

MCAZ Accredited in Inspection of Pharmaceutical Premises and Persons

SADCAS is proud to announce the accreditation of the Medicines Control Authority of Zimbabwe (MCAZ) - Licensing and Enforcement Division in the scope of Inspection of Pharmaceutical Premises and Persons to ISO/IEC 17020:2012. This makes MCAZ - Licensing and Enforcement Division, situated at 106 Baines Avenue, Harare, Zimbabwe, the first inspection body to be accredited by SADCAS in the Pharmaceutical sector. Through this accreditation, the MCAZ - Licensing and Enforcement Division has been granted the unique accreditation number **INSP-9 001** (Inspection of Pharmaceutical Premises and Persons), indicating that MCAZ - Licensing and Enforcement Division is now a SADCAS accredited inspection body. The certificate which was issued on 22 April 2021 expires on 21 April 2026.



MCAZ Offices in Harare



Pharmaceutical Inspector at work

The initial assessment of MCAZ - Licensing and Enforcement Division was undertaken over 12 days in November and December 2020 by a team of assessors and technical experts competent in assessing inspection of pharmaceutical premises and persons. The Team Leader, Technical Assessor and one Technical Expert conducted the assessment virtually while the other Technical Expert was on-site. The assessment techniques employed by the assessment team included review of documented information, interviewing personnel, vertical assessments and witnessing the inspectors undertaking inspections.

The SADCAS Inspection Bodies Accreditation Scheme (IBAS) was established in June 2010 and is operated in accordance with ISO/IEC 17011 the standard that specifies requirements for accreditation bodies accrediting conformity assessment bodies. Accreditation certificates issued by SADCAS for inspection bodies are internationally recognised following the achievement of signatory status in the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement (ILAC MRA) for inspection in accordance with ISO/IEC 17020 in October 2017. ISO/IEC 17020 specifies criteria for the operation of various types of inspection bodies irrespective of the sector involved. It is the international standard against which inspection bodies are accredited.

The Medicines Control Authority of Zimbabwe is a statutory body established by an Act of Parliament and is responsible for protecting public and animal health by ensuring that accessible medicines and allied substances and medical devices are safe, effective and of good quality through enforcement of

adherence to standards by manufacturers and distributors. As part of this enforcement, the MCAZ carries out pharmaceutical inspections, including inspections of pharmaceutical manufacturers, pharmacies, dispensing clinics, dispensing medical practitioners, public institutions, veterinary medicines general dealers (VMGD), wholesale dealers and medicine distributors and makes decisions concerning the issue or withdrawal of establishment and person's licences or authorizations of their activities, the issue or withdrawal of GMP compliance recognition and handling suspected quality defects.

The pharmaceutical sector which develops, produces, and markets drugs/medicinal plant materials for use as medications is identified in the SADC Industrial Policy as one of the priority sectors for development in selected value chains. Within this sector accreditation plays a key role from research to production of medicines and in strengthening the regulatory capacity. Accreditation which is an independent evaluation of inspection bodies by an authoritative body, in this case SADCAS, confirms the competence, consistency and impartiality of the inspection body. Throughout the world many countries now rely on accreditation as a means of independently evaluating competence of inspection bodies.

To date SADCAS has accredited eight (8) inspection bodies and has another four (4) applications at different stages of the SADCAS accreditation process. Scopes of accreditation under IBAS include but are not limited to food, gas tests stations, textiles/clothing/leather/footwear, vessels under pressure, timber, electrical, metallic tanks etc.

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