EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Veterinary SME experience

Presented by: Dr Karen QUIGLEY
European Medicines Agency

SME-Veterinary

Growth area on veterinary side

63 companies registered vet interest

Same incentives as human side – SME office

Pre-submission meetings -teleconference

Scientific advice

MUMS / limited markets

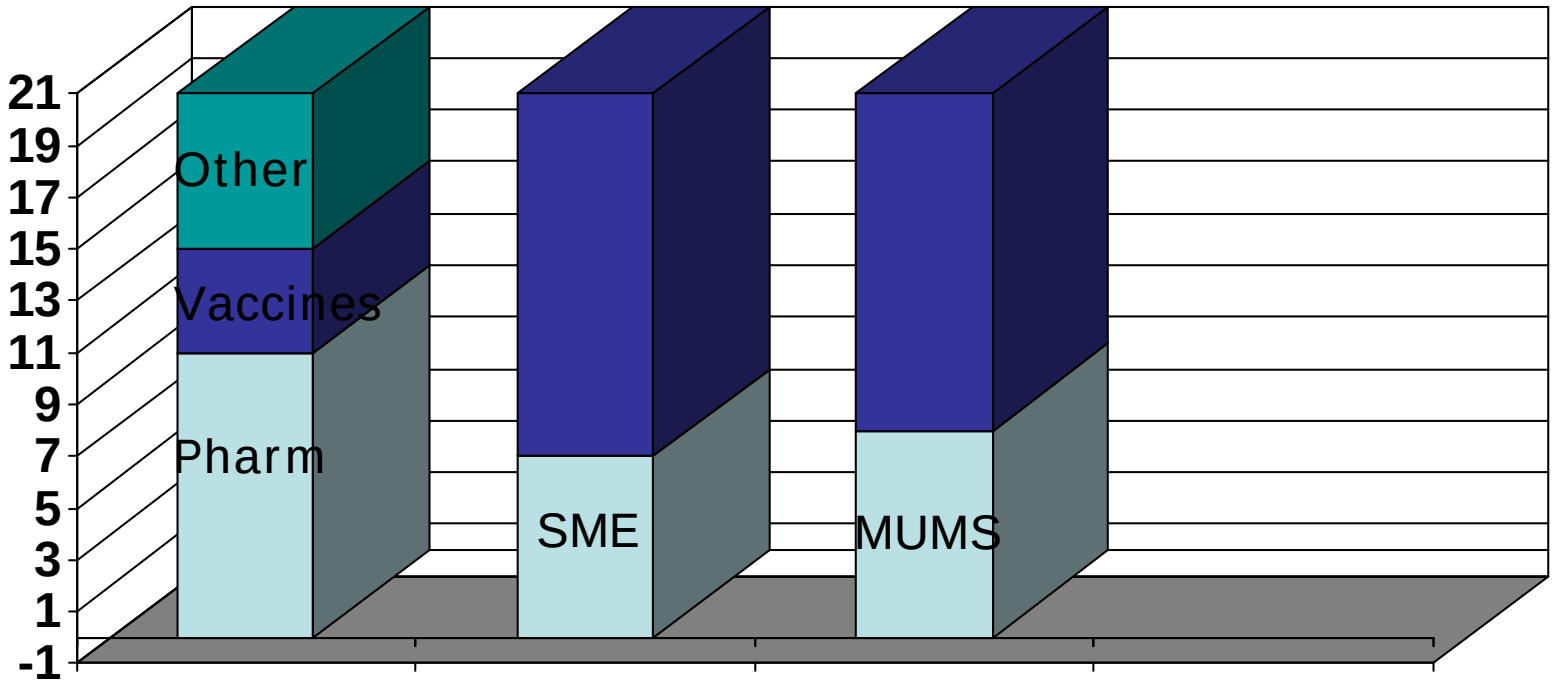
Scientific advice

- Submit request 2 weeks prior to monthly SAWP-V meeting
- Independent of route of authorisation
- Co-ordinator appointed + experts ± other WPs
- Timetable 30 or 60 days
- Draft report discussed SAWP-V
- Adopted by CVMP- not binding

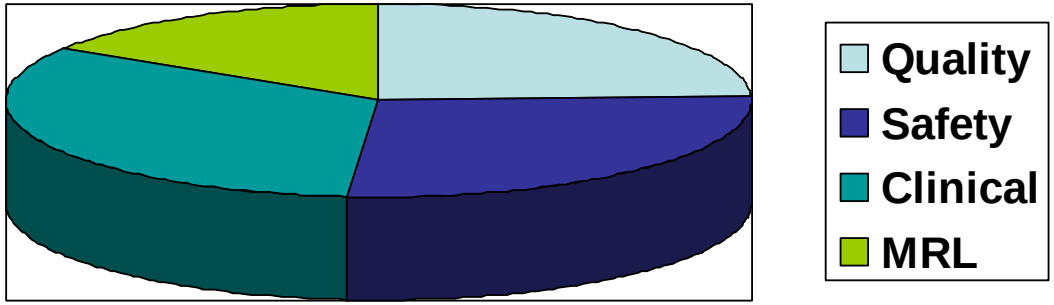
Procedure

- Fees depend on area advice
- SME applicants 90% fee waiver – inform SME office prior to request
- Minor use minor species (MUMS) request - if benefit from financial incentives = free
- MUMS dossier requirements for authorisation

2010 Figures - SA



Areas of Advice in 2010



Parallel Advice FDA

Confidentiality Agreement FDA

Applicant to address request to both Agencies

Agreement principles since 2004 pilot

Applicant initiative- exceptionally Agency initiative

Minor Use Minor Species (MUMS)

To stimulate applications for minor species and minor uses in major species

Policy published on website

Started September 2009

43 requests for classification to date and 19 of those from SMEs

MUMs data requirements where applicable

Financial incentives-some products

Centralised procedure

In 2010 four applications validated (~20% total)

Biosimilar, oncology, 2 generics of centrally authorised product

Include in EPAR if an SME

E-submission

Translation product information

Conclusions

Apply SME office registration

Guidance on web for SA-MUMS-authorisation

Increased requests recent years from SMEs

Queries vet.applications@ema.europa.eu