

Rational Pharmaceutical Management Plus

Technical Meeting of the Southern African Development Community (SADC) Medicine Regulators on the Harmonization of Medicines regulation in the SADC Region: Trip Report

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About RPM Plus

The Rational Pharmaceutical Management Plus (RPM Plus) Program, funded by the U.S. Agency for International Development (cooperative agreement HRN-A-00-00-00016-00), works in more than 20 developing countries to provide technical assistance to strengthen drug and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning and in promoting the appropriate use of health commodities in the public and private sectors.

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Acronyms

ADDO	Accredited Drug Dispensing Outlet
AIDS	Acquired Immunodeficiency Syndrome
CPM	Center for Pharmaceutical Management
CRHCS	Commonwealth Regional Health Community Secretariat
HIV	Human Immunodeficiency Virus
ICH	The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
MSF	Medecins Sans Frontieres (Doctors Without Borders)
MSH	Management Sciences for Health
RPM Plus	Rational Pharmaceutical Management Plus Program
SADC	Southern African Development Community
SEAM	Strategies for Enhancing Access to Medicines
TB	Tuberculosis
TFDA	Tanzania Food and Drug Agency
USAID	U.S. Agency for International Development
WHO/AFRO	World Health Organization Regional Office for Africa

Background

The Southern African Development Community Program (SADC) hosted a technical meeting and workshop titled SADC Medicine Regulators on the Harmonisation of Medicines Regulation from March 26 – 28, 2004. Management Sciences for Health (MSH)/Rational Pharmaceutical Management Plus Program (RPM Plus) was invited to attend and provide technical assistance to finalize five technical guidelines developed by the Medicine Regulators. RPM Plus has been supporting regional organizations in Africa, such as the Commonwealth Regional Health Community Secretariat (CRCHS) in harmonization and standardization of guidelines to enhance management of pharmaceuticals since 2001.

The guidelines presented were:

- Registration Guidelines
- Registration form
- Good manufacturing practices
- Bioequivalence / Bioavailability and
- Stability

The subsequent adoption of these guidelines is expected to pave the way for closer cooperation among the fourteen member states (Angola, Lesotho, Mozambique, South Africa, Zambia, Botswana, Malawi, Namibia, Swaziland, Zimbabwe, Democratic Republic of Congo, Mauritius, Seychelles and Congo) in pharmaceutical management.

Purpose of Trip

Bannet Ndyanabangi and Tom Layloff traveled to Johannesburg, South Africa from March 24 to March 29, 2004 was invited to attend and provide technical assistance to finalize five technical guidelines for harmonisation of registration of medicines in the fourteen SADC countries, developed by the Medicine Regulators. This followed a request by the SADC secretariat to MSH/RPM Plus to provide support to the activity of harmonization of registration of medicines in the SADC member states.

Scope of Work

1. Participate and provide technical assistance in the discussions to finalize five of the various technical guidelines for harmonisation of registration of medicines in the fourteen SADC countries
2. Make presentations on the work of MSH/RPM Plus and indicate the areas of potential support for and collaboration with SADC
3. Meet with the Chief Director of SADC and discuss areas of collaboration
4. Meet with the SADC Senior pharmaceutical Officer and the Chairperson SADC Medicines Registration Working Group on implementation of Workshop outcomes

Activities

1. Participate and provide technical assistance in the discussions to finalize five of the various technical guidelines for harmonization of registration of medicines in the fourteen SADC countries

Tom Layloff and Bannet Ndyabangi participated in the two and a half days' workshop, where the key documents required for harmonization of registration of medicines were reviewed and modified. The documents reviewed were:

1. Application form for registration and marketing of a medicine in the SADC Region
2. General guidelines for submitting applications for registration of a medicine in the SADC Region
3. Guidelines for stability Studies
4. Guidelines for bioequivalency and bioavailability studies

Agreement was reached on the first three documents. The guidelines on bioequivalency and bioavailability studies were reviewed and found not to be very user friendly although they were sound in content. It was noted that bioequivalency and bioavailability guidelines recently developed for use in South Africa were more user friendly and similar in content. The team that had developed the draft guidelines was therefore requested to revise the regional guidelines and make them as user friendly as the South African guidelines.

2. Make presentations on the work of MSH/RPM Plus and indicate the areas of potential support for and collaboration with SADC

A 25 minute video presentation on the MSH/ Strategies for Enhancing Access to Medicines (SEAM) Accredited Drug Dispensing Outlet (ADDO) in Tanzania was made on request by the workshop organizers. Other activities of MSH/RPM Plus (especially of regional nature) were also presented briefly. Brochures on various MSH/Center for Pharmaceutical Management (CPM) activities were distributed to the participants.

3. Meet with the Chief Director of SADC and discuss areas of collaboration

A meeting was held with Mr. Stephen Sianga (Supervisor Social and Human Development Directorate), who represented the SADC Chief Director. The meeting focused on areas for collaboration by MSH and the implementation of the recommendations by the Committee on harmonization in the individual countries. Mr. Sianga inquired about the possibility of MSH initiating programs similar to the Accredited Drug Dispensing Outlet (ADDO) program in Tanzania, in other SADC countries. MSH and the SADC will continue to communicate after discussions with organizations interested in similar programs like ADDO.

4. Meet with the SADC Senior Pharmaceutical Officer and the Chairperson SADC Medicines Registration Working Group

- a) Bannet Ndyanabangi and Tom Layloff met with the SADC Senior Pharmaceutical Officer and the Chairperson for the SADC Medicines Registration Working Group who appreciated the contribution of MSH and requested further support to see the harmonization process thoroughly implemented in the member states. Areas specifically mentioned by the SADC secretariat where support would be crucial for the harmonization process included the following:

Area for harmonization	Country Responsible for first draft
<i>Clinical Trials</i>	South Africa
<i>Complementary medicines</i>	Botswana
<i>Nutritional supplements including the so called borderline products (nutraceuticals)</i>	Tanzania
<i>Pre-Clinical Studies (toxicological and pharmacological information about this)</i>	?

Further discussions will be held and a concept paper written outlining n areas of collaboration.

- b) The SADC member states were impressed with the MSH/ (SEAM)/ADDO in Tanzania and would like to investigate a SADC-MSH collaboration to develop SADC-based infrastructure to assist and support the development of similar programs in interested member states. It was noted that the model required imbedding the training in pharmacy programs and that the active cooperation of national and regional regulatory authorities was essential in building viable and sustainable systems. Further discussions between SADC and MSH/SEAM to investigate how cooperation could be developed and disseminated would be held. The active assistance of the Tanzania Food and Drug Agency (TFDA) and other Tanzanian partners would be important in advancing this effort.
- c) The SADC countries are interested in pursuing pooled procurement of health commodities, although the effort is still at a planning stage. RPM plus and Rockefeller foundation had carried out a survey about the feasibility of pooled procurement in the East Central and Southern Africa region and the report would be availed to the SADC secretariat for further follow up. MSH would offer technical support to SADC pooled procurement activities as need arose. It was also noted that some aspects of the TFDA inspectional and testing functions might assist in developing a common inspection and public testing standards for the region which also would facilitate the harmonization efforts. Concept papers and documents to further elaborate on these possibilities would be developed. After consensus is achieved, resources to advance the effort would be mobilized

Collaborators and Partners

SADC Secretariat

Stephen Sianga (Supervisor Social and Human Development Directorate).
T. Angula (SADC Senior Pharmaceutical Officer)
K. Nyirenda (SADC Legal Advisor)
P. Matsoso (Chairperson SADC Medicine Registration Working Group)
Dr. Nditonda B. Chukilizo (Head of Drug Registration - Tanzania Food and Drug Authority)

Adjustments to Planned Activities and/or Additional Activities

It was not possible to meet with USAID representatives because the meeting was held outside Johannesburg starting on Friday, 26 March and ending on Sunday, 28 March 2004.

Next Steps

Immediate Follow-up Activities

1. Follow up with the SADC secretariat to obtain reference materials from other organizations such as ICH to enable them to finalize the remaining areas of harmonization
2. Provide copies of the reports on feasibility of pooled procurement in the East Central and Southern Africa region carried out by MSH/RPM+ to the SADC
3. Develop concept papers to support the SADC Harmonization activities in consultation with USAID Washington, USAID Regional offices and the SADC secretariat

Recommendations

1. Harmonization of Medicines regulation is an important activity which could enable the improvement of pharmaceutical management in the fourteen SADC countries. It will provide a springboard for other areas of collaboration in standardizing and harmonizing of guidelines and practices in other areas of health commodities management such as treatment guidelines, essential medicines lists, formularies and pooled procurement of health related commodities. It is therefore important that MSH, having been chosen by the organizers to support the process reciprocates by mobilizing the necessary resources to support the activity to a successful conclusion. One possibility is to seek funding for the activity from the USAID regional offices in Nairobi, Kenya and/or Pretoria, South Africa. The activity could fit well in issues of HIV/TB and Malaria management, allowing for resource mobilization from these programs at regional levels.
2. Individual countries will need support to adapt the standardized guidelines to the country situations. It would be necessary to support a process that would identify any potential obstacles to implementation of harmonized registration in the individual countries.

Important Upcoming Activities or Benchmarks in Program

The participants agreed that by June 2005, the guidelines should be ready for presentation to the SADC Council of Ministers for approval. This will allow the country processes to commence leading to ratification of the harmonized guidelines and procedures for implementation in the individual SADC countries.

Annex 1: SADC Agenda



TECHNICAL MEETING OF SADC MEDICINE REGULATORS ON THE HARMONISATION OF MEDICINES REGULATION IN THE SADC REGION, 26 – 28 MARCH 2004.

VENUE: THE GARDEN LODGE AND CONFERENCE CENTRE, Swartkops Road, Swartkops, Johannesburg, South Africa.

DAY 1: 26 MARCH 2004 **Meeting open to all available stakeholders in addition to medicines regulators, WHO and SADC officials**

08:30 – 09:00 **OPENING SESSION**

Chairperson: Ms P Matsoso, Registrar, Medicines Control Council of South Africa and Chairperson, Medicines Registration Working Group.

Secretariat: Mrs T Angula, SADC Secretariat, and the Technical Editor(s)

1. Opening remarks by the Chairperson
2. "Relevance of Harmonisation of Medicines Regulation to the goals and strategies of NEPAD", by Prof. Eric Buch, Health Advisor, NEPAD Secretariat.
3. Official opening by Dr T Mhlongo, the Chief Director, SADC Secretariat.

MEETING DELIBERATIONS

09: 05 – 09: 15	Brief introductory remarks, Ms T Angula, SADC Secretariat
09: 15 – 09: 40	Background to the harmonisation process, by Ms Gugu Mahlangu, Director, Medicines Control Authority of Zimbabwe
09: 40 – 10: 00	Discussion.
10:00 – 10:30	TEA BREAK
10:30 – 13:00	Discussion of draft guidelines continues.
13:00 – 14: 00	LUNCH BREAK
14: 00 – 15: 30	Discussion of draft guidelines continues.
15: 30 – 16: 00	TEA BREAK
15: 30 – 17:30	Further discussions, summary of major issues and conclusion.

DAY 2: 27 MARCH 2004 Morning session open to all stakeholders in addition to medicines regulators, WHO and SADC officials

Chairperson:	Ms Gugu Mahlangu, Director, Zimbabwe Drug Regulatory Agency and Chairperson, Medicines Control Working Group
Secretariat:	Mrs T Angula and the Technical Editor(s)
08: 30 – 10: 00	Discussion of draft guidelines continues.
10: 00 – 10: 30	TEA BREAK
10: 30 – 13: 00	Summary of major issues and conclusion of the first part.
13: 00 – 14: 00	LUNCH BREAK
14: 00 – 15: 30	Discussion of issues from the first part of the meeting and building of consensus.
15: 30 – 16: 00	TEA BREAK

16: 00 – 17: 30 Discussion continues, including setting of time table for the conclusion of the guidelines still under development, and the communication structure.

DAY 3: 28 MARCH 2004

Chairperson: Ms P Matsoso, Medicines Control Council, South Africa

Secretariat: Mrs T Angula and the Technical Editor(s)

08: 30 – 10: 00 Discussion of:

- Draft memorandum of understanding for implementation of harmonized state of medicines regulation.
- Proposed terms of reference of the ICH/GCG
- Any other business

10: 00 – 10: 30 TEA BREAK

10: 30 – 13: 00 Discussions concluded and meeting closed.

Annex 2 Participant List

Botswana

Dr. S. Selelo
Ms. Motlalepula Segopolo
Mr. Duncan Thela

Malawi

Mr Patrick S.P. Tembo
Mr. Anthony Kamanga
Mr Wynn Chalira

Mauritius

Mrs S Jankee
Mr Mohammad Iqbal Magbhoora

Mozambique

Mr Paulo Nhaducue
Mr Chonguiça Moreira

Namibia

Mr Johannes Gaeseb
Dr Gabriel T Uahengo
Mr Free Zenda

South Africa

Mr Makgale Manchidi
Mr Enos Motshitela
Mr Frank Hlangwane
Ms Estelle Haute
Ms Joy Oudtshoorn
Ms Maureen Kirkman
Professor CM Dangor
Ms Lebogang Lebeso
Prof. S. Banoo
Ms. Val Beaumont
Ms Allison Viennings
Ms Engela Dedwith
Ms Lorraine Hill
Mr Viral Desai
Ms Miranda Viljoen
Ms Hazel van der Meer
Ms Ella van der Merwe

Swaziland

Ms Gabsile Mabuza
Mrs Thuli Sibiya
Mr Stanley Banda

Tanzania

Mr LR Mhangwa
Mr K Mababida
Md Nditonda B Chukilizo

Zambia

Ms. Esnat Mwape
Ms Nana Mudenda
Mr Lotty Chumpuka

Zimbabwe

Mr. Dauramanzi
Mrs Mandaza
Mr Archibald Chimuka
Ms Gugu Mahlangu
Mrs W Chipwere
Dr Mazhindu
Mr Victor Basopo

SADC Secretariat

Mr Stephen Sianga
Mrs Angula
Mr K Nyirenda
Ms Marti Bredenmann

MSF

Dr Wilbert Bannenberg
Ms Cecile Mace

WHO/AFRO

Joseph Serutoke Jr

MSH

Mr. Tom Layloff
Dr Bannet Ndyanabangi