



Association of Veterinary Consultants

- ☐ **Why is the availability of VMP for bees so narrow?**
- ☐ **What could be done to increase this availability ?**

Bill VANDAELE
KLIFOVET BVD, Germany



Association of Veterinary Consultants

Content

- ➔ 1 - AVC and its place in the debate
'Availability of Medicines'
- ➔ 2 - Availability of VMP
is much broader issue than just for bees
- ➔ 3 - Specificities of Bees and Honey
- ➔ 4 - Situation on availability of VMP for bees in EU
- ➔ 5 - Proposed Solutions
- ➔ 6 - Future

❑ 1- AVC and its place in the debate 'Availability of Medicines'

- ➡ www.avc.at > 50 Members
- ➡ Interested Party to EMEA / CVMP
- ➡ Often link between Regulators and Companies, mostly SME's
- ➡ Consultants to trade associations, including *those representing the Owners of Minor Species*
Therefore...
special interest in the Availability of VMP in MUMS !!
- ➡ AVC Members are in ideal position to make link between those 'Interested Parties'

✓ see ANNEX 1-
EAVPT 2003

- **MAIN INTEREST for VETS and FARMERS**
- **but INDUSTRY CAN'T BE THE DRIVING FORCE ...**



❑ 2- Availability of VMP is a much broader issue than just for bees

See the Report of Task Force on Availability of VMP, headed by HMAv from February 2007

<http://www.hma.eu/203.html>

or direct link:

http://www.hma.eu/uploads/media/TF_Report_Availability_Vet_Medicines.pdf



❑ 3- Specificities of Bees and Honey

- - As bee is a *food producing animal* (honey), all active ingredients of VMP for bees need a MRL !!!
- List of MRLs specific for bees: very limited (see EMEA presentation).
- - *Metabolism* of bees is *very specific* and bees tend to “*keep in their body*” all that they receive:
“*Residues, once present in honey, largely remain there*” (EMEA)
See publications on ‘degradation’ of
sulphonamides in honey !!!
- - Small market, most honey consumed in EU is imported !!



❑ 3- Specificities of Bees and Honey (2)

Albert Einstein said:

“If the bee disappears from the surface of the earth, man would have no more than four years to live. No more bees, no more pollination ... no more men!”

Therefore ... under “Request for classification under MUMS/limited markets” this “environmental benefit” is becoming a critical classification criteria!!!



❑ 4- Situation on Availability of VMP for bees in Europe

4.1- Situation in Spain, early 2000

Odón Sobrino
**MINISTRY OF AGRICULTURE,
FISHERIES AND FOOD**
Subdirección General de Sanidad Animal
sganimal@mapya.es

✓ see ANNEX 2-



❑ 4- Situation on Availability of VMP for bees in Europe

4.2- Situation in Germany, in 2003

✓ see ANNEX 3-



☐ 4- Situation on Availability of VMP for bees in Europe

4.3- Situation 2009, described at APIMONDIA (Sept. 2009-10.000 participants)

→	A/ Public Statements on authorised VMP
→	B/ Other comments and 'rumours'

✓ see ANNEX 4-

→	C/ Status <ul style="list-style-type: none"> ▪ Authorised Products in Belgium ▪ A lot of illegal market ▪ No one antibiotic authorized ▪ Cascade system
---	--



❑ 4- Situation on Availability of VMP for bees in Europe

4.3- Situation 2009, described at APIMONDIA → C/ Status

■ Authorised Products in Belgium

Based on the decision to consider Belgium as “*infected all over the country with varroosis*”, regularly ‘programs are published with ‘allowed substances’.
Last one A.M. 7 March 2007:

Organised campaigns against varroosis, by Min. of Health and authorised Substances’

January	February	March	April
Oxalic Acid Coumaphos	Oxalic Acid Coumaphos Fluvalinate	Oxalic Acid Thymol	Oxalic Acid Thymol
May	June	July	August
Oxalic Acid Thymol	Oxalic Acid Thymol	Oxalic Acid Thymol	Coumaphos Thymol Fluvalinate
September	October	November	December
Coumaphos Thymol Fluvalinate	Oxalic Acid Coumaphos	Oxalic Acid Coumaphos	Oxalic Acid Coumaphos

Apimondia- Montpellier, France/ 16.09.2009



❑ 4- Situation on Availability of VMP for bees in Europe

4.3- Situation 2009, described at APIMONDIA → C/ Status

■ Authorised Products in Belgium

Real situation of those 'substances' authorised in A.M.07.03.2007

■ Coumaphos (PERIZIN)	Registered as pesticide for agricultural use till 15.03.2010; but no longer available as VMP.
■ Fluvalinate (APISTAN)	was authorized as pesticide for agricultural use till 13.05.2009.
■ Thymol (THYMOVAR)	ONE VMP registered in Belgium.
■ Oxalic acid	No VMP authorized in Belgium; but via ' <u>cascade</u> ' vets have access to two VMP authorised in other EU member states. OXUVAR (Germany) / ECOXAL (Spain).

Apimondia- Montpellier, France/ 16.09.2009

= unfair competition of 'substances which are NOT VMP'



❑ 4- Situation on Availability of VMP for bees in Europe

4.3- Situation 2009, described at APIMONDIA

→ C/ Status



Association of Veterinary Consultants

⇒ Illegal market = 95%

“Only 5% of bees are treated via legal ways with authorized VMP. The rest ???”

- BE
 - Pesticides ‘legally’ still authorised in BE
 - Import from NL
 - use of bulk / raw materials- eg. Oxalic acid
- Fr / It / Spain / Turkey: *“the same in our country”*
- UK
 - Formic acid used as such (PS: there is no VMP)
 - web full of remedies and drug recommendations !
= illegal drugs

⇒ No one antibiotic authorised yet in the EU for bees:

strong opposition from COPA-COGECA

⇒ Cascade system’ is used as..no alternatives



❑ 5- Proposed Solutions

- ➡ 5.1- Work all together
- ➡ 5.2- Give support to ongoing EMEA proposals
- ➡ 5.3- Get more support in MS for registered VMP for bees
- ➡ 5.4- Share Responsibility and Costs

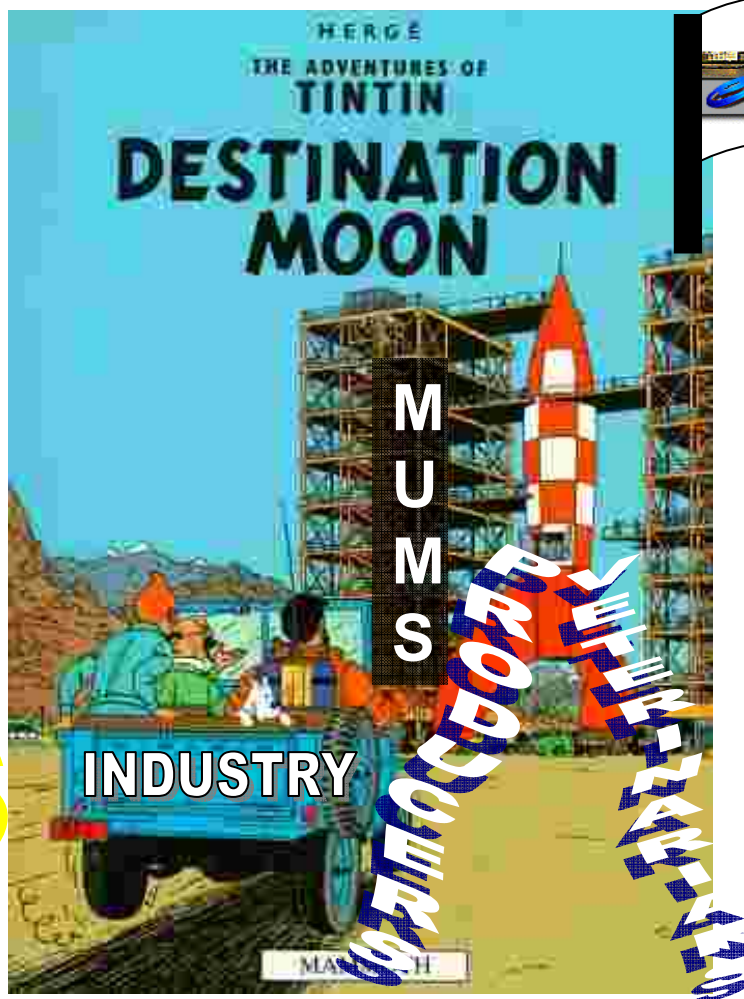


❑ 5- Proposed Solutions

- 5.1- Work all together: now much better

a/ **Owners**
of Minor
Species
are **here**
to day !!

M
U
M
S



CVMP

b/ **FVE** with
approach
for a **GL** on
GVP
eg: against
varroasis

Thanks, G. Moulin !



❑ 5- Proposed Solutions

■ 5.2- Give support to ongoing EMEA proposals

- Propose to apply a real cost benefit system taking in account environmental benefits of bees.
 - See pollination need!!!

- Propose more pragmatic approaches
eg: **AVC's Comments** on **CVMP 'Concept Paper'** (2007)*
and now **Guideline** (Oct. 2009)*, released for consultation on VMP controlling varroa parasitosis in bees.
 - * cfr **CVMP Documents** / **EMEA** Presentation



❑ 5- Proposed Solutions

■ 5.2- Give support to ongoing EMEA proposals

AVC's Comments to Concept Paper

- Applicants are faced with the costs and fees for a dossier.
- Referring to:
 - 2007 Report of Task Force on the Availability of VMP; economic considerations of the VMP sector...
 - '*Technical GL for the evaluation of treatments for control of Varroa mites in honey bees colonies*' implemented the recommendations since late 1990's.

✓ see ANNEX 5-

<http://www.alp.admin.ch/themen/00502/00567/00573/index.html?lang=en>

- AVC suggested simply to take those Technical GL over...

“Why reinvent the wheel ???”



❑ 5- Proposed Solutions

■ 5.3- Get more support in MS for registered VMP for bees

- Avoid unfair competition during review of old VMP for bees: apply same rules as for recent VMP's

eg.

« It is so hard to market a veterinary product for a Minor Species in the EU, I have the impression that almost everybody - especially some authorities - just work against us.

The investments, we had to do for answering the sophisticated MRP-question from one MS, are in bad proportion to the price we can get for (Trade Name) in the market.

So my general impression right now is, that all MUMS guidelines are just a drop in the ocean.

If the idea of MUMS will ever become true, massive changes are needed. »

SME 02.11.07

- Take out authorisation for phyto products still authorised for bees in some MS even if VMP for bees are registered.



❑ 5- Proposed Solutions

■ 5.4- Share Responsibility and Costs

Among: - EU + Nat. Regulators
- Academic + Research Institutes
- Industry

=
a specific role for
AVC members

eg: - See MUMS System in the US.
- In EU... 'step by step' / eg. MRL oxalic acid is there
"free of charge"... but only 2 companies "used it" to
make a VMP.
- Look for European Funds eg. ETPGAH...
- Funds for Beekeepers: eg. Directive 'Honey'
2001/110/EC

✓ see ANNEX 6-



□ 6- Future

- Message from APIMONDIA 2009:
Bees more and more needed for pollinization
- So, more and more pressure to find PRACTICAL solutions:
eg. a Workshop as this one: EMEA 14-15/12/2009
- What will be the outcome?
- At least, THANKS to EMEA to have organised this workshop !



Association of Veterinary Consultants

thanks for your attention

- ❑ Why is the availability of VMP for bees so narrow?
- ❑ What could be done to increase this availability ?



Bill VANDAELE,

bill.vandaele@klifovet.com

www.klifovet.com

❑ 1- AVC and its place in the debate 'Availability of Medicines'

- **AVC Members are in ideal position to make link between all 'Interested Parties'**

Eg: EAVPT- Lisboa, 13-18 July 2003

✓ ANNEX 1-

ANALYSIS of the FORCES

1- | **ALL Interested Parties:**

- IFAH-EUROPE
- FVE
- COPA-COGECA
- **AVC**

Sometimes, also:

- BEUC (Consumers)
- PGEU (Pharmacists)

2- |

AVC Identified that the KEY PLACERS, THE 'OWNERS of MINOR SPECIES' are 'under represented'.

Eg: Aquaculture.. Rabbits.. Turkeys.. Goats/Sheep (milk).. Bees (COPA-COGECA)

NB: Some actions were undertaken by AVC representatives

EAVPT - LISBOA 13-18 July 2003

THERAPEUTIC GAPS IN HONEY BEES

DISEASE	THERP. GROUPS NEEDED	MRL FOR HONEY	THERAPEUTIC GAPS
American foulbrood	Sulfatiazol Oxytetracilin Lincomicin Erithromycin Tylosin Monensin	None None None None None none	⚡⚡⚡⚡ ANNEX 2,1-
European foulbrood	Tetraciclines Estreptomycin Neomicin	None None None	⚡⚡⚡⚡
Pseudomona apiseptica	¿?		
Varroa mite	Amitraz Bromopropilate Thimol Formic, lactic acid Oxalic acid Fluvalinate Coumaphos Cimiazole	yes yes yes yes no yes yes yes	⚡⚡ Despite there are several authorized products, development of new ones is requested because of resistences
Nosema apis	Fumagilin	none	⚡⚡⚡⚡
Acarapis woodi	Metil salicilate Mentol Bromopropilate Cimiazole Coumafes	Yes Yes Yes Yes	⚡⚡⚡ Very limited therapeutic possibilities
A.apis & A. niger	¿Enilconalzole?	None	⚡⚡⚡⚡

THERAPEUTIC GAPS IN HONEY BEES

COMING SOON.....?

ANNEX 2,2-

- *Tropilaelaps spp.*
- *Aethina tumida*

No legislative framework for a quick
therapeutic answer

❑ 4- Situation on Availability of VMP for bees in Europe

4.2- Situation in Germany, in 2003

ANNEX 3,

➤ Medicaments for bees in Germany - F. Mutinelli, 2003			
Approved medicaments	Active substances	Medicaments no longer allowed	Active substances
Illertisser mite plate	Formic acid	Folbex VA Neu	Brompropylat
Long-term evaporation (Nassenheider Evaporator)	Formic acid	Cekafix	Coumaphos
Perizin	Coumaphos	Nosemack	Mercury compounds
Bayvarol	Flumethrin	Fumidil B	Fumagillin
Apitol	Cymiazol hydrochloride	Fumagillin	Fumagillin
		Berovacid	Brompropylat

❑ **4- Situation on Availability of VMP for bees in Europe**
4.3- Situation 2009, described at APIMONDIA



A/ Public Statements on authorised VMP (1)

Member States	Trade Name	Active Ingredients	Comments
Belgium	THYMOVAR	thymol	
France	APIVAR	amitraz	Resistance? 'Yes' and 'No'
	THYMOVAR	thymol	Via mutual recognition and as concerned MS, lot of requests from F
	APIGUARD	thymol	'old AMM' just renewed 2006 = without new requests as for THYMOVAR !!
	APISTAN	tau-Fluvalinate	' lot of resistance'
	API LIFE VAR	thymol and 3 essential oils	seems to be in mutual recognition process

ANNEX 4,1-

❑ **4- Situation on Availability of VMP for bees in Europe**
4.3- Situation 2009, described at APIMONDIA



A/ Public Statements on authorised VMP (2)

Member State	Trade Name	Active Ingredient (s)	Comments
Spain	APIGUARD	thymol	« expensive and use restricted due to Spanish climate »
	THYMOVAR	thymol	Recent Registration
	ECOXAL	oxalic acid	“Not expensive but uses not adapted to Spain”(1 unit for 50 colonies)
	APIVARD	amitraz	‘a lot of resistance’
	APISTAN	tau-Fluvalinate	‘ lot of resistance’
Germany	THYMOVAR	thymol	Recent Registration
	OXUVAR	oxalic acid	Not as ‘complete’ VMP: but as Standardzulassung
	PERIZIN	coumaphos	Status?
	BAYVAROL	flumethrin	Status?

ANNEX 4,2-

❑ 4- Situation on Availability of VMP for bees in Europe
4.3- Situation 2009, described at APIMONDIA

→	B/ Other Comments and 'Rumours'
---	--

ANNEX 4,3-

Member State	Trade Name	Active Ingredient (s)	Comments
UK	FLUMIDIL B	fumagilline	Tolerate even without MRL as nothing else exist against Nosemosis
Italy	API LIFE VAR	thymol and 3 essential oils	Re-registered and planning for mutual mutual recognition in other MS
Other EU Countries	THYMOVAR	thymol	Via mutual recognition: authorized also in Greece/Hungary/ Romania/ Cyprus/Portugal
PS: Canada			MA for VMP based on tetracycline and fumagillin

FAIR CT97-3686

**"Coordination in Europe of integrated control of *Varroa* mites in
honey bee colonies"**

APPENDIX VI

to

Final Technical Report for the period
from **98-01-01** to **99-12-31**

ANNEX 5-

Wolfgang Ritter

Strategies for varroa control

Building Strategies for Varroa control

Wolfgang Ritter

Tierhygienisches Institut
Abteilung Bienenkunde
Am Moosweiher 2
79018 Freiburg, Germany
E-mail: dr.wolfgang.ritter@T-ONLINE.DE

FUNDS for BEEKEEPERS

- Directive 'MIEL' 74/409/EC latest update 2001/110/EC:
 - Harmonises the definition of Honey and
 - Allows funds for beekeepers:eg: in 2000, 12 million €
 - 42 % Varroasis
 - 20 % Technical assistance
 - 17,5 % Transport
 - 12,5 % Analysis of Honey
 - 8 % for Qualitative Improvement
- In Theory, this directive doesn't allow funds for development of VMPbut, in reality, it does:

ANNEX 6,1-



FUNDS for BEEKEEPERS

.... BUT in reality, it does:

ANNEX 6,2-

Eg.

Varroasis: funds used mainly as compensation for the beekeepers as nearly 100 % of the bees die

But also to ‘develop new strategies against the disease’;

eg. Avoid resistance to amitraz with ... new products

PRACTICALLY: it all depends how the case is presented !!!

AND, in addition to EU Funds,
there are a lot of National Funds available for
Minor Species !!!