Therapeutic gaps in the sheep & goats sector

Hearing on 03/07/25

Participants: Julien Visse (veterinarian in Lacaune, SNGTV ovine commission), Claire Combelles (veterinarian in Valençay, SNGTV caprine commission), Christophe Hugnet (veterinarian in the Drôme, representative of the CSMV). **Excused:** Carine Paraud (Anses Niort)
for ANMV: L Baduel, B Leroux, N Bridoux, J Bietrix **Excused:** L Fabry, C Miras
for FVE*: Wiebke Jansen (Policy lead_Federation of Veterinarians of Europe (FVE), Marine Delsaute (FVE).
**Exceptional participation, for observation, in connection with the FVE project to draw up lists of essential veterinary medicinal products (for sheep/goats in the test phase)*

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 words expressed.

Prioritisation and evolution of gaps since the last hearing in June 2023: see p 12 and 13 to 15

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 medicinal product with a veterinary MA for the species and indication concerned**

Disease	**Problem encountered:** **PhV:** Pharmacovigilance (efficacy or safety perceived as unsatisfactory) **Disp: Availability, disruption** **Reg: Regulatory (cascade application, waiting time, restricted access)** **0 VMP: Absence of appropriate veterinary drugs** **0 TS: Absence of therapeutic solution**	**Problem type** **PhV** **Disp, Reg** **0 VMP** **0 TS**	**Alternatives identified**	**PRIORITIES** **Major: M** **minor: m** **Sheep**	**Goats**
Digestive strongylosis, with increased resistance to benzimidazoles, levamisole and eprinomectin	Feedback from the field of lack of efficacy of benzimidazoles, levamisole and eprinomectin (and not only when pour-on). Questionable relevance of the pour-on route, especially in sheep and goats, as it does not allow targeted treatment (licking). In addition, the pharmacokinetic properties are very heterogeneous. Risk also for the user's safety. Recent studies (ENVT) have confirmed that the **situation is very worrying with significant declines in efficacy for all anthelminthic families.** ***For the record*** ***Anses Info:*** *the survey conducted in the 2 Sèvres (Anses PARASCOPE project) showed*	PhV	The MA of eprinomectin solution for injection (EPRECIS) has been extended to sheep and goats since November 2020. Of interest only when there is no resistance to eprinomectin (see opposite). ***ANMV info****: an Anses self-referral has just started in order to obtain an inventory of current knowledge on the resistances, lack of efficacy and environmental impact of antiparasitic VMPs for pour-on administration in ruminants.* The sector communicates a lot about oral administration (off-label). Project in progress at IDELE for communication on Good Practices.	**M n°1**	**M n°3**

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	that the anthelmintic most used (by volume and exposure) is oral moxidectin and that the efficacy was insufficient (< 95%) for all the anthelmintic used (fenbendazole, ivermectin, monepantel and moxidectin) in the farms included in the survey. Several issues: 1. Pour-on administration which generates very low and variable blood concentrations 2. oral administration at ½ dose (0.1 mL/kg) of VMPs approved for pour-on administration with arbitrary WP of 0 day 3. in dairy farming, the only VMPs with a 0-day milk WP are : injectable EPRECIS and EPRINEX multi pour-on => the exclusive use of eprinomectin increases the risk of resistance development => in case of documented reductions in efficacy, no other alternative is possible in dairy farming with 0-day WP The problem is critical in the Roquefort and Ossau Iraty areas. 4. in goat farming, farmers do not like the injectable route too much => wish for a MA with an oral administration. => the presence of 3 different strongyles complicates the parasiticide approach. **Monepantel (ZOLVIX)**, which belongs to another family, has a MA only for sheep. Despite a milk MRL, it "Must not be used in animals producing milk for human consumption" (see §4.11 of the SPC). However, it "may be used in breeding sheep including pregnant and lactating ewes" (see §4.7 of the SPC). A Belgian study would have revealed residues in milk 35 to 70 days after treatment. ***ANMV info:*** *In the absence of a depletion study and knowing that a milk withdrawal period of 35 days is mentioned in the MA of the VMP in New Zealand, a cascade WP of at least 35 days should therefore be applied in case of treatment at dry-off. No new data available to date.* A standard WP of 35 days remains possible in case of treatment at dry-off. Selective treatment only for young animals is also interesting because it increases the refugia populations.	1 VMP Wish for MA for oral route for vaccines Reg	**Wish for new antiparasitics.** INRAe of Toulouse is working on membrane glycoprotein inhibitors to improve parasite sensitivity. The organic sector studies the value of walnut leaves with a Swiss institute. Why could levamisole not be an alternative to eprinomectin in dairy farming? (see SPC § Withdrawal period: Milk: In the absence of a withdrawal period for milk, do not use in females producing milk for human consumption, lactating or dryed females or in future producers within 2 months prior to parturition). ***ANMV info:*** *MRLs should be defined for levamisole: see EPMAR levamisole levamisole-summary-report-2-committee-veterinary-medicinal-products_en.pdf: "There is inadequate analytical information to establish an MRL for levamisole in milk."* The Moredun Institute has developed a vaccine against haemonchosis, available in Australia (BARBERVAX®) and the US. See https://doi.org/10.1016/bs.apar.2016.02.011; 10.1016/j.vetpar.2018.11.006 Wish for new EU marketing authorisations for vaccines. ***ANMV info:*** *No new MA since 06/2023.* *An import request was refused for BARBERVAX in 10/23.* ZOLVIX (monepantel drug, anthelmintic of the amino acetonitrile derivative family effective against nematodes resistant to other anthelmintic classes). **In order to be able to use it in the dairy sector (milk MRL exists) without risk for the consumer, a residue study should be available to define a milk WP.** This alternative to benzimidazoles and ivermectin would indeed be advantageous, even if the treatment can only be carried out at dry-off and/or during the dry period. The dry period is long, particularly in sheep (5 months + 28 days of non-marketing of milk). In goats, the dry period is shorter (about 2 months) with 7 days of milk withdrawal. The problem of the cost of treatment remains high. 25-30% resistances are raised for benzimidazoles. **The need for alternatives is therefore urgent for goats and sheep (in particular in the Pyrenees).**		
Blue tongue (multi-strain vaccine)	Wish for a vaccine with more (3 to 5) valences for better anticipation of serotypes present in the field. Differences in national financial management according to serotype contribute to a sense of confusion. ***ANMV info:*** *it is the responsibility of the multistrain MA holders to initiate procedures to amend the MA to increase the number of components of the authorised multistrain vaccines*	PhV	Use of approved vaccines.	**M n°2**	

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Neonatal colibacillosis/ enterotoxaemia	***ANMV info:* IMOCOLIBOV has not been marketed since the end of 2023, but MA has not been abandoned.** *FENCOVIS MA granted on 27/06/22 (MA only for cattle, and without IMOCOLIBOV CS31A valence) - replacing TRIVACTON 6 (MA for cattle used via the cascade).* *For the record:* **Discontinuation of the marketing of IMOCOLIBOV will necessarily lead to an increase in the use of antibiotics (in particular colistin).** **In the event of cessation of marketing , there should be an obligation to transfer MA,** for political and societal considerations, in particular animal welfare. ***ANMV info:*** *monitoring figures show a slight increase in antibiotics in 2024 compared to 2023.Nevertheless, the level of exposure to colistin decreased by almost 70% compared to 2016. CalypsoVet data are far from exhaustive at the moment, but early years of collection show that colistin accounts for less than 1% of the tonnage of antibiotics for each of these species.* Lack of information on possible serotypes of *E.Coli* responsible for septicemic, diarrhoeal, soft lamb, drooling lamb. **Problem of non-typable serotypes.** Lack of field feedback on field use (only sharing info from users). Vaccines with "broad valences" would be needed. **Auto-vaccines:** very long production (10 weeks), not acceptable. Recommendations without defined protocol or precise data. Lack of "checkable" guarantees on autovaccines and strains may vary from year to year **Quinolone use possible but too late** (post AB gram) => 25 to 50% mortality - multiresistance (on average: 16% in meat sheep, 10% indairy sheep)	Disp 1 VMP	Overall, the strengthening of sanitary and zootechnical measures (colostral intake) is important. ***ANMV info:* COLIVAC 3S trivalent vaccine** *(antigens F5, F17, F41 & CS31A) has granted a cattle and sheep Temporary Authorisation for Use (TAU)* Field feedback rather positive in goat farming, even if there are no published data. Why are TAU vaccines not available at wholesalers, with the exception of FCO vaccines? What is the regulatory basis? Presentations of 6 vials => extra quantity for small flocks. ***Post-meeting ANMV info****: An TAU, as a specific and temporary authorisation, does not normally fit into the standard framework for the marketing of VMPs with a MA.* *For FCO vaccines (under TAU), an authorisation was issued, as a derogation, allowing exceptionally delivery via conventional wholesalers' distributors (during a transitional period, stocks of VMPs under TAU and authorised via centralised MA coexisted).* **Auto-vaccines** (but too long development, access more complicated than a vaccine with MA as was IMOCOLOBOV). Some auto-vaccine applications – on the other hand genotyping requested according to the matrix. Difficult in goat farming (seasonal births), interesting in lambs but too expensive and without guarantee of efficiency. Given the lead time, would it be possible to make grouped requests for the following bands? ***Post-meeting ANMV info:*** *3 requests since 06/2023.* *For the same breeding (and therefore successive bands), an auto-vaccine renewal does not require to repeat the sampling. Depending on the stability of the auto-vaccine, if possible, anticipate the renewal of application. It should be noted that for the production of autovaccines containing E. coli, 2 laboratories are authorised for sheep and goats: there is therefore no need for derogation.*<u>*For the record:*</u> **Anti-tetanus valence is essential in lambs.** An "Ultrachoice 8" vaccine exists in the US/Canada for cattle & sheep against clostridia but does not contain E.coli.	**M n°3**	**M n°4bis**
Cryptosporidiosis	**Goats:** safety concerns with halofuginone (off-label use): this is rather a dosage problem on goat kids because the product is suitable for cattle - Administration difficulties. Paromomycin (off-label use) satisfactory.	0 VMP	**Paromomycin sulphate (Parofor®) via the "cascade" is widely used in sheep and goats**, good efficacy reported. ***ANMV info:* MA dated 06/20/22 for GABBROVET multi 140 mg/mL**	**M n°3bis**	**M n°4**

	Sheep: paromomycin (off-label use): abomasal ulcers observed at 2x the dose (i.e. 100 mg/kg), every 2 days, during 7 days. 1x dose would be sufficient to resolve clinical signs in the majority of cases. **First pathology but over-diagnosed:** not necessarily related to clinical signs. Lab diagnostic problem: it would be necessary to better identify the E.coli responsible and request a cryptosporidium count to avoid over-use of paromomycin. ***ANMV info:*** *New (?)immunochromatographic diagnostic kit for the detection of Rotavirus, Cryptosporidium, Coronavirus and Escherichia coli K99 (F5) in cattle fecal samples: specificity of 92-100% and sensitivity between 92.6% and 100%. Rapid diagnostic test for gastrointestinal diseases - C-1540 - Coris BioConcept - veterinary / for animals / coronavirus A-2024-065.pdf* Prevalence of 50% in sheep flocks: association of criminals: *E.coli* and *Cryptospridium* (also in goats). Diarrhoea at 4-8 days, tenesmus and colics, immunochromatography test (speed V-Diar 4 or 5) in 10 minutes (many false positives, overdiagnosis).Very variable results depending on the kits. A count can be requested from the lab. It is difficult to disinfect because it is carried by mothers. In goats, the chevrettes are often raised away from the mothers, then disinfection of the boxes is possible.		***solution*** *for pre-ruminant cattle and pigs with indication colibacillosis (Dosage: 25-50 mg/kg/day for 3 to 5 days. WP meat and offal: 20 days) and cryptosporidiosis (Dosage: 150 mg/kg/day for 5 days. WP meat and offal: 110 days).* *=> in case of "cascade" use for cryptosporidiosis in sheep or goats, the fixed WP is of 165 days.* **Field conclusion:** not usable for "Roquefort" lambs during fattening. OK for renewal female lambs and breeding female kids. The prescribed dosage is usually between 50 and 100 mg/kg with good efficacy and never at 150 mg/kg.Confusion +++ on the ground due to the PAROFOR Crypto AMM in certain European countries. Dose and BP misuse, which may increase the risk of resistance. Prevention and vaccination must be promoted. ***ANMV info:*** *since the previous hearing of 06/2023:* *- no extension in France of the MA for paromomycin in sheep/goats for the cryptosporidiosis indication. MA extension granted in some countries, but* ***not in France****.* *- New centralised MA dated 23/11/23 for the* ***BOVILIS Cryptium vaccine****, for cattle only* Off-label field use (via "cascade") of BOVILIS Cryptium in sheep at ¼ dose. For goats, the MAH advises against such use because of "protein differences between cattle and goats". What is the opinion of the ANMV? ***ANMV post-meeting information:*** *we cannot give an opinion on off-label use.* Halofuginone authorised in cattle may be used via the "cascade" (different species, same indication). Reporting of alternative products on the market: Kryptophyt (food additive with Yucca extract) and Multigen (oral immunoglobulin). Reinforcement of the intestinal flora (lactic acid bacteria). Phytotherapy: how effective?		
Respiratory pasteurellosis (with increased prevalence of *Pasteurella multocida* ± mycoplama not always identified)	**Mixed vaccine (SALMOPAST) combining salmonella components not very useful or specific vaccine but not containing all strains involved in ovine and caprine disease (OVILIS PASTOVAX).** **OVILIS PASTOVAX is moderately effective in sheep (due to the small number of strains in the vaccine), works moderately in goats.** Vaccine not frequently prescribed but better than nothing and essential to keep. Underreporting of lack of effectiveness as wellknown and not always easy to document. Yet essential to be able to identify the modalities of appearance (weather, building, age of animals, immunity, etc.)	PhV	Injectable antibiotic (macrolides with good pulmonary diffusion) for metaphylaxis. Ingestion of 250 to 500 mL colostrum at birth.	**M n°4**	**M n°2**

	ANMV info: *23 reports of lack of efficacy received with this vaccine since June 2023 (16 sheep cases, 7 goat cases). Causality assessment: O/O1 in most of cases, 1 case B, 2 cases N.* *No pharmacovigilance signal being monitored with this vaccine in IRIS or at national level.* **Critical lack of a Pasteurella vaccine for goats** (+ atmosphere parameters to be adjusted). The typing of pasteurella strains cannot be done at present: this is an issue. Difficult differential diagnosis (*vs* adenomatosis) in sheep farming. **Auto-vaccines, yes but:** - Sampling matrix (deep nasal swab, lung, etc.) not allowed if non-genotyped resistant to EST. Difficult in goats, unlike in sheep - Pharmacovigilance report needed showing the lack of efficacy of a commercial vaccine adapted to the isolated strain - Absence of the serotype of *Mannheimia haemolytica* in the commercial vaccine (but serotyping problem etc.).	0 VMP	**Autovaccines** (see opposite). ***ANMV Info:*** *Authorisations have been issued by the ANMV: 15 requests since 06/2023*		
Hormons	For the record: **WP problem for CHRONOGEST goats LC sponges**: 36 h whereas 0 day for SYNCROPART and CHRONOGEST CR. ***ANMV info:*** *Abandonment in May 2025 of the sponges for goats Chronogest goats LC.* **Nothing more to treat pseudogestations (common) in goats.** Availability concerns for SYNCROPART. ***Post-meeting ANMV info:*** *no shortage declared since 06/2023 for SYNCROPART 30 mg.* **Effectiveness concerns in sheep** (young pre-puberty animals) - see breeding conditions. Environmental and societal considerations regarding the production of PMSG (on pregnant mares). If no more access => impact ++ (in non-organic sector) **In goats:** ESTRUMATE (cloprostenol) availability concerns resolved but for large vials only. Is zero-day WP always safe in case of off-label use of SYNCROPROST, even if the protocols are different according to the indications ? ***Post-meeting ANMV info:*** *The WPs for SYNCROPROST 0.250 mg/ml (MA dated 02/05/2022) are: 1 day for meat and 0 day for milk. In the event of off-label use with a dose higher than that recommended in the SPC, the fixed WP to be applied is therefore, at least, 2 days for meat and 1 day for milk (see IT DGAL/SDSBEA/2023-390 of 19/06/2023). Increasing a dose can generate much longer WPs, and it is the responsibility of the veterinarian to ensure/check (literature) that the prescribed WPs are sufficient.*	0 VMP (goat) Disp PhV	Flugestone sponges in goats: SYNCROPART 45 mg Special sponges for goats. CIDR OVIS 0.35 G vaginal diffusion system for sheep: off-label use possible for goats.	**M n°5**	**minor n° 1**

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Mycoplasmosis (including mastitis)	**Two intra-mammary antibiotics for dry-off with MA for sheep (cefazolin), and 1 single in sheep+goats (**benzylpenicillin, nafcillin, dihydro-streptomycin**: Nafpenzal): are not effective against mycoplasma (increasing occurrence in certain regions).** To avoid residues in milk, only Nafpenzal can be used in goats. **No vaccine.** There is no existing vaccine solution on the market, even via the cascade. No new MA since 06/2023 **Critical in goats, as leading to slaughtering.** In the presence of mycoplasma, culling of the affected animals is preferable, as regard to acquired resistance (especially to macrolides) and low bacteriological cure rates. Antibiotic treatment promotes healthy carriage within the herd. However, bacterial excretion from asymptomatic females is common; no satisfactory response can actually be given to breeders to date.	0 VMP (MR for spanish vaccines)	**Possibility of importing from Spain inactivated sheep vaccines (*M. agalactiae*) AGALAX Tres, AGALAX Uno (inactivated vaccine) and ALGONTEX.** Satisfactory results but **very high shipping costs**: 500 € whatever the quantities. Desire for Mutual Recognition (MR). ***ANMV info:*** *55 import requests for AGALAX TRES between June 2023 and today. There have been requests for AGALAX UNO and ALGONTEX, but there have been no requests since June 2023* **Auto-vaccines:** good results If lack of efficacy is declared in post-marketing surveillance: possibility of manufacturing an auto-vaccine from milk isolates. Interest of manufacturing laboratories only if the demand is large enough. ***ANMV info:*** *no requests since 06/2023*	minor	**M n°1**
Coccidiosis	**No MA for goats.** **Evidence by ENVT of resistance to diclazuril in the Southwest of France.**	0 VMP (goats) PhV	Be careful to follow the recommendations on the timing of treatment.	minor	**M n°4$_{ter}$**
Contagious echtyma	Lambs mortality and mastitis (viral disease). **A commercially available vaccine (ECHTYBEL®) exists with variable perceived results in the field** (superior efficacy by intradermal (ID) route than by subcutaneous route) – effective in 70% of cases in sheep when used as ID and as a cure (as soon as the first lesions appear). ***ANMV info:*** *Some reports of lack of efficacy in sheep and goats reported to the ANMV: 3 cases of suspected lack of efficacy reported since 2023: sheep cases, 2 cases B, 1 case O1.* *No pharmacovigilance signal being monitored in IRIS or at national level* Some ECHTYBEL availability concerns - to be monitored. ***ANMV info:*** *shortage from 09/2022 to 03/2023, OK since. No more recent shortage declared.* **Vaccine must be imperatively preserved. Beware of any risk of MA abandonment. OVERVAC® import no more possible**. ***ANMV Info:*** *The Spanish MA has been suspended.*	PhV 1 VMP Disp,	**Only one existing vaccine = must be imperatively preserved.** Various alternative therapies (homeopathy, phytotherapy, etc.) Echtymatisation (scarification from crust samples taken in infected livestock): isotherapy prohibited.	minor	Vigilance

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Sheep scabies	**Too many treatments done with macrocyclic lactones, risks of consecutive resistance on the digestive strongyles.** No new more specific treatments since 06/2023. New serological tool ID. ***ANMV info:*** *Problems with evacuating pest control baths due to environmental and user's safety concerns (experienced case of transfer of a breeder to the emergency department by helicopter).* *Human cases are regularly reported to the ANMV with phoxime or deltamethrin based VMPs. Information on the circumstances of use or on the target species is not always provided. Cases often come from poison control centres. Mainly cases of accidental contact at the time of application or accidental ingestions of dilutions prepared in advance. Symptoms vary: headache, digestive disorders, irritation at the site of contact (skin, eyes, mouth), respiratory disorders following inhalation.* *For information, see ppt C.Piquemal AFVAC 2022 & article on human cases published in the Semaine vétérinaire french Journal in 2022.*	(0 VMP)	Balneations but difficult disposal of treatment products + toxicity for the user. ***ANMV info:*** *See Anses self-referral (with 90 recommendations): Opinion published on 30/05/23 -* AVIS et RAPPORT de l'Anses relatif à l'évaluation des risques pour la santé humaine et l'environnement et recommandations pour leur maîtrise, dans le cadre de l'administration des médicaments vétérinaires antiparasitaires externes sous forme de bains, douches et pulvérisations en élevages ruminants *See ppt S.Barreteau at JNGTV 2023.* Field practices are often far from the recommendations. An IDELE project of communication on the subject (notably on the residues disposal) could be very useful. There are currently no better diagnostic tools available Is not a problem in goats, except some cases of psoroptic scabies on grazing goats, which are not very contagious but respond poorly to treatments. Culling is recommended in such cases.	minor	-
Border disease	No effectiveness. Lack of foetal protection. Low prevalence (<1% in Roquefort). In lambs in fattening units => use ++ of antibiotics (oxytetracycline and sulfadimethoxin)	0 VMP	Serological screening (3 to 4% of farms are positive) and disposal of animals is recommended prior to transfer to fattening units. Bovine BVD vaccines not effective against Border disease in sheep and goats	minor	
Staphylococcal mastitis or dermatosis of teats (prevention)	**Efficacy of VIMCO**: perceived in the field as not conclusive on cell counts. No indication for staphylococcal dermatosis*. It is difficult to conclude on effectiveness (due to Morel's micrococcus impact). A priori lack of efficacy in the field on goats. ***ANMV info:*** *only 1 case of PhV declared in 2023 (clinical mastitis on dairy goats) but imputed N, due to vaccination too long ago. 5 cases of lack of efficacy declared since 2023, all in goats. 4 cases O/O1, 1 case N. No pharmacovigilance signal being monitored for this vaccine.* Good advertising communication but no information on efficacy in sheep. The breeders who vaccinate are those with the best milking techniques. Many farms use amoxicillin or penicillin.	0 VMP	**Hygiene measures address 90% of the problems.** **VIMCO®: indication for staphylococcal mastitis*, in sheep and goats.** Indication: Reduction of subclinical mastitis => interest for milk quality Autovaccines with Morel *micrococcus*: quite good results 20 years ago. ***ANMV post-meeting note:*** *SPC indications: "Active immunisation of healthy animals in herds with recurrent mastitis problems to reduce the incidence of sub-clinical mastitis (reduction of udder lesions, somatic cell count and S.aureus count) caused by Staphylococcus aureus. etc."*	minor	minor

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Caseous (or lymphadenitis) disease (*Corynebacterium*)	**No vaccine in France** Use of auto-vaccines (risk questioned) is possible in the theoretical case of a lack of efficacy of the imported vaccine. However, the efficacy of autovaccines is low (low immunogenic agent). Low-critical disease in sheep, more in goats (prevalence around 30%, with limited consequences).	0 VMP	**Possible import of a Spanish vaccine** for caseous lymphadenitis caused by *Corynebacterium pseudotuberculosis (rare in sheep)*. ***ANMV info:*** *2 applications for GLANVAC 3 vaccine (MA in Australia) for goats, authorised in Oct and Nov 2024.* Questioning on the maintenance of the cold chain on such a long shipment (guarantees to be requested from the carrier if necessary). Abscess disease due to Morel micrococcus (staphylococcoccus) can be prevented using VIMCO® with cross-protection (*Staphylococcus aureus*/ Morel micrococcus); doubt about efficacy.	minor	minor
Adenomatosis (sheep)	Lack of therapeutic solution and increasing impact. Big problem that impacts among other things Causse lamb (adults are affected)	0 VMP	Monitoring to be improved.	minor	-
Anesthesia of "companion" sheep/goats	No anaesthetics with MRLs for sheep/goats. Problem with the use of anaesthetics for dogs/cats (without MRLs) e.g. for bucks castration, due to lack of knowledge of vets in pets practice. Wish for MA for xylazine or local anesthetics such as lidocaïne or procaïne.	Reg 0 VMP	Training of vets in pets practice on obligations and justifications needs.	*vigilance*	minor

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Pathology: in the process of resolution / with existing solution	Initial problem of the sector	Problem type	Solution / Alternatives Reason for: Resolution in progress / Elimination of therapeutic gap	GAP initially Major: M minor: m	
				Sheep	Goats
Cestodosis	**CESTOCUR: too concentrated (3 mL/20 kg) to use for Taenia on young animals. Lack of efficiency because volume is too low.** Widely used on grazing young sheep. (see opposite). ***ANMV Info:*** *9 reports of lack of efficacy in sheep between 2015 and 2020 + 2 cases of lack of efficacy reported in 2023 in sheep + 3 cases of sheep recorded since 2023: all for lack of efficacy. Cases assessed as O/O1. No signal being tracked.*	PhV	**Follow the treatment recommendations, i.e. leave the animals inside for 72 hours after treatment (not precised in the SPC).**	minor	
Visna maedi (ovine) **(lentivirus viral disease)**		0 ST	**Screening and culling.**	minor	-
Treatments against flies	Abandonment of FLECTRON (1 day WP for milk). *For the record:* There is a lack of VMPs against flies with short TA (for dairy animals).	Reg	VMPs with MA for sheep & goats for: SEBACIL, EPRINEX multi (0 d milk WP). With EU Reg 2019/6, the "cascade WP" of VMPs without MA for goats is 1.5x that for sheep or 1 day if 0d => **for goats: milk WP of 1 day for DELTANIL pour-on and 1.5 days for BUTOX and VERSATRINE**	**Under resolution**	
Myiasis due to *Wohlfahrtia magnifica*	**Geographic extension of the myiasis due to Wohlfahrtia.** **Lack of effective treatments due to the location of these myiasis and their seasonality (insufficient duration of action of existing VMPs).** No action of CLIK on areas without wool and under the shoe (manual removal required). No new reports of lack of efficacy on Wohlfarhrtia in sheep since 2018	PhV	**Local management** (trimming, removal of larvae) and **GDS information/training** have made good progress on the difficulties encountered previously. Use of essential oils (need to inform users), or BUTOX or VERSATRINE off-label use. **ADDENDUM dated 14/11/23** ***Post-meeting ANMV Info:*** *the use of VMPs with the myiasis indication in their MA, namely DELTANIL (for treatment) and ECTOFLY (for prevention and treatment) must be preferred to off-label "cascade" use of other VMPs that do not have this indication for myiasis.*	**Under resolution**	-

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Anti-inflammatory, analgesics	**No NSAIDs with Ovine/Caprine MA:** animal welfare (AW) concerns for convenience operations (caudectomy, dehorning, etc.). Problem in some organic farms with specifications requiring a marketing authorisation for the species. Absence of defined milk WP => Lack of pain control in dairy sheep and goats	(0 VMP)	*For the record:* **No VMP with MA for sheep, but in case of use via the "cascade" the fixed WP are now more advantageous thanks to EU Reg 2019/6.** The ideal would be to have MAs for the species concerned with a 1-day milk WP. => VMPs authorised for cattle: - **Tolfenamic acid:** milk WP= 0d (IM), 12-24h (IV) => **1d milk WP via cascade (IM)** - **Flunixin meglumine:** milk WP 24-36h, meat WP 10-31d (1)FINADYNE, EMDOFLUXIN, CRONYXIN, WELLICOX, FLUNIJECT, ANTALZEN, GENIXINE (2)MEGANYL (IV), (3)FLUNIXYL, FLUNIXIN, (IV), (4)FINADYNE transdermal => **when "cascade" use:** : **meat WP=(2) 4d (IV)**; (1) (3) 10d **=> 15d (IV)**, 31d => **47d (IM)**; (4) 7d **milk WP = (1) (2) (3) 24h (IV),** 36h (IM), (4)36h=> **3d** - **Dexamethasone:** 11 MAs for goats with milk WP from 3 to 7 days, no sheep MAs - **Ketoprofen:** new MRL status with same MRLs for all ruminants. => when "cascade" use: meat WP=3 to 6* d (IM), 2d (IV), milkWP=1d *according to VMPs	**Under resolution**	
Mastitis (intramammary)	Only 2 intramammary VMPswith MA for sheep (NAFPENZAL T and CEFOVET HL) and only one for goats (NAFPENZAL T).	1-2 VMP	**Intramammary antibiotic treatment during lactation is of little interest** see **Semaine vétérinaire journal No. 2046:** *"In case of clinical mastitis during lactation, early parenteral antibiotic therapy is required in particular in case of general symptoms (at least for "animal welfare"). Bactericidal actives concentrating in the mammary parenchyma should be chosen. The frequency of resistance of some bacteria isolated from mastitis should be known.* ***Intramammary antibiotic treatment during lactation is of little interest*** *due to the absence of specialties with extension of MA, frequent bacteraemia and possible absence of bacteriological cure during lactation.* ***Clinical mastitis should be a cause for immediate culling.***»	minor	minor
Paratuberculosis	***For the record:*** **Possible import of the Spanish GUDAIR vaccine** (many import requests) moreover, less expensive than Silirum. Very good efficacy, but does not prevent excretion in sheep. Is there any information on the possible impact of the age of the animals, especially in the case of late vaccination at 4 months? ***Post-meeting ANMV Info:*** *All available information is in the SPC and Public Report* Ensure there is no cross-reaction with tuberculin.	1 VMP	**New vaccine in France: New MA (15/05/2024) GUDAIR** emulsion for injection for sheep and goats which "eases life". Very good results => vaccination is continued.		**M n°3**
Piroplasmosis	**No VMP with MA in sheep.** **Only one WMP with MA for cattle:** CARBESIA The meat withdrawal period of 213 days (CARBESIA) is not applicable.	1 VMP Reg	**Very minor issue due to the questionable relevance of treatment or prevention of piroplasmosis.**	minor	minor
Uterine infections	**No VMP with an MA for sheep or goats -** only authorised for cattle. ***ANMV Info:*** *CENTRAUREO® was abandoned on 05/2023* *For the record:* Abandonment of MA (30/11/22) of Auréomycin Merial. A single intrauterine chlortetracycline oblet remains, for cows & mares: Centrauréo° Oblet with meat WP = 11d and milk WP= 1d	0 VMP	**Irrelevant issue due to the unrecommended use of local antibiotic therapy.** **HISTABIOSONE:** MA for goats. Compliance with the fixed WP via "cascade" is not problematic in this case.	minor	minor

Therapeutic gaps in the sheep & goats sector

Hearing on 03/07/25

Ringworm	**No vaccine with MA for ovine-caprine.** see communication JNGTV 2024 on the use of RINGVAC on a ram in an allotment center.	0 VMP	**Hygiene and breeding conditions.** Vaccines authorised in cattle: ***ANMV Info:*** ***BOVILIS Ringvac, TRICHOLOR (AMM 18/05/22), BOVIGEN T (MA dated 04/2021).*** IMAVERAL but not approved for ovine or caprine species.	**minor**	**minor**

Therapeutic gaps in the sheep & goats sector

Hearing on 03/07/25

Prioritisation of identified gaps

	Sheep		Goats		Prioritisation at the previous hearing (06/06/23)	
	Julien VISSE	Christophe HUGNET	Claire COMBELLES	Christophe HUGNET	Sheep	Goats
Digestive strongylosis, with increased resistance (to benzimidazoles, levamisole and eprinomectin)	MAJOR n°1	MAJOR n°1 + shortage issues (closantel)	MAJOR n°3		MAJOR n°1	MAJOR n°1
Blue tongue (multistrain vaccine)	MAJOR n°2		-		-	-
Neonatal colibacillosis// enterotoxaemia	MAJOR n°3		MAJOR n°4_{bis}		MAJOR n°2	minor
Cryptosporidiosis	MAJOR n°3_{bis}		MAJOR n°4		MAJOR n°2_{bis}	MAJOR n°5
Respiratory pasteurellosis	MAJOR n°4		MAJOR n°2		minor	MAJOR n°2
Hormons	MAJOR n°5		minor n°1		MAJOR n°4	minor
Mycoplasmosis (including mastitis)	minor		MAJOR n°1		minor	MAJOR n°4
Coccidiosis	minor		MAJOR n°4_{ter}		minor	minor
Contagious echtyma	minor		*Vigilance*		MAJOR n°3	-
Sheep scabies	minor		-		minor	
Border disease	minor				minor	
Staphylococcal mastitis/ teat dermatosis (prevention)	minor		minor		minor	
Caseous disease (or lymphadenitis) (*Corynebacterium*)	minor		minor		minor	
Adenomatosis	minor		-		minor	-
Anesthesia of "companion" sheep/goats	*Vigilance* *(Regulatory framework to be recalled)*		minor *alert on training of vets for pets*			
Cestodosis	Under resolution				minor	
Visna maedi	Under resolution		-		minor	-
Treatments against flies	Under resolution		Under resolution		Under resolution	
Myiasis (*Wohlfahrtia magnifica)*	Under resolution				Under resolution	
Anti-inflammatory, analgesics	Under resolution				Under resolution	
Mastitis (intramammary)	Under resolution (minor)		Under resolution Effective mastitis vaccine		minor	
Paratuberculosis	Existing solution		Existing solution		minor	MAJOR n°3
Piroplasmosis	Existing solution				minor	
Uterine infections	Existing solution		Existing solution		minor	minor
Ringworm	Existing solution				minor	minor

Therapeutic gaps in the sheep & goats sector

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Changes in gaps since the last hearing in June 2023 (see tables below):

Favourable trend for:

- Paratuberculosis, thanks to the new MA in France for the GUDAIR vaccine
- Contagious ecthyma, thanks to the lack of reported shortages since 2023, but it is important to remain very vigilant as it is the only existing vaccine
- Piroplasmosis and uterine infections, in case of compliance with treatment or prevention recommendations
- Ringworm, thanks to improved hygiene and breeding conditions
- Ovine cestodosis, in case of compliance with treatment recommendations
- Mastitis, in case of follow-up of general recommendations in terms of intramammary use
- Visna maedi, with screening and culling of the herd in case of positivity

Less favourable trend for:

- Respiratory pasteurellosis, due to perceived insufficient effectiveness in the field for existing vaccines (in sheep) and the critical lack of vaccine with MA for goats
- Absence of vaccine for Blue tongue with more than 2 serotypes
- Caprine mycoplasmosis, due to the persistent absence of vaccines with MA in France, and the cost of importing Spanish vaccines
- Neonatal colibacillosis/enterotoxaemia, with the abandonment of some vaccines at the end of 2023. The temporary authorisation for use (TAU) for a new vaccine for cattle and sheep is welcomed. However, this TAU does not cover goats.
- Coccidiosis in goats, due to lack of MA for goats and detection of resistance to diclazuril
- The lack of anaesthetics with MAs and MRLs (listed in Table 1) that can be used for “companion” sheep/goats, prompting the inappropriate use of VMPs pets which are not authorised for sheep/goats.

Therapeutic gaps in the sheep & goats sector

Hearing on 03/07/25

	Sheep	
	Hearing dated 06/06/23	**Hearing dated 03/07/25**
MAJOR PRIORITIES	**1. Digestive strongylosis, with increased resistance to benzimidazoles, levamisole and eprinomectin** **2. Neonatal colibacillosis / enterotoxaemia** **2bis Cryptosporidiosis** **3. Contagious echtyma** **4. Hormons**	**1. Digestive strongylosis, with increased resistance to benzimidazoles, levamisole and eprinomectin** **2. Blue tongue (multistrain Vaccine)** **3. Neonatal colibacillosis / enterotoxaemia** **3bis Cryptosporidiosis** **4. Respiratory pasteurellosis** **5. Hormons**
Minor priorities	• Respiratory pasteurellosis • Mycoplasma mastitis • Paratuberculosis • Coccidiosis • Staphylococcal mastitis or dermatosis of teats (prevention) • Caseous disease (or lymphadenitis) • Piroplasmosis • Uterine infections • Ringworm • Border disease • Sheep scabies • Adenomatosis • Cestodosis • Mastitis (Intramammary) • Visna maedi	• Mycoplasmosis (including mastitis) • Contagious ecthyma • Coccidiosis • Staphylococcal mastitis or dermatosis of teats (prevention) • Caseous disease (or lymphadenitis) • Border disease • Sheep scabies • Adenomatosis • Anaesthetics for “companion" sheep
Under resolution	➢ Treatments against flies **thanks to EU Reg 2019/6 – shorter milk WP in case of “cascade” use** ➢ **Myiasis at *Wohlfahrtia magnifica* through local support and GDS training** ➢ Anti-inflammatory, analgesics **thanks to EU Reg 2019/6 – shorter milk WP in case of “cascade” use**	➢ Cestodosis, **in case of compliance with recommendations** ➢ Mastitis (intramammary), **thanks to compliance with recommendations** ➢ Visna maedi, **thanks to screening and culling in case of positivity** ➢ Treatment against flies ➢ Myiasis (*Wohlfahrtia magnifica)* ➢ Anti-inflammatory, analgesics
Existing solution	☑ Q fever **thanks to extension of MA to sheep (04/23)** ☑ SONO **thanks to Eprinex multi extension of indication (2022)** ☑ Footrot **thanks to MA modification**	☑ Paratuberculosis, **thanks to new MA in France for the GUDAIR vaccine** ☑ Piroplasmosis, **in case of compliance with recommendations** ☑ Uterine infections, **if recommendations are followed** ☑ Ringworm, **thanks to improved hygiene and livestock conditions**

Therapeutic gaps in the sheep & goats sector

Hearing on 03/07/25

Goats

	Hearing dated 06/06/23	Hearing dated 03/07/25
MAJOR PRIORITIES	**1. Digestive strongylosis, with increased resistance to benzimidazoles, levamisole and eprinomectin** **2. Respiratory pasteurellosis** **3. Paratuberculosis** **4. Mycoplasma mastitis** **5. Cryptosporidiosis**	**1. Mycoplasmosis (including mastitis)** **2. Respiratory pasteurellosis** **3. Digestive strongylosis, with increased resistance to benzimidazoles, levamisole and eprinomectin** **4. Cryptosporidiosis** **4_{bis} Neonatal colibacillosis / enterotoxaemia** **4_{ter} Coccidiosis**
Minor priorities	• Neonatal colibacillosis • Coccidiosis • Hormons • Staphylococcal mastitis or dermatosis of teats (prevention) • Caseous disease (or lymphadenitis) • Uterine infections • Ringworm • Mastitis (intramammary)	• Hormons • Staphylococcal mastitis or dermatosis of teats (prevention) • Caseous disease (or lymphadenitis) • Anaesthetics for “companion" goats
Under resolution	➢ Treatments against flies **thanks to EU Reg 2019/6 – shorter milk WP in case of “cascade” use** ➢ Anti-inflammatory, analgesics **thanks to EU Reg 2019/6 – shorter milk WP in case of “cascade” use**	➢ Mastitis (intramammary), **thanks to compliance with recommendations** ➢ Treatment against flies ➢ Anti-inflammatory, analgesics
Existing solution		☑ Paratuberculosis, **thanks to new MA in France for the GUDAIR vaccine** ☑ Uterine infections, **if recommendations are followed**