Challenges in regulation of novel Veterinary Medicinal Products

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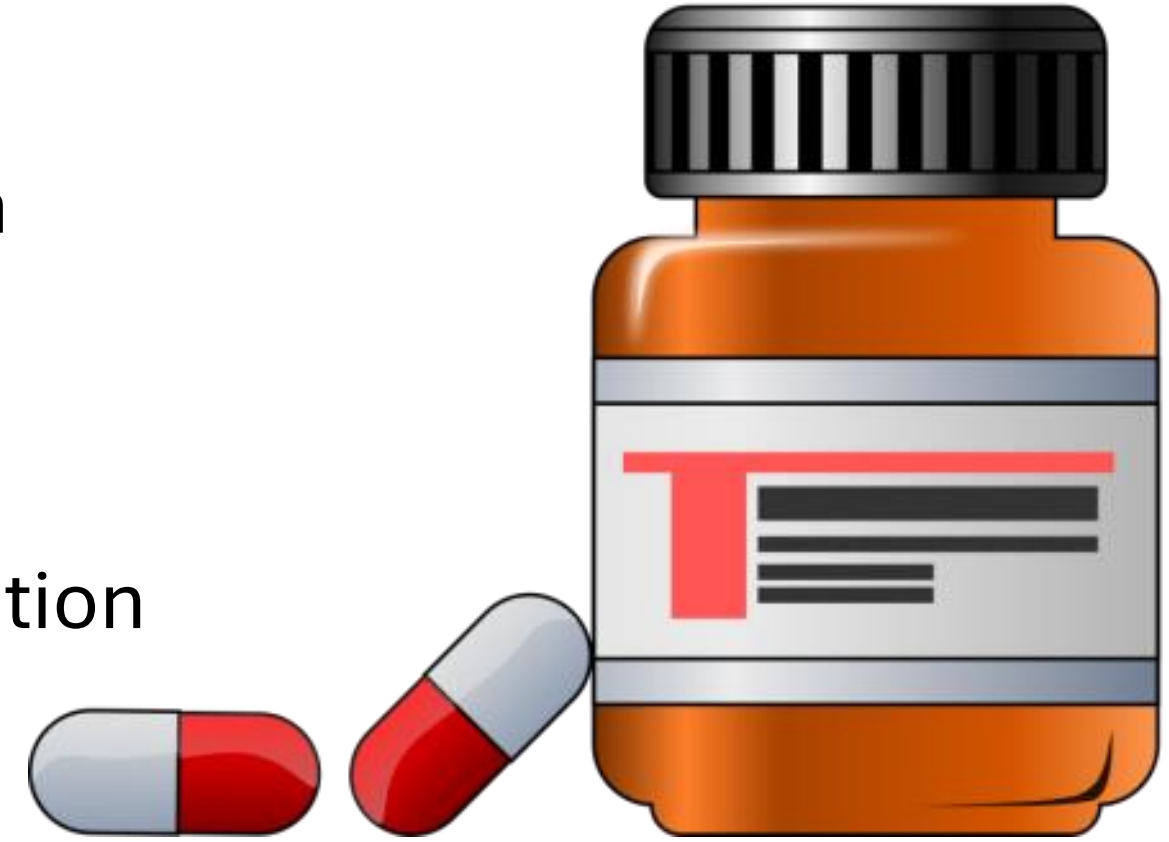
What is a Veterinary Medicinal Product?

In the UK, a product requires a Marketing Authorisation if:

- It is medicinal by function
- It is medicinal by presentation



This also applies to topicals, medicated feed and pre-mixes containing medicines

Medicinal by Function?

‘Any substance or combination of substances that may be used in, or administered to, animals with a view either to **restoring, correcting or modifying physiological functions** by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis’

Medicinal by Presentation

‘any substance or combination of substances **presented as having properties for treating or preventing disease** in animals’

- product label/ package refers to treatment or prevention of disease or adverse condition, or to improving the state of health of the animal treated

- The form in which a product is presented – e.g. a vitamin supplement administered by injection may be considered medicinal by the nature of its presentation.

VMP or not?

- product administered to an animal, which contains a substance that kill insects or external parasites
- product applied internally to teats and udders for the prevention of mastitis
- Probiotic administered in food for use as aid to prevent diarrhoea in calves

- product containing a repellent (provided they claim only to repel external insects)
- product applied topically to disinfect teats and udders (no medicinal claims are made)
- Probiotic/ prebiotic administered in food (no medicinal claims made)

.....other legal frameworks may apply

- Food and Environment Protection Act
- Control of Pesticides Regulations
- Biocidal Products Regulations
- Animal Feed Regulations

Application for VMP MA: the Dossier

Part 1
Summary of Dossier

- (1.A) Administrative Information
- (1.B) **SPC**, Label and Package Leaflet
- (1.C) Detailed and Critical Summaries

Part II
Quality

- (2.A) Qualitative & Quantitative Particulars
- (2.B) Description of the Method of Manufacture
- (2.C) Control of Starting Materials
- (2.D) Control Tests – Intermediate Stages of Man. Process
- (2.E) Tests on Finished Product
- (2.F) Stability Tests
- (2.G) Other Information

Part III
Safety and Residues Tests

- (3.A) Safety Tests
- (3.A.1) Precise Identification of Product & Active
- (3.A.2) Pharmacology
  (3.A.3) Toxicology
- (3.A.4) Other requirements
  (3.A.5) User Safety
- (3.A.6) Environmental Risk Assessment
- (3.B) Residues Tests
  (3.B.1) Introduction
- (3.B.2) Metabolism & Kinetics
  (3.B.3) Residues Analytical Method

Part IV
Efficacy (Preclinical & Clinical Trials)

- (4.1) Pre Clinical Requirements
- (4.A) Pharmacology
- (4.B) Tolerance in the Target Species
- (4.2) Clinical Requirements
- (4.2.1) Results of pre-clinical Trials
- (4.2.2) Results of Clinical Trials

Scientific Assessment - **Quality**

Part II
Quality

(2.A)
Qualitative & Quantitative Particulars

(2.B)
Description of the Method of Manufacture

(2.C)
Control of Starting Materials

(2.D)
Control Tests – Intermediate Stages of Man. Process

(2.E)
Tests on Finished Product

(2.F)
Stability Tests

(2.G)
Other Information

What is in it? How is it made?

How is consistency controlled?

How stable is it?

.....translates onto the SPC as:

declared strength (e.g. 50 mg/ml of ..)

How it should be stored (Do not store above 25°C)

expiry date (shelf life)

Incompatibilities (Do not mix with other medicines)

Scientific Assessment - **Safety**

Part III
Safety and Residues Tests

Pharmacology

Toxicology:
Single/multi/repeat dose

Reproductive/genotoxicity/
carcinogenicity

User Risk Assessment

Environmental Risk
Assessment

Maximum residue limits (novel
actives)

Residues studies/ WP
calculation

How shall I handle the product?

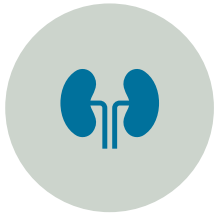
How safe is it for my animal?

Does it harm the environment?

Can I eat produce from treated animals?

…translates onto the label/leaflet/SPC to:

WARNINGS TO PROTECT USERS (E.G. WEAR GLOVES)



WARNINGS TO PROTECT THE ANIMAL (E.G. DO NOT USE IN ANIMALS WITH KIDNEY DAMAGE; WEIGH ANIMALS TO CONFIRM CORRECT DOSE)

WARNINGS TO PROTECT CONSUMERS (E.G. MEAT/MILK/EGG WITHDRAWAL PERIOD)

DISPOSAL INSTRUCTIONS

Scientific Assessment - **Efficacy**

- Part IV Efficacy (Preclinical & Clinical Trials)
- Pharmacology
- Pharmacokinetics and dynamics
- Tolerance in the Target Species
- Dose Determination/ confirmation
- Resistance
- Clinical/ Field Trials

Does the product work?

What is the optimal dose regimen?

What side effects occur?

…translates onto the label/leaflet/SPC to:

Dose

Dose interval

Length of treatment

Precautions

Possible side effects

Legislation and Guidance

National Legislation

- UK Veterinary Medicines Regulations 2013 (as amended)

International Guidelines

- VICH
- OECD
- Codex Alimentarius

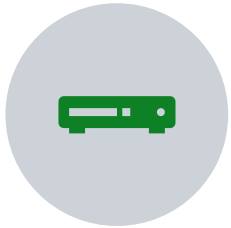
National guidance

- National Guidelines
- Pharmacopoeias
- Scientific advice

Benefit:Risk Evaluation – is the MA approved?

The direct therapeutic benefits for each target species and each claim

The indirect benefits



The risk assessment for all relevant risks (to the target species, user, consumer & the environment)

The ability to minimise risk through appropriate mitigations

The conclusion

Benefit:Risk is not an exact science – it is a judgment call made at a point in time

Challenges in Regulating Novel Products

- Is Legislation fit for purpose?
- Do appropriate scientific guidelines exist?
- Do regulatory staff have the right skillsets?
- Do regulators have sufficient resource?

Regulating novel therapies – updating legislation

- 2024 amended UK VMR to reflect advancements in VMPs
- Still require full dossier containing Parts 1, 2, 3 and 4
- Deviations from the requirements may be possible when justified
- Can request additional data in order for a thorough assessment of the benefits and risks
- To address data gaps or uncertainties at the time of product authorisation, **implementation of post-authorisation measures or studies** may be considered on a case-by-case basis, detailed in a **risk management plan**
- For any novel therapy product, in particular those considered as a nascent field in veterinary medicine, it is recommended to seek the advice of the Veterinary Medicines Directorate in a timely manner before submission

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New guidelines: Bacteriophages

Offer promising alternatives to traditional antibiotics in combating AMR in animals

Many are borderline products

Guidance being developed for bacteriophage-based products for use in veterinary and human medicines:

- Ph. Eur. general chapter 5.31. Phage therapy active substances and medicinal products for human and veterinary use. Offers a framework of requirements for phage therapy active substances and medicinal products for human and veterinary use and their production and control.
- EMA Guideline on quality, safety and efficacy of veterinary medicinal products specifically designed for phage therapy
- UK MHRA: Regulatory considerations for therapeutic use of bacteriophages in the UK - GOV.UK

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Solutions

- Flexible regulatory frameworks
- Develop better guidance and test, e.g. regulatory sandboxes
- Proactive engagement between product developers and applicants - innovation hubs/ company meetings
- Enhanced access to regulatory training – Uni of Pretoria
- Collaboration between regulators – reliance/ worksharing/ mutual recognition

THANK YOU