# CAUSES OF ANTIBIOTIC RESISTANCE

HANDLE ANTIBIOTICS WITH CARE

**Antibiotic resistance** happens when bacteria change and become resistant to the antibiotics used to treat the infections they cause.

Over-prescribing of antibiotics

Patients not finishing their treatment

Over-use of antibiotics in livestock and fish farming

Poor infection control in hospitals and clinics

Lack of hygiene and poor sanitation

Lack of new antibiotics being developed

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www.who.int/drugresistance

#AntibioticResistance

World Health Organization

MINISTRY FOR THE ENVIRONMENT, SUSTAINABLE DEVELOPMENTAND CLIMATE CHANGE
PARLIAMENTARY SECRETARIAT FOR AGRICULTURE, FISHERIES AND ANIMAL RIGHTS

# Veterinary Medicines Section

## Annual Meeting with Wholesaler Dealers and Pharmacies 2018

# AGENDA

1. New Team
2. Antimicrobial Resistance monitoring
3. Wholesale, Pharmacy, Feed inspection
4. Registration of Veterinary Medicinal Products
5. Closure and Questions

# 1. New Team

- Stephen Spiteri – Senior Principal Pharmacist
- Bernard Soler – Pharmacist
- Elena Vella – Pharmacist
- Nathalie Fenech – Pharmacist

- Michael Chiaramonte – Senior Vet Officer
- Godwin Farrugia – Principal Agri. Officer

# 1. New Team

## FOCUS 2018-2019

### i) Antimicrobial data, monitoring and resistance

- **Wholesale Dealers – Sales Data**
- **Pharmacy – Dispensing and Prescriptions**
- **Farm – Withdrawal period, storage and use**

# 1. New Team

## ii) Registration and Extensions of Veterinary Medicinal Products

- **Review of every veterinary medicinal product**
- **Latest documentation and signatures**
- **Updating system to make registration of new veterinary medicinal products a faster process**
- **Process of shifting everything online**

# 1. New Team

## iii) Educational Seminars and Meeting with stakeholders

- **Planning on more Veterinary Public Health Promotion, and Correct use of Veterinary Medicines especially Antimicrobials**
- **More input from Wholesalers and Pharmacies**
- **Pharmacist – Informative Material on corrective use of Medicines**

# 1. New Team

## iv) Inspections and Investigations

- **Joint farm inspections held on a more frequent basis**

**More data on what medicines are being used on farms**

- **Improving Pharmacy and Wholesale dealer inspection**
- **Wholesalers align themselves to GDP guidelines**

# 1. New Team

## iv) Inspections and Investigations

- **Inspection on Wholesale dealers and Veterinary Pharmacy**

- **Operation**
- **Distribution and Dispensing**
- **Temperature Control**
- **SOP (Standard Operating Procedures)**
- **Documentation**
- **Personnel Training and Qualification**
- **Recalls and Expired Medicines**

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# AGENDA

2. Antimicrobial Resistance monitoring

**Registration and Distribution**

# 2. Antimicrobial Resistance monitoring

**Registration and Distribution**

- **New and Renewal of antibiotics classified as POM only**
- **Prescriptions – importance and Kept for a min. of 3 years**

**Importance is given from Pigeons to Cows**

# 2. Antimicrobial Resistance monitoring

## PROBLEMS ON FARM

- **Withdrawal periods – highlighted and explained.**

**Importance of dispensing EU REGISTERED products and NOT EXPORT PACKS – DIFFERENT WITHDRAWAL PERIOD**

- **Instruct farmers to include any medication administered in herd book**
- **Storage conditions and Shelf life once open**
- **Promotion of vaccines**

# AGENDA

2. Antimicrobial Resistance Monitoring

**DATA COLLECTION OIE AND ESVAC 2018**

# 2. Antimicrobial Resistance monitoring

## DATA COLLECTION

**Thanks for the 2017 data.**

- Calculations and criteria remain the same as explained in 2017
- Raw data should be made available and attached together with new excel (validation purposes)
- Unregistered antimicrobials should be registered or all documentation submitted by **end of January 2019.**
- All cells should be filled and calculated correctly.

# 2. Antimicrobial Resistance monitoring

DATA COLLECTION

Switch to Excel

And

Explain data entry

# 2. Antimicrobial Resistance monitoring

DATA COLLECTION

QUESTIONS ??

# AGENDA

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# 3. Wholesale Inspection

## GDP GUIDELINES

- Commission has published EU Guidelines on Good Distribution Practice (GDP)
- Appropriate storage and distribution of medicinal products in the European Union

- Pharmacist visits recorded +signed
- Vet visits recorded + signed
- Pharmacist to countersign records especially GDP records like expired goods, temperature records, pest control, cleaning, incoming stock etc
- Temperature monitoring; Calibration of temperature logger + certificate
- Pest control + certificate
- Training of personnel - documented
- VMP storage area - light, labelling, full accessibility
- Prescriptions to tally with outgoing stock records
    - Fully traceable stock movements
    - Expired records must tally with physical expired stock
    - Records to be inspected invoices etc

# 3. Wholesale Inspection

- Good Record keeping
- Quality manual and SOPs:
  - FEFO and stock movement
  - Expired goods
  - Waste disposal of expired goods
  - Temperature monitoring
  - Incoming goods etc
- Recalls
- Pest control & records
- Stock rotation & checks
- Expiry date checks
- Housekeeping / cleaning procedures

# 3. Pharmacy Inspection

- Dispensed properly? POM? Prescription?
- Record keeping – Dispensing records,
  Cleaning, Temperature, Locums
- Calibration of Temperature Monitors and Fridge servicing
- Expired items and Stock Rotation
- Distinction between Wholesale trading and Pharmacy dispensing and stocks

# 3. Feed Production, Testing & Records

- Feeds: 'simple'; coccidiostats; VMPs
- Residues: carry over; cross contamination
- Sequencing of feed production & records
- Flushing, identification, storage and use
- Testing for carry over and homogeneity (Council Directive 167/1990, article 4E/S.L. 437.73, rule 4E and EU Regulation 183/205, Annex II, *Facilities and Equipment, 3B)*
- Regular checks of equipment and facilities: maintenance, cleaning, records
- Dosage testing: legislation (coccidiostats), SPCs (VMPs)
- Prescriptions (medicated feed): three months, farmers' copies, herd book, FBO's copy

# 3. Feed Production, Testing & Records

## Traceability

Throughout the WHOLE process: sourcing of ingredients; production; storage; dispatch

- Inputs and outputs
- Batch numbers
- Client identification: Annex II to EU Regulation 183/2005 and Council Directive 167/1990, article 4F 9S.L. 437.73, rule 4F); prescriptions

# 3. Feed Production, Testing & Records

## Bagging, Bulk storage and dispatch

- Cleaning of equipment and records
- Cleaning of transport vehicles and records (S.L. 437.73, rule 5.2)
- Proper loading/unloading of feeds (bulk) from trucks
- Testing of 'clean' feeds after dangerous feeds

# AGENDA

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# 4. Registration of Veterinary Medicinal Products

**Centrally Authorised**

**MRP/DCP**

**Regulation 7**

**Regulation 4.2**

# Centrally Authorised

**Application 1D**

- Curriculum Vitae of the Qualified Person (QP) for pharmacovigilance

- Electronic and hard copies of the most recently approved Summary of Product Characteristics (SPC), Package Information Leaflet (PIL) and Mock-ups. (English language)

- Letter of access from the Marketing Authorisation Holder to the local distributor (if applicable)

- Proof of payment and Signed Annexes

# MRP/DCP

**Application 1A**

- Curriculum Vitae of the Qualified Person (QP) for pharmacovigilance

- Electronic and hard copies of the most recently approved Summary of Product Characteristics (SPC), Package Information Leaflet (PIL) and Mock-ups. (English language)

- Letter of access from the Marketing Authorisation Holder to the local distributor (if applicable)

- Proof of payment and Signed Annexes

# Regulation 7

**Application 1B**

1) Copy of the Marketing Authorisation for the concerned veterinary medicinal product, issued by the official agency in the Member State.

1) Curriculum Vitae of the Qualified Person for Adverse Drug Reactions (ADR) and product defects

1) Electronic and hard copies of the most recently approved Summary of Product Characteristics (SmPC) and Package Information Leaflet (PIL) of the product authorised in the EU/EEA country of source.

1) Letter of Access from the Marketing Authorisation Holder to the registration holder

# Regulation 7

**Application 1B**

1) Mock-up/specimen of the outer and immediate labelling of the product to be placed on the market in Malta (electronic and hard copy). The Marketing Authorisation number of the EU/EEA country of source should be clearly visible on the outer pack.

1) Proof of establishment of the proposed Registration Holder in an EU/EEA country (valid wholesale dealer licence (if available) or copy of the Marketing Authorisation of the Product)

1) Proof of payment and Annexes

1) Relevant extract from the table of allowed substances in Regulation (EU) 37/2010. Only the page where the relevant active substance(s) are mentioned and its Maximum Residue Limits (MRL).

# Regulation 7

## ISSUES

- Registration of a particular MA and trade a different product. Product registered AIC (Italy) and trade ESP (Spain)
- Packaging of export packs instead of actual EU packs.
- Withdrawal periods change or different from one registered product to another (could be same as EU)
- Mock Up visible MA number
- English PIL very important

# Regulation 4.2

**Application 1C**

- Good Manufacturing Practice (GMP) granted to the manufacturer of the product
- Curriculum Vitae of the Qualified Person (QP) in charge of Adverse Drug Reactions (ADR) and product defects reporting
- Proof of establishment of the proposed Authorisation Holder in an EU/EEA country
- Proof of Payment and signed Annexes
- Patient Information Leaflet or instruction to use.
- **Labelling** – only on small non-food animals (does not include cats and dogs)

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