



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Medicines for Bees

An introduction to the subject and aim of the workshop

Role of the Agency in the initiative

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An agency of the European Union



Concerns regarding Bees

Decline in bee population observed in Europe and other parts of the world

Complex issue; reasons:

- Diseases
- Environmental Factors
- Colony Collapse Disorder (CCD)
- Other reasons ?

Concerns and wide reaching impact discussed in many fora

Bee diseases

The spread of diseases varies between regions and countries in Europe:

- Most important diseases in Europe:
 - Varroasis (*Varroa destructor*)
 - Nosemosis (*Nosema apis*)
 - American Foolbrood (*Paenibacillus larvae*)
 - European Foolbrood (*Melissococcus plutonius*) (?)
 - Colony Collapse Disorder (CCD)

Concerns regarding Bees

One issue repeatedly mentioned by interested parties and Member States:

Lack of adequate veterinary medicines to treat bee diseases

Lack of critical medicines relevant also for other animal species, in particular minor species

Reasons (in general):

- Costs of R&D and maintenance vs return
- High quality and safety of products and high degree of harmonisation but also reduction of range of medicines
- Rationalisation and consolidation of industry



Availability of medicines

Numerous activities by European Medicines Agency and partners to improve availability of veterinary medicines, for example

- Guidelines on data requirements for products for minor uses and minor species (MUMS)
- Extrapolation of MRLs to other species
- Free scientific advice for MUMS
- Other incentives for MUMS products, e.g. fee reduction
- Assistance to applicants that are small to medium sized enterprises (SME)



Why “essential” substances for bees

- Only few authorised medicines for treatment of bees available
- Mainly against varroa only. Enough? Concerns regarding resistance development
- No authorised products for some important diseases.
- Products for bees are small market segment (=limited market)
- Development costs for veterinary medicine vs return



Why “essential” substances for bees

- If a small number of essential substances could be identified: then to be explored with the different parties concerned, how concerted efforts could be made to establish an MRL, obtain marketing authorisations and bring authorised veterinary medicines on market



What are the concerns if no authorised veterinary medicines are available?

- Illegal use of unauthorised products/substances
- Incorrect use of medicinal products/chemical substances
- No knowledge on efficacy
- Potential for undesired or illegal residues in honey
- User safety
- Environmental impact
- No control over substances/products used

Aim of the workshop

Discussions have been going on for several years, demands by interested parties – however no clear direction of needs given to regulators

Views of interested parties seems to differ regarding use of “chemical substances” i.e. veterinary medicines in bees treatment:

- honey as pure food commodity vs allowing acceptable residues

Interested parties are brought together

Opportunity for discussions with all parties involved



Aim of the workshop

To identify substances that are essential for the treatment of bee diseases in Europe for which subsequently veterinary medicines could be developed



Thank you for your attention

European Medicines Agency