

AVAILABILITY FOR VETERINARY MEDICINES FOR BEES IN THE EUROPEAN UNION

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Problem

Very few Veterinary Medicines (VM) for bees are registered in the EU: due to

- High cost for small market and
- Unfair competition of non-registered products

Two examples are

- Formic acid : today no VM based on formic acid are registered in the EU
- Thymol: only one VM went through the recent requirements: THYMOVAR; other VM based on Thymol are not registered or were registered more than 5 years ago and re-registration did not yet come through



Description on requirements to satisfy for any Veterinary Medicine

Quality part:	Need for pharmacopeia grade (expensive) active ingredients High requirements for final formulation and packaging material
Safety	
for Target Animals:	Trials with 1x- 3x -5x the recommended dose
for Consumers:	MRL (Maximum Residues Levels) dossier is needed Two parts: - Safety file: toxicity data of active ingredient - Residue file: amount of active substance in honey Specificity of active substances in honey: very slow degradation
for Users/ Workers:	Safety of final presentation for beekeepers when they apply the VM
for Environment:	Need to assess the environmental impact
Efficacy:	For each claim biostatistically significant efficacy trial(s) needed
Practical case:	A dossier was submitted for THYMOVAR (Thymol) and the VM obtained a Marketing Authorisation in 12 countries in the EU

MUMS: Minor Uses and Minor Species: now defined in the EU as “Limited Market”

- US: well defined approach with financial support: collaboration among beekeepers, research institutes/ universities and companies
- EU took some measures via specific Guidelines to facilitate market access for MUMS products and Financial assistance for SME (Small Medium Enterprises)

Future

Implementation in the EU of a MUMS approach as in the US with financial support from State and beekeeper associations. Better control via National Agencies on unauthorized products used as treatment today through Europe for varroaosis. Guidelines for authorization better adapted for VM for limited markets.



For more information:
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