EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Marketing Authorisation Issues for SMEs

Veterinary SME Workshop
"Veterinary regulatory support for SMEs"
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What is a Marketing Authorisation?

- Requirement of EU Medicines Directive

- Allows a veterinary medicinal product (VMP) to be legally sold i.e. full access to the market

- Supported by data to show product is manufactured to a quality standard and is safe and efficacious within the schedule and claims for the product

Centralised MA procedure

Allows access to all EU member states through one procedure √

Managed by EMA and considered by all member states at CVMP √

Standardised timetable with designated clock stops √

Financial incentives for SMEs √

Can't chose member states involved x

Limited ability to alter timetable x

Marketing Authorisations: what we want out of the process

Company:

- to develop a safe and effective product that will have the maximum possible market and the minimum possible development costs:

maximise benefit/risk: best claims/minimal warnings/mitigations

Regulator:

- consistently safe and efficacious product within legislative requirements, protection of animal and public health

positive benefit/risk: claims and mitigations reflect data package

Risks!

Company:

- Product development can be lengthy, expensive and resource intensive
- MA process also costs and no assurance of outcome

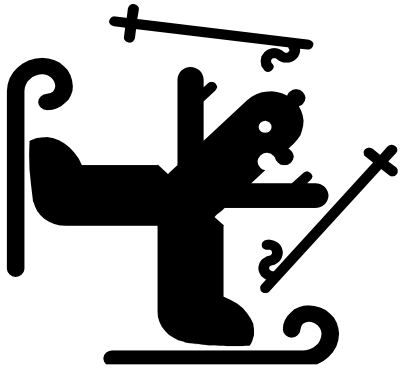
Regulator:

- Inappropriate data package leads to lengthy assessment –resource intensive
- No product to market or severely limited product claims

Mitigation Tactics!

Companies and Regulators discuss at appropriate points throughout development.

- Pre submission meetings
- Meetings during development
- Start of development meetings



What is a VMP?

- "Any substance or combination of substances presented for treating or preventing disease in animals.

- Any substance or combination of substances which may be administered to animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action in animals is considered a veterinary medicinal product."

Directive 2001/82/EC

Definition of an IVMP

- "immunological veterinary medicinal product" means a veterinary medicinal product administered to animals in order to produce active or passive immunity or to diagnose the state of immunity

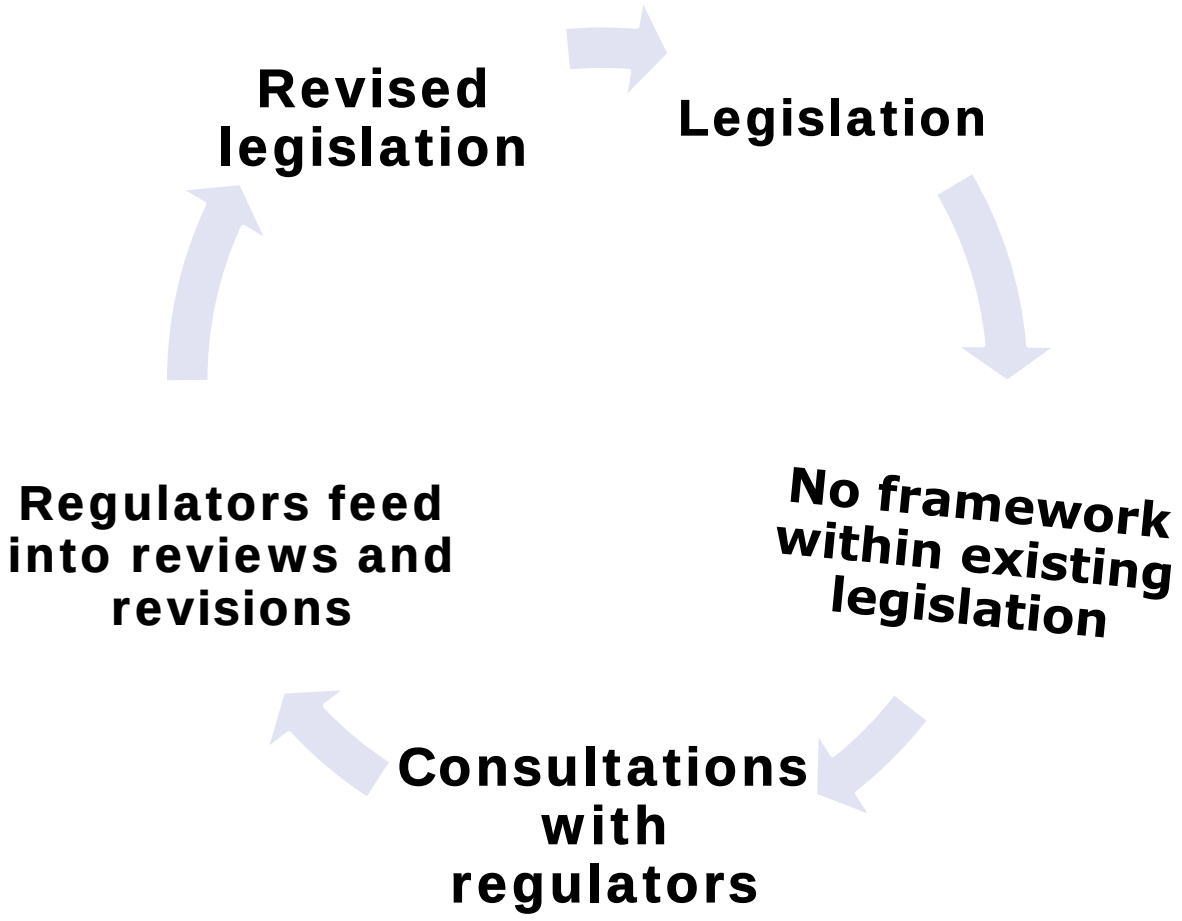
Directive 2001/82/EC

VMP or Not?

- Presentation/function
  - Colostrum supplements
  - Blood products /boosted antibody content
  - Stem cells

- Grey areas new types of products
  - Biologicals
  - Monoclonal antibodies
  - Gene therapy products

What if my product does not fit a definition?



Define your product at the start

- **Does it clearly fit into current VMP definitions**?

Implications for developing and trialling the product

If it is not valid for a MA now it may be subject to some form of national regulation e.g. UK inspection scheme for stem cell /blood bank producers

How does the product go to the market place if not?

- **Will it fit into VMP definitions in the future?**

Review of legislation: new definition of a VMP?/ definition of a veterinary biological?/development of biosimilar guidance?

So your product is a VMP but where does it fit?

- Clear guidance for technical requirements for pharmaceutical and immunological (vaccines) products

- What if your product is a biological molecule/ biopharmaceutical?

- What if your product is a biosimilar?

- What if your product is a generic or hybrid of a generic?

Data Derogations

- Minor use/Minor species/limited market products
- Exceptional MAs
- Multi Strain dossiers
- Generics: Bioequivalence
- Biosimilars????

And not forgetting manufacture.....

- Safety and Efficacy to be generated with actual product as defined in the quality dossier
- Formulation: maximum/minimum titre
- Scale up issues
- Change of manufacturing sites for Biological/vaccine
- Stability data

…… And finally

EU authorisation processes require a comprehensive dossier with a clear product rationale to allow efficient process and positive outcome

Data requirements are dependent on product type and indications

Engagement with regulators is possible early in development process via scientific advice