



Training Seminar for National Veterinary Products Focal Points

Veterinary Products: A Vital Tool for Improving Animal Health and Welfare

05 – 07 September 2023 Lilongwe, Malawi



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English Speaking Africa Training Seminar for National Veterinary Products Focal Points

Quality of Veterinary Products: An Overview

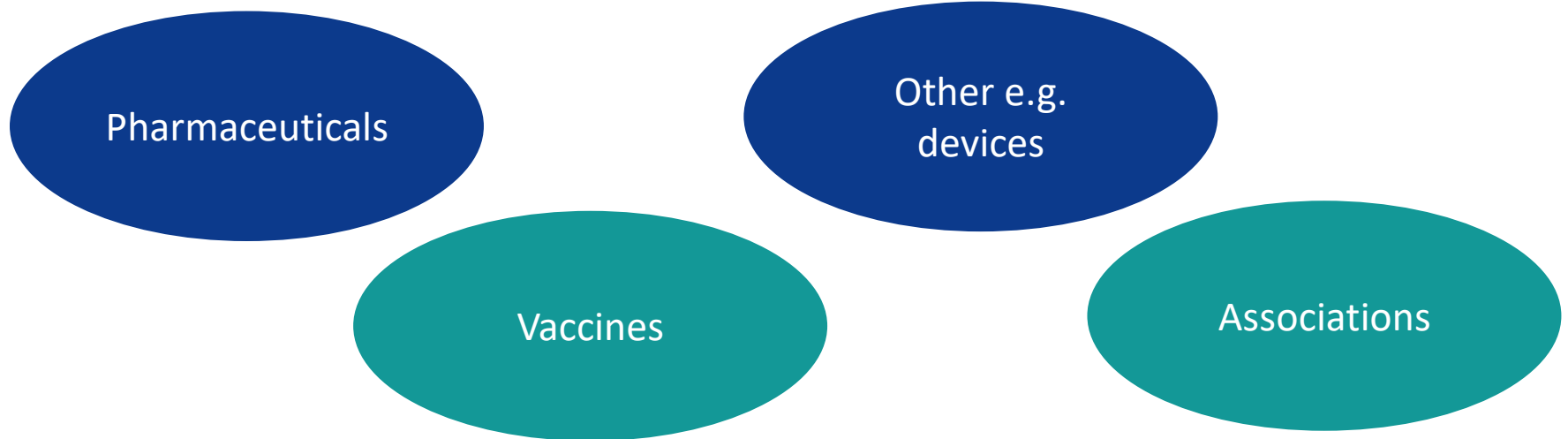
5 September 2023

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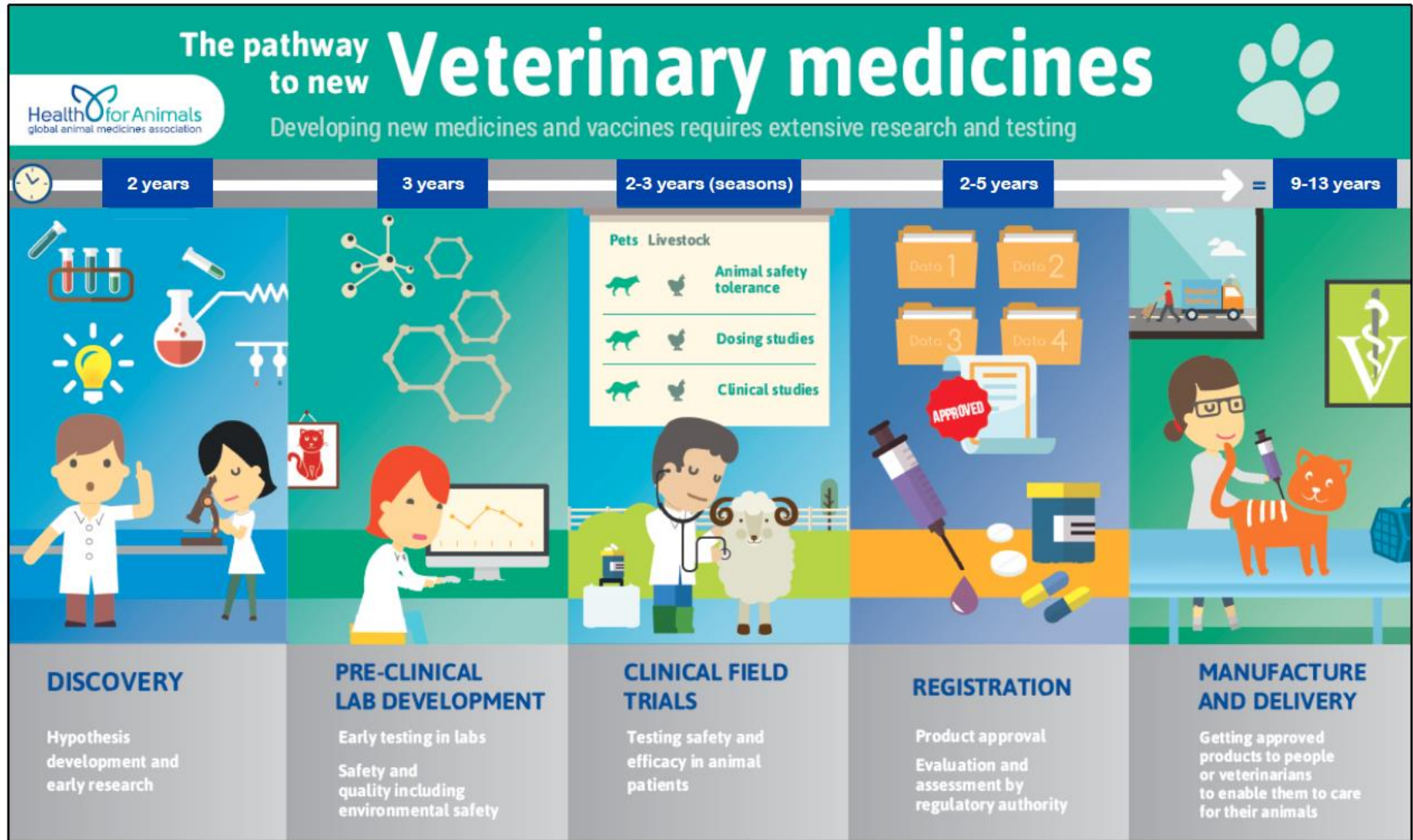


1. Who is HealthforAnimals?
2. Product development
3. Research and development costs
4. Why are quality VMPs so important?
5. Why does animal health matter?
6. Assessment and authorisation of VMPs
7. Laboratory and Quality control
8. Residue monitoring
9. Pharmacovigilance
10. Counterfeit medicine

HealthforAnimals represents the animal health sector:



Members = 90% of the global market for veterinary medicinal products



Research and Development costs

Biologicals

\$2,5 – 52 million

Known API

\$3,6 – 29,8 million

New API

\$11 – 99,2 million

Why are quality VMPs so important?



- Disease prevention and control
- Animal health and welfare
- Pain and suffering reduction



- Public health
- Food safety
- Healthy animals = healthy humans



- Economic impact
- Environmental impact

Why Does Animal Health Matter?

Animal health is an engine of growth for the world's most vulnerable communities

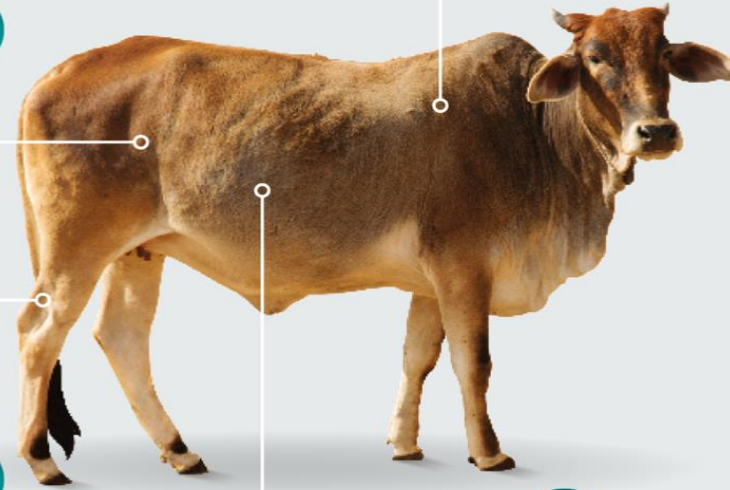
The health of animals is utterly crucial for the 1 billion people across the world who are entirely dependent on livestock to live.

Around 70% of income in the world's poorest countries comes from livestock production.

Feeding a growing population relies on healthy animals

Everyday, we ask livestock farmers to provide us with the milk, meat and eggs that are so essential to our health and wellbeing. This job can only become more difficult as our population grows.

The global population is expected to rise from 7 billion to 9 billion by 2050 – it's like adding the entire population of Africa to our world twice over – and our food supply needs to keep up.



Human lives and livelihoods across the world are dependent on healthy animals

The impact of disease can be catastrophic, impacting animal welfare, food supply and trade.

Over 12 years at the start of the millennium, six international incidents of animal disease caused economic losses of \$US 60 billion – more than the entire gross domestic product of countries like Kenya, Tanzania, Ghana and Uganda.



Controlling animal disease protects our health

Each year, zoonosis – diseases transmitted from animals to humans – sickens 1 in 3 people around the world. Keeping animals healthy controls zoonosis and safeguards our wellbeing.

60% of the infectious diseases we face in our lives originate in animals – only by safeguarding their health can we protect our own.

Product registration procedure:

- Submission of dossiers
 - All data collected during product development
- Administrative review
 - Ensure dossier is complete and meets requirements
 - Helps to avoid delays due to missing or inadequate information
- Quality assessment
 - Evaluate manufacturing and quality control procedures
 - API, starting materials, formulation, manufacturing, control tests, stability, packaging and labelling
- Review of properties
 - Identification of potential risks of the medicine e.g. adverse reactions, side effects and drug interactions
 - Pharmacology, toxicology and environmental safety



→ Clinical assessment

- Critical data on the efficacy and safety in the target animal specie
- These studies also help determine appropriate dosages, routes of administration, and treatment protocols

→ Regulatory decision

- Based on the comprehensive assessment of the dossier and assessing the benefits of the medicine balanced with the risk, a decision is made on whether to approve the veterinary medicine or not

Key points related to laboratory and QC are:

Quality control and laboratory testing is the only way to guarantee the safety and efficacy claims of a VMP

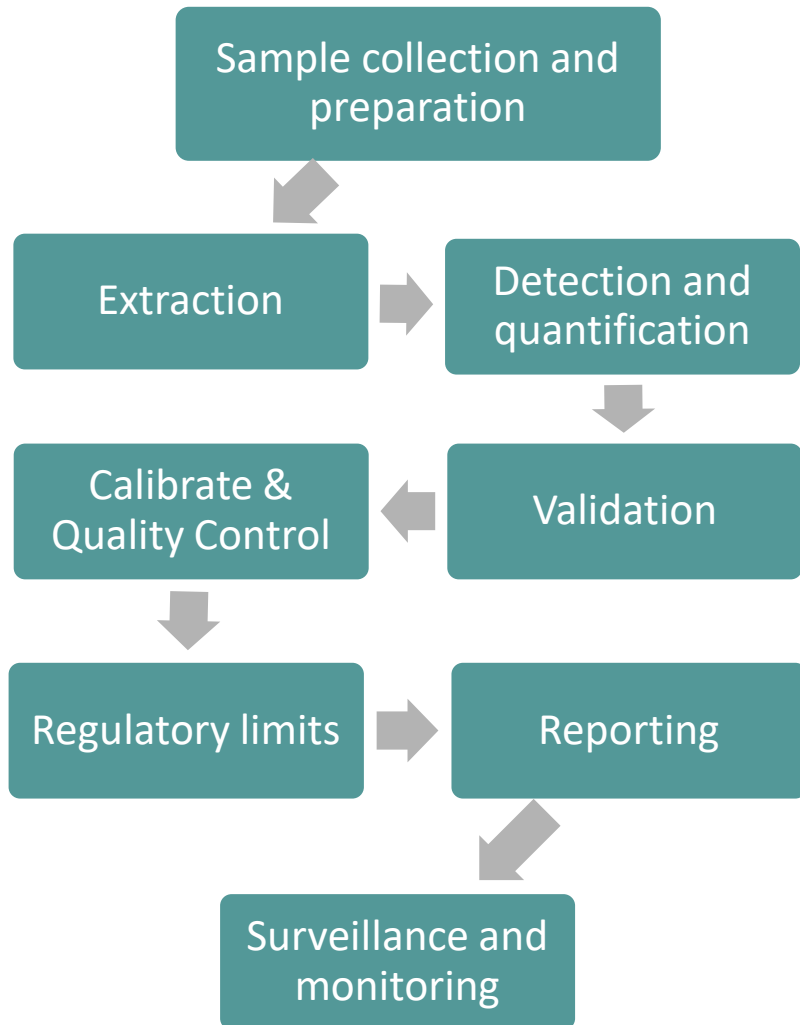
Effective quality control relies on well-equipped and accredited laboratories

Rigorous quality control testing to adhere to established standards

Manufacturing facilities must adhere to GMP guidelines to ensure consistent quality vet meds production

Capacity building may be required in some countries with limited resources. Intl org, donors & other countries can assist to strengthen capacities

Effective tracking, tracing and testing can combat the circulation of counterfeit medicine



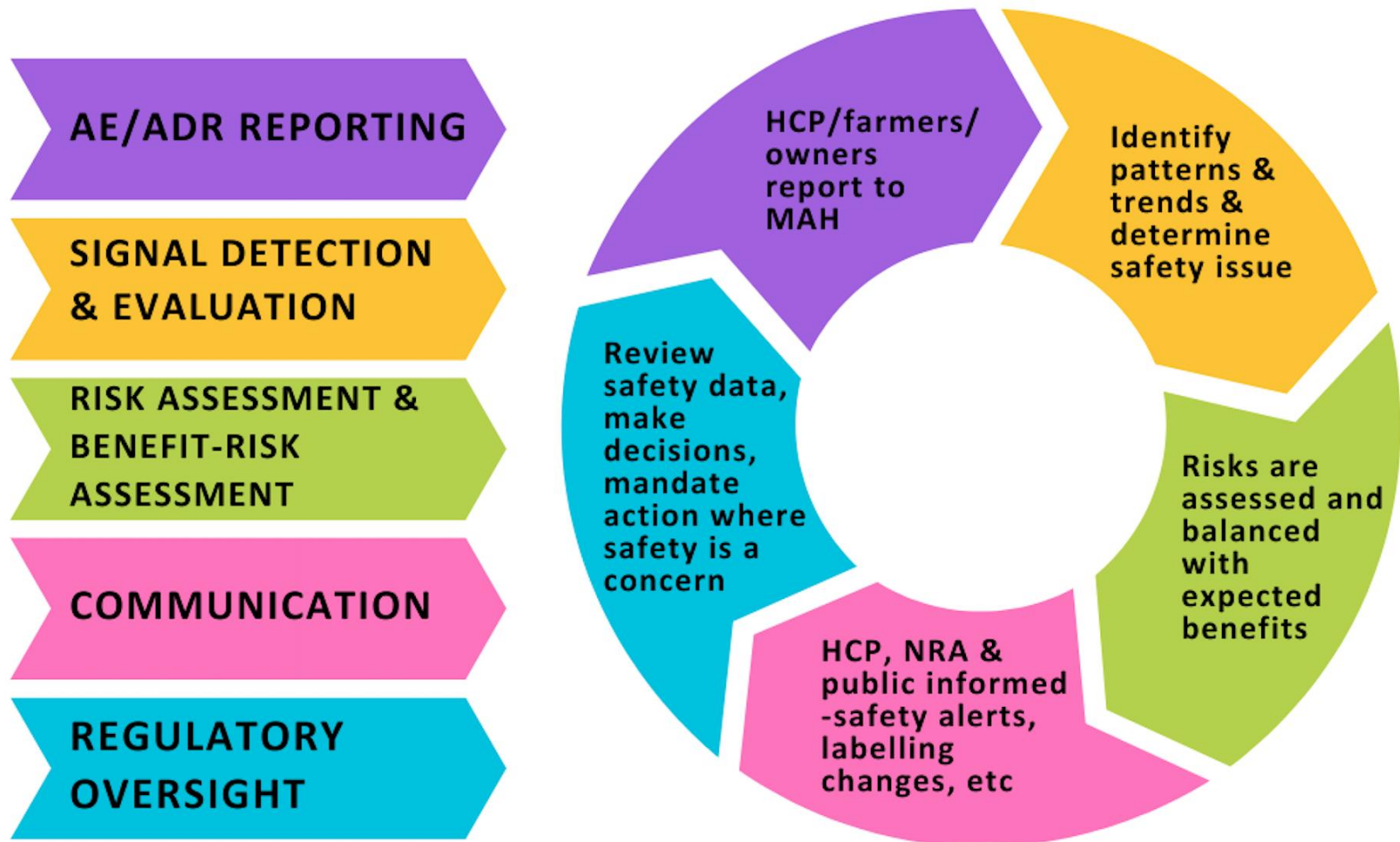
Why it's important:

- Food safety
- Antimicrobial resistance
- Human health concerns
- Regulatory compliance
- International trade
- Consumer confidence

The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem – World Health Organisation (2002)

- ✓ Crucial to ensure animal health and welfare
- ✓ Identify safety concerns – NRAs and manufacturers can take action
- ✓ Unforeseen/specie specific AEs only become apparent when used in large/diverse groups of animals over a longer period than clinical trial
- ✓ Animals can't communicate their pain/discomfort, PV critical to detect potential issues
- ✓ Essential for safety data collection
- ✓ Transfer of harmful residues to humans which can lead to AMR
- ✓ Regulatory compliance
- ✓ Improvements of medicine
- ✓ Transparency and trust





How to set up a pharmacovigilance system for veterinary medicinal products



[https://www.woah.org/en/document/
pharmacovigilance/](https://www.woah.org/en/document/pharmacovigilance/)

Counterfeit medicine

Nearly half a million people are estimated to be killed by counterfeit medicines in sub-Saharan Africa every year – UNODC threat assessment report (Feb 2023)



Measures to take:

- Increase **field sampling and targeted laboratory testing**, counterfeit medicines won't meet the required quality standards
- **Don't waste limited resources** on repeating the scientific assessment of products that have already been authorised by a stringent or trusted regulatory authority
- **Enhance regional and international collaboration** between NRAs, vet associations, manufacturers, and other stakeholders to share information, best practices and intelligence on counterfeit veterinary medicines
- Invest in **public awareness** campaigns to **educate farmers and veterinarians** about the risks of counterfeit medicines
- Implement **technology** solutions like barcoding, serialisation, and digital tracking to ensure the authenticity of veterinary products



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Credit: Jake Lyell for HCC