Therapeutic gaps in the Horse sector

Hearing of 18/12/25

Participants: Charles-François Louf (Vice-President AVEF, veterinary practitioner in Vosges), Laurent Mangold (Vice-President AVEF, antibiotic referent, veterinary practitioner in Argonnay), Valérie PICANDET (AVEF representative therapeutic commission, veterinary practitioner in Normandy), Marie-Noëlle Lemouland (SNGTV Commission, practitioner in Finistère), Claire SCICLUNA (AVEF, veterinary practitioner in Oise) **Excused** : Séverine Boullier (Professor ENVT, representing CSMV)
for ANMV: L. Baduel, S. Barreteau, M. Salery, M.Zerrouki, S.Rougier, L. Fabry **Excused:** B. Leroux

Reminder of the responsibility of the remarks made during the hearing and reported in this report:
- The identification of therapeutic gaps (and the 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 and regulatory questions addressed. These supplements are systematically preceded by "Info ANMV: ... to distinguish the origin of the words expressed.

Prioritization and Evolution of gaps since the last hearing in November 2023: see pages 9 and 10

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

0 VMP (Absence of appropriate veterinary medicinal product_VMPs **is highlighted in yellow when requesting a medicinal product with a veterinary marketing authorisation for the species and indication concerned**

Disease	**Problem encountered:** **PhV:** Pharmacovigilance (efficacy or safety perceived as unsatisfactory) **Disp :** Availability, shortage **Reg:** Regulatory (cascade application, withdrawal period, restricted access) **0 VMP:** Lack of appropriate veterinary medicinal products (VMPs) **0 TS:** Lack of a therapeutic solution	**Problem Type** PhV, Disp, Reg 0 VMP 0 TS	**Alternatives identified**	**PRIORITES** **Major: M** **minor : m** **(see p9)**
Penicillins injectable via IV route, for intensive care.	Need for non-critical ATBs: **penicillin sodium**, **amoxicillin or gentamicin** that can be administered via IV route, with marketing authorisation for horses. **There should be a 1st line ATB is needed that does not risk laying the horses on the ground and that can be injected by the IV route.**	**0 VMP** Disp/ Reg	Use of critical antibiotics is forbidden: marbofloxacin or EXCENEL. Purchase of "human" sodium penicillin possible at Panpharma, but overpriced. **ANMV info:** End of supply tensions for amoxicillin, alone or in combination with clavulanic acid since 02/04/2025 in France.	**M n°1**

Therapeutic gaps in the Horse sector

Hearing of 18/12/25

	STOP M®: MA for horse obtained after PENETAVET® withdrawal, but IM administration only. *For the record:* MA discontinued for CLAMOXYL 5G in 2009. PENETAVET stopped. BELCOPENI 5 (Benzylpenicillin sodium + colistimethate, for all species, and slow IV) no longer marketed since 2017. "Cascade" use of drugs for cattle impossible for various reasons: - penethamate (PENETHAMATE, PENETHAONE, PERMACYL, REVOZYN): indicated in IM only and **contraindicated in IV** (suspensions). - Penicillin, procaine and benzathine unusable: risks of neurological reactions (procaine), significant shock if the product passes into the blood during the injection with a risk of a very violent reaction of the animal (unacceptable for any valuable horse) and local reactions and pain ++ during IM injection. Inappropriate penicillins SPC dosage ("cf 100 publications in the US"): experience of therapeutic failures with 10 days of SCP dose, solved in 3 days of the same treatment with increased dosage. **Dosage to be reviewed** (see Elodie Lallemand's work at ENVT) Few choices because only 2 penicillins with MA for horses: DUPLOCILLINE® and DEPOCILLINE® among the 10 VMPs with Benzylpenicillin procaine. **Heterogeneity of the SPCs contents:** doses expressed in mg/kg or ml/kg (or /10 kg or /100 kg), dose scale sometimes ranging from one to three times (the veterinarian often chooses the highest dose), and an imprecise frequency of administration. DUPLOCILLINE®: 12.4 mg/kg, in one single injection DEPOCILLINE®: 12 to 30 mg/kg, frequency not indicated (once a day?) Dosages of other VMPs that can be used “via the cascade”: 4 to 11 mg/kg, 11 to 17 mg/kg, 6 to 11 mg/kg, 11 mg/kg, 13 mg/kg once a day... or 1 x/72h. No PhV declarations because too well-known problem, and vets not so used to declare for lack of effectiveness (complex and difficult to identify) knowing that off-label dosages are used for a very long time. **ANMV info:** Analyses of the PhV declarations had been made but indeed there were not conclusive. However, such feedback would be useful. **No statement has been recorded at the ANMV**	PhV	See ANSM website: https://ansm.sante.fr/disponibilites-des-produits-de-sante/medicaments. **ANMV info:** the software most used by equine veterinarians is not qualified due to a governance blockage, which prevents recording via Calypso. **Post-meeting info:** A new application has just been qualified.	

Therapeutic gaps in the Horse sector

Hearing of 18/12/25

	since the last hearing. Prioritization exercise of dosage revisions, launched at EMA. It is the responsibility of the MA Holder (MAH) to review and update the MA and the SPC based on current scientific data. The implementation of a field survey and the transmission of the results and publications to the MAH is recommended. *For the record:* **ANMV note:** It is important to report this type of declaration of lack of efficacy to the ANMV, to have data that justify the need to update the dosages. The need to revise the dosages of some old ATBs is known to the authorities, but implementation also depends on the investments to be made to carry out the studies necessary to justify new dosages and to assess the impacts in terms of withdrawal period (WP), antibiotic resistance (ABR) and safety for the environment. **ANMV post-meeting info:** Since the publication in 2017 of the Anses report on the revision of the dosages of old antibiotics, work has been initiated at the EMA. At the Committee for Veterinary Medicinal Products (CVMP) in December 2023, a questionnaire was adopted, with the aim of collecting evidence of lack of effectiveness of antibiotics at the authorised dosage. This questionnaire was sent to many stakeholders including the Federation of European Veterinarians (FVE) in order to feed into the prioritisation exercise of the substances to be reviewed. **Info ANMV:** There have been reports, particularly from the ANMV, but the overall reports have mainly concerned food-producing animals. Prioritization was established with amoxicillin in pigs and cattle on respiratory infections.			
Tetanus	There is only one VMP marketed by CEVA: TETANISERUM 150. If it is out of stock: no other alternative. Shortage was declared "without restocking delay" in some wholesalers, not out of stock in others (Alcyon & Covéto) *For the record:* The horse is the species most susceptible to tetanus. There is no longer any anti-tetanus toxin. Shortages and then discontinuation of the marketing of Equine Trivalent Serum and Anti-Tetanus Serum 300 => only Tetaniserum 150 remains: **a very, very fragile situation.** "**Unacceptable situation**": veterinarians must let animals die of tetanus. Why no obligation to transfer marketing authorisations? **ANMV info**: the last shortage was declared in March-April 2023.	1 VMP	Only one VMP, marketed by CEVA: TETANISERUM 150.	**M n°2**

Therapeutic gaps in the Horse sector

Hearing of 18/12/25

	NB: new marketing authorisation (14/05/2025) for a vaccine: BIOEQUIN FT injectable suspension for horses against tetanus and equine influenza. Not yet marketed in France.			
Asthma	Problems of difficulties in administering ASERVO®: a real commercial failure, because of the non-recyclable device (to be thrown away after 10 days of treatment) and too expensive... ASERVO is often no longer used due to disappointments about its effectiveness or adverse effects on horses or users, due to difficulty in application. VMP no more available since 2025. **ANMV info:** It is important to report to the ANMV this type of report of lack of effectiveness or adverse effects on horses **or on the user**. Only 1 case of lack of efficacy reported in 2025. *For the record:* Why are there no medical devices that can be used in horses in France, unlike in other European countries? It is important to find a solution for these treatments that ultimately breeders buy and do on their own while veterinarians cannot prescribe or use them, as it would would be outside the legislative framework.	PhV (1 VMP)	**ANMV info:** no new MA since last hearing. To date, there is no status for medical devices in animal health. *For the record:* Autologous treatments (interleukins) prepared by the company 'Animal Immune' which has gone bankrupt. Experience of a vet on 8 horses with variable results. => continue to work on blood derivatives Field use of "Boldair" inhaler of pine essences.	**M n°3 or 4**
Prevention of infection (hyperimmune plasma)	No drug available with marketing authorisation in France	0 VMP	Ask for import authorisation of the VMP with MA in Italy	**M n°3, 4 or 5**
Anoplocephalus (praziquantel alone)	Since the discontinuation of TENIVALAN (MA dated 2001), no more VMPs available in France with only praziquantel (and approved for horses), without associated avermectin, which would allow targeted treatments and limit the impact on the risk of resistance and on environmental safety. **ANMV info post-meeting:** No other MA for horses available in Eu with praziquantel alone.	0 VMP (praziquantel alone)	**ANMV post-meeting note**: "Cascade" use of CESTOCUR SUSPENSION 2.5% for sheep may be possible, provided it is well tolerated and with appropriate bioavailability in horses at a dosage of 1 mg/kg.	**M n°5 or m+**
Leptospirosis	Vaccine exists in the US (Zoetis). Would avoid antibiotic treatments. Resurgence of seropositive horses according to some opinions in the field. It is a zoonosis with compulsory declaration in humans (since 24/08/23), but with a low zoonotic risk.	0 VMP (vaccine)	Curative treatment: tetracycline, penicillins or doxycycline. ⇨ Registration of the US vaccine to be promoted in the EU (market > West Nile vaccine and ≈ 1/2 influenza market). See RESPE epidemiological data, EU & US figures. Few declarations via the RESPE.	**M n°4 or m**

Therapeutic gaps in the Horse sector

Hearing of 18/12/25

	Clinical expression of the infection resulting from the direct action of leptospira, rare according to ENV, poorly detected in the acute phase. If the vaccine were on the market, would it be used? There is little evidence of the incidence of leptospirosis. An investigation will be launched via the **RFSA, involving AVEF, RESPE,** AFVAC & QualitéVet.		**ANMV info:** no import authorisation applications or new marketing authorisations since the last hearing in 2023.	
Chronic corneal abscesses or ulcers	**Only one ophthalmic VMP with antibiotics autorised for horses:** OPHTOCYCLINE ointment. This gap is very detrimental, although alternatives exist via the cascade use of VMPs authorised for dogs or cats or of medicines for humans or of extemporaneous preparations. Frequent shortages of available eye drops or ointments (not currently). Ophthalmic ointment for dogs with cyclosporin, but with two low concentration (0.2% instead of 2% desired). *For the record:* **ANMV info:** sterile eye drops are ordered to be manufactured by certain hospitals with substances that are not legally authorised in veterinary medicine (e.g. voriconazole, 5 FU, mitomycin C, ceftazidime, amphotericin B) **ANMV info post-meeting:** aciclovir, ganciclovir, valaciclovir and cyclosporine A are listed as essential substances for equines in the EA 2025/901.	1 VMP Disp	Prescription of "reinforced eye drops" (highly concentrated) in extemporaneous preparation with enilconazole + gentamicin + NAC or with gentamycin + ciclosporin or use of medicinal products for human use. **ANMV info:** at the moment these uses cannot be recorded via CalypsoVet	**m + or m**
Shock	Discontinuation of SOLUMEDROL (methylprednisolone)	(0 VMP)	Dexamethasone but with risk of laminitis. Veterinarians have to make do with it.	m
Osteoarthritis	*For the record:* Wish to have injectables from ZEEL and TRAUMEEL: don't forget that we need simple, cheap and non-harmful products to relieve osteoarthritis in horses. Some of the homeopathic specialties mentioned opposite are regularly used in France, but do not have an MA. Some have a registration in countries other than France.	Reg	*For the record:* Traumeel gel obtained an MA in France in 2020. Homeopathic specialties in particular based on arnica with references in humans and animals, including horses for several decades. Products manufactured by the Heel laboratory in Germany and available abroad. These products are useful for the treatment of synovitis, joint and paravertebral pain in horses, including in the long term, without the deleterious effects of corticosteroids on cartilage, and at a reasonable cost. Regularizing the status of these products would allow the situation to be regularized when they are used in the field. Clinical studies for an objective evaluation of effectiveness in practice may be set up if necessary to support the dossiers.	m

Therapeutic gaps in the Horse sector

Hearing of 18/12/25

			ANMV info: no applications for import authorization since the last hearing in November 2023. To date, there has been no declaration of shortages, marketing discontinuation or abandonment of TRAUMEEL gel.	
Induction of lactation	Need for a VMP (small market). Anecdotal need and a solution exists in human medicine: sulpiride, but only for stimulation, not for the induction of lactation in non-lactating females.	0 VMP	Human drug: sulpiride (discontinued as an injectable, now only available as tablets, capsules, or oral suspension). Domperidone less effective but works.	m
Botulism (very rare)	No equine vaccine or serum available. *Very rare.*	0 VMP	Possible importation of a bovine vaccine ANTRAVAX. Possible import (and storage?) of a serum available in another European country? **ANMV info:** 7 applications for import authorisation for ANTRAVAX accepted since last hearing. Bovine serum	m
Chemical castration	Vaccine reactions with IMPROVAC (not reported because known and predictable). There is currently no strong demand but is likely to come in a general context of animal welfare consideration. Small market but responding to societal demand. Only IMPROVAC vial available from 100 to 1000 doses (10*50 doses = 800€) => Use of a vial shared between several veterinary practices... Lack at wholesalers => check if there is a shortage?	0 VMP	IMPROVAC (it's already a solution, even if it's expensive). Reports of possible adverse events to be declared. There is EQUITY in Australia and NZ (with less AE than with IMPROVAC?). *For the record:* **ANMV info:** Improvac was the subject of a European signal in horses in August 2022 which possible letal issues: 4 cases from 01/12/19 to 30/06/22. In 2 cases a preliminary anaphylactic reaction was recorded. In the other 2 cases, anaphylaxis was strongly suspected. Section 3.5 of the SPC has been updated to add a warning for use in horses. All AEs combined in horses, there are a total (to date) of 18 cases in the European database, including 11 in EU but no cases in FR. Signal closed, no new cases to date	m
Respiratory tract mycosis	Nystatin? No antifungal inhaled in vet. Very questionable inhalation use... Only fungal pneumonia should be concerned.	0 VMP		m

Therapeutic gaps in the Horse sector

Hearing of 18/12/25

Therapeutic gap: in the process of being resolved **with existing solution**	**Initial problem**	**Problem type**	**Solution / Alternatives** **Reason for:** **Resolution in progress /Removal of the therapeutic gap**	**GAP initially** **Major: M** **minor: m**
Rhodococcosis	**Vaccine expected**. Would avoid the use of critical antibiotics. Veterinary erythromycin is not always effective and there is a risk of diarrhoea in foals. Efficacy of autovaccines to be evaluated. *Pay attention to the diagnosis*		See AVEF recommendation => Peni Genta. According to ATB Gram. Framework revised in the ATB good practices In curative mode: use of medicines for humans: azithromycin/ tulathromycin + rifampicin. **ANMV info:** no new MA since last hearing Rifampicin removed from the new list of essential substances, in favor of azithromycin and clarithomycin => rifampicin still usable but only until May 2027.	**Under resolution**
Piroplasmosis	CARBESIA: withdrawal period for cattle of 213 days (i.e. 320 days for horses via the cascade) is inapplicable in practice and is back in the spotlight with doping concerns.			
Myositis	Vit E not very effective. A veterinary drug based on dantrolene would be a plus. **ANMV info**: New list of essential substances for equines published in May 2025. Substances from the old list (and removed from the new list) can still be used until May 2027.		Myositis is becoming increasingly rare (thanks to food supplements) Veterinary or medicines for humans: Dantrolene (DANTRIUM)	
Antibiotic against anaerobes (pleuropneumonia)	Need for a metronidazole-based veterinary medicinal product (IV?) *Only in horses not intended for human consumption* **ANMV info:** no new MA since last hearing		Metronidazole orally (15 to 25 mg/kg bid) Active substance (powder) could be purchased at vet distributors for extemporaneous preparations. Human medicinal product (tablets)	
Mycotic keratitis	Need a VMP suitable for ophthalmic application. Rare problems. **ANMV info:** no new MA since last hearing		Human injectable medicines: natamycin or fungizone	
Alpha2agonist antagonist (detomidine)	A VMP would be welcome. (interest?) **ANMV info:** no new MA since last hearing		Atipamezole, OK	
Chondroprotection	**Difficulties for the veterinary use of products without an EU marketing authorisation, thus which are not authorised by regulation as a first-line treatment** when VMPs exist, e.g.: • Hyaluronic acid in single-dose syringe (medical devices for humans) • Athramid Vet (medical device in the US – polyacrylamide hydrogel), without MA in EU. MA in Australia: possible application for import authorisation *For the record:*	Reg	**ANMV post-meeting info:** No veterinary medical device status defined in the EU. The injectable route of administration is a major point taken into account for the qualification of "borderline" products as veterinary medicinal products. However, this remains a case-by-case qualification. When applying for the qualification of this type of product, national and European case law have always qualified them as medicinal products by presentation. The existence of polyacrylamide gels (PAAG) with MA in third countries allows to apply for import authorisation from the ANMV,	**Under resolution**

Therapeutic gaps in the Horse sector

Hearing of 18/12/25

	Triamcinolone is the only corticosteroid considered chondroprotective (with an appropriate dose) by intraarticular injection. No corresponding VMP for horse. The CANITEDAROL VMP for dog & cat based on triamcinolone diacetate is no longer marketed. The chondroprotective effect seems controversial according to the latest scientific publications. If necessary, report to the EMA the interest of its inclusion on the list of essential substances for equines. VMP with triamcinolone available in the US => why not in Eu? Human medicinal product based on triamcinolone acetonide (Unidose Kenacort 40 or 80 mg available in pharmacies, €6-7) New VMPs with stem cells (Articell Forte and Horstem) with different indications (osteoarthritis and cost +++). **ANMV info:** There is a product for dogs/cats with marketing authorisation in NL (no MA in France): Cortalone, 10 mg/ml suspensie voor injectie voor honden en katten. **Post-meeting note:** If it is of interest to some practitioners, it is possible to send applications for import authorization to the ANMV. But no MRL status => exclusion from the meat sector.		unless the indications are already covered by a product with MA in the EU. Since 2023, 23 import authorizations have been granted for Arthramid® (MA in NZ, USA, Australia) and 2 for Noltrex® (Russian MA). Once the import authorisation has been granted, the product may only be supplied to establishments authorised to distribute these categories of products in the country of origin, whether in Europe or in third countries. Regarding the MRL status, these are substances without required MRLs nor withdrawal period (WP=0day in the Australian MA) (https://www.ema.europa.eu/en/veterinary-regulatory-overview/research-development-veterinary-medicines/maximum-residue-limits-mrl#substances-considered-not-to-exert-pharmacological-effects-10715; with impurity concentrations of acrylamide ≤ 1.5 ppm, and N,N,-methylene-bis-acrylamide ≤ 1 ppm, for intra-articular use in horses up to a dose of 0.08 ml/kg bw).	

For the record:

- **Undeclared/anticipated shortages:** Information to be reported systematically and as soon as possible to the ANMV (Internet address: DQ_ANMV@anses.fr) by the laboratories but also by the vets, if necessary.
- **Problems of borderline claims on non-medicinal products**: Declaration and management by the ANMV (Market Surveillance Unit): usm@anses.fr

Therapeutic gaps in the Horse sector

Hearing of 18/12/25

Prioritization of gaps by representatives of the veterinary profession (outside ANMV)

Prioritization of participants (excluding ANMV) Gaps identified	Laurent MANGOLD	Charles-François LOUF	Valérie PICANDET	Claire SCICLUNA	Marie-Noëlle LEMOULAND	PRIORITIES in 2023 Major: M minor: m
Penicillins injectable IV, for intensive care	M n°1	M n°1	M n°1	M n°1	M n°1	M n°1
Tetanus	M n°2	M n°2	M n°2	M n°2	M n°2	M n°2 to 4
Asthma	M n° 4	M n° 3	M n° 4	M n° 3	M n° 3	M n°5 or m
Infection prevention (hyperimmune plasma)	M n°3	M n°4	M n°3	M n°4	M n°5	
Anoplocephalus (praziquantel alone)	M n°5	M n°5	M n°5	m+	m+	
Leptospirosis	m	m	m	m	M n° 4	M n°2 to 3
Chronic corneal abscesses or ulcers	m+	m+	m+	m	m	m
Shock	m	m	m	m	m	M n°3 to 4
Osteoarthritis	m	m	m	m	m	M n°5 or m
Induction of lactation	m	m	m	m	m	m
Botulism (very rare)	m	m	m	m	m	m
Chemical castration	m	m	m	m	m	m
Respiratory tract mycosis	m	m	m	m	m	m
Rhodococcosis						Under resolution
Piroplasmosis						Under resolution
Myositis						Under resolution
Antibiotic for anaerobes (pleuropneumonia)						Under resolution
Mycotic keratitis						Under resolution
Alpha2agonist antagonist						Under resolution
Chondroprotection	m Regulatory clarification	m	m	m	m	M or solved

Therapeutic gaps in the Horse sector

Hearing of 18/12/25

Changes in gaps since the last hearing in November 2023:

Rather favourable evolution for:

- Leptospirosis, a zoonosis with compulsory declaration in humans (since 24/08/23), but whose clinical impact needs to be clarified
- Osteoarthritis and shock, which for the importance as a gap has been revised as minor

Less favourable change for:

- Tetanus: a very fragile situation with only one single anti-tetanus serum remaining on the market
- Asthma, because of the poorly suited delivery device of the only drug available.

Addition of 2 major gaps: due to the wish for new MAs in horses:
for infection prevention (hyperimmune plasma) and for a VMP with praziquantel alone authorized in horses against anoplocephalus.

	Meeting of 20/11/23	Meeting of 18/12/25
MAJOR PRIORITIES	**1. Penicillins injectable IV for intensive care** **2. Leptospirosis** **3. Tetanus** **4. Shock** **5. Osteoarthritis or Asthma**	**1. Penicillins injectable IV for intensive care** **2. Tetanus** **3. Asthma** 4. ✚ **Prevention of infection** (hyperimmune plasma) 5. ✚ **Anoplocephalus** (praziquantel alone)
Minor Priorities	• Induction of lactation • Botulism • Chemical castration ✚ Chronic corneal abscesses or ulcers ✚ Respiratory tract mycosis	• Leptospirosis • Chronic corneal abscesses or ulcers • Shock • Osteoarthritis • Induction lactation • Botulism • Chemical castration • Respiratory tract mycosis
in the process of being resolved	• Rhodococcosis • Piroplasmosis • Myositis • Antibiotic for anaerobes (pleuropneumonia) • Mycotic keratitis • α2agonists antagonist (detomidine)	• Rhodococcosis • Piroplasmosis • Myositis • Antibiotic for anaerobes (pleuropneumonia) • Mycotic keratitis • α2agonists antagonist (detomidine) • Chondroprotection: **Possible application for import authorisation for medicines with MA outside the EU**

Therapeutic gaps in the Horse sector

Hearing of 18/12/25

Existing solution	☑ Chondroprotection (Synvet access): **import possible from Belgium, without application for authorisation** (**MA Fr)**	