Hearing of 12/06/25

Participants: Clément Moriceau (veterinary practitioner for dairy cattle in Normandy, SNGTV Medicines Commission), Corinne Jaureguy (beef calf veterinary practitioner, SNGTV medicines commission & beef calf commission), Lionel Grisot (mixed dairy cattle veterinary practitioner in Franche Comté, member of the CSMV).

for ANMV: L.Baduel, B.Leroux, M. Zerrouki, C.Lorteau, J.Bietrix, L.Fabry.

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

- The identification of therapeutic gaps (and the details of the situations expressed and of the alternatives envisaged) are 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.

New elements since the last hearing: in blue below.

The priority areas identified and wishes for vigilance expressed by the participating representatives of the veterinary profession are:

- 1. Need for topical antibiotic treatments: for local administration in case of eye infections, teat lesions, etc.
- 2. Bovine antiparasitic agents with MA, in particular for the paramphistomosis and dicroceleliosis indications, with appropriate and validated dosages and withdrawal periods
- 3. Antipyretics and tranquilizers that can be administered per os, analgesics that can be used in dairy farming.
- 4. Some markets are very fragile, with recurrent shortages and alarming decrease in the available pharmacopoeia (see "alerts" mentioned in p7), favouring the systematic transfer of responsibility to practitioners.
- 5. Too few MAs for certain routes of administration (e.g. IV or local).
 - There are now only a few usable antibiotics for which the MA indicates the IV route: fluoroquinolones and TMP-sulfamides (withdrawal periods with gentamicin are too long in calf farming).

A worrying decrease in the marketing of small presentations, despite the existence of MAs and the numerous generics on the market.

This trend is not consistent with current policies, particularly on antibiotics, aimed at limiting "self-medication", promoting rational use and limiting risks to the environment.

Axes 1 and 3 mentioned above are paramount in terms of animal welfare (AW).

<u>Phyto-Aromatherapy</u>: the sector uses these herbal products a lot for various therapeutic applications. This poses a real problem linked to the absence of MRLs, products without MA, food products without control. Food manufacturers offer this type of product through direct sales of dietary products to farmers. Many "gurus" who offer many food supplements: supervision is necessary even if it is very fashionable.

<u>ANMV info:</u> ANMV presented its reflections and proposals to the European Commission during several European meetings (from 2022 to 2024) on the issue of the MRL status of these substances (plants, parts of plants, herbal preparations, etc.). Under Article 157 of Reg 2019/6, a consultation by the Commission has been initiated with conclusions expected in 2027.

Prioritisation and evolution of gaps since the last hearing in May 2023: see p. 8 and 9

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

O VMP (Absence of appropriate veterinary medicinal products) is highlighted in yellow, when requesting a veterinary medicinal product with MA for the species and indication concerned

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	Tab.	*5 !!		
Disease Unsatisfactory Disp: Availability, sho Reg: Regulatory (casc O VMP: Absence of ag O TS: No therapeutic s	rtage ade application, withdrawal period, restricted access) appropriate veterinary medicinal product solution	*Problem type: PhV Disp Reg 0 VMP 0 TS	Alternatives identified	PRIORITY Major:M minor: m
specifications prohibitimpasse. Very painful lesions at concern for animal w (tarsorraphy) as the concern for animal w with a long WP and it EcoAntibio. In addition self-medication. Practicing a subconjuit Audits have sometimes	nent with MA for cattle, whereas some breeding it "off-label" use of VMPs leading to therapeutic and nothing to relieve pain and protect the cornea: a real reliare (AW), often requiring the eyelids to be sutured	O VMP topical	Off-label use of intramammary, eye drops or ophthalmic ointments (MA for other non-food-producing species): OPHTOCYCLINE (tetracycline) or FRADEXAM (framycetin, dexamethasone), with fixed WPs (≥ 28d for meat, ≥ 7d for milk) that are too long in dairy cattle farming (economic impact) or that may not be respected by farmers. The injectable tulathromycin VMPs have the indication for keratoconjunctivitis but it cannot be used in lactating cows (MRLs: restriction on the use of tulathromycin: "Do not use in animals producing milk for human consumption"). Ophthalmic ORBENIN available in Switzerland but cannot be imported due to other European or national alternatives via the cascade. Why is there no MA in France for ophthalmic ORBENIN or extension of OPHTOCYCLINE to cattle? ANMV info: The application for import is possible by the vets for Opticlox ointment which has an MA in NL or Latvia for cattle and IKC (indication of Moraxella in MA in NL) - see FAQ DGAL p3 line 1. No request to import OPTICLOX since the last hearing. Veterinarians are reluctant to make requests "because of the administrative burden and the difficulty of entering into contact with a Latvian or Dutch distributor. An application for a MA extension in France would be the best solution." ANMV post-meeting info: An import authorisation request has been registered post-meeting for the MORAXEBIN NEO vaccine (MA in CZ)	MAJOR n°1 (AW)

Deep and superinfected teat traumas (wounds, cracking, scratches, etc.)	DERMAFLON does not treat anything (detersive properties). Marketing while stocks last, prior to product abandon. The only topical treatment with MA is COTHIVET. COTHIVET dries a lot. Need for healing ointment treatment with antibiotics. Currently not available. ANMV info: shortage declared since November 2024.	1 VMP topical Disp	Current use of the combination of COTHIVET (shortage) / lodine and honey* or teat isolation. • VETEBIOL (hygiene product but claims like therapeutics & milk smell problem) • SULMIDOL (Sulfapiridine): with fixed WP (MRL exists for all species) *Benefit of using VETRAMIL, but insufficient if an antibiotic is needed. ANMV Info: no new MA for ointment with antibiotics for cattle since the last hearing	MAJOR N°1 _{bis} (AW)
Paramphistomosis	No MA for this indication for cattle: the required dose of oxyclozanide is different from that authorised for the treatment of fasciolosis. Wish for a paramphistomosis MA with specific studies on this parasite. Many protocols are proposed without proof of efficacy meeting the MA requirements. No studies available on the efficacy of oxyclozanide on the immature form, the only which is pathogen. The increase in doses causes diarrhoea, hence the current recommendation of a stop-dose (3,5g per animal). Practitioners wonder whether the current fixed WP according to Reg 2019/6, lower than the previously prescribed WP of 28 days, is sufficiently safe (commitment of the prescriber's responsibility). A MA or at least depletion studies with published recommended dose would be useful. ANMV info: fixed WPs are minima, so if the veterinarian thinks they are not sufficient, he can prescribe longer ones. From the MRL perspective, nothing new for oxyclozanide	O VMP	Oxyclozanide used via the cascade. The MRL of oxyclozanide is icluded in Table 1 for all ruminants with a milk MRL. ANMV info: "Cascade" use possible at dry-off with 2 doses 3 days apart, with a fixed milk WP ≥ 7 days (i.e 1.5 x 4.5 days) for RUMENIL and ≥ 11 days for other VMPs, also indicated for sheep with a milk WP of 7 days. The FLUKIVER SPC mentions the indication Paramphistomum spp. only for sheep (with meat WP of 107 days and 77 days in cattle) and mentions (§ 3.12 Withdrawal period): "Do not administer to cattle producing milk for human consumption, including during the dry period. ". Closantel is in Table 1 with a milk MRL. In the absence of specific restrictions in Table 1, the cascade is therefore possible in the dairy cattle and the fixed WP must take into account the available information (see SPC). Farmers no longer deworm and prefer the use of herbal products (how effective? consumer safety?)	MAJOR n°2
Dicroceliosis	No MA for cattle and for this indication. Albendazole MA for cattle and sheep, but dicroceliosis indication only for sheep. Application of the cascade with usual WP if the dosage used is the MA's one. As a reminder: The "cascade" use of HAPADEX (WP of 3days for milk in cattle) is no longer possible because it has not been marketed for several years (in France).	<mark>0 VMP</mark> Disp	Need for a cattle MA, with confirmation of the dose and determination of an appropriateWP <u>ANMV info:</u> MA 02/04/25 for Albendis° 100 mg/mL: 2 nd VMP (with Valbazen° 1.9%) to have the indication "dicrocoeliosis", but for sheep only.	MAJOR n°2 _{bis}
Oral antipyretics	No MA for cattle for <u>oral</u> antipyretics. Paracetamol MA only for pigs ("no MRLs required" with restriction of oral use _no bovine MRLs). Some integrators prohibit off-label use of VMPs. Risk of ulcers in calves with aspirin => mixed in the field with bicarbonate. <u>ANMV info:</u> There is an MA for an oral ketoprofen for cattle: DINALGEN 300 MG/ML ORAL SOLUTION FOR CATTLE AND PIGS with a 1day meat WP (risk of ulcers mentioned in §4.5 of the SPC).	(0) VMP	Possible "cascade use" of paracetamol with restriction of oral use. ANMV info: The WP to be applied depends on the WP of the drug used. This must therefore be clearly defined: there are WPs of 0 and 1 day, which will lead to a respective fixed WP of at least 1 or 2 days. Possible cascade use of oral meloxicam (MA for horses with WP of 3 days and MA for pigs with WP of 5 days). Reduced incidence of ulcers thanks to more fibrous food.	MAJOR n°3 (AW)

	MA was granted in 07/2023 for DOPHACYL SB 1000 MG/G powder for administration in drinking water/milk for cattle and pigs. No cases of PhV recorded in the French database with DOPHACYL or DINALGEN. Ketoprofen is not used in the field in calves because it has a bad press, nor DOPHACYL => see why?			
Abomasum ulcers	No VMPs with MA for cattle Omeprazole, MRL status for oral administration (no MRL required for horses).	0 VMP	No omeprazole MRL status established for cattle but cascade possible with fixed WP (validated by DGAL). WP meat ≥ 2 days for oral paste and 3 days for EQUIZOL gastroresistant granules. But price is high and the SPC mentions in § 4.11 "Milk: do not use in animals producing milk intended for human consumption". Omeprazole listed in Table 1 for horses with no MRLs required and restricted to oral use.	MAJOR n°4 or 5
Antacids and mucosal protection	Future discontinuation or discontinuation of VMP with kaolin or aluminium silicate. Detrimental discontinuation because of its possible role in preventing infections and use of antibiotics. In the beef calves and fattening calves sector, where specifications prohibit off-label use, vets no longer have a solution since the end of marketing VMPs such as ALUMINAL, KAOPECTATE, ALUSSALINE was stopped.	Disp	Purchase of commercially available clays, without MA and not controlled.	MAJOR n°4 _{bis} or 5 _{bis}
Oral tranquilizers	No MA for oral antipyretics for cattle. Shotgun injection is no longer possible because the appropriate lyophilized xylazine formulation (ROMPUN) no longer exists. What is more, shotgun injection is like a circus game, with the responsibility of the one who shoots. ANMV info: no new MA for oral use, but 2 new MAs for injection: XYLAMIDOR 20 MG/ML (xylazine hydrochloride) and PRESEDINE (detomidine hydrochloride). No acepromazine MRL status. ANMV info: nothing new since 2023. The use of oral VMP (acepromazine) for horses is illegal and results in the slaughter/destruction of the treated cattle. The use via "cascade" of DOMOSEDAN GEL 7.6 MG/ML for horses does not meet the need, as administration is individual and sublingual. ANMV info: Detomidine MRL is listed in Table 1 for cattle and horses.	O VMP	Potential interest of oral azaperone administration?Currently only available for injection ANMV info: azaperone is listed in Table 1 (MRL) only for pigs	MAJOR n°4 or 5

Long-term analgesics	Wish for long-term analgesics to respond to animal welfare (AW) considerations, especially for groups of heifers, animals going to summer pasture.	<mark>0 VMP</mark>	Potential interest of Butorphanol? Butorphanol tartrate is listed in Table 1 "no MRL required" for equidae, only intravenously.	
Flies (stomoxes and others)	Deltamethrin: but development of resistance. The only molecules that can be used, especially in dairy production, are pyrethrinoids, which have been used for several decades. Safety issues for the user, for the environment and risks of resistance. No alternative at the moment .High risk related to vector diseases Problems especially for calf horns flies and also for biting or chewing lice. Very disappointed by the unavailability of ear tags (preferred to pour-on). Some import via Internet, permethrin ear tags from the Netherlands or New Zealand. ANMV info: Since 2021, only one reported case of lack of efficacy on flies and 8 cases of lack of efficacy with deltamethrin-based VMPs for other indications (mainly lice). Keep in mind that these are old products, with known and multifactorial possible lack of efficacy concerns (parasitic pressure in the environment in particular), and probably not reported by the vets. Since the last hearing in May 2023, 12 new cases of lack of efficacy were reported for cattle, including 4 against flies, for various deltamethrin-based VMPs. Please note that lack of efficacy does not mean resistance, knowing that other external factors may play an important role, such as the overall control of parasites in the farm or the level of parasitic pressure. The cases remain generally poorly documented. It is also necessary to balance this number of cases with the use of WMPs in the field. It is important to continue to declare, even if these are old products, as this helps to identify changes.	PhV Reg. Disp	Avoid fibrous foods that are excellent substrates for flies. Improvement of buildings. Frequent use of biocides against flies on animals or udder, while this does not correspond to their claims and is not allowed. Biological control with wasps. Be careful of the underdosing of treatments related to an under evaluation of the weight of the animals and also of the risk of licking with the pour-on/spot-on.	minor or Vigilance
Culicoids: disinsectisation before export	Deltamethrin (off-label indication): Efficacy perceived as random in the field, and actual application by farmers even more doubtful.	<u>0 VMP</u>	Would it be possible to develop an isoxazoline (a "Bravecto" for calves)? It would also be of interest for biting flies (see below), provided there is no environmental safety issue. There would be an MA for cattle in the USA. Publications on efficacy in Brazil. Neurological risks in young calves. ANMV info: The environmental toxicity of isoxazolines and their persistence is proven (see literature; moreover, this family of substances meets the EFSA criteria for classification as PFAS). To date, no new MA for cattle in Eu.	minor

Besnoitiosis	No VMP approved for cattle - Sulphonamides at high doses (significantly higher than those currently authorised for cattle => current unsuitable presentations). Geographical extension, going north, related to commercial transactions (healthy carrier animals). The national territory is almost entirely contaminated, but with low prevalence in general. It is urgent to clean up as quickly as possible, but active research for drug and vaccine development would put us in a more comfortable position. Spain is a Eu contaminated country. Lack of efficacy of sulphonamides. Culling of animals and elimination of seropositive animals. Eradication plan in place (see SNGTV parasitology commission). Wish for a VMP for high-value animals.	O VMP	The outbreaks management policy varies with regions and national harmonisation is not really on the agenda, many departments are starting to be in a "living with" logic. No vaccine available in Europe — 1 vaccine exists in Israel. ANMV info: still no vaccines authorised in Europe. No information on the vaccine available in Israel Extension of clusters throughout France, but exposure varies depending on the region. In the absence of vaccines and/or satisfactory treatments, the current approach is health-related with the attempt to eradicate "super spreaders" (see Pr Jacquiet's ppt at JNGTV 2023).	minor
Piroplasmosis	Frequent cases. Increasing impact, due to the geographical and temporal extension: the risk period, initially from May to September, extended from April to the end of November. The concerned geographical areas have also increased. Farmers practice injection prevention a lot in some areas. In acute clinical cases, treatment is mandatory. Only one VMP with MA = CARBESIA and with too long WP meat (WP of 213 days for meat, and 6 days for milk). WP is not respected because farmers forget (far too long for fattening animals and cull cows in the pasture). Why is WP the same whether the use is preventive or curative when the recommended doses are 2.5 times lower (0.85 mg vs 2.125 mg/kg)? Post-meeting ANMV info: available depletion studies were conducted only at the highest dose. Essential in curative and only molecule available (recurrent shortages until May 2020 – stable since). ANMV info: No new shortage reported since the last one ended in 11/2023	1 VMP	Treatments for ticks lower the incidence but do not eradicate the disease (for animals that are not immune) and deltamethrin is toxic to aquatic organisms and bees. Individual treatment, preventive use in general for 6-month-old animals or on introduced animals. Different doses for curative/preventive. Illusory in practice.	minor
Topical NSAIDs for bruisies, trauma, sprains	No topical medication => animal welfare (WA) concerns	O VMP	In absence of topical products, hygiene products are sold instead. No topical capsaicin available (QUTENZA skin patch in humans). ANMV info: MA dated 17/08/20 for the homeopathic VMP TRAUMEEL gel. Ruminants are not mentioned in the target species (which are dog, cat, horse): cascade use possible with a fixed WP of 1 day (as WP for meat and milk is of 0 day in horses). Several MAs with NSAIDs since May 2023, but none topical (6 injectable solutions of meloxicam, flunixin, ketoprofen or carprofen and a sodium salicylate powder for administration in drinking water)	minor

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Mastitis of fungal	No treatment	0 VMP	minor
(Candida, Aspergillus,	Very rare		
etc.) or algal origin			
(Prototheca)			

Special VIGILANCE required for:

- <u>Vit AD₃E injectable:</u> Only one presentation is available at wholesalers and with frequent availability concerns. In addition, the meat WPs, which are now too long, are a dissuasive factor for use in the short-cycle fattening sector, and detrimental in other sectors.
- Gynaecological oblets: important in case of reproduction follow-up and preferred to systematic injection of cefalexin.

 Disappointment following the discontinuation of CENTRAUREO. CLAMOXYL intrauterine tablets are still on the market. Another alternative: intrauterine suspension of cefapirin.

 ANMV info: CENTRAUREO® was discontinued on 05/2023. Sustainable return to the market of CLAMOXYL® intrauterine tablet on 07/08/2024. MA withdrawal for Auréomycin notified on 30/11/22.
- <u>Clostridiosis:</u> cyclic and repeated shortages issues for existing vaccines, which require to administer boosters with a vaccine different from that given as a primary vaccination.
- Salmonellosis vaccine (and respiratory infections): the precited gap has been solved but the situation remains fragile for this single vaccine against salmonellosis and Pasteurella multocida (see below)

Pathology: in the process of resolution with existing solution	Initial problem	Initial roblem type	Solution / Alternatives Reason for: Resolution in progress / Solving the therapeutic gap	GAP initially Major:M minor: m
Respiratory vaccines against Salmonella	Allocated dose quotas, valid only one year. Essential vaccine: great concern, fear of divestment. As a reminder: Frequent shortages of SALMOPAST (not officially since the end of 2018). 50 mL presentation not very suitable. On these types of vaccines, quality control problems lead to regular shortages. SALMOPAST is also a vaccine against Salmonella typhimurium and S.dublin, it is the only salmonella vaccine that claims prevention against clinical forms but does not prevent excretion. S.montevideo is not uncommon in cattle and there is no vaccine for this strain.	Disp 1 VMP	ANMV info: Critical shortage of SALMOPAST occurred from end of February to end of August 2023. It is currently available. Auo-vaccine for S.montevideo: no requests to date.	

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Prioritisation of identified gaps

	Clément MORICEAU	Corinne JAUREGUY	Lionel GRISOT	Prioritisation at the previous hearing (30/05/23)
Eye infections with corneal lesions (topical treatment)	MAJOR n°1	MAJOR n°1	MAJOR n°1	MAJOR n°1
Deep and surinfected teat traumas	MAJOR n°1 _{bis}	MAJOR n°1 _{bis}	MAJOR n°1 _{bis}	MAJOR n°1 _{bis}
Paramphistomosis	MAJOR n°2	MAJOR n°2	MAJOR n°2	MAJOR n°2
Dicroceliosis	MAJOR n°2 _{bis}	MAJOR n°2 _{bis}	MAJOR n°2 _{bis}	MAJOR n°2 _{bis}
Oral antipyretics	MAJOR n°3	MAJOR n°3	MAJOR n°3	MAJOR n°3
Abomasum ulcer	MAJOR n°4	MAJOR n°4	MAJOR n°5	Resolved
Antacids and mucosal protection	MAJOR n°4 _{bis}	MAJOR n°4 _{bis}	MAJOR n°5 _{bis}	
Oral tranquilizers + long-term analgesics	MAJOR n°5	MAJOR n°5	MAJOR n°4	MAJOR n°4
Flies	Vigilance	minor	Vigilance (abandonment of cypermethrin, only remaining deltamethrin pour-on)	minor
Culicoids: disinsectisation before export	minor	minor	minor	minor
Besnoitiosis	minor	minor	minor	minor
Piroplasmosis	minor	minor	minor	minor
Topical NSAIDs for bruises, trauma, sprains	minor	minor	minor	minor
Mastitis of fungal or algal origin	minor	minor	minor	minor
Respiratory vaccines against Salmonella (shortages monitoring)	Resolved but Vigilance ++	Resolved but Vigilance ++	Resolved but Vigilance ++	Resolution in progress
ATB: for IV route & small presentations	Vigilance	Vigilance	Vigilance ++	
Postpartum: gynecological oblets in case of caesarean section, endometritis, prolapse	Vigilance	Vigilance	Vigilance	
Clostridiosis vaccines	Vigilance	Vigilance	Vigilance	
Vitamines AD₃E	Vigilance	Vigilance	Vigilance	

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Changes in gaps since the last hearing in May 2023:

Favourable trend for:

- The vaccine against salmonellosis (and respiratory infections): gap resolved thanks to the end of shortages, but it is important to remain vigilant as this vaccine is unique on the market and is subject to "quota" allocation measures

Less favourable trend for:

- Abomasum ulcers, in absence of VMPs authorised for cattle.
- Antacids and mucosal protectors: subject to availability issues.
- VMPs against flies, because of: problems of availability on ear tags, possible lack of efficacy of deltamethrin and biocides wrongly used as VMPs

Hearing dated 30/05/23	Hearing dated 16/06/25
1. Eye infections with corneal lesions	1. Eye infections with corneal lesions
1.bis Deep and surinfected teat traumas	1.bis Deep and surinfected teat traumas
2. Paramphistomosis	2. Paramphistomosis
2.bis Dicroceliosis	2.bis Dicroceliosis
3. Oral antipyretics	3. Oral antipyretics
4. Oral tranquilizers	4. or 5. Abomasum ulcers
+ long-term analgesics	+ 4.or 5.bis Antacids and mucosal protection
_	5. or 4. Oral tranquilisers
	+ long-term analgesics
Besnoitiosis	Flies
Piroplasmosis	Culicoids: disinsectisation before export
Culicoids: disinsectisation before export	Besnoitiosis
• Flies	Piroplasmosis
Topical NSAIDs for bruises, trauma, sprains	Topical NSAIDs for bruises, trauma, sprains
	, , , , , , , , , , , , , , , , , , ,
	Mastitis of fungal or algal origin
	0 0
	Respiratory vaccines against Salmonella (and respiratory infections), thanks to end
	of shortage, but remain vigilant because only one vaccine on the market.
	 Eye infections with corneal lesions 1.bis Deep and surinfected teat traumas Paramphistomosis 2.bis Dicroceliosis Oral antipyretics Oral tranquilizers + long-term analgesics Besnoitiosis Piroplasmosis Culicoids: disinsectisation before export Flies Topical NSAIDs for bruises, trauma, sprains Abomasum ulcers Mastitis of fungal or algal origin Salmonella vaccines (and respiratory infections)