



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 December 2009
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Veterinary Medicines and Product Data Management

European Medicines Agency Workshop

Medicines for bees - What the Agency can do to increase availability

14 – 15 December 2009, European Medicines Agency, London

Breakout sessions

Two break-out groups will discuss in parallel and prepare proposals for possible solutions / actions.

The focus of the two groups is as follows:

GROUP 1

Analysis of current situation

- a) Critical diseases in the beekeeping sector
- b) Available options for treatment
- c) Are the options for treatment sufficient?
- d) If not, could possible reasons for lack of treatment options be identified?

Proposals for possible solutions / actions the groups should focus on different elements

- e) Medicines that are needed to treat bee diseases
- f) Proposals for essential substances

GROUP 2

Proposals for possible solutions / actions the groups should focus on different elements

Group 2 should consider more issues of feasibility and prepare proposals for actions that could support the availability and development of authorised veterinary medicinal products for bees.



GROUP 1, chair: Mr E. Bruneau (COPA COGECA)

Analysis of current situation

a) Critical diseases in the beekeeping sector

The group is asked to identify, based on the presentations made and expert knowledge available, the critical diseases in the beekeeping sector for Europe.

The group should also address any emerging new diseases that may be relevant in the future (issue of preparedness, lower priority to address?)

- Varroasis (*Varroa destructor*)
- Nosemosis (*Nosema apis*)
- American foulbrood (*Paenibacillus larvae*)
- European foulbrood (*Melissococcus plutonius*)
- Colony collapse syndrome (CCD)

New threats are expected from:

- *Nosema ceranae*
- *Tropilaelaps mite*
- Small hive beetle
- Kashmir bee virus

b) Available options for treatment

c) Are the options for treatment sufficient?

The group is asked to address the available treatment options regarding the different diseases considering also other available measures than treatment with chemical substances/veterinary medicines or prevention measures, as well as need to therapeutic choice or avoidance of resistance.

The aim is not to identify all possible available options in detail, but to work towards identifying lacking treatment options.

d) Identify possible reasons for lack of treatment options

Possible reasons for lack of treatment options could be :

- *Lack of availability of existing authorised products in all member states*
- *Lack of veterinary medicinal products entirely for disease*
- *Inadequate treatment options, lack of choice,*
- *Resistance development*
- *Incorrect use of chemicals*
- *Others?*

Proposals for possible solutions / actions

e) Medicines that are needed to treat bee diseases

The group is asked to identify based on the conclusions under point a) - d). i.e. critical diseases and lack of treatment options identified, the types of medicines that are needed in Europe for the treatment of bee diseases.

This should identify the types of medicines needed to treat

- *current critical diseases (first priority?),*
- *but also, if possible, any emerging new diseases that may be relevant in the future (second priority?)*

The identified medicines should not only include lacking medicines but also available ones.

The questions should address which classes of substances are needed, including e.g whether should antibiotics, coccidiostats be recommended or not, specifying conditions.

Should veterinary medicines, e.g. antibiotics, be used for prevention?

The group may also list proposals for actions and better practices aimed to prevent spread or manifestation of bee diseases (for possible further action in other fora)

f) Proposals for essential substances

The group is asked to identify a small number of essential substances needed to treat critical diseases in bees (current and emerging diseases, differentiated) and indicate priorities, if appropriate.

Can substances with existing MRLs / no MRLs required (old Annex II substances) be identified as being essential?

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

GROUP 2, chair: Dr J.G. Beechinor (Irish Medicines Board)

Proposals for possible solutions / actions

- Proposed actions to support the availability and development of authorised veterinary medicinal products for bees.

The group is asked to prepare proposals that would help support the use of authorised vet medicines by beekeepers instead of relying on chemical substances/own preparations, as it is often current practice.

The proposals should address availability of existing authorised products as well as development of new products, (entirely new molecules or substances with MRLs (with or without MRL for honey, Annex II)

The proposals could consider :

Availability of existing products

- *Better use of existing marketing authorisations for bees products:*
- *How can existing marketing authorisations be extended to other countries across EU? Authorised products made available in other countries across EU?*
- *Use of cascade? Is this solution? Obstacles: exceptional use, MRL for substance required, vet prescription, withdrawal period, MRLs for honey for residue control.*
- *Access of bee keepers to authorised medicines (vet prescription, price, others?)*

Development of new products

- *Compilation of dossier for MRL (if this is necessary necessary):*
 - *Extension of existing MRLs to honey*
 - *Could example oxalic acid be used as model?*
 - *???*
- *Which are incentives for animal health industry that will allow bringing new product for bees on the market? (in place: fee reduction, 13 yrs data protection, MUMS requirements)*
- *What are main obstacles in bringing vet medicines for bees on the market?*
- *Regulatory hurdles*
- *Could they be overcome within current legislation by better use of existing legal provisions?*
- *Which changes in veterinary legislation could improve situation?*

Access of beekeepers to veterinary medicines/correct advice on use of vet medicines

- *What measures are necessary ensure that beekeepers have access to veterinary medicines? /*
- *Use appropriate medicines*
- *Training of vets on bee diseases?*
- *Better communication and information of beekeepers of good beekeeping practice?*
- *Information centres?*
- *Others?*

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