Europe IFAH
Representing the European Animal Health Industry

EMEA Transparency workshop

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IFAH-Europe views

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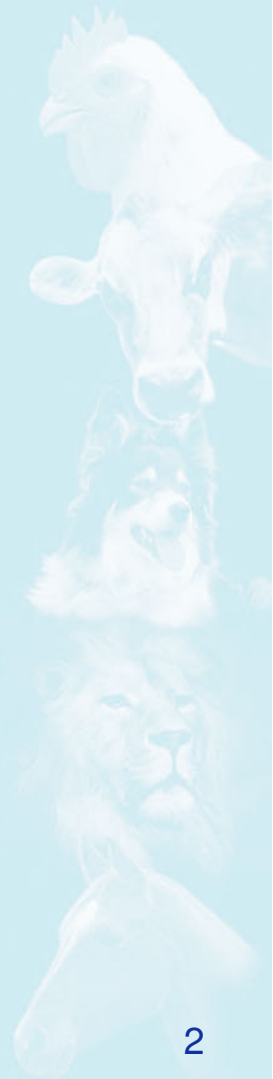
1. Experience with the current EMEA transparency measures
2. Expectations on product related issues
3. Expectations on non-product related issues
4. EMEA interaction with stakeholders
5. Commercial confidentiality aspects



Items 1 and 2

1. Experience with the current EMEA measures

   IFAH-Europe feels that an appropriate level of transparency currently applies.

2. Expectations on product related issues

- Before and after authorisation:
  - Document reference EMEA/659316/2008
  - Proposed level of disclosed information appropriate (consultation on going till 2nd March 2009);
- Specific measures for emerging issues irrespective of the status of the authorisation of the product?
  - Yes where necessary and always in close collaboration with the concerned applicant/MAH.

Item 3. Expectations on non-products' related issue

- Drafting of Guidelines
  - IFAH-Europe promotes early involvement of industry experts / Focus Group meetings;
- Public consultation
  - 6 months should be the standard period for all documents, except Concept Papers (3 months);
  - Consultation may be reduced from 6 to 3 months in exceptional circumstances only; such consultation must fall within the January to June or September to December periods.

Item 4. EMEA interaction with stakeholders

- Meetings
  - IFAH-Europe welcomes the EMEA efforts to involve stakeholders in its activities;
  - The late announcement of meetings and exchange of relevant documents must be prevented;
  - Benefits:
    - To allow industry to prepare in an appropriate manner;
    - To increase the output of meetings.

5. Commercial confidentiality aspects

- Reference: EMEA/45422/2006
- IFAH-Europe commented on 06/10/2006
- Revised version released on 15/04/2007
- Some improvements noted, e.g.:
  - Detailed information on the synthesis or manufacture of the active substance that is commercially confidential now also includes **details on the by-products and degradation products of active ingredients and validation of the manufacturing / synthesis process**.

5. Commercial confidentiality aspects

- Two issues remain in version dated 15/04/2007
- Final qualitative formulation (page 4, Chap.I.1, 2nd §):
  - IFAH-Europe views: the final qualitative formulation (composition) of the authorised product, including the 'names of excipients', is commercially confidential;
  - Ingredients may only be disclosed in cases where public interest and safety prevail;
  - Thus, only excipients that could potentially cause an undesirable effect, e.g. known allergens, may be disclosed.

5. Commercial confidentiality aspects

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- The user will not have the knowledge to predict any risk that may be associated with a 'new excipient';
- An authorised product is supported by sufficient safety data and continuous PhV monitoring;

=> Disclosing excipients' names will harm the animal health industry and hinder innovation.

- Outcome of scientific discussion (Page 6, Chap. IV, 3rd §)
  - Divergent views within the Committee, as well as the summarised reasons (and not the data) related to the concerns raised are not commercially confidential.