



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

MUMS Designation and latest developments



Presented by: Dr Karen Quigley
European Medicines Agency

An agency of the European Union





Overview

- Current MUMS policy started September 2009
 - Background
 - Policy explained
 - Definitions applied-major/minor species/limited market
 - Products classified
- UPDATED July 2013 – what has changed
- Review of Policy Ongoing
 - Implementation 2014



Background

Article 79 of Regulation (EC) No 726/2004

“The Management Board shall, in the case of veterinary medicinal products which have limited markets, or in the case of veterinary medicinal products intended for diseases with a regional distribution, adopt the necessary measures to provide assistance to companies at the time of submission of their applications”

Directive 2009/09/EC gives legal basis- ‘more flexible approach’ for smaller market sectors

Policy endorsed by EMA Management Board and Heads of Medicines Agencies (HMA)

Endorsed by CVMP July 2009 - Policy started 1 Sept 2009



Aims of policy

- Stimulate applications MUMS/limited markets
- Link different strands –MRLs, scientific advice, marketing authorisations for limited markets- benefit-risk approach
- Apply common definitions
- Best use of available budget – public money
- Provide advice on appropriate data requirements
- Transparency
- Co-operation with Member States



Definitions

Major / Minor species

Limited markets

All the situations in which the market for a veterinary medicinal product is limited in term of size:

- ❖ Minor species (any species not listed as 7 major ones in EU)
- ❖ Minor indications
 - ❖ Limited geographical distribution
 - ❖ High level criteria listed in policy (prevalence)
- ❖ IWP produced for non-exhaustive list of priority MUMS immunologicals (Gap list)



Procedure for Classification

Complete template for classification on website

Provide supporting evidence minor use – prevalence data

SPC useful if available

Indicate if on IWP published list

Current- alternative treatments

Indicate if MRL established or will be needed

Agency can review prior to submission



Procedure for Classification

Submit completed template – supporting data

Request sent to next CVMP meeting

CVMP decide on classification based on information provided

More in depth review/additional information some cases

Two step process (1) data (2) financial incentives

Decision notified to applicant

Decision published on Agency website and in CVMP press release
in general terms



MUMS / Limited market

- More flexible data requirements
 - MUMS guidelines on data requirements on quality, safety and efficacy for pharmaceuticals, and for immunologicals (since 2004)
- Financial incentives
 - Pre-review of MAA/MRL dossier outline
 - Free scientific advice
 - Fee reductions for MRL, centralised MAA, post-marketing procedures, Reduced annual fee
- Classification valid for 5 years
- All routes of authorisation – HMA involved



Products Classified

September 2009-July 2013 a total of 92 requests received

11 were not considered as intended for MUMS/limited markets

One was withdrawn

32 (35%) were classified as MUMS without financial incentives

48 (52%) were classified as MUMS with financial incentives

34 came from SMEs (37%)



July 2013 – what changed

Management Board review June 2013 concluded:

- Policy successful stimulating applications
 - No change data for MUMS products
 - Need to refine criteria – direct resources at products most deserving of public support
 - Only food producing species eligible financial incentives
 - Request more fundamental review ensure target most appropriate products
- (EMA/327514/2013 Adopted –press release on website)



Latest Developments

Workshop held Agency/CVMP/HMA to discuss

Involve FVE in any changes

Work closely with HMA/Member States

Consider new veterinary legislation –terminology, legal basis

Best use of available resources

Prioritise food producing animals

Aim to get policy endorsed by MB mid 2014



**Thank you for your
attention!**

