



NEWSLETTER - ISSUE 11 (July to September 2013)

AMRH News

Update on the Biennial Scientific Conference on medicines regulation in Africa, 2-3 December 2013, Johannesburg South Africa

The first biennial scientific conference which will take place from 2 to 3 December 2013 in Johannesburg South Africa is fast approaching.

This conference, the first of its kind in Africa, is set to provide a forum to share scientific advances and current best practices in regulatory science disciplines amongst policy makers, regulators, industry and scientists. It will also provide an opportunity for stakeholders to review current global developments in the regulatory environment and assess their impact on the commercialization of health research products as part of implementation of the African Union Pharmaceutical Manufacturing Plan for Africa (PMPA).

Limited seats are still available, please email nthabiseng@nepadst.org for registration and logistics information or visit [here](#) to download the registration form and updated programme.

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Establishing the Pool of Regulatory Experts in Africa and Diaspora!

The African Medicines Regulatory Harmonization (AMRH) Programme is pleased to announce a Request for Expressions of Interest for eligible regulatory experts in Africa and Diaspora to submit applications for consideration as members of the pool.

In support of the capacity building framework initiated by the AMRH Programme, the need for a database of a pool of regulatory experts in Africa and in the diaspora who will serve as a resource in regulatory capacity development has been identified as a priority. The pool of regulatory experts will be significant resource for the development of the pharmaceutical sector in Africa in particular and promotion of health in general.

Selection will be conducted following an open call for expression of interest and application of interested potential experts made public, principally via the AMRH website found [here](#). Applications can be made continually on a rolling basis, and there is no deadline. For additional resources visit: www.amrh.org. Email all inquiries to: paul@nepadst.org or call Paul Tanui at +27 12 841 4979.

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Progress on the draft Model Law

Following the review of the Draft Model Law on Medicines Regulations which took place during the meeting of the Technical Working Group on Medicines Policy and Regulatory Reform in Nairobi earlier this year (June 2013), a sub-committee working on the finalization of the model law was convened in Durban from 12-16 August 2013. The model law was revised in consideration of comments from stakeholders and the incorporation of WHO guidelines.

The revised model law from the TWG-PRR Subcommittee on the finalization of the Model law is to be presented to the Pan African Parliament Committee on Health Labour and Social Affairs and the Regional Caucuses on the 20th October 2013. This will be by regional and national consultations with governments, legal experts, NMRAs and Parliamentarians from all AU Member states beginning early 2014.

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Call for Expression of Interest for inclusion to the Regional Centres of Regulatory Excellence (RCOREs) in Africa!

As part of its mandate to strengthen regulatory capacity development, the AMRH Programme is in the process of establishing Regional Centres of Regulatory Excellence (RCOREs). The NEPAD Agency AMRH Programme is therefore pleased to announce a Call for Expressions of Interest for eligible institutions to submit applications for consideration to be a Regional Centre of Regulatory Excellence in Africa.

The selection process for RCOREs will follow the following steps:

- Application: Call for bids and submission of expression of interest
- Assessment: Assessment of expressions of interest, short-listing and audits
- Selection: shall be based on the eligibility criteria outlined above
- Performance Evaluation/Review: monitoring for continued performance

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Update on MRH Programme Implementation in the EAC

EAC Stakeholders National Consultation Meetings to validate harmonized technical guidelines for the East African Medicines Regulatory Harmonization Programme, took place from 16-17 September in the Republic of Burundi; 19-20 September the Republic of Rwanda, 23-24 September the Republic of Uganda and 26-27 September 2013 in the Republic of Kenya. For United Republic of Tanzania, consultation meetings are to be held from 2-3 October in Tanzania-Zanzibar and 28-29 October, in Tanzania-Mainland.

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First African Regulatory Forum on Medical Diagnostics, Nairobi, Kenya, 24th to 26th July 2013

NEPAD Agency made progress in guiding the development of a roadmap for continent-wide harmonization of regulation of medical devices and diagnostics at the occasion of the First African Regulatory Forum for Medical Diagnostics took place in Nairobi Kenya from July 24-26th 2013. . As a collaborating partner in this initiative NEPAD Agency participated in the forum and lead in some of the sessions.

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Resources from AMRH Partners

WHO

[WHO Pharmaceutical Newsletters](#)

World Bank

[GMRH Progress Report 2013](#)

NEPAD Agency

[Situation Analysis Study On Medicines Registration Harmonisation In Africa: Final Report For The East African Community \(EAC\)](#)

[Policy Brief: No. PMPA/AMRH/ 1. African Medicines Regulatory Harmonisation \(AMRH\) Programme contribution to the African Union \(AU\) Pharmaceutical Manufacturing Plan for Africa \(PMPA\)](#)

Upcoming Events

13 November 2013

[Pre-meeting course - American Society Tropical Medicine and Hygiene from 13 November, Washington, USA](#)

25-27 November 2013

Regional Consultation meeting on Model Law in EAC from 25-27 November, Bujumbura, Burundi

29 November 2013

[EDCTP Regulatory Stakeholders meeting on 29 November, Antwerp, Belgium](#)

2-6 December 2013

[1st Scientific Conference on Medicines Regulation and 3rd African Regulators Conference from 2-6 December, Johannesburg, South Africa](#)

4-6 December 2013

[WHO African Drug Regulatory Authorities Conference, from 4-6 December 2013, Johannesburg, South Africa](#)

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African Medicines Regulatory Harmonization (AMRH) is a programme of the [AU-NEPAD Agency](#)