COMPETENCE - BASED FELLOWSHIPS FOR AFRICAN MEDICINES REVIEWERS (REGULATORY SCIENCES PROJECT) 2018 – 2022

This project is part of the EDCTP2 programme supported by the European Union

About the MCAZ RCORE

The regulation of medicines in Zimbabwe began in 1969 through an Act of Parliament, the Drugs and Allied Substances Control Act of 1969 (Chapter 15.03). The Medicines and Allied Substances Control Act was promulgated in 1997, creating an autonomous agency independent of the fiscus, the Medicines Control Authority of Zimbabwe (MCAZ). The MCAZ is responsible for ensuring that medical products marketed in Zimbabwe are safe, effective and of good quality. The MCAZ's chemistry laboratory is prequalified by the World Health Organization and accredited by the Southern African Development Community Accreditation Services . The MCAZ has a robust quality management system, which resulted in the ISO 9001 certification by the Standards Association of Zimbabwe in 2019. In addition, the MCAZ is a founding member of the ZAZIBONA collaborative medicines registration initiative and is also responsible for coordinating the Southern African Development Community (SADC) Medicines Registration Harmonization (MRH) project as the implementing agency.

The MCAZ has offered training to regulators on the continent for years including hosting staff from other regulatory agencies for periods of time and as a result was designated as a Regional Centre of Regulatory Excellence (RCORE) by the African Union's Development Agency – New Partnership for Africa Development (AUDA – NEPAD) in 2014 with the goal to increase human and institutional capacity for the regulation of medical products and other health technologies on the African continent. The MCAZ was designated as an RCORE for;

- Medicines Evaluation and Registration
- Quality Assurance / Quality Control
- Clinical Trials Oversight

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Background

The European and Developing Countries Clinical Trial Partnership (EDCTP) under the Ethics and regulatory capacities scheme (2017) made funding available for actions that aimed to support sub-Saharan African countries to establish and develop robust national medicines regulatory systems and capacities for ethical review of clinical research and use of medicinal products and technologies for humans. From our experience working with regulators in Africa, we found that a lot of regulators lacked the skills required to conduct research to address the various challenges faced in regulation. In addition, there was limited capacity to assess new medicines and biologicals. Therefore, the MCAZ RCORE in medicines evaluation and registration in partnership with the University of Zimbabwe submitted a proposal to the EDCTP for support to achieve the following objectives:

- Build capacity of African medicines reviewers to conduct research in regulatory science by offering fellowships to 8 assessors working in national medicines regulatory authorities (NMRAs) over a 2-3 year period
- Build capacity in the assessment of medicines through the development of modules on various topics. Target: 100 assessors working in NMRAs and regulatory science professionals working in Industry offered short courses on a cost recovery basis.

Dr Tariro Makamure – Sithole

Project Coordinator

The Regulatory Sciences project titled, 'Competence-based fellowship for African medicines reviewers and regulatory science professionals' which began on the 1st November 2018 and ended on the 31st October 2022 was co-funded by the EDCTP and MCAZ.

Felllowships

The part time fellowship involved completion of short courses through block release training at the MCAZ / University of Zimbabwe (UZ), completion of the summer course and winter mini-conference at the Utrecht-WHO Collaborating Centre for Pharmaceutical Policy and Regulation in the Netherlands, practical work assignments, case studies, specific hours of practice (dossier assessments) over the fellowship period and a capstone project in an area selected by the fellow, addressing a specific problem, issue or research question in regulatory science. The fellows were assessed using the Regulatory Affairs Professional Society (RAPS) RAC exam and the World Health Organisation (WHO) global competence framework for regulators.

Short Courses

The project also sought to develop modules for short courses on various topics for the RCORE. These courses were then offered to regulators including the fellows and regulatory affairs professionals working in pharmaceutical industry on a cost recovery basis and the target was to train a 100 people by the end of the project. The courses were often a combination of theory and the practical hands-on experience of reviewing dossiers making the courses useful and impactful in the participants' day to day work and their organisation's review processes.

Overall, the regulatory sciences project was implemented to support the development of institutional and personnel capacities of medicines assessors to enable improved regulatory activities directly related to registration of new and established medicinal products. The Covid 19 pandemic presented challenges, but we were able to adapt and implement all planned activities.

Key Objectives of the Project

1. 8 competent medicines reviewers (WHO level II) who in turn train personnel in their agencies
2. At least 4 RAPS certified regulatory affairs professionals from African medicines regulatory agencies (MRAs)
3. 8 Publications in regulatory science
4. Development of new modules for the MCAZ RCORE enabling approximately 100 regulators and industry personnel to be trained on a cost recovery basis

Achievements

Fellowships

Eight medicine reviewers were offered the fellowship after a competitive selection process. These were Patience Phuti Shabangu from the South African Health Products Regulatory Authority, Ethel Sebua from the Botswana Medicines Regulatory Authority, Sibongile Mabuza from the Ministry of Health Eswatini and Chile Lungu from the Zambian Medicines Regulatory Authority, as well as Linda Mudyiwenyama, Brilliant Samunda, Lerato Makhurane and Grace Matimba from the Medicines Control Authority of Zimbabwe. Their mentors were selected from the following mature regulatory authorities and academic institutions: University of Zimbabwe, Utrecht University, University of Western Cape, Newcastle University, World Health Organisation, Swedish Medical Products Agency, Federal Institute for Drugs and Medical Devices in Germany and the United States Food and Drug Administration.

Name and Surname:	Brilliant Tinashe Samunda
Country:	Zimbabwe
Organisation:	Medicines Control Authority of Zimbabwe (MCAZ)
Cohort:	Regulatory Science Fellow (2019 Cohort)
Regulatory mentor:	Dr Annika Ridell (Swedish Medical Products Agency, Sweden)
Academic Mentor:	Prof Star Khoza (University of Western Cape, South Africa)
Certification	RAPS Regulatory Affairs Certification (Drugs)
Publication	Samunda, B.T., Sithole, T. & Khoza, S. A Retrospective Analysis of Applications for Registration of Generic Medicines Processed by the Medicines Control Authority of Zimbabwe. Ther Innov Regul Sci (2022)

Name and Surname:	Linda G. Mudyiwenyama
Country:	Zimbabwe
Organisation:	Medicines Control Authority of Zimbabwe (MCAZ)
Cohort:	Regulatory Science Fellow (2019 Cohort)
Regulatory mentor:	Dr Simbarashe Zvada (Formerly, United States Food and Drug Administration, USA)
Academic Mentor:	Dr Helga Gardarsdottir (Utrecht University, The Netherlands)
Certification	RAPS Regulatory Affairs Certification (Drugs)
Research title	Utilisation of printed package inserts by healthcare providers in Harare, Zimbabwe

Name and Surname:	Ethel Sebua
Country:	Botswana
Organisation:	Botswana Medicines Regulatory Authority (BOMRA)
Cohort:	Regulatory Science Fellow (2019 Cohort)
Regulatory mentor:	Dr Luther Gwaza (World Health Organisation, Switzerland)
Academic Mentor:	Prof Aukje Mantel-Teeuwisse (Utrecht University, The Netherlands
Research title	Common deficiencies in submissions to demonstrate in vivo bioequivalence of generic products reviewed in a regional medicines registration initiative in Southern Africa (ZAZIBONA): A content analysis

Name and Surname:	Patience Phuti Shabangu
Country:	South Africa
Organisation:	South African Health Products Regulatory Authority (SAHPRA)
Cohort:	Regulatory Science Fellow (2019 Cohort)
Regulatory mentor:	Rutendo Kuwana (World Health Organisation, Switzerland)
Academic Mentor:	Prof Admire Dube (University of Western Cape, South Africa)
Certification	RAPS Regulatory Affairs Certification (Drugs)
Publication	Shabangu PP, Kuwana RJ, Dube A. Collaborative reliance in medicine safety and quality regulation: Investigation of experiences in handling N-nitrosamine impurities among ZaZiBoNa participating countries. Frontiers in Medicine. 2022;9

Name and Surname:	Lerato T. Makhurane
Country:	Zimbabwe
Organisation:	Medicines Control Authority of Zimbabwe (MCAZ)
Cohort:	Regulatory Science Fellow (2020 Cohort)
Regulatory mentor:	Dr Jean Christian Krayenbuhl (Formerly, Swedish Medical Products Agency, Sweden)
Academic Mentor:	Dr Petra Sevcikova (Newcastle University, United Kingdom)
Certification	RAPS Regulatory Affairs Certification (Drugs)
Research title	Registration of essential medicines in Zimbabwe

Name and Surname:	Grace R. Matimba
Country:	Zimbabwe
Organisation:	Medicines Control Authority of Zimbabwe (MCAZ)
Cohort:	Regulatory Science Fellow (2020 Cohort)
Regulatory mentor:	Dr Karoline Buhre (Federal Institute for Drugs and Medical Devices in Germany, BfArM)
Academic Mentor:	Dr Star Khoza (University of Western Cape, South Africa)
Certification	RAPS Regulatory Affairs Certification (Drugs)
Research title	An Analysis of Legislative Compliance of Labels and Package Inserts for Household Remedies (General Sale Medicines) Registered in Zimbabwe

Name and Surname:	Chile Lungu
Country:	Zambia
Organisation:	Zambian Medicines Regulatory Authority (ZAMRA)
Cohort:	Regulatory Science Fellow (2020 Cohort)
Regulatory mentor:	Roy Chihaka (Botswana Medicines Regulatory Authority)
Academic Mentor:	Dr Tsitsi Monera-Penduka (University of Zimbabwe, Zimbabwe
Research title	An Evaluation of the Requirements for Marketing of Complementary Medicines in ZAZIBONA Countries

Name and Surname:	Sibongile Mabuza
Country:	Kingdom of Eswatini
Organisation:	The Ministry of Health
Cohort:	Regulatory Science Fellow (2020 Cohort)
Regulatory mentor:	Dr Luther Gwaza (World Health Organisation, Switzerland)
Academic Mentor:	Prof Aukje Mantel-Teeuwisse (Utrecht University, The Netherlands
Research title	Availability and conformity of package inserts in selected medicines distributed to public and private sector health facilities in Eswatini

The fellows participated in various competence based short courses, research seminars and conferences and were able to satisfy the level II requirements for medicine reviewers on the WHO Global Competence Framework for regulators by the end of the fellowship. In addition, five of the fellows, Briliant Samunda, Patience Phuti Shabangu, Grace Matimba, Lerato Makhurane and Linda Mudyiwenyama passed the Regulatory Affairs Professional Society (RAPS) exam and are now RAC certified regulatory affairs professionals which was one of the key deliverables of the Reg Sciences Project. Two of the fellows, Patience Shabangu and Briliant Samunda published articles on their capstone projects while the remaining 6 have either submitted or are in the process of finalising their manuscript.

Highlights

Fellows attending the Utrecht University WHO Summer Course on Pharmaceutical Policy Analysis, 11 – 15 July 2022, Utrecht, The Netherlands

Patience Shabangu, a fellow from the South African Health Products Regulatory Agency (SAHPRA) presenting on her research project at the fourth biennial scientific conference on medical products regulation in Africa (SCoMRA IV) in Victoria Falls, Zimbabwe in September 2019,

Brilliant Samunda, a fellow from the Medicines Control Authority of Zimbabwe (MCAZ), presenting on his research project at the Utrecht WHO CC Winter meeting, Utrecht, The Netherlands, January 2020.

Short courses

Another key deliverable for the project was the development of modules for competence-based short courses for the MCAZ's Regional Centre of Regulatory Excellence (RCORE). 20 modules (11 regulatory and 9 academic/research) were developed for the RCORE on the following topics;

- Special dosage forms,
- GMP considerations for assessors (included a visit to a Quality Control laboratory and a pharmaceutical manufacturing plant),
- Bioavailability and bioequivalence,
- Advanced Drug Delivery Systems,
- Clinical consideration for Product Registration,
- Bioequivalence 101 (basic),
- Bioequivalence 201 (advanced),
- Assessment of Clinical Trial Data submitted for product registration,
- Clinical Assessor Talent Building: A Primer for Clinical Assessors within African Regulatory Agencies (co-funded by Bill and Melinda Gates Foundation),
- Bioavailability and bioequivalence,
- Advanced Bioequivalence,
- Foundations in Biosimilars,
- Research Methods & Study Design,
- Literature Review,
- Medical Statistics for Regulators,
- Research Ethics,
- Technical/Scientific Writing,
- Introduction to Statistics,
- Regulatory Toxicology,
- Effective Planning for Research Projects,
- Academic Writing and Reference Management.

344 regulators and regulatory affairs professionals from Southern African region and beyond (India, Rwanda, South Sudan and Zanzibar) were trained over the 4-year period exceeding the initial target of 100 professionals set at the beginning of the project.

Highlights

Participants from Zambia, Botswana, South Africa, Zimbabwe and Namibia in the Special Dosage Forms training held in Harare, Zimbabwe – May 2019

Participants from Zambia, Botswana, South Africa, Zimbabwe and Rwanda in the GMP Considerations for Assessors training that included a site visit to a local pharmaceutical manufacturing plant in Harare, Zimbabwe – August 2019

Conclusion

The Regulatory Sciences Project met its objectives to support 8 fellows to complete a capstone project, to have 50% of the fellows attain certification by RAPS and to build competencies in the review of different types of medicines evidenced by the fellows satisfying the requirements for Level II of the WHO global competence framework for regulators. The fellows have in turn trained and mentored other staff in their regulatory agencies. Recommendations made from the fellows' research projects will contribute to the strengthening of the regulatory review processes and systems in their countries as well as in the SADC region.

The project also capacitated the MCAZ RCORE to train other regulators and regulatory affairs professionals in the pharmaceutical industry and this will go a long way in improving the quality of submissions made by industry and the quality of reviews produced by regulators thereby shortening the time to approval for life-saving medicines.

Regional Centre of Regulatory Excellence (RCORE)

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For more information visit
https://www.mcaz.co.zw/rcore-trainings/

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