



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Workshop Medicines for Bees – What the Agency can do to increase availability 14-15 December 2009

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Report from Breakout session:

## **GROUP 2**

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Veterinary Medicines

European Medicines Agency

An agency of the European Union





# Proposals for possible solutions

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## Proposed actions to support development of VMPs for bees



# Proposals for possible solutions

## Basic conclusions

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- Beekeepers must have access to authorised veterinary medicines and have choice
- Better communication and information of beekeepers of good beekeeping practice
- Information to beekeepers/training should be provided to ensure adequate use of products – governments role
- National Information centres? as example France
- Training of vets on bee diseases? as example France



# Proposals for possible solutions

## Availability of medicines

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- Access of bee keepers to authorised medicines often difficult, as vet prescription required, high price, no adequate information on existing products
- Should countries provide support? Financial support? Information centres (see before)
- Exempt from prescription for some medicines? Examples in Germany





# Proposals for possible solutions

## Availability of existing veterinary medicines

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- Establish strategy on what, when and how to use veterinary medicinal products, e.g. on national level, and publish information
    - e.g. advice on how to alternate varroa medication summer/winter
    - Exempt from prescription for certain veterinary medicinal products
    - Obstacle: at present only on active substance level



# Proposals for possible solutions

## Availability of existing products

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How can existing marketing authorisations be extended to other countries across EU? Authorised products made available in other countries across EU?

- Better use of existing marketing authorisations for bees products
- Explore possibilities under Art 7 of Directive 2001/82/EC to accept MAs of other countries
- Automatic mutual recognition – not possible under current legislation
- UK: encourage MRs for bee products, fee waivers





# Proposals for possible solutions

## Availability of existing veterinary medicines

- Use of cascade? Is this solution?
  - Not preferable solution, vet to be consulted, expensive, impractical, vet cannot have knowledge on appropriate withdrawal period
  - Other obstacles: exceptional use requirements, MRL for substance required: MRLs for honey for residue control.
  - Pro: Cascade allows to use authorised veterinary medicines for bees in other countries



## Development of new veterinary medicinal products

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- Compilation of dossier for MRL (if this is necessary):
    - Extension of existing MRLs to honey
      - Would be good basis to develop bee medicinal product, more chance than entirely new molecule without MRL
    - Could example oxalic acid be used as model? Yes, good example. First step MRLs achieved, so far MA not so successful; but this should not discourage and should be continued
    - Review substances with JECFA/Codex MRLs
  - New molecules: Possibilities for substances used in plant protection?





## Development of new veterinary medicinal products

- Which are incentives for animal health industry that will allow bringing new medicines for bees on the market? (in place: fee reduction, 13 yrs data protection, MUMS requirements)
  - Data protection is key: 13yrs adequate, must be unique for formulation. However only for new products, not applicable for extensions in current legislation, 5yrs window for extensions to be omitted - No data protection for MRLs is a concern
  - Facilitate access to bee keepers: preferably not prescription only
  - Therefore, centralised authorisation not optimal, as centralised marketing authorisation products prescription only (innovative/novel products)

# Proposals for possible solutions



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## Development of new veterinary medicinal products (contd.)

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- Uncertainty on data requirements can be overcome by scientific advice: free of charge by European Medicines Agency for MUMS, i.e. bees
  - Other issue: Withdrawal period for veterinary medicines for bees



# Thank you for your attention

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