Workshop Medicines for Bees – What the Agency can do to increase availability
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Report from Breakout session:

GROUP 2

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Proposals for possible solutions

Proposed actions to support development of VMPs for bees
Proposals for possible solutions

Basic conclusions

• 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

- 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

- 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

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
Proposals for possible solutions
Development of new veterinary medicinal products

- 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?
Proposals for possible solutions
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

Development of new veterinary medicinal products (contd.)

- 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

European Medicines Agency