World Organisation for Animal Health

Substandard and Falsified Veterinary Products Workshop

4 - 6 March 2025. Dar es Salaam, Tanzania.

The Fleming Fund

WHO Definitions

Substandard: also called “out of specification”:

- Authorised medical products that fail to meet either their quality standards or specifications or both
- Manufacturing error/degradation
- Transportation/storage/expired
- Require a regulatory response

Falsified

- Deliberately/fraudulently misrepresent their identity, composition or source

Unregistered/Unlicensed medical products

- Have not undergone evaluation/approval by the NRA for that market

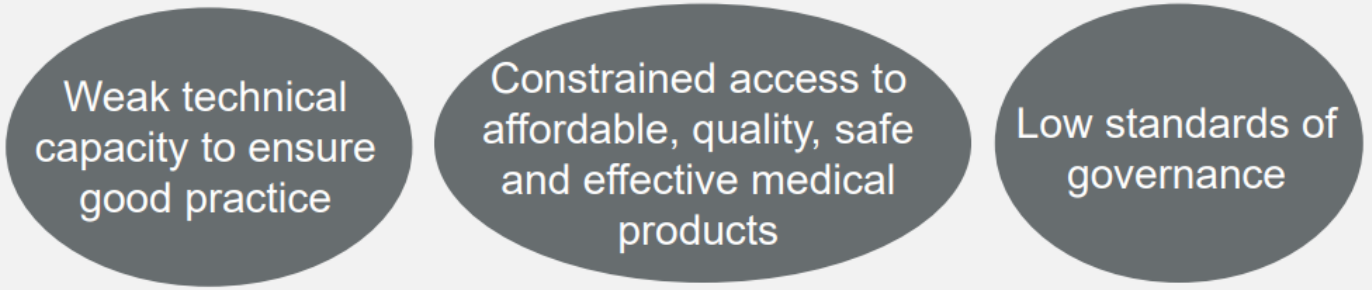
IMPACT OF SFs

- 1/10 medical products sold in Africa are SSF
- Africa has 40 % prevalence globally
- Serious adverse effects
- Antimicrobial resistance
- Increase in disease progression
- Decreased animal production and food security
- Loss in confidence in regulation and control of medicines

What causes the problem?

- HealthforAnimals – qualitative analysis found that illegal veterinary products are associated with:

- Consistent with findings of primary drivers for SF medical products for human use by WHO:



South African environment: Challenges

- RSA imports numerous human and veterinary medical products imposing a huge risk of substandard/falsified medicines
- Porous borders: existence of unofficial ports of entry
- Unscrupulous dealers
- Inadequate support/cooperation of other Law Enforcement agencies
- Failure of some manufacturers to comply with cGMP
- Dual registration of veterinary products in the country
- Use of compounded veterinary products

South African Strategies

- Section 2B(1)(d) and Section 35(1)(xiii) of Act 101/1965 make provision for performing PMS in South Africa
- Developed and implements post marketing measures to ensure that products circulating in the market are of quality
- Planned sampling: Evaluation of labelling, sample collection, analysis and reporting
- Reporting of OOS testing results and label non-conformances
- Sources of information: experience from inspection activities, vigilance activities, consumer complaints, importation data, previous surveillance
- Targeted sample collection sites: ports of entry, warehouses, wholesalers, health facilities, retail outlets, informal outlets/street vendors
- Public searchable database of registered veterinary medicines and PIs

Orthodox/ Veterinary Medicines

Inputs

- Paperwork handed to SAHPRA BMCT by Importer agent (from SARS)
- SAHPRA assesses the documents

Requirements: Registered products

- SAHPRA assesses section 22C licence
- Medicine Registration certificate or old medicine letter
- Ensure Importer is the same as licence holder

Requirements: Unregistered

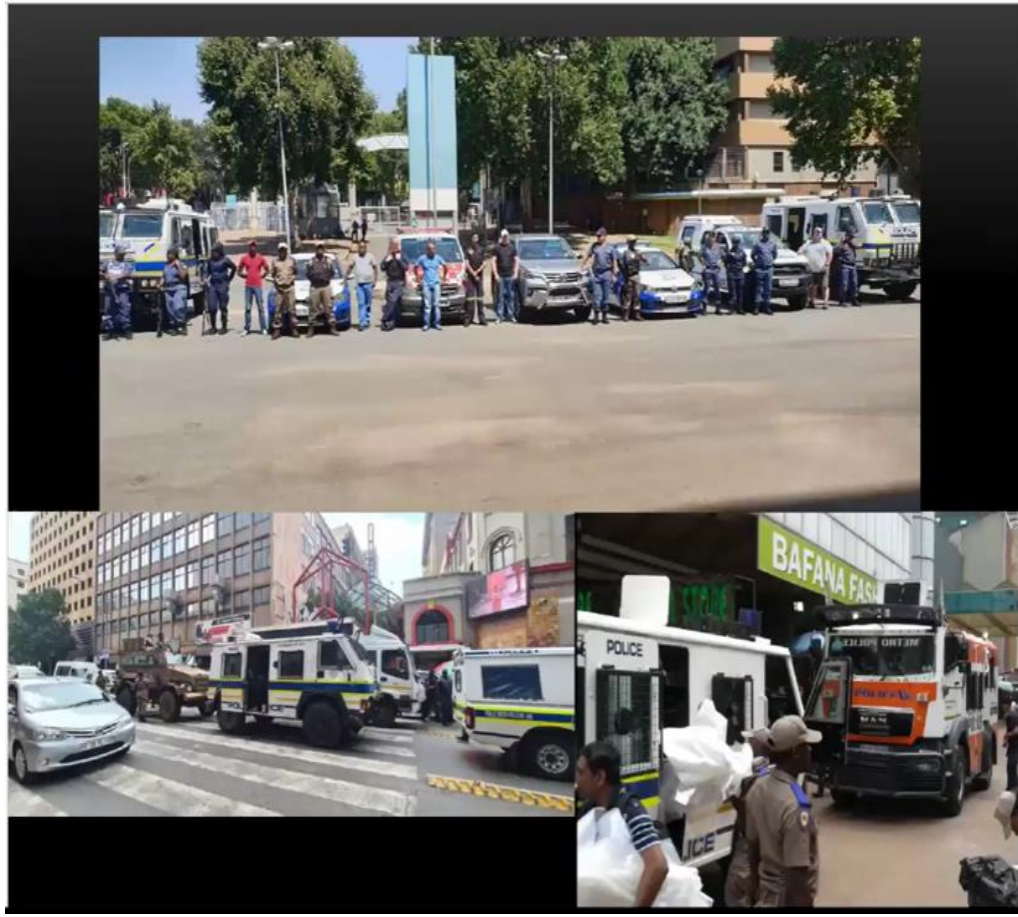
- Clinical Trial: Clinical Trial Authorisation Letter (not including vet medicines)
- Section 21: Section 21 Authorisation letter and verify quantities against the letter

Requirements: Scheduled substances

- APIs: companies importing on behalf of manufacturer - licence to distribute scheduled substances
- Manufacturer: Section 22C licence and medicine registration certificate

Joint national strategies to combat SFs

- Numerous anti-counterfeiting joint operations and raids
- Strengthen enforcement and make prosecutors understand the SFs impact
- Education and awareness
- Sharing information and lessons learnt
- Impose appropriate penalties that are deterrents for perpetrators



Zero tolerance to perpetrators

Law enforcement measures to protect animal and public health:

- Withdrawal of such medicines from the market and destruction thereof
- Medicine recalls and rapid alerts
- Cancellation of registration of the medicine
- Institution of disciplinary proceedings and imposing penalties
- Suspend or revoke the licenses of the Holder of the Certificate of Registration

Global collaboration

- Technological adaptation: to track websites and mailed packages
- Adoption of blockchain to identify and verify product authenticity
- International cooperation between govts, law enforcement and businesses across borders
- Increased awareness to influence consumer behaviour
- Harmonised stricter regulations and penalties

Operation Pangea: Interpol

- Started in 2008
- Collective approach involving police, customs, drug and health regulatory authorities and private sector
- To protect public health and foster cooperation between member countries to disrupt organised crime networks distributing pharmaceuticals online

Message to veterinarians

- SFs contain unknown concentrations of actives/have no actives
- Contain potential contaminants (heavy metals etc)
- Lack of efficacy/treatment failure, absence of disease control, worsening of disease, ADRs and death
- Risk of AMR and disease dissemination

How to identify SFs

- Target groups: products in high demand especially for health emergencies, high sales volumes/prices/advertised at low prices, drugs under shortages due to product alert/recall

Assisting veterinarians to identify SFs

- Be alert and aware of the sources: new trading partners/sources
- Unsolicited sales offer/unknown source over the internet
- Packaging: suspicious PI in foreign language, missing information, spelling and grammatical errors, change in font, images, colour
- Medication: unusual shape, colour, imprint, odour, chips/cracks

THANK YOU