

Therapeutic gaps in the Dogs/Cats/NCA sector

Hearing of 10/12/2024

Participants: Jean François ROUSSELOT (former President of AFVAC, delegate for national affairs); Eric GUAGUERE (veterinary practitioner, dermatology specialist, honorary president of AFVAC); Dan ROSENBERG (veterinary practitioner, expertise in endocrinology, oncology); Sylvain LARRAT (veterinary practitioner, NCA specialist); Christophe HUGNET (veterinary practitioner, CSMV representative); Séverine BOULLIER (Professor of Immunology ENVT, representative of CSMV)
Excused: Claire Beaudu-Lange (veterinary practitioner, expertise in oncology); Erik ASIMUS (ENVT lecturer, surgical specialist, vice-president of AFVAC continuing training);

of which ANMV: Laure BADUEL, Béatrice LEROUX, Anne SAGNIER, Laurent FABRY, Jacques BIETRIX. Excused: Céline LORTEAU

Reminder of the responsibility for the comments expressed during the hearing and reported in this report:

- The identification of therapeutic gaps (and details of the situations expressed and the alternatives envisaged) is the responsibility of the representatives of the veterinary profession
- The ANMV provides additional information or answers to the technical-regulatory questions addressed. These supplements are systematically preceded by “ANMV Info:” to distinguish the origin of the comments expressed.

General remarks:

- **The absence of veterinary Marketing Authorisations (MA) or availability for non-critical antibiotics** (cefalexin, amoxiciline or ampiciline):
 - **for IV route**, very detrimental for dogs and cats because it requires the use of human medicines, which are not always available
 - **for New Companion Animals (NCA)**, also detrimental because it leads to the use of the only antibiotic with a MA for these species, i.e. enrofloxacin, whereas this is contrary to national and European recommendations (EcoAntibio and AMEG).⇒ **Marketing authorisations are highly desirable for these limited markets or minor species**, especially as costs and fees reductions are permitted by Reg 2019/6.
- **The update of the Appendices to the Decree of 08/08/12 amending the Decree of 29/10/09 listing human medicinal products with restricted prescription** (hereinafter referred to as the “RP Decree”) **accessible to veterinarians is back on the agenda.**

The revision of the list of the human medicines with restricted prescription (RP) accessible to vets and their publication procedures are ongoing.
The articulation of the national provisions with the new European regulation 2019/6 will be reviewed in a 2nd step.

⇒ **The drafting of arguments for the inclusion of new substances is back on the agenda**, if this has not already been done, **with as much as possible an estimate of veterinary needs.**
Implementing Regulation 2022/1255: It should be noted that **antimicrobials reserved for humans** (see <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022R1255>) **may not be prescribed** as part of the “cascade” (according to Art 112.1.b).
- **The use of extemporaneous preparations** (see Art 112 1.c) **is facilitated by the possibility of subcontracting to a pharmacy.** However, they cannot be dispensed at the moment by the veterinarian, except during hospitalization.
⇒ **A proper veterinary MA therefore remains greatly preferable, particularly in terms of guarantees of quality, safety and efficacy.**

Evolution of gaps since the last hearing in December 2022: see p12

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Table summarising the comments of representatives of the veterinary profession (*new elements since the last hearing – in blue*)

0 VMP (Absence of appropriate veterinary medicinal products) is highlighted in yellow, when requesting a new medicinal product with veterinary MA



Pathology	Species concerned Dog (CN) Cat (CT) New pets (NCA)	Problem encountered by the sector*: PhV: Pharmacovigilance (efficacy or safety perceived as unsatisfactory) Disp: Availability, shortages Reg: Regulatory (cascade application, restricted access) 0 VMP : Absence of appropriate VMPs 0 TS : Absence of therapeutic solution	*Problem type PhV Disp Reg 0 VMP 0 TS	Alternatives identified	PRIORITIES Major: M minor: m
Bacterial infections	CN, CT	RILEXINE POWDER FOR INJECTION 1 G, is approved for IV route (see iRCP) but not available for 3 or 4 years. Wish for a return to the market and/or new veterinary MAs with IV route approved, for cefalexin, amoxicillin or ampiciline. This means prescribing other antibiotics, often more critical, and not being able to comply with the recommendations of EcoAntibio. Why isn't it possible to forbid the abandon of MAs for this type of non-critical antibiotics or to create a consortium of companies to maintain their presence on the market? For the record: No non-critical IV injection of ATBs (e.g. cefalexin, cefazolin): wish for a veterinary specialty with a non-modifiable price (unlike human medicines ordered from wholesalers). NB: The extension of the route of administration for an existing MA is eligible for an increase in the duration of protection according to Art 40.5 of Reg 2019/6 (modification of pharmaceutical form, adm. route or dosage)	Disp 0 VMP	Human medicines approved for IV route (if non-critical ATB): Cefazolin IV can be ordered from the company. As a reminder: Cefazoline IV not registered as a restricted prescription (RP) medicine but only reserved to communities (case of CIP code "5"). Information not well known by pharmacies who generally refuse to order this product, requiring direct order from the dispensing company. Ampicillin inj. Delivered by pharmacies AUGMENTIN IV available, but HS reactions more frequent than with cephalosporins.	MAJOR group 1
FIP (feline infectious peritonitis) Coronaviriosis (ferrets)	CT, ferrets	No medicinal product with veterinary MA that can be dispensed by the veterinarian. Extemporaneous preparation manufactured in France: without guarantee of quality, efficacy or safety. Current survey of possible side effects thanks to sentinel vets. Delivery possible by the veterinarian only in case of hospitalization. The regulations on the conditions for the delivery of extemporaneous preparations by the veterinarian is not yet finalized. GS-441524, Remdésivir or Mutian X available on the black market via the Internet, without any guarantee of quality, efficacy and safety.	0 VMP Reg	ANMV Info: possible use of extemporaneous preparations. (See ANMV info: Feline infectious peritonitis: prescription of magistral preparations Anses - Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail) No pharmacovigilance reports to date	MAJOR Group 1 or 2

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High-grade B lymphomas	CN	Wish for Tanovea in 1st intention treatment or relapse; registered for dogs in the USA (Elanco), no European MA. <i>ANMV Info: no import request to date</i>	0 VMP		MAJOR Group 1 or 2
EPO deficiency anaemia (end-stage renal disease)	CN, CT	Darbepoetin not accessible (to prevent misuse of human medicines containing EPO, especially in the context of sports doping in humans). Not mentioned in Appendix I of “the RP Decree”, a rationale has been drawn up for the addition of the injectable presentation (transmission in March 2020: <i>the ANSM issued a negative opinion to the ANMV, due to the risks of misuse</i>) However, the risk of misuse can easily be traced and controlled with a specific register of veterinary requests to the holder (and seems more important with xylazine for example).	Reg 0 VMP	Transfusion Veterinary medicinal product with MA available in the US for cat anemia: molidustat oral suspension (<i>Varenzin™-CA1</i> from Elanco)	MAJOR Group 1
Vasoplegic shock	CN, CT	Noradrenaline in RP for dental use. This medicinal product should be accessible to all veterinary structures. Otherwise, sometimes fatal for dogs/cats. Arguments sent on 04/12/20 by I.Goy-Thollot (VetAgroSup) for an application for inclusion in Annex I. <i>ANMV Info: Consultation in progress on updating Appendix I of the “RP Decree” (Decree of 08/08/12 amending the Decree of 29/10/09 listing human medicines with restricted prescription accessible to vets).</i>	Reg	Adrenaline (but more species-dependent action). <i>ANMV Info: there are 3 human medicinal products with noradrenaline (NORADRENALINE AGUETTANT, RENAUDIN and VIATRIS 2 mg/ml (without preservatives), solution for infusion), which are not subject by RP</i>	MAJOR Group 2
Analgesia*	CT	Desire for veterinary anti-pruritic agents suitable for cats, *when there is no response to existing analgesics (rapid effect of corticosteroids, slower for ciclosporin). No cat indication for oclacitinib (APOQUEL) due to <i>too variable dosage</i> and side effects in this species. <i>ANMV Info: Some pharmacovigilance signals were filed in 2023 and 2024 in IRIS for APOQUEL, concerning off-label use in cats (kidney failure, pancreatitis, death, dermatitis/eczema) but they were all refuted after analysis by the MAH.</i>	0 VMP	Oral gabapentin (human drug) , but poorly supported excipient. Wish for a veterinary marketing authorisation for gabapentin <i>ANMV Info: Consultation in progress on updating Appendix I of the “RP Decree”. But there are 100 mg capsules not subject to RP (NEURONTIN 100 mg, GABAPENTIN TEVA 100 mg, GABAPENTIN VIATRIS 100 mg, GABAPENTIN ZENTIVA 100 mg, GABAPENTIN ZYDUS 100 mg, etc.).</i>	MAJOR Group 3

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Difficulties in accessing the drug					
Anti-cancer drugs	CN, CT	Access to human medicines* subject to RP, reserved for hospital prescription *see opposite: substances proposed by ANMV (March 2020) for inclusion in Appendix III of the "RP Decree".	Reg	<p>Bleomycin*, dacarbazine*, epirubicin*, etoposide*, 5FU*, vinorelbine*, Gemcitabine, Procarbazine, Temozolomide, Actinomycin D, Mechlorethamine**, Docetaxel, Bortezomib, Thalidomide**.</p> <p>Recombinant asparaginase*</p> <p>The quantities for veterinarians are 10 to 100 times less than the requirements for humans. Information on quantities can be obtained from the declared veterinary structures (see CNOV) and the supplying companies.</p> <p>The risks of oral presentations** are taken into account by the Decree of 18/06/09 (relating to good practices for the use of anticancer drugs in veterinary medicine) which prohibits the supply to owners of oral human drugs under restricted prescription (see technical sheet no. 10): "(7) It is recalled that with regard to drugs for human use classified in one of the categories of restricted prescription, these drugs are for professional use and therefore cannot be supplied to an animal owner or holder. Therefore, only the veterinarian has the right to administer medicinal products from this list. »</p> <p>ANMV info: Consultation in progress on updating Appendix III of the "RP Decree" => Supporting documents to be completed or updated with veterinary quantities concerned (information accessible from supplying companies).</p> <p>For 5 FU: DPD deficiency screening tests required by ANSM</p>	MAJOR Group 2
Lymphocytic leukaemia	CN	Chlorambucil (CHLORAMINOPHENE) in hospital reserve (changed on 01/07/19 to hospital prescription ANMV Info: Consultation in progress on updating Appendix III of the "RP Decree" => Request for addition well considered. Supporting document available: to be updated with the veterinary quantities concerned.	Reg	<p>Simple, effective, well tolerated and inexpensive conventional chemotherapy.</p> <p>Available in extemporaneous preparation</p>	MAJOR Group 2

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<p>New immunomodulators (for immunological glomerulopathy, idiopathic polyarthritis)</p>	<p>CN, CT</p>	<p>Mycofenolate mofetil and Leflunomide Need for alternatives or supplements to corticosteroids and cyclosporine in case of failure, contraindication, or need for combination. Particularly relevant in immunological glomerulopathy and idiopathic polyarthritis respectively <i>ANMV Info: no new marketing authorisations since the previous hearing. Arguments already provided for the addition of mycophenolate to Appendix III, but unfavourable ANMV opinion (as regard to user safety // teratogenic substance)</i></p>	<p>Reg 0 VMP</p>	<p>No real alternative in terms of safety and efficacy. Extemporaneous preparations but even worse for user safety: it would be better to allow veterinarians' access to human medicines subject to RP.</p>	<p>MAJOR Group 2 or 3</p>
<p>Ventricular arrhythmias, congenital myotonia, neuromyotonia and ventricular arrhythmia</p>	<p>CN, CT</p>	<p>Oral mexiletine not available (no access in France). Also requested by GEN AFVAC (17/05/22), even if this "will not solve the problem of price", and the excessive size of the packaging delivered, compared to the occasional veterinary needs. <i>ANMV Info: Consultation in progress on updating Appendix I of the "RP Decree"=> Request for addition well considered. Now only capsules presentations are available. Arguments to be provided with the veterinary quantities concerned.</i></p>	<p>Reg</p>	<p>Mexiletine oral (human medicine - no equivalent VMP available). Extemporaneous preparations.</p>	<p>MAJOR Group 3</p>
<p>Serious gastrointestinal infections, anaerobic germ infections</p>	<p>CN, CT</p>	<p>Restricted prescription (RP) for metronidazole injection (IV) – uncommon. Also requested by GEN AFVAC (17/05/22) for the management of metabolic disorders and portosystemic shunt</p>	<p>Reg</p>	<p>Metronidazole IV (human drug) in hospital emergency (RP access) <i>ANMV info: already listed in Appendix I (=> authorised access to veterinarians)</i></p>	<p>minor</p>
<p>Hypoalbuminaemia</p>	<p>CN, CT</p>	<p>Human albumin 5% IV: Not accessible <i>ANMV Info: arguments already provided for addition to Appendix I, but ANMV and ANSM opinions unfavourable (because issued from human donors)</i></p>	<p>Reg</p>		<p>minor</p>
<p>Status epilepticus</p>	<p>CN, CT</p>	<p>Phenobarbital 200 mg/4 ml IV Also requested by GEN AFVAC (17/05/22) <i>ANMV info: drugs not in RP (=> veterinary access possible)</i> Midazolam IV: Hospital reserve, possible orders <i>ANMV Info: new veterinary MA for horses (MA dated 09/09/24 DORMAZOLAM 5 MG/ML SOLUTION FOR INJECTION).</i></p>	<p>Reg</p>		<p>minor</p>
<p>Status epilepticus (shunt)</p>	<p>CN, CT</p>	<p>Levetiracetam IV: Hospital reserve List I, possible orders. Also requested by GEN AFVAC (17/05/22) Wish for a veterinary MA for this substance.</p>	<p>0 VMP</p>	<p><i>ANMV info: There are 3 injectable VMPs with MA for dogs and cats containing diazepam. A new veterinary MA for midazolam (MA dated</i></p>	<p>minor</p>

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		<i>ANMV Info: Injectable human medicinal products containing levetiracetam are not in RP (=> veterinary access possible). As a reminder: Arguments written in January 2021 by JP Jaeg of the ENVT (following our therapeutic gaps meeting of 16/10/20) for an application for inclusion in Appendix I</i>		<i>09/09/24 DORMAZOLAM 5 MG/ML SOLUTION FOR INJECTION) was granted for horses.</i>	
Dysuria (bladder atonia)	CN, CT	Oral betanechol: not marketed in France, preparation possible in some pharmacies. Also requested by GEN AFVAC (17/05/22) for the treatment of detrusor hypotonia <i>ANMV Info: no new MA since the previous hearing.</i>	0 VMP	Extemporaneous preparation of betanechol	minor
Dysuria	CN, CT	Oral alfuzosin: wish for a veterinary presentation <i>ANMV Info: no new MA since the previous hearing.</i>	0 VMP	Prescription of the human drug (URION, XATRAL & generics)	minor
Gastric ulcers (antiacids)	CN, CT, NCA	No omeprazole MA for CN, CT or NCA => Frequent cascade. Wish for a veterinary MA with this active for the species concerned. <i>ANMV info: no new MA since the previous hearing.</i>	0 VMP	Omeprazole, pantoprazole IV and oral, esomeprazole (human medicines). "Cascade" prescription facilitated with NVR.	minor
Monovalent vaccine	CN, CT, NCA (ferret)	Monovalent vaccine does not exist for: C, H, P, Pi. However, the scientific duration of immunity is not the same, and this would prevent overvaccination in a context of reluctance to vaccination in France. R, C and P in cats where the difference in duration of immunity is even more obvious than in dogs (almost 9 years on typhus, compared with about 3 years depending on the epidemic conditions of the RC) Also true for distemper vaccine in ferrets – many allergic shocks during vaccination in this species with a multivalent vaccine, risk increased by unsuitable vaccines.	(0) VMP	The demand for monovalent vaccines is rather at odds with recent MAs although the investment would be minimal to register a monovalent vaccine from a polyvalent vaccine dossier. However, this seems utopian for market rationales. <i>Application for import authorisation for a monovalent distemper vaccine for ferret.</i> <i>ANMV info: no new MA since the previous hearing.</i>	minor
Ectoparasiticide for fleas/ticks in tablets Endoparasiticide against Toxocarosis	CN, CT	Lack of targeted <u>and not broad-spectrum</u> ectoparasiticide presentations against: fleas ± ticks in tablets Endoparasiticide: against toxocarosis, with only nematocide activity (as regard to the significant zoonotic risk), which also larvicidal action, in tablets and spot-on, for dogs and cats as this only exists in combination with other molecules	(0) VMP	The demand for monovalent antiparasitic drugs is rather at odds with recent Mas, although, as for vaccines, investment would be minimal to register a monovalent from a polyvalent file. However, this seems utopian for market rationales. <i>ANMV info: no new MA since the previous hearing.</i>	minor
Analgesia, welfare, quality of life	CN, CT	Oral buprenorphine, Tramadol LP, Cannabidiol extract: Wish for VMP <i>ANMV info: no new MA since the previous hearing.</i>	0 VMP	Dietary supplements with cannabidiol (no therapeutic claim, efficacy?). <i>Pregabalin (BONQAT® oral suspension) with veterinary MA for cats since 13/07/2021</i>	minor

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Bone healing (in the absence of fusion of humeral condyles)	CN	Bone Morphogenetic Protein: Unavailable	Disp		minor
Chemotherapy side effects	CN	Dexrazoxane, cardiac protector: Hospital reserve <i>ANMV info: 2 human medicines subject to RP: CARDIOXANE 500 mg and SAVENE 20 mg/ml => request for addition to Appendix III of "RP Decree"?</i>	Reg		minor
Haemorrhagic cystitis	CN	Mesna (prevention of haemorrhagic cystitis): Hospital reserve <i>ANMV info: 6 human medicines subject to RP: MESNA EG 100 mg/ml and UROMITEXAN (in 5 strengths) => request for addition to Appendix III of the "RP Decree"?</i>	Reg		minor
Inappropriate galenic or packaging presentation					
Anti-fungal treatment (ringworm) of the environment	CT, NCA (guinea pig)	Had existed in vet practices (Cinafarm) but withdrawn. A treatment of the environment should be considered as a biocide rather than a veterinary medicine.		Enilconazole spray. Can be used in catteries but not suitable for the treatment of private home. This is also a real problem in general practices, especially as ringworm is a frequent zoonosis. See if this is still a problem?	MAJOR Group 2 or 3
Chronic inflammatory bowel diseases (IBD)	CN/CT	Wish for budesonide : far fewer side effects such as Cushing's syndrome than prednisolone, which is very effective, but inadequate human medicines presentation (3 mg capsules too much for small animals) <i>ANMV info: BUDESONIDE TEVA SANTE 3 mg modified-release capsule, human speciality not in RP</i>	0 VMP	Prednisolone	MAJOR Group 3
Anti-glaucoma	CN, CT	No veterinary antiglaucoma medicines to be prescribed for chronic glaucoma while it is a common condition.	0 VMP	Prescription of human eye drops: TRUSOPT (dorzolamide), TIMOPTOL (timolol) or COSOPT (dorzolamide+timolol).	MAJOR Group 2 or minor
Anti-viral or immunosuppression ophthalmic eye drops	CN, CT	Wish for anti-virals, immunosuppressants, other than ciclosporin. In particular, a tacrolimus-based ointment would be of interest. <i>ANMV info: tacrolimus in injectable presentation is already mentioned in Appendix I. Request for addition of the ointment presentation.</i> <i>AFVAC wish already transmitted previously but ANMV is not favourable due to existing MAs for this use => Justification to be completed/updated.</i>	0 VMP	FRADEXAM (see remark opposite): the submission of a MA extension would be eligible to Art 40.5 of the NVR. Extemporaneous preparations.	MAJOR Group 3 or minor

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		Another formulation for dexamethasone: FRADEXAM contains dexamethasone phosphate and it appears that acetate (MAXIDROL) has better eye penetration.			
Anti-coagulant	CT	Very low palatability of clopidogrel for cats. Poor knowledge of its usefulness/effectiveness	0 VMP	Clopidogrel (22 human medicines + 2 in combination with aspirin). Long-term processing=> possible submission as "limited markets" dossier ? <i>ANMV info: no new MA since the previous hearing.</i>	minor
Anxiolytic	CT	Fluoxetine: mint presentation not suitable for cats.	0 VMP	Oral fluoxetine (RECONCILE) <i>ANMV info: Fluoxevet 32 mg quadriseccable tablet for dogs MA dated 20/09/2024.</i> <i>Off-label use for cats?</i>	minor
Localized bacterial infections	CN, CT	Wish for a veterinary antibiotic for topical application, other than fusidic acid (FORUDINE ointment for CN&CT, BETAFUSE gel for CN). <i>ANMV info: no new MA since the previous hearing.</i>	(0) VMP	Self-medication and misuse with risks of ABR (subject of off-label practices for local antibiotic therapy followed by the CSMV - <i>see publication Dépêche vétérinaire n°207 of Sept 2023 (p8-11).</i> SULMIDOL ointment, antiseptic ointments or honey-based ointments.	minor
Hepatocutaneous syndrome	CN	Wishes for an amino acid sugar-free solution for infusion: only the AMINOPLASMAL 25 sugar solution (for humans) is available in pharmacies.	0 VMP	AMINOPLASMAL 25 (for humans) – see opposite <i>ANMV info: no new MA since the previous hearing.</i>	minor

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NCA specific issues					
Bacterial infections	Reptiles etc.)	No MA/galenic appropriate for first-line ATBs. Few PK/PD data for non critical ATB, especially in reptiles: need for studies / waivers. The need for applications to extend MA for ATBs (such as tetracyclines, TMP sulfa, penicillins, amoxi-clavulanic acid) to NCA species, was communicated via RFSA website with the minutes of the previous hearing. <i>ANMV info: no MA extensions to new species since the previous 2022 hearing</i>	0 VMP	The only ATB VMPs approved for reptiles, birds, amphibians, rodents are with enrofloxacin (4 MA) <i>This situation where the indication of the MA takes precedence over the nature of the antibiotic imposes a major discrepancy with the current recommendations in terms of combating antibiotic resistance (AMEG, EcoAntibio, etc.), while required taxes and studies may be reduced for limited markets and minor species according to Eu Reg 2019/6. The use of extemporaneous preparations imposes supply times that are not always acceptable in practice.</i>	MAJOR or minor
	Rabbit, chicken	Unsuitable packaging: ex ADJUSOL - 100 mL -> treatment of 30 kg of rabbits for 10 days or 1 rabbit of 1.5 kg for 200 days. Problem with deconditioning at the clinic = only possibility although not allowed => what to do? (less) good practices to be defined?	(0) VMP	MA for rabbit, chicken but inappropriate pharmaceutical or packaging presentations. See good practices for extemporaneous preparation of VMPs (possibility of subcontracting Art. L5143-9-1), but not possible in case of emergency.	MAJOR or minor
	Rabbit	Need Antibiotic with good accumulation in pus/bone	0 VMP	Azithromycin	minor
Chlamydia	Birds	VMP approved for a powder for oral solution: permanent supplier shortage + inappropriate galenic. Need for an oral and injectable formulation (inj reserved for hospital use) According to iRCP, Doxycycline VMPs for poultry have inappropriate packaging: - Powder for drinking water: DOXIPULVIS 500 MG/G (SP Veterinaria), DOXYVETO-C 433 MG/G (VMD), GALLUDOX 433 MG/G (Huvepharma), RONAXAN 500 MG/G (Dopharma) - Concentrate for oral solution: DOXSOL 10% (KARIZOO), SOLDOXIN 100 MG/ML (Vetpharma))	Disp	Doxycycline cp (DOXYTAB VET.15 & 50 mg tablets for dogs and cats). <i>An injectable presentation with MA is available in Spain and Belgium, but 21 days of injection at home are required.</i> ANMV info: ORNICURE (Doxycycline from OROPHARMA) exists in 4x130 mg bags but the orders do not succeed... Shortages declared in 01/2021, then return on the market confirmed in 06/2021. Moreover, advertising is expensive for an antibiotic (esp. considering the initial registration costs when sales are of 2 units/month only!) <i>Solution for drinking water is suitable for farms (e.g. pigeons) but not for limited clinical cases in practice or in climatic conditions where water intake is too variable.</i> Oxytetracyclines would be another option but their bioavailability is too variable.	MAJOR or minor

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Fish medicines	Fish	Over-the-counter sale of AB, API/APE, anaesthetics, formalin, malachite green etc. see for example https://www.koi-prestige.com/soin-du-koi/medicaments-poisson/	Reg.	The only MA for fish (see iRCP) is FLUMIQUIL 3% powder (flumequine) Reg 2019/6: exemption from MA but mandatory registration => will help to better know (composition, instructions) and regulate these products. Pending adoption of the order being prepared and the implementing decree.	MAJOR or minor
Difficulties in accessing the drug					
Respiratory aspergillosis	Parrots, falcons	Treatment of choice in the literature includes voriconazole ± amphotericin B injectable. However, voriconazole (VFEND) prescription in humans is restricted (for fear of misuses?). Wish for oral voriconazole (only one single oral HMP: VFEND 40 mg/mL). Progress about “RP decree” expected (see general remarks in the introduction). Justification provided by S. Larrat. <i>ANMV info: Amphotericin B is listed in Implementing Act 2024/1973 of 18 07 2024 (Applicable from 8 August 2026) concerning antimicrobials not authorised under the “cascade” or under certain conditions. Its use is prohibited except “In the case of the treatment of leishmaniasis or other diseases in areas where leishmaniasis is endemic, the use of amphotericin B is only allowed as a last resort. (see https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L_202401973)</i>	Reg	Itraconazole, but better safety with voriconazole (VFEND) _ to be used sparingly. <i>ANMV info: Need for an updated vet argument (with estimated quantities) if confirmation still requested to be added to Appendix I of the “RP decree”</i>	MAJOR
Egg retention	Birds	Prepidil (topical gel) as a restricted prescription for humans. Progress about “RP decree” expected (see general remarks in the introduction). Arguments written by S.Larrat (post-meeting) <i>ANMV info: Need for an updated vet justification (with estimated quantities) if confirmation still requested to be added to Appendix I of the “RP Decree”</i>	Reg	Surgery on dying animals (no cervix dilatation => abdominal laying). Purified pig semen Dinoprostone not effective.	MAJOR or minor
Heavy metal poisoning	Birds	Suction (DMSA) with restricted prescription for humans while Suction PO could be used at home in other countries	Reg	Ca EDTA injectable IM	minor
Analgesia	Rabbit, rodents	Buprenorphine long acting available in USA - not available in Fr Butorphanol long acting - not available in Fr No liquid tramadol available for oral route.	PhV	Doubts about the actual efficacy of meloxicam (METACAM - MA for guinea pigs) as pharmacodynamic	minor

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				studies showed a much higher dose needed than that mentioned in the SPC for rodents)	
Anaesthesia	Fish	Import of tricalne.	Disp	Import Europe	minor
Hypocalcaemia	Reptiles	Frequent "cascade" use		Ca gluconate Eligible Art 5.6 if not subject to a prescription	minor
Candidiasis	Birds	Frequent "cascade" use		Nystatin	minor
Inappropriate galenic or packaging presentation					
Insulinoma	Ferret	Wish for diazoxide (PROGLICEM) for oral use. Only available in human capsules with RP): unsuitable galenic. Disease prevalence: 3,000/100,000 (3%) Progress about "RP decree" expected (justification to be provided)	Reg	Could be manufactured at the pharmacy of ENVA Prednisolone tablets.	MAJOR or minor
Vaccines for Marek's disease and coccidiosis	Poultry	Inappropriate packaging: maintenance of diseases in backyards that could be prevented => use of antibiotics for treatment rather than vaccines for prevention. 12 millions private poultry (// 7 millions dogs): enthusiasm for Indian ducks who consume slugs and are compatible with permaculture.	(0) VMP	Vaccines for intensive farming available only with 1000 or 5000 doses	MAJOR
Pituitary adenoma (prolactinoma)	Rat	Veterinary medicinal product (cabergoline) inadequately dosed => too large volume mechanically impossible to administer to a rat (<=> 1 vial of 4 mL every 2 days). ⇒ Use of tablets for human medicine crushed by the owner who then has to handle the suspension and daily treatment. Non-compliance with the extemporaneous preparation GPs despite the facilitated option for outsourcing (Art. L5143-9-1).	(0) VMP	Preparation by pharmacy, but the repackaging is complicated by the intermittent medicine availability and the lack of reactivity: in the meantime, risk of death of the rat.	MAJOR or minor
Renal impairment	Ferret, rabbit, rodents, birds	Lack of an oral formulation for proper dosing / patient weight	0 VMP	Furosemide injection/tablet	minor

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GnRH vaccine: sterilization, adrenal disease of ferret, control of reproduction problems in poultry.	Ferret, poultry	Unsuitable packaging: sold by 12*150mL. Scientific articles on Gonacon (US). No data on IMPROVAC.	0 VMP	Improvac	minor
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Therapeutic gap: being resolved		Initial problem	Problem type	Solution / Alternatives Reason for: Resolution in progress / Elimination of therapeutic gap	GAP initially Major: M minor: m
with existing solution					
Appetite-stimulating anxiolytic	CT	No oral mirtazapine accessible: reconditioning required	Disp	Marketing of a VMP Q1 2022. <i>As a reminder:</i> MIRATAZ® (mirtazapine ointment) obtained a centralised marketing authorisation on 12/10/19. <i>ANMV info:</i> a 2nd drug with a similar indication (weight recovery in cats) ELURACAT was authorised in 2023 (oral solution).	MAJOR
Endectoparasiticide (red mite)	Poultry	Unsuitable packaging EXZOLT small bottle = €150 (=> deconditioning is mandatory), 50mL <=> 2x2tmts at 7 days interval for approximately 80 hens	(0) VMP	Fluralaner (EXZOLT): available since June 2023 in a 50 ml bottle for family farms and individual hens (50 ml allows the treatment of 250 hens weighing 2 kg). Selamectin (STRONGHOLD kitten): but egg consumption is prohibited (no MRLs)	MAJOR

Changes in gaps since the last meeting in December 2022:

Positive trend for:

- **Appetite-stimulating anxiolytic for cats**, thanks to the MA and commercialization of new VMPs to stimulate appetite in cats
- **Treatment of FIP**, thanks to the possibility of outsourcing to specialized pharmacy the production of suitable extemporaneous preparation.
However, a proper VMP with MA would be greatly preferable, for delivery concerns and also to have officially assessed and approved guarantees for quality, efficacy and safety.
- **Treatment of red mites for “family hens”**, thanks to the sales of small packaging of a VMP already available for intensive poultry breeding.