

Minor Use, Minor Species

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Context

- Minor Use
 - When a disease occurs rarely in a major species
 - Cost of registration too high compared to target market
- Minor Species
 - Species other than a major species
 - E.g. not dogs, cats, cattle, horses, sheep,

Purpose

- Allows for the registration of medication when the market share is small
- Allows quality medication to be available to the benefit of the animals
- E.g. Wildlife industry, exotic pets, species important to one country

Registration Requirements

- Mutual Recognition
 - Automatically accept registration from another regulator e.g. MCC, FDA, EMA
 - Based on mutual cooperation with regulator in question
 - Not dependant on just a registration certificate

Registration Requirements

- Quality
 - As good as other conventional medicines
 - GMP approved facility
 - Can be mutual recognition of GMP inspections e.g. PIC

Registration Requirement

- Nonclinical Safety Testing
 - Required as a standard
 - Minimum testing requirements can be limited to species e.g. Reproductive toxicity may be waived for exotic pets
 - Product needs to be safe
 - Food safety species – No waivers, as MRLs need to be set if not available

Registration Requirements

- **Efficacy**
 - Applicant needs proof of efficacy
 - Not necessary to have full clinical results
 - Allowed period of time to generate results, while being marketed
 - Reliant on a well established pharmacovigilance system

Registration Requirement

- **Food Safety**
 - Not meant for a major species
 - If to be use, public safety needs to be met
 - Depletion study is required
 - MRLs may be extrapolated??? (But is a crocodile a prehistoric chicken?)

Registration Requirements

- Re-evaluation
 - After the allocated market authorisation (e.g. 5 years)
 - Product is re-evaluated for proof of efficacy
 - Market authorisation may be granted for a another period thereafter.

Potential Problems

- Applicant markets product, so that a so called minor indication becomes major.
- A disease outbreak makes a minor disease a major one

Conclusion

- For ease of access of medication for the benefit of minor species
- Requires a strong regulatory system