World Organisation for Animal Health

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Training Seminar for National Veterinary Products Focal Points

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

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The Fleming Fund

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Health for Animals
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English Speaking Africa Training Seminar for National Veterinary Products Focal Points

Registration, authorisation, and harmonisation of regulations: Pharmaceutical industry perspective

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Contents

Registration and authorisation

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Registration: The registration process involves submitting **comprehensive data and documentation** about a veterinary pharmaceutical product to the **regulatory authority** of a particular country or region. This includes information on the product's **safety, efficacy, quality, manufacturing process, labelling,** and more. The regulatory authority assesses this data to ensure that the product meets the **required standards** and poses **minimal risks** to animal health, human health (if applicable), and the environment.

Authorisation: Once a veterinary pharmaceutical product **successfully passes** the regulatory assessment, it is **granted authorisation** to be marketed and sold within the jurisdiction. This authorisation might come in the form of a **marketing authorization, product license**, or similar document. It signifies that the product meets the necessary criteria and can be **legally distributed and used.**

Benefits of harmonisation

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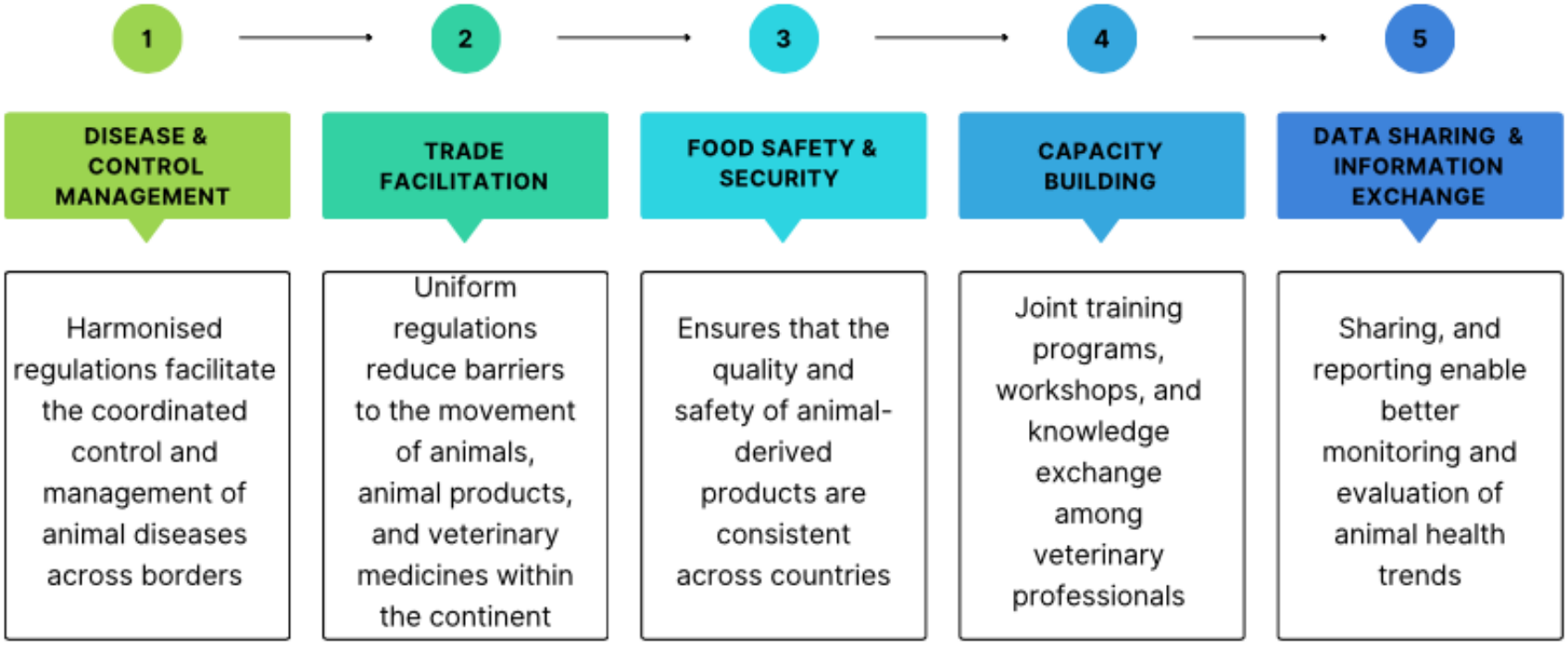
Harmonisation: The process of aligning regulations, standards, and requirements across different countries or regions



Challenges of harmonisation

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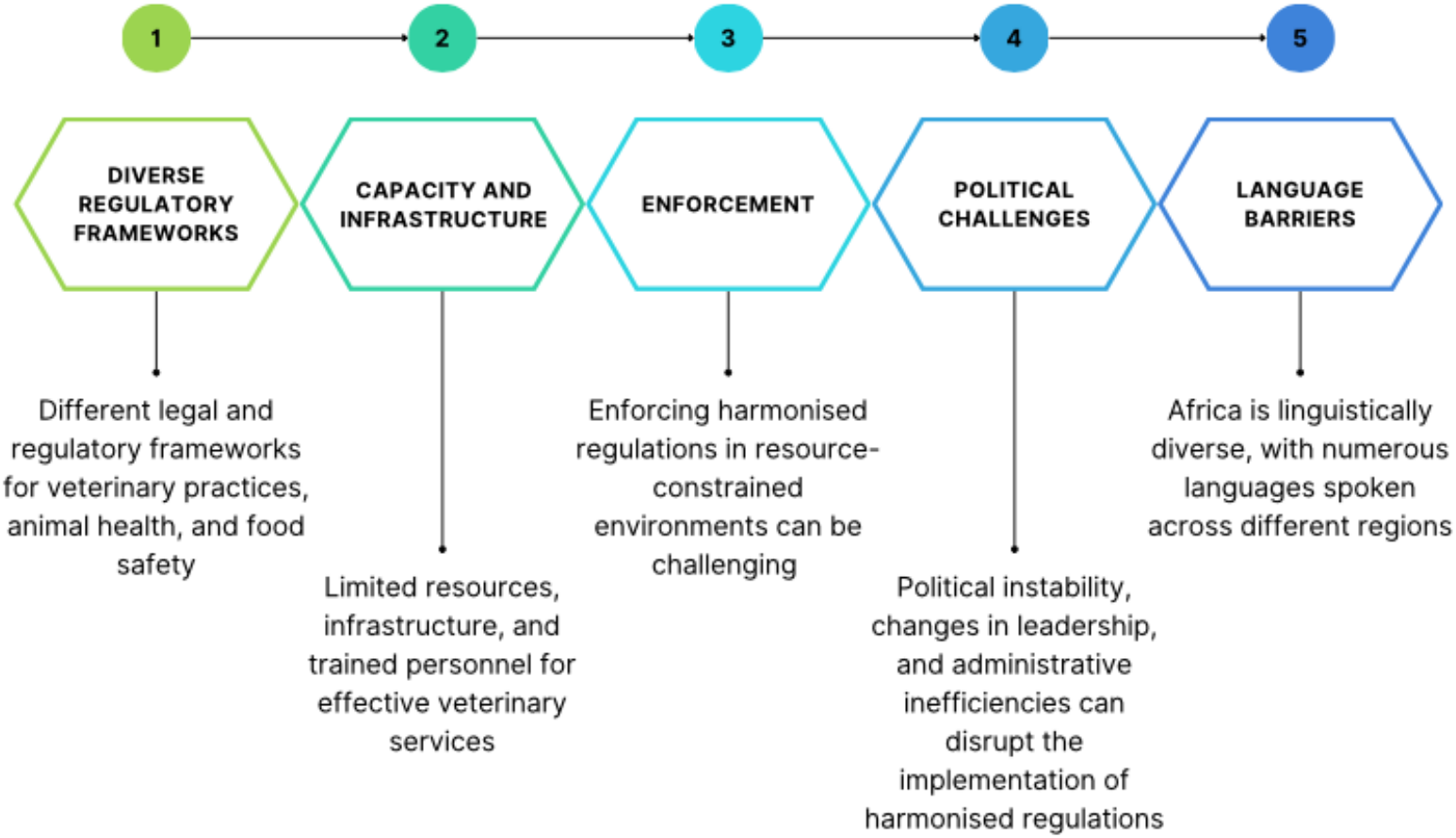

Harmonisation for industry

- Harmonised guidelines and requirements
  - Harmonised and National submissions – simplification of regulatory overload
- Harmonised labels and claims
  - Resolves minimum order quantity issue
- Sensitisation/training on harmonised procedures
- Fixed timelines – improves predictability, reduce average time to market
- Return on investment
- One submission, multiple registrations
- One set of questions, consistent evaluation responses
- Joint GMP inspections
- Acceptance of other NRA's GMP inspections

Harmonisation for industry

- Capacity building
- Reduce the administrative burden for regulators and industry
- Enhanced compliance
- Fewer field efficacy trials → regional trials
- Harmonised post marketing activities - variations & renewal times harmonised & granted/approved at the same time and hence rapid re-introduction of VMP in the market

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