EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

MUMS policy – an update

EMA/IFAH-Europe Info Day 2015

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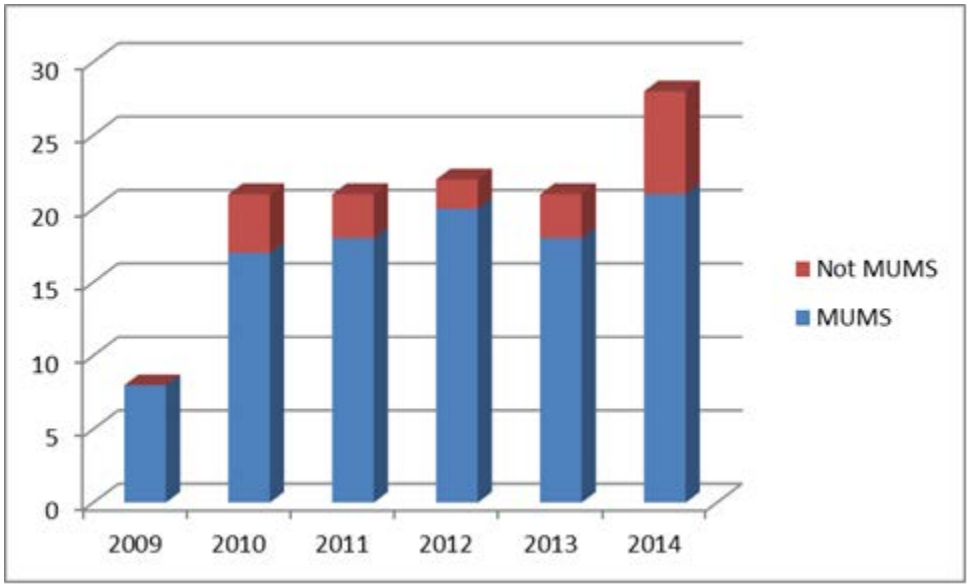
A reminder

- Policy started 2009 – measures to promote availability
- Collaborative approach – Agency – CVMP - HMA
- Experience gained – over 120 requests
- Policy updated to reflect current experience
- Consultation of stakeholders as part of review
- Definitions provided – Minor species
  – Minor use
  – Limited market

Classification requests - 124



Classification Procedure

- Two step process – data requirements and financial incentives
- Financial incentives food producing species only
- Applicants to complete template for classification by CVMP
- Supporting documentation
- Immunologicals IWP listing species-indication considered limited market
- Alternative product – same broad indication in same target species
- Classification valid for 5 years - renew

What's New?

- MUMS Policy (EMA/308411/2014) – the principles
- Guidance Document (EMA/CVMP/388694/2014)
- Adopted by Management Board December 2014
- Main changes – greater clarity and predictability
- Prevalence – maintain case by case approach - insufficient data to establish objective cut-off values
- Financial incentives food producing animals only
- Establish short list of "high need" pharmaceuticals in future

Horses-special considerations

- Horses are a minor species - food producing species in EU
- Provisions for authorisation for sports horses in legislation
- MUMS policy only provide financial support for products for horses where MRL will be established
- Must be destined for food chain and market must be limited
- No alternative product authorised

MUMS Guidelines

- CVMP guidelines on data requirements for MUMS applications are nearly 10 years old
- Review initiated to ensure that guidance is in line with current knowledge and best practice and also provides more predictability and regulatory certainty to applicants.
- Update acceptable data requirements in light of experience gained.
- Clarify in what cases these requirements may or may not apply e.g. new active substances, novel technology or first in class products

MUMS Guidelines

- Concept paper released – end consultation Feb 2015
- Revision of individual MUMS GLs by working parties in 2015
- Public consultation of revised draft guidelines planned to be initiated Q1 2016

Going forward

- Continue to welcome requests for classification (28 in 2014)
- MUMS products authorised increasing slowly
- Draft for revised veterinary legislation – provide a clear legal basis for specific measures for MUMS

Thank you for your attention!