EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Clarification of MUMS Policy

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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.*"

Background

EMA policy, EMEA/429080/2009

- Recognises lack of availability of VMPs
- Implications for animal welfare and public health

To stimulate development of VMPs for MUMS/limited markets

Background

Assistance provided in respect of:

- Scientific Advice
- Establishment of MRLs
- Application for product authorisation

What form does the assistance take:

- Administrative assistance
- Financial incentives (available for 5 years)
- Specific data requirements

Background

Financial assistance:

- Specific measures aimed at SMEs
  - See EMA website

- MUMS
  - Scientific advice: Free
  - MRL application: 50% fee reduction
  - Application for MA: 50% fee reduction
  - Maintenance: 75% fee reduction

Background

Policy subject to annual review

- To be refined based on experience gained
- To develop more objective criteria for classifying a market as limited

Annual Report 2012

2009 to end 2012:

- 73 requests
- Overall 60 % classified as MUMS with financial assistance
- 15 of 73 requests relate to products authorised or under assessment for CP

2012:

- 27 Requests (8 from SME) – 23 MUMS, with 18 given financial incentives.
  - Minor species: horses, mice and rats, rabbits, bees, goats, turkeys, farmed foxes and mink
  - Major species: cats, dogs and cattle

Annual Report 2012

- Policy successful average 2 requests/month
- Not as many FPS requests as companion animal
- SA applications increasing for MUMS products
- Products starting to be authorised

Review by EMA MB June 2013

- Noted the success of the policy
- Noted the implications in terms of financial and human resources
- Incentives should be directed more accurately to products that have potential to be of most benefit to public/animal health (best use of public resources)

Review by EMA MB June 2013

Proposal for amendment to policy agreed

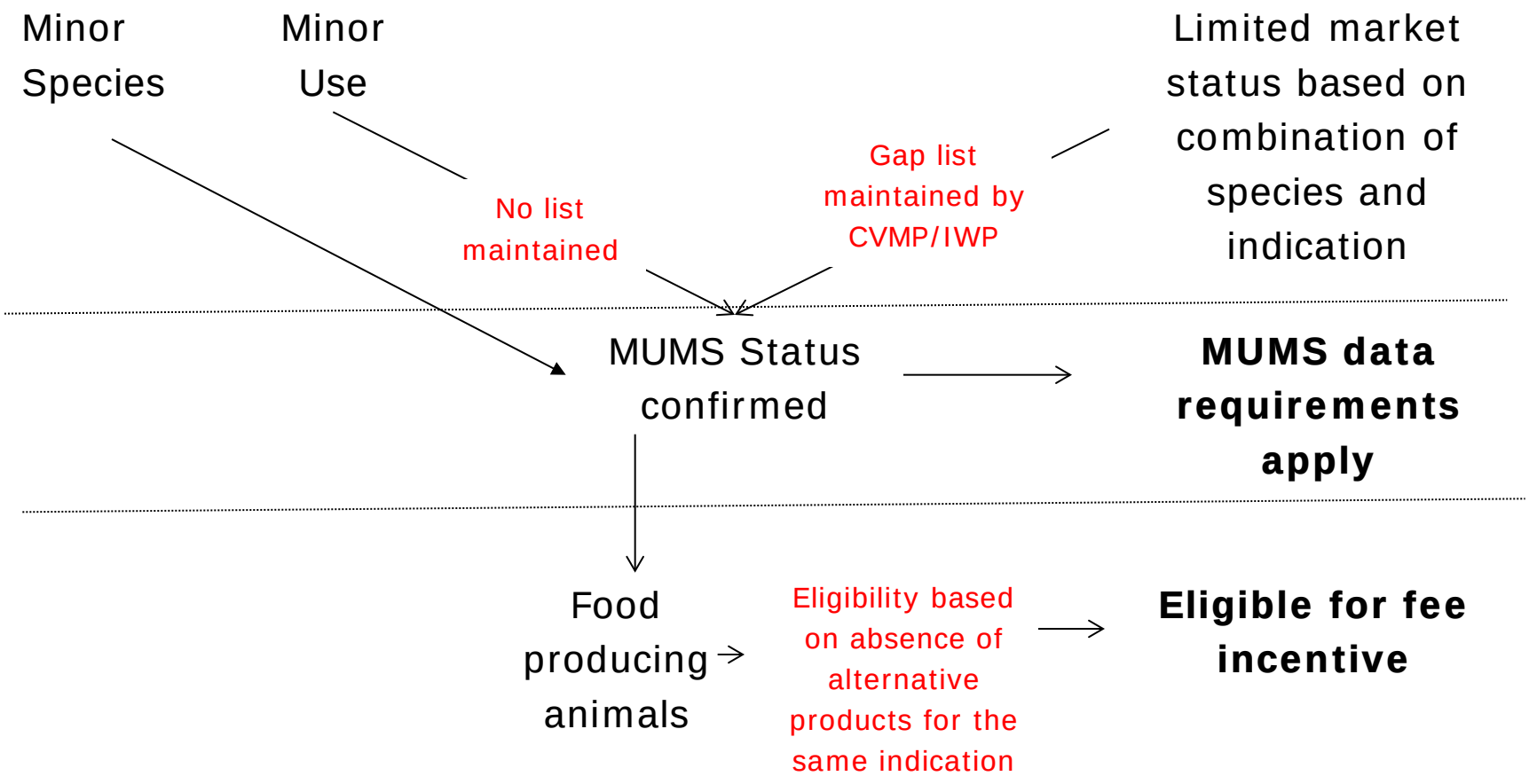
- Specific data requirements continue to apply to all products classified by CVMP as MUMS
- Fee incentives restricted to FPS only:
  - Need in terms of availability of medicines greatest
  - Greatest potential for improving animal and public health

Review by EMA MB June 2013

- Requests for classification considered in accordance with revised policy from Sept 2013
- Products previously classified are not affected (valid for 5 years)
- The MB also requested that the Agency conduct a more fundamental review of the MUMS policy and its implementation to ensure that the policy is effective in terms of targeting incentives to those products most deserving of support with a focus on food producing species
- Revised policy published July 2013

Pharmaceuticals (and biologicals)

Immunologicals



Ongoing Review

Further consideration required in respect of:

- Criteria for defining minor use
- Need for additional criteria for the awarding of financial incentives
- Need for review/updating of MUMS guidelines

Revised policy to be adopted in 2014 following consultation for coming into force in 2015

Horses as a special case (19 requests up to Sept 2013)

Application of the MUMS scheme with respect to horses is being considered in line with the following principles:

- Horses are considered a minor species in the EU and therefore specific MUMS data requirements will apply
- Although considered a food producing species, the majority of horses are not destined for the food chain at the time of treatment with a VMP. For the purposes of applying the MUMS scheme horses will therefore not be considered as food producing animals and fee incentives will generally not apply
- In exceptional cases, applicants may request fee incentives on the basis that they intend to make (an) MRL application(s)

MUMS Data Requirements

- MUMS guidelines on data requirements on quality, safety and efficacy for pharmaceuticals, and for immunologicals (2004)
- Applicability of aspects of the guidelines are determined on a case-by-case basis
- EPAR will include reference to where reduced data in accordance with MUMS guidance has been accepted.
- SA can be used to get feedback on how the guidelines can/should be interpreted for a specific product

Procedure

Request submitted 20 days in advance of CVMP meeting

EMA make initial recommendation (consult with MS re authorised alternatives)

CVMP discuss recommendation

- Decision, or
- Appoint rapporteur (one) to review and decision taken at subsequent meeting

Possibility of appeal

Further information

www.ema.europa.eu