

The Spec

MCAZ LABORATORY SERVICES

NEWS LETTER



MEDICINES CONTROL
AUTHORITY OF ZIMBABWE

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THEME FOR THE QUARTER : ROLE OF LABORATORIES IN REGULATORY DECISIONS



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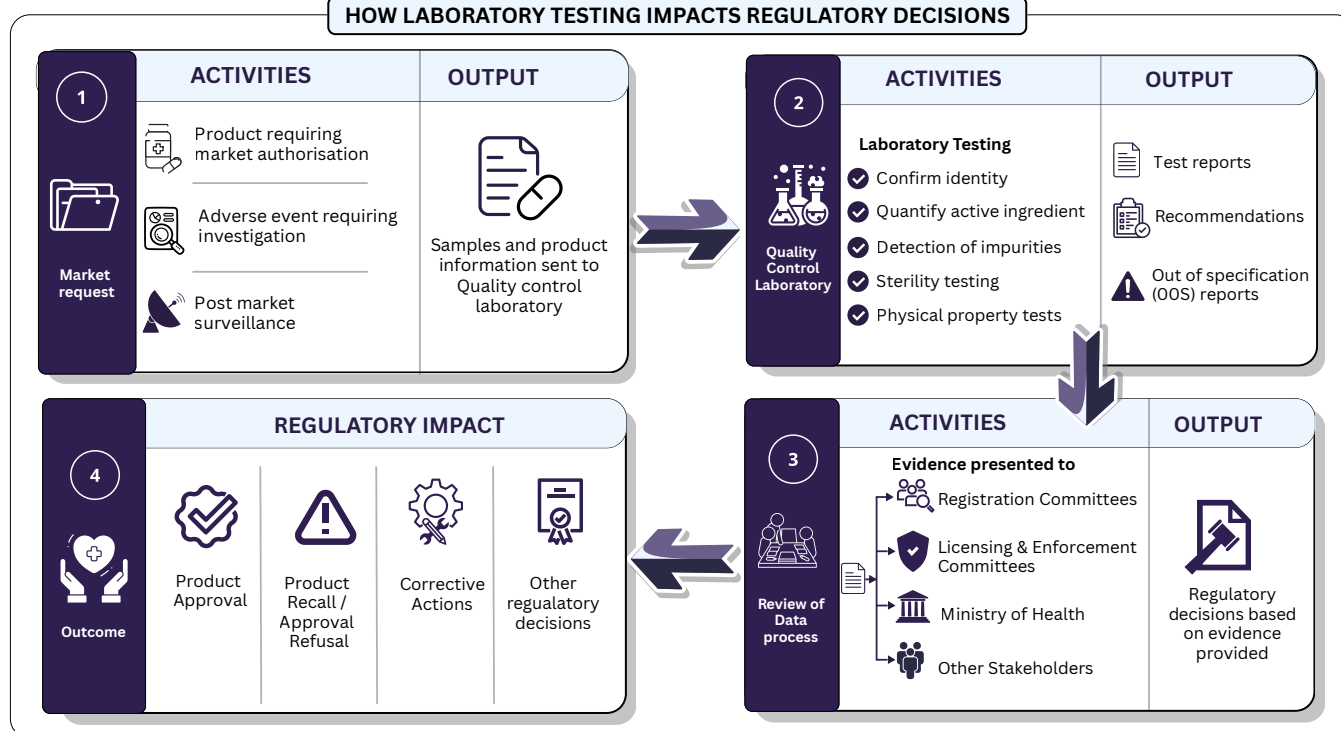
Have you ever taken a moment to think about how decisions are made on whether the medicine you take is **good for you or not? Has it been tested?** That cough mixture over there, yes, right there on the second shelf on the left, usually next to allergy medicine at that pharmacy at the mall, **was it tested before it got there?** What about anti retroviral therapy medication that has been stored at a district warehouse for the past year: **is it still working as claimed?** Then there are moments when a product is recalled. **What was the basis—and was it investigated?** National Regulatory Agencies (NRAs) determine whether medicines are safe and good quality and those decisions must be backed by solid evidence. As highlighted in the World Health Organisation Global Benchmarking Tool, **'The laboratory testing regulatory function is intended to ensure that the National Regulatory Authority (NRA) is able to assess the quality of medical products by performing quality tests on them in certain situations'**. If a country is able to provide all the resources needed, a laboratory under the responsibility of the NRA or a governmental laboratory represents the best choice.

In Zimbabwe, this work is done by MCAZ's Chemistry, Microbiology, and Medical Devices laboratories. These laboratories provide evidence by testing medical products — before and after they reach the market—to confirm that they meet required standards to support registration, investigations, recalls, and enforcement. In this edition of *The Spec*, you will get a behind-the-scenes look at how these laboratories shape regulatory decisions by providing evidence-based data to protect the right to safe medical products.

TESTING LABORATORIES AND PHARMACEUTICAL QUALITY CONTROL

Pharmaceutical quality control refers regulatory and analytical activities that ensure medical products comply with established standards. Laboratory testing is a core part of this work, supporting Marketing Authorisation evaluation, Good Manufacturing Practice (GMP), and Post-Market Surveillance (PMS). At MCAZ, each laboratory performs specific analyses that collectively strengthen pharmaceutical quality control in Zimbabwe. The diagram below describes the overarching set of activities in this regard.

HOW LABORATORY TESTING IMPACTS REGULATORY DECISIONS



The Chemistry Laboratory

The Chemistry Laboratory performs chemical analysis of medicines and allied substances. Its testing confirms identity, purity, content (strength), and performance. For a new product seeking market approval, the laboratory may confirm the correct active pharmaceutical ingredient (API)—the component responsible for the intended health effect—verify that the API content is within acceptable limits, and assess how the medicine releases in the body through dissolution testing. During Post-Market Surveillance, the laboratory may check uniformity of dosage units in samples collected from different parts of the country and investigate quality issues through tests such as degradation profiling, impurity testing, and moisture content, especially following adverse events.

The Medical Devices Laboratory

The Medical Devices Laboratory regulates male condoms and medical gloves in Zimbabwe. Its results support Market Authorisation decisions and batch release for distribution in-country. As condoms and gloves are critical for infection prevention and clinical care, laboratory findings inform whether a new product is approved for sale—or rejected if it fails conformity testing requirements. Zimbabwe is also unique in conducting 100% batch testing of all imported condoms and medical gloves before they are released for distribution (post-shipment, pre-distribution). As a result, condoms and gloves that are legally distributed all possess laboratory testing information. This strengthens regulatory enforcement and helps prevent poor-quality products from reaching the market.

The Microbiology Laboratory

The Microbiology Laboratory conducts microbiological analyses of medicines and allied substances to ensure products are sterile where required, microbiologically safe, manufactured under controlled conditions, and protected from contamination throughout their lifecycle. For example, sterile products such as intravenous solutions and sterile water must be free of microorganisms when administered; testing confirms they do not pose infection risks. This is especially important during Post-Market Surveillance, where results can indicate whether products were transported and stored under appropriate distribution and storage conditions. The laboratory also confirms the antimicrobial activity of certain medicines (e.g., antibiotics) through antimicrobial assays, comparing potency against the manufacturer's claim—information that supports decisions during evaluation of new medicines.

REVIEW OF THE FIRST QUARTER OF 2026

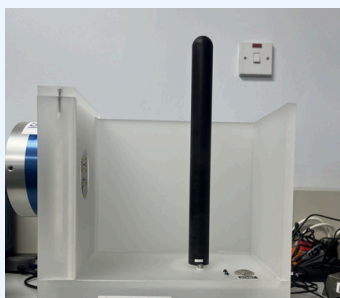
BENCH MARKING VISIT OF ABREMA :BURUNDI



The **MCAZ** welcomed The Burundi Food and Medicines Regulatory Authority (**ABREMA**) for a five day benchmarking visit. This visit took place from the 2nd to the 6th of March 2026 a part of its on - going efforts to strengthen regulatory capacity. The visit aimed to support ABREMA's journey toward ISO/IEC 17025 accreditation and the attainment of WHO Global Benchmarking Tool (GBT) Maturity Level 3. MCAZ was identified as a strategic regional partner from whom practical lessons and best practices could be drawn. The team engaged with MCAZ in the areas of Quality Management System implementation, Product Evaluation, Enforcement, and Regulatory Information Management Systems and other regulatory functions. The Laboratory Services Division (LSD) participated by sharing on management of the quality control laboratories with focus on alignment of work flows and key performance indicators to the ISO/IEC 17025.

The LSD also outlined its strategy for business continuity and demonstrated how its processes are integrated in End to End product evaluation. The benchmarking exercise provided ABREMA with valuable insights into structured regulatory processes and effective laboratory and quality systems management from MCAZ perspective. It also reinforced the importance of regional collaboration in strengthening medicines regulation and ensuring access to safe, effective, and quality assured medical products.

NEW CONDOM TESTING EQUIPMENT FOR THE MEDICAL DEVICES LABORATORY



The Medical Devices Laboratory has experienced significant expansion with the addition of new equipment. Notably, the laboratory has successfully installed an eight-header Air Inflation System Tester (AIS), an Enhanced Electric Leak Tester, and automated dimension testers for condoms (Length, Width and Thickness). The equipment was purchased through the aid of The Global Fund through the United Nations Development Programme (UNDP). These advancements enhance the laboratory's capacity to ensure the safety and efficacy of medical devices. Of particular importance is the acquisition of the Enhanced Electric Leaks Tester, (EELT) which is the latest state of the art equipment for the Freedom From Holes test currently. The EELT brings advanced detection for small holes, with enhanced testing mode meant to meet the requirements for the upcoming revisions to ISO 4074. The Dimensions testers employ optical sensors to assess the length and width of condoms, with the measurements being transmitted directly to a calibrated software. The AIS adds to equipment capacity in the laboratory. The additions to will significantly

increase the laboratory's ability to conduct conformity testing through accelerated testing efficiency and increased equipment capacity.

OUR WORK IN NUMBERS : JANUARY - MARCH 2026



CHEMISTRY LABORATORY

188 Samples were received for Chemical analysis.

265 Samples were analysed in the quarter.



MICROBIOLOGY LABORATORY

20 Samples were received for Microbial analysis.

18 Samples were analysed in the quarter.



MEDICAL DEVICES LABORATORY

85 Samples were received for conformity testing.

94 Samples were tested in the quarter.

OUR LAST WORD

Pharmaceutical quality control is not only a laboratory activity but a comprehensive regulatory and technical system integrating manufacturing control, regulatory oversight, analytical verification, and post-marketing surveillance.



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