EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH
Veterinary Medicines

Europe IFAH
Representing the European Animal Health Industry

2014 EMA/IFAH-Europe info-day

Second announcement - save this date in your diary!

The latest developments

Scientific review, marketing authorisation procedures and legislation

EMA (London), 13-14 March 2014

- **Schedule:** 13 March 2014 13:30 hrs. to 14 March 2014 13:00 hrs.
- **Added value:** An opportunity for professionals to get first-hand information on current developments in the regulatory scene with good networking opportunities.
- **Fee:** €300 (same as every year)
- **Registration:** Please book this date in your diary! Registration forms will be circulated in late January 2014.

Outline programme

The programme will follow the established format covering science, procedures and legislation. The programme is currently being finalised and an outline is provided below for information.

Session I: Scientific Developments

- CVMP workplan for 2014
- Pre-submission guidance for novel products and Innovation Task Force
- MRLs, withdrawal periods and injection sites
- Demonstrating efficacy of antimicrobials
- Update on guidance on user safety

Session II: EU procedural updates

- Clarification of MUMS Policy and Industry feedback
- Packaging and labelling – QRD template, reduced label text and multi-lingual labels
- Pharmacovigilance – vision and needs for the future

Session III: Variations and IT

- Variations, progress on worksharing
- Variation guidelines and impact on administrative burden
- EMA IT Strategy Update