Fellowship in Regulatory Science for African Medicine Reviewers

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Background

- The Medicines Control Authority of Zimbabwe (MCAZ) has provided training to regulators on the continent for years;
  - Medicines registration, laboratory analysis, pharmacovigilance, GMP inspections e.t.c
  - Attachment of regulators at the MCAZ
- AUDA - NEPAD Agency designation as a Regional Centre of Regulatory Excellence (RCORE) 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.
Background

• The MCAZ was designated an RCORE for:
  • Medicines evaluation and registration
  • Laboratory Quality Assurance / Quality Control
  • Clinical Trials Oversight
Background

Activities of the Medicines Evaluation and Registration RCORE thus far...
Technical training in bioequivalence, biosimilars and special dosage forms has been conducted:

2. Biosimilars – February 2018
3. Special Dosage Forms – May 2019
4. GMP considerations for assessors – August 2019
The European and Developing Countries Clinical Trial Partnership (EDCTP) under the Ethics and regulatory capacities scheme (2017) provided funding 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.
EDCTP Reg Sciences Project

• The MCAZ RCORE in medicines evaluations and registration submitted a proposal to do the following:
  • Build capacity of African medicines reviewers to assess new medicines and conduct research in regulatory science by offering fellowships to 8–10 assessors working in national medicines regulatory authorities (NMRAs) over a 2-3 year period
  • Develop modules and train 100 assessors working in NMRAs and regulatory science professionals working in Industry on a cost recovery basis through short courses
  • Grant awarded for EUR 270,019 over a 36 month period starting 1 November 2018
Outline of the Fellowship

• The 2-year part time fellowship in regulatory science is offered to 8 – 10 assessors working in medicines regulatory authorities (MRA) in the Southern African Development Community (SADC region).

• Fellows are admitted in two groups, the first in 2019 and the second group in 2020.
Outline of the Fellowship

Year 1

• Undertake 2 basic and 2 advanced courses;
• Participate in the WHO MOOC on implementation research;
• Attend Utrecht summer school on Pharmaceutical Policy Analysis;
• Decide on a topic of interest for capstone project;
• Prepare a research protocol for the project;
• Conduct first review of 3 dossiers of the applicable dosage form after a basic training
• Attend the Biennial Scientific Conference on Medical Products Regulation in Africa (SCoMRA), for 2020 cohort this will fall in their year 2

A Decade of regulatory harmonization in Africa: Where are we? Where do we go from here?
Outline of the Fellowship

Year 2 - 3

- Undertake basic and advanced courses;
- Undertake research activities encompassing quantitative, qualitative, and policy analysis methods resulting in a paper(s) of publishable standards;
- The research project should be accompanied by a literature review and annotated bibliography.
- Attend Utrecht - WHO Collaborating Centre Winter meeting.
- Finalise paper(s) for publication in journals;
- Take RAPS Regulatory Affairs Certification (RAC) examination
Deliverables of the Fellowship

- 8 - 10 competent medicines reviewers (WHO level II and III) who in turn train personnel in their agencies
- 8 - 10 RAPS certified regulatory affairs professionals from African medicines regulatory agencies (MRAs)
- 8 – 10 Publications in regulatory science
- Development of new modules for the MCAZ RCORE enabling approximately 100 regulators and industry personnel to be trained on a cost recovery basis

* In addition each fellow benefits from a one on one relationship / interaction with a regulatory mentor and an academic mentor.
Results 1 year into implementation

• 4 fellows selected for 2019 Cohort (2 Zimbabwe, 1 South Africa, 1 Botswana)
• 4 regulatory mentors from SRAs and 4 academic mentors from Universities
• 2 new modules developed for the RCORE i.e Special dosage forms and GMP considerations for assessors
• 2 short courses offered on a cost recovery basis. Surplus made from the first training used to offer scholarships to regulators for the second training. (See attached EVR RCORE 2019 financial statement)
• 60 regulators and industry personnel trained to date
Lessons learnt

- A lot of regulators have expressed interest in attending the short courses offered on a cost recover basis but have no funding for course fees, travel and accommodation.
- Fellows facing challenges balancing their work and the fellowship