained an average score of 4.1/5 (for an average of 3.5/5 for all of the agencies) and thus showed improvement compared to the previous exercise in 2014.

The ISO 9001 certification audit took place on 11 October at the ANMV. The auditor reaffirmed his confidence in the system developed by the ANMV to meet the requirements of the ISO 9001 standard. The results of this audit were highly satisfactory, as no non-compliances were observed.

The Joint Audit Programme (JAP) was implemented from 5 to 9 November. This is a European peer audit whose scope encompasses the inspection and quality control of veterinary medicinal products (including the management of quality defects and batch recalls). Its objective is to confirm the recognition of French inspections in the European Union. The audit was conducted by three European auditors.

Moreover, the team was accompanied by three inspectors from the US Food and Drug Administration visiting as observers within the framework of the creation of the mutual recognition agreement between the European Union and the United States for chemical veterinary medicinal products. During this week, three auditors interviewed inspectors about the management of the inspection system at the ANMV, while three others monitored an on-site inspection.

Areas of improvement were identified through all of these audits. They have already been taken into account in the ANMV's action plan for quality management.

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