

Risk-based approach to pharmacy inspections /assessments (Zimbabwe)

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Presentation Outline

- Who is responsible for pharmacy inspections in Zimbabwe?
- Implementation of the risk-based approach in Zimbabwe
- Merits and demerits of risk-based approach



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Mandates of the Pharmacists Council Zimbabwe versus the Medicines Control of Authority of Zimbabwe (MCAZ)

- **Pharmacists Council of Zimbabwe**

- Created by the Health Professions Authority Act [27:19]
- Regulates and promotes the Pharmacy Profession (together with Pharmacy Technicians, Optometrists, Hearing AID Specialist)

- **MCAZ created by an Act of Parliament**

- Medicines and Allied Substances Control Act [15:03] of 1969
- Complementary Medicines Regulations SI 97 of 2015
- Condoms SI 183 of 2005
- Glove Regulations SI 1 of 2006

- Board, Technical Committees and a Registrar
- To protect public and animal health by ensuring accessible medicines, allied substances and medical devices are safe, effective and of good quality.

MCAZ's Core Functions Regarding Pharmacies

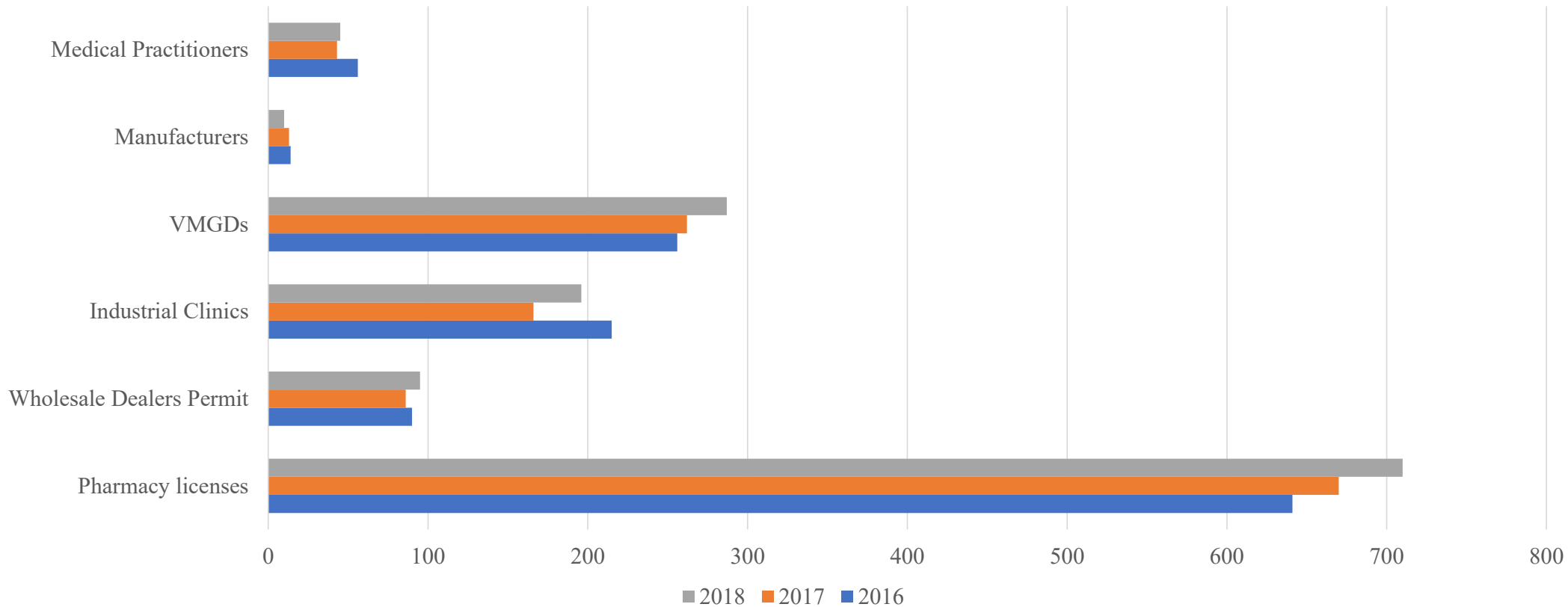
Licensing of Persons and Premises

- **Persons**
 - Pharmacists, Medical Doctors, Veterinarians, Nurses, Pharmacy technicians
- **Premises**
 - Manufacturing, Wholesalers, Pharmacies, Dispensing Practices, Industrial clinics, Research pharmacies

Enforcement Activities

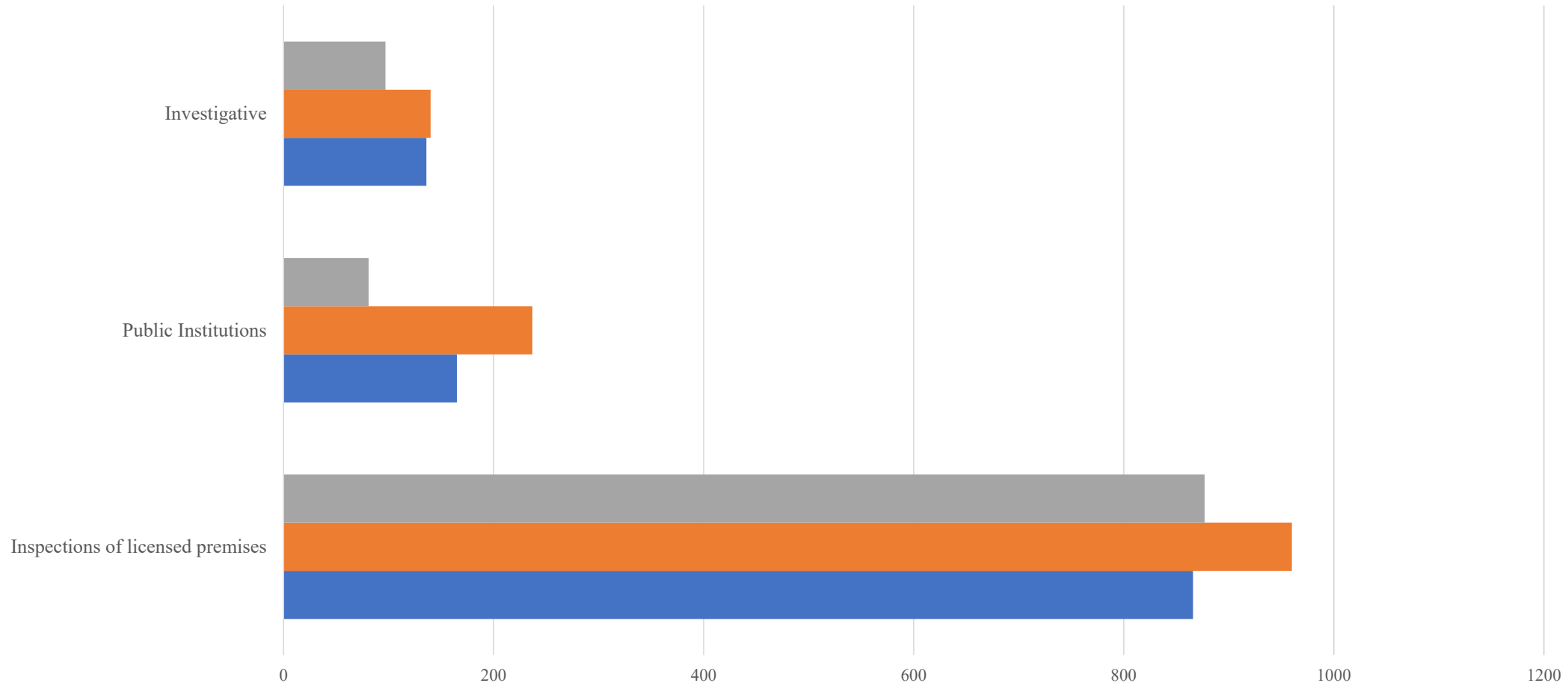
- **Enforcement Inspections**
 - Unauthorised persons and premises
 - Authorised persons and premises breaching MASCA
- **Review and authorise medicines advertisements**
- **Routine inspections**
 - Check compliance by authorised persons and premises, these are **risk-based**

Number of licenses issued: 2016 - 2018



There has been a general increase in total number of licenses issued from 2016 i.e. 1272 in 2016; 1240 in 2017 and 1343 in 2018

Inspections conducted: 2016 - 2018



	Inspections of licensed premises	Public Institutions	Investigative
■ 2018	877	81	97
■ 2017	960	237	140
■ 2016	866	165	136

Regulatory Environment

- Current economical environment is characterized with shortages and competing priorities
- Shortage of essential medicines
- Cost minimization dominating over cost effectiveness of regimes
- Increase in donated medicines which are brought into the public sector unregistered
- Increase in numbers of unsupervised premises
- Supervision of premises by students and pre-registration pharmacists
- Sale of medicines on the streets



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Regulatory Environment

- Advent of many complimentary medicines
- Loss of ethics and professionalism
- Pharmacy becoming a business than a professional health practice
- Fatalities including death
- Case Example;
 - Large amount of unregistered medicines were found hidden at the back cottage of a licensed premises



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Approach to scheduling of routine inspections (Pharmacies)

- The scheduling of inspections is based on risk assessment and residual risk from previous inspections
- Risk based approach based on the following;
 - Period since last inspection (> 2 years considered high risk)
 - If contraventions were previously found (how they were mitigated by licensee?)
 - Nature of contravention, e.g., poor supervision, sale of expired medicines amongst others
 - Any regulatory related complaints by members of the public regarding the premises
 - Premises
 - invited for a hearing and have been given a period to implement Corrective Actions are also flagged as high risk
 - High risk as determined by deliberations of the Authority (Licensing and Advertising Committee).

Merits of Risk-based approach

- **Efficient use of limited personnel and resources within the inspectorate Division of MCAZ**
 - Only less than 10 inspectors from MCAZ for the whole country
 - Liaison with other regulatory bodies (MRCZ, DVS, NBA etc) to provide seamless, timely service



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De-merits of Risk-based Assessment of Pharmacies

Mostly the issue of fairness and transparency

- Lack of trust from the general public (suspicion of unfair targeting)
- System's potential biases
- There is need for checking and balancing among independent committees dealing with the cases, e.g., Licensing and Advertising Committee, The Hearing Committee and full Authority in order to achieve transparency
- This system depends on accurate data capturing and sharing in order to function fairly



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