



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**

Presented by: Ifigenia Koudouna  
Scientific Administrator, Veterinary Medicines Sector  
European Medicines Agency

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