

Therapeutic gaps in French GUIANA

Hearing on 13/06/24

Participants: Brice AUGUSTIN-CONSTANTIN (Secretary General INTERVIG), Benoît BALMELLE (Veterinary practitioner in French Guiana), Xavier BAUDRIMONT (Head of Unit for Animal and Plant Protection Health Correspondent IFCE French Guiana DEAAF/SALIM/IFCE), Patrick LABRANCHE (Farmer, President of INTERVIG), Emmanuel TILLARD (Veterinarian PHD, CIRAD UMR SELMET: Mediterranean and tropical livestock systems), Elise ACH (Project Manager INTERVIG) - **Excused:** Frédéric BUFFARD

for ANMV: Laure BADUEL, François BRUNEAUX, Mickaëlle SACHET, Béatrice LEROUX, Aline HANOUEÏT, Justine TIMONNIER - **Excused:** Franck FOURES

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.

Disease	Animal species concerned	Problem encountered: PhV: Pharmacovigilance (efficacy or safety perceived as unsatisfactory) Disp: Availability, shortage Reg: Regulatory (cascade application, withdrawal period, restricted access) 0 VMP: Absence of <u>appropriate</u> veterinary medicinal products (VMPs) 0 TS: Lack of therapeutic solution	Problem Type: PhV, Disp, Reg 0 VMP 0 TS	Alternatives identified	PRIORITY Major: M minor: m (see p 3)
Trypanosomiasis	Cattle (bubalins?)/ small ruminants	Medicines exist but do not have a MA granted for Europe. Lead time issues. Regular needs => storage and concerns about the expiry of stocks.	(0 VMP)	Import of drugs without Eu MA but manufactured in France (for Africa in particular): VERIBEN®, VERIDIUM® (Ceva AFRIQUE). ANMV info: import is possible after ANMV acceptance of request for authorisation (as it was the case in 2015). Procedure: see Request an import authorisation Anses - Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail	M n° 1

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<p>Myiasis due to <i>Cochliomyia hominivorax</i> (New World Screwworm – NWS fly)</p>	<p>Cattle a minima</p>	<p>The risk of myiasis is very high around the umbilical cord of calves at birth, even after disinfection, at the level of the ears when ear tags are placed, and as soon as there is a wound. Matabicheiras, an insecticidal and healing aerosol containing gentian violet and dichlorvos, made in Brazil and used throughout South America, used for a very long time (low cost and effective) is now formally banned. ⇒ Treatments with DECTOMAX® injectable (big farms) or pour-on are not satisfactory. The import from Brazil of cheaper VMPs manufactured in Brazil containing doramectin or ivermectin is wished, but illegal. ⇒ SEBACIL (phoxim) is used, but its effectiveness does not last very long.</p>	<p>0 VMP ?</p>	<p>DECTOMAX® injectable or SEBACIL pour-on, but this is not sufficient (see opposite). ANMV Info: several pour-on VMPs have a MA in France against sheep myiasis. They contain: - dicyclanil (IGR) – indicated for prevention of myiasis due to <i>Lucilia sericata</i> and <i>Wohlfahrtia magnifica</i>; - deltamethrin, indicated for treatment of <i>Lucilia spp</i> myiasis. - Cypermethrin, indicated for treatment and prevention of myiasis A field trial assessment would help to determine whether these pour-on are effective against NWS (<i>Cochliomyia hominivorax</i>). Post-meeting note: efficacy of isoxazolins could also be explored (see publications about efficacy on NWS in dogs, i.e: https://doi.org/10.1016/j.vprsr.2021.100569)</p>	<p>M n° 2, 3 or 4</p>
<p>Chagas disease</p>	<p>Dogs</p>	<p>The only available treatment in humans is benznidazole. Its import from Brazil is not always authorised by the ANSM for veterinary use</p>	<p>0 VMP</p>	<p>Benznidazole (human medicine) ANMV Info: As it is a human medicinal product, it is the ANSM and not the ANMV that can handle this type of request. The ANSM usually receives import requests from pharmaceutical laboratories or distributors. An agreement between the ANMV and the ANSM is currently being signed (Editor's note: signed since the meeting). ⇒ Send the request to the ANSM, which will see with ANMV in case a clinical evaluation is needed.</p>	<p>M n° 2 or n° 5 or m</p>

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Equine protozoal myeloencephalitis (EPM) due to <i>Sarcocystis neurona</i>	Horses	No drug with a MA available in France => import of ponazuril (MARQUIS® marketed in the US by Boehringer Ingelheim). Ponazuril (or toltrazuril sulfone) is the main metabolite of toltrazuril.	0 VMP	Importation of MARQUIS®, ponazuril oral paste with MA in the US for horses. ANMV info: import is possible after ANMV acceptance of request for authorization. Procedure: see Request an import authorisation Anses - Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail	M n° 3 or m
Abortions	Cattle, Bubalins, small ruminants	We have whole herds of bubalins above all, but this has also happened in cattle and recently in small ruminants, who abort in large numbers; analyses gave nothing or only hunches! It remains to be specified on which agents the analyses were carried out, in bubalins, cattle and small ruminants ? This is catastrophic for farmers; LY KA SO Phia has stopped the buffalo and Carbo because of this, a small ruminant farmer is wondering about maintaining his herd. We sometimes find ourselves without a solution to these issues. Post-meeting notes from E. Tillard : On which agents did the analyses focus on, in buffalo, cattle and small ruminants? Beyond these aspects, one of the priorities would be to assess the epidemiological situation (through sero-epidemiological survey) in cattle and beef farms in Guiana (pathogens, vectors), and which prophylactic approaches should be offered to farmers.		To be further investigated according to the causes identified.	M n° 4 or m
Leptospirosis	Cattle a minima	No cattle vaccines available for the European market. "Blinded" treatments with tetracyclines in case of clinical signs (e.g. unjustified abortions). No real diagnostic follow-up.	0 VMP	Import of bovine vaccines (from Ireland?)	M n° 2 or m

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PRIORITISATION

Prioritisation of participants (excl. ANMV)	Xavier BAUDRIMONT	Benoît BALMELLE	INTERVIG (Brice AUGUSTIN-CONSTANTIN and Elise ACH)
Identified gaps			
Trypanosomiasis	M n°1 (wish for regular stocks)	M n°1	M n°1
Myiasis due to <i>Cochliomyia hominivorax</i> (New World Screwworm – NWS fly)	M n°2 (effectiveness of existing VMPS?)	M n°4 (wish for solutions with long-term efficacy)	M n°3
Chagas disease	m	M n°2	M n°5
Equine protozoal myeloencephalitis (EPM) due to <i>Sarcocystis neurona</i>	M n°3	M n°3 (more sporadic)	m
Leptospirosis	m	Prevalence to be investigated	M n°2
Abortions	m	Investigation of causes needed on a larger scale	M n°4