AFRICAN MEDICINES REGULATORY HARMONIZATION INITIATIVE (AMRH)

THE REPORT OF THE NORTH-NORTH-EASTERN AFRICAN REGIONS CONSULTATION MEETING CAIRO, EGYPT, 13-15 DECEMBER 2010

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NEPAD

EXECUTIVE SUMMARY

The NEPAD Coordinating and Planning Agency (NPCA) undertook since 2008 to contribute to the implementation of the Pharmaceutical Manufacturing Plan for Africa, (PMPA) through the African Medicines Regulatory Harmonization (AMRH) Initiative. The AMRH initiative was initiated at a consultation meeting in February 2009, which was hosted by NPCA, Pan-African Parliament (PAP) in collaboration with their Consortium partners namely the World Health Organization (WHO), Bill and Melinda Gates Foundation (BMGF), the UK Department for International Development (DFID) and the Clinton Foundation. The meeting attracted representatives from nine of the continent's Regional Economic Communities (RECs) and over 40 national medicines regulatory authorities (NMRA). This provided a strong endorsement for the consensus plan that emerged and hence the approach that RECs and NMRAs are now taking to develop project proposals outlining their plan for medicines registration harmonization, and for which the Consortium is working to mobilize donor funding and other stakeholder support.

To date, the Consortium has received six project proposals for harmonization of medicines registration in the East African Community (EAC), Southern Africa Development Community (SADC), Central African region, Economic Community of West African States (ECOWAS), West African Monetary Union (UEMOA) and the East, Central and Southern African Health Community (ECSA-HC). The Organization for the Coordination of the fight against Endemic Diseases in Central Africa (OCEAC) is spearheading the medicines registration harmonization initiative for the Central African region in collaboration with the Economic Community of Central African States (ECCAS). The proposals are at different stages of development and the EAC Proposal is ready for funding.

This meeting was the final consultation aimed at sensitizing RECs, NMRAs and the pharmaceutical industry in North/North-East Africa region on the value of harmonization and collaboration in the area of medicine regulation with a particular focus on registration. Specifically, the meeting aimed at discussing the results of the medicines regulation and harmonization situation analysis in the region, identify the bottlenecks and find solutions for regulatory harmonization and collaboration as an important aspect for improving medicines access to patients. In addition the role of NMRAs and RECs in facilitating harmonization and collaboration as means of improving access to medicines were to be explored. Furthermore, the meeting aimed at charting out strategies and framework for regional harmonization with a view to agree on how RECs and NMRAs will develop project proposals for harmonization of medicines registration for submission to the AMRH Consortium.

Two RECs were represented namely Intergovernmental Authority on Development (IGAD) and Community of Sahel-Saharan States (CEN-SAD) while the representatives of NMRAs and Industry were from Algeria, Comoros, Ethiopia, Egypt, Libya and Sudan. In addition, a number of partner organizations were also represented including the Bill and Melinda Gates Foundation (BMGF), the World Health Organization (WHO-HQ and WHO-EMRO), AU Commission and the NEPAD Agency.

It is important to note that countries in this region (which have not been covered by other RECs) include Algeria, Tunisia, Libya, Mauritania, Egypt, Sudan, Djibouti, Somalia, Ethiopia, Eritrea and Comoros; they all belong to more that one REC namely Common Market for Eastern and Southern Africa (COMESA), CEN-SAD, the Arab Maghreb Union (AMU) and IGAD. Morocco, much as is a member of the AMU, is not a member of the African Union.

Analysis of the situation in the North-Eastern African region shows that countries in AMU namely Algeria, Libya, Tunisia with the exception of Mauritania have a more developed socio-economic status and therefore different public health needs and priorities for medicines regulatory harmonization. Egypt on the other, although under CENSAD and COMESA regions, has a similar level of socio-economic development including a well developed pharmaceutical industry similar to that in AMU region. Furthermore, IGAD whose member states have low socio-economic status, have priorities that are

similar taking into account most of the countries in this region rely on livestock for their economic development. It was also noted that Kenya and Uganda which belong to IGAD, are already covered under the EAC medicines registration harmonization (MRH) project. Although CEN-SAD has 23 member states, only 7 countries have not been covered under the other RECs MRH projects.

In as far as RECs capacity to take up the AMRH project in this region, IGAD and CEN-SAD have the appropriate governance structure and interest in pushing the harmonization agenda in their respective countries. There is need for the Consortium to re-consider the AMRH strategy for this region taking into account the public health and socio-economic needs of the region.

In view of complexity of country membership to more than one REC in the North/North-Eastern African region, and taking into account that some countries have already been covered under the EAC, SADC, ECOWAS/UEMOA, OCEAC/ECCAS MRH projects, the meeting considered the following three options in as far as implementation of AMRH is concerned:

Option I: IGAD to cover Djibouti, Ethiopia, Somalia, Sudan and **CEN-SAD** to cover Algeria, Egypt, Comoros, Eritrea, Libya, Mauritania and Tunisia. **Option II: AMU** to cover Algeria, Libya, Mauritania and Tunisia; **IGAD** to cover Djibouti, Ethiopia, Somalia, Sudan and **COMESA/CEN-SAD** to cover Egypt, Comoros, Eritrea. **Option III: IGAD** to cover Djibouti, Ethiopia, Somalia, Sudan, **Countries from AMU and CENSAD** i.e. Algeria, Libya, Mauritania and Tunisia & Egypt, Comoros and Eritrea to join together for the purpose of this initiative. The meetings agreed unanimously with **Option III.** It was further agreed that the proposed approach for RECs and NMRAs engagement in the North/North-Eastern region shall be submitted to AU Conference of Ministers of Health scheduled for April 2011 for endorsement.

It was further agreed that RECs, NMRAs and Industry representatives who have not completed the situation analysis questionnaire should do so and submit to NEPAD Agency before end of January 2011. The results of the situation analysis are aimed at informing the project proposal write up for harmonization of medicine registration in the IGAD and CEN-SAD/UMA regions. The preliminary draft MRH projects for IGAD and CEN-SAD/AMU shall be further developed in consultation with the RECs and NMRAs. Members of the Consortium further emphasized on the need for RECs, NMRAs and Industry in this region to understand what is needed to draft the proposals and the required time frame which will be communicated by NEPAD Agency.

MAIN REPORT

1. INTRODUCTION

The AU Ministers of Health adopted a Pharmaceutical Manufacturing Plan for Africa, which was developed in line with the AU Heads of State, and Government decision that was taken in Abuja in January 2005. The overall aim of this Plan is to harmonize local production of the much-needed generic medicines in Africa while ensuring economic and technical viability. The plan was endorsed by the AU Heads of State and Government during the July 2007 Summit in Accra, Ghana. As a way forward, the AU Ministers of Health established a Technical Committee, which was mandated to study detailed implications of local production and come up with a concrete plan for the second Phase. The members of this committee are: North Africa (Egypt and Libya), West Africa (Ghana, Nigeria and Senegal), Central Africa (Burundi, Cameroon and Gabon), Eastern Africa (Kenya and Ethiopia) and Southern Africa (South Africa and Angola). The inaugural Meeting of the Technical Committee was held in Addis Ababa, Ethiopia, 24 to 26 October 2007.

The NEPAD Coordinating and Planning Agency (NPCA) undertook since 2008 to contribute to the implementation of the PMPA through the African Medicines Regulatory Harmonization (AMRH) Initiative. The AMRH was initiated at a consultation meeting in February 2009, which was hosted by NPCA and Pan-African Parliament (PAP) in collaboration with their Consortium partners namely the World health Organization (WHO), Bill and Melinda Gates Foundation, the UK Department for International Development (DFID) and the Clinton Foundation. The meeting attracted representatives from nine of the continent's Regional Economic Communities (RECs) and over 40 national medicines regulatory authorities (NMRA). This provided a strong endorsement for the consensus plan that emerged and hence the approach that RECs and NMRAs are now taking to develop project proposals outlining their plan for medicines registration harmonization, and for which the Consortium is working to mobilize donor funding and other stakeholder support.

To date, the Consortium has received six project proposals for harmonization of medicines registration in the East African Community (EAC), Southern Africa Development Community (SADC), Central African region, Economic Community of West African States (ECOWAS), West African Monetary Union (UEMOA) and the East, Central and Southern African Health Community (ECSA-HC). The Organization for the Coordination of the fight against Endemic Diseases in Central Africa (OCEAC) is spearheading the medicines registration harmonization initiative for the Central African region in collaboration with the Economic Community of Central African States (ECCAS). The proposals are at different stages of development and the EAC Proposal is ready for funding.

This meeting was the final consultation for all the regions aimed at engaging the Northern and North-Eastern regions.

2. ATTENDANCE

The RECs present included Intergovernmental Authority on Development (IGAD) and Community of Sahel-Saharan States (CEN-SAD) while the representatives of NMRAs and Industry were from Algeria, Comoros, Ethiopia, Egypt, Libya and Sudan. In addition, a number of partner organizations were also represented including the Bill and Melinda Gates Foundation (BMGF), the World Health Organization (WHO-HQ and WHO-EMRO), AU Commission and the NEPAD Agency. The list of participants is provided as **Annex 1.**

3. SESSION 1: OPENING CEREMONY

The Opening Ceremony was moderated by a representative of the NPCA. Remarks were made by the following representatives from various organizations: BMGF- Represented by Dr Vincent Ahonkhai,

WHO -HQ represented by Dr Alain Prat, the NEPAD Agency CEO - Represented by Prof Elarbi Auoani and the AUC - Represented by Dr Benjamin Djoudalbaye. The opening statement and key note address was given by, Dr Ashraft Bayoumi, the representative of the Minister of Health of Egypt.

The meeting agenda, the speech by the NEPAD Agency CEO and key note address by Ministry of Health Egypt are attached as **Annexes 2, 3 and 4 respectively.**

4. SESSION 2: PRESENTATIONS

4.1. Presentation of an Overview of African Medicines Registration Harmonization Initiative and Objectives of the Meeting

This item was introduced by Ms. Margareth Ndomondo-Sigonda representative of the NPCA who outlined the objectives of the meeting

4.2. Presentations by the RECs

Presentations on the ongoing medicines regulation harmonization initiatives in the region were made by representatives from CENSAD and IGAD. Summary of key issues presented were as follows:

4.2.1. CEN SAD

- The current president of CENSAD readiness and efforts to participate in all relevant programmes in the region.
- CEN SAD countries hope to cooperate and to seek help from experts and specialized people to support this initiative.
- CEN SAD readiness to develop medicines and pharmaceutical policies.
- High prevalence of epidemics and lack of access to medicines in the region.
- African manufacturing capacity should be enhanced to better manage drug shortage situations.

4.2.2. IGAD

- Although the AMRH main focus areas are on human health but this should be extended to include animal health.
- Human medicines should be harmonized alongside veterinary medicines since this is the priority of the region.
- Their critical partners in the initiative are the WHO for human medicines and World Organization for Animal Health (OIE) for Animal medicines.
- Medicines Registration Harmonization should take cognizance of the weaknesses in existing single regulatory authorities in providing effective and efficient medicines for both humans and animals to support human health and development.

4.3. Presentations by the Industry representatives

4.3.1. Algeria

- Algeria has a WHO Regional Reference Centre with a strong political will to support industries and it is key for improving access to medicines.
- Algeria supports the initiative on harmonization and exchange of information between the various countries.
- The existence of strong Laboratory system, inspection of imported pharmaceutical products and a stable and improving generic medicines manufacturing industry.
- Harmonization of Registration mechanisms is not an end in itself with regard to increasing market prospects there is need for a multi-sectoral approach.

4.3.2. Sudan

- Need to improve local production of raw materials for pharmaceutical manufacturing.
- Need to increase the variety of products being manufactured.
- Need for fostering south-south partnerships for financing the industry.

4.3.3. Ethiopia

- Dependency of country on imported medicines, limited manufacturing.
- The pharmaceutical market has grown steadily by 10% annually.
- Existence of about 10 multinational pharmaceutical companies in the country.

4.4. Presentations by NMRAs

The presentations made by representatives of the NMRAs were as follows:

4.4.1. Algeria

- Objectives of the Ministry of Health are the rationalization of the supply through the national classification taking into account the concept of essential medicines.
- Need to improve and increase domestic pharmaceutical industry performance.
- Keen on the promotion of generic medicines.
- Need to consider the creation of an agency for national pharmaceutical products.
- Supports strengthening systems for Registration and Harmonization of pharmaceutical products.

4.4.2. Egypt

- Well established NMRA systems with different departments for inspection, registration and licensing.
- The registration department is responsible for the registration of human drugs, veterinary drugs, biological and vaccines, cosmetics, medical devices and dietary supplements.
- On explaining the process of registration in Egypt and on traditional medicines, traditional medicines that are used in Egypt are only extracts but these are not used for treatment, they are only used as supplements.
- Egypt is in the process of developing Common Technical Documents for evaluation of medicines.

4.4.3. Ethiopia

- The vision of the board is safe and quality health products and services for all Ethiopians
- Well established NMRA system which also covers food and medicines and their raw and packaging materials.

4.4.4. Libya

- Registration system established since the 60s and has developed/improved
- Inadequate human resources.
- Supports the medicines registration harmonization but also looking for training of its professionals to be able to do this.

4.4.5. Comoros

- Existence of a national pharmaceutical policy and an implementation programme including NMRA mission
- No medicines registration system available
- No Quality control laboratories
- Inadequate human resources
- Inadequate financial allocation

5. SESSION 2: BREAK-OUT SESSIONS

5.1. Break- Out Session 1: SWOT Analysis

Participants were divided into three groups depending on the organizations they belong to namely; RECs, NMRAs and Industry**.** The main points for the discussion the discussions were guided by the following points:

a. As far as harmonization of medicines registration is concerned in your organization (REC, Industry and NMRA), what are the Strengths, Weaknesses, Opportunities and Challenges (SWOT analysis)
b. What does your organization (REC, Industry or NMRA) expect to benefit from the African Medicines Regulatory Harmonization initiative?
c. Propose how the African Medicines Regulatory Harmonization initiative can be structured in your respective regions**.**

Conclusions of break-out session 1 are summarized in a **Table 1** below:

Participants were thereafter taken through the Situation Analysis questionnaire with a view to clarify on the Questions and information required which is critical in the medicines registration harmonization project write-up. It was noted that IGAD, Ethiopia (NMRA) and Comoros (NMRA) are the only organizations that filled the Questionnaire as required. Participants were urged to ensure that questionnaires are filled and returned to NEPAD Agency before the end of January 2011.

5.2. Break- Out Session 2: Proposal Drafting

Participants were divided in two groups depending on the regions and country membership. It was agreed that groups are formulated based on the participating RECs and countries present i.e:

a) REC and country members: **Group I:** IGAD: Ethiopia, Sudan; and **Group II:** CEN-SAD/UMA: Algeria, Egypt, Comoros, and Libya.

b) The groups were required to draft proposal for their respective regions with SMART Goals, Objective and Activities as a starting point to guide the medicines registration were required to draft proposal for their respective regions with SMART Goals, Objective and Activities as a starting point to guide the medicines registration harmonization

Conclusions of break-out session 2 are summarized in a **Table II** below**:**

Table I: SWOT Analysis Results

Organization	Strength	Weaknesses	Opportunities	Threats /Challenges	Benefits	Proposed Structure
REC	IGAD-CENSAD each member state has its own regulatory authority	Single regulatory authorities for both human and animal medicines based in ministries of health.	There is limited availability of good quality medicines sold in the IGAD region. One of the best possible solutions to this is harmonized regulatory cooperation between the IGAD States.		Improvement of quality of medicines and quality life.	Governance: Summit, Council of Ministers, Line Ministers and Technical Committees and NMRAs (human and veterinary divisions)
	IGAD-CENSAD Member states are collaborating under the Minimal Economic Integration Programme (under trade and manufacturing)	Limited human resource capacities - technical	Affordable medicines through the use of the TRIPS exclusions in times of crisis to gain access to generic medicines there by bringing down the costs of essential medicines.		It shall be possible to have a consolidated policy that will be implemented throughout the region this in effect will improve the quality of medicines while lowering the costs	An autonomous coordinating mechanism (regional committee of experts) to oversee the implementation of the MRH
	IGAD – CENSAD Governance structures – technical, line ministers, council, summit already exist under the treaty that formed the two RECs.	Limited physical resources i.e. infrastructure	Shared services, costs and infrastructure.		The time taken to register medicines will be reduced as the information used to register a medicament in one member state shall be used in the others	Physical, financial and human resources should be contributed by member states

Organization	Strength	Weakneses	Opportunities	Threats/Challenges	Benefits	Proposed Structure
	IGAD and CENSAD Political will exists	Limited financial resources allocated by the member states	Economies of scale: The increase in efficiency of production as the number of goods being produced increases. The fixed costs are shared over an increased number of goods in the REC		Member states are able to be protected from unfair external trade practices	
	IGAD, COMESA, EAC and IOM - Coordination mechanisms for Regional Economic Commissions exist, currently housed in COMESA and funded by the EC.	Poor political will		Multiplicity of RECs: For example a member may belong to two or more RECs one of which has already adopted the AMRH. This creates an opening for a member state that does not want to implement the MRH.	Pharmaceutical Manufacturing Plan for Africa will benefit from the process	

Table II: Proposal Drafting

REC	Overall Goal	Objectives	Activities
IGAD	To harmonize strengthen and expedite medicines registration within the IGAD member states in accordance with international, regional and nationally recognized standards	**Objective 1:** To implement an agreed common document of technical requirements and procedures for registration of medicines in the IGAD member states (taking into account the international standards set by World Health Organization for Animal Health (OIE), World Health Organization of the United Nations (WHO) and International Conference on Harmonization (ICH)}	1. Establish technical working groups at national and regional levels 2. Develop draft common documents on technical requirements and procedures for registration of human and veterinary medicines. 3. Organize consultative meetings at national and regional levels to validate the drafts 4. Prepare the final draft for consideration and adoption by member states 5. Assessment of the present human, physical and financial capacities of the existing local manufacturers in the region 6. Support and facilitate the local medicine manufacturers to address the gaps identified 7. Support and facilitate the establishment of regional and national associations of medicine manufacturers. Support the public and private sector partnerships in developing and implementing a quality assurance programme 8. Promote marketing of locally manufactured medicines 9. Encourage local medicine manufacturers to produce both veterinary and human medicines 10. Encourage the public sector to pre-finance locally produced veterinary and human medicines.

			11. Facilitate the establishment of bio-equivalence center for the region (this has started in Ethiopia). 12. Accreditation of laboratories in the region (this has already been started in Ethiopia
		Objective 2: Create awareness of the goal and objectives of the programme	
		Objective 3: To improve access and safe use of human and veterinary medicines in the member states and the region	1. Strengthen the regulatory authorities especially at ports of entry and exit 2. Enhance the inspection and surveillance capacity of regulatory authorities in the member states 3. Sensitize the public to use approve medicines and shun counterfeits. 4. Support regular meetings of national regulatory authorities 5. Support consultative meetings between the regulatory authorities and the medicine manufacturers in the region
		Objective 4: To develop and implement a common information management system for human and veterinary medicines in the region and member states	1. Develop a protocol / memorandum of understanding allowing for the sharing of information in the region 2. Establish a coordination mechanism for information gathering, analysis and exchange in the region 3. Establish and interactive database of drug manufacturers, registered drugs, registered distributors and outlets, list of registered and/or licensed pharmacists / chemists / medicine

			dispensers and banned and illegal medicines 4. Sensitive the stakeholders including members of the public to access and use this information harmonize the essential national drugs lists.
CEN-SAD /UMA		**Objective 1:** Unify the CTD	1. Analyze the current situation of registration dossier. 2. Collecting the proposals of the CTD format. 3. Issuing the final CTD
		Objective 2: Implement common information technical system.	
		Objective 3: Implement quality management systems	1. Training the staff for the QMS 2. Monitoring the implementation of QMS
		Objective 4: Develop HR for regulatory	1. Training staff & transfer technical expertise 2. Implementing certain criteria for recruitment 3. Improve common economic & technical information system
		Objective 5: Provide a protected electronic platform for regulators to share information	
		Objective 7: Exchange GMP inspectors to obtain qualified products.	1. Develop mutual recognition between countries 2. Exchange GMP inspectors to develop our inspections in different region

6. CONLUSION AND RECOMMENTATIONS OF THE MEETING

6.1. Recap on AMRH processes for engaging RECs and NMRAs

The Bill and Melinda Gates Foundation provided on behalf of the Consortium a reminder on the process and the format for project proposals for medicines registration harmonization. He reiterated that the AMRH Johannesburg meeting report provides reference for drafting a proposal and cited the relevant sections as follows:

- Page vi - executive summary with the essential goals of the proposed approach and the benefits of the AMRH.
- Page vii, outlines the agreement and the timelines the RECs were required to forward a proposal to the Consortium within an agreed time frame.
- After the submission of the proposal, the Consortium partnership reviews the proposal and provides feedback to respective RECs.

He therefore emphasized the need for RECs, NMRAs and Industry in this region to understand what is needed to draft the proposals and the required time frame which will be communicated by NEPAD Agency.

6.2. Recommendations of the meeting

6.2.1. It was recommended that RECs, NMRAs and Industry representatives who have not completed the situation analysis questionnaire should do so and submit to NEPAD Agency before end of January 2011.

6.2.2. In view of complexity of country membership to more that one REC in the North/North-Eastern African region, and taking into account that some countries have already been covered under the EAC, SADC, ECOWAS/UEMOA, OCEAC/ECCAS MRH projects, the meeting considered the following three options in as far as implementation of AMRH is concerned:

i. Option I:
   1. IGAD – Djibouti, Ethiopia, Somalia, Sudan
   2. CEN-SAD – Algeria, Egypt, Comoros, Eritrea, Libya, Mauritania and Tunisia

ii. Option II:
   1. AMU – Algeria, Libya, Mauritania and Tunisia
   2. IGAD – Djibouti, Ethiopia, Somalia, Sudan
   3. COMESA/CEN-SAD – Egypt, Comoros, Eritrea

iii. Option III:
   1. IGAD – Djibouti, Ethiopia, Somalia, Sudan
   2. Countries from UMA and CENSAD to join for the purpose of this initiative i.e. Algeria, Libya, Mauritania and Tunisia & Egypt, Comoros and Eritrea.

Participants considered the proposed options and agreed unanimously with **Option III.**

7. CLOSING SESSION

The Closing Ceremony was moderated by a representative of the NPCA. Remarks were made by the following:

a) The Ministry of Health of Egypt - Represented by Dr Ashraft Bayoumi, made a closing statement and offered to host the next AMRH meeting on behalf of the region.

b) AUC - Represented by Dr Benjamin Djoudalbaye thanked the representatives of RECs, NMRAs, Industry and Partners for their participation and successful deliberation of the meeting.

c) The NEPAD Agency Director for NAB/NET Prof Elarbi Auoani made closing remarks and thanked all delegates and organizing committee for a successful meeting. The closing speech is attached as **Annex 5.**

Annex 1

List of Participants:

Country	First Name	Last Name	Organization
Algeria	Mohamed	MANSOURI	Laboratoire Nationale de controle des produits pharmaceutiques Algerie
Algeria	Malik	AIT SAID	Union National des operateurs pharmaceutiques de l'Algerie
Comoros	Ahamada	FAZUL	Direction de laboratoire et de Pharmaceutique - Comores
Egypt	Ashraf	Bayoumi	Ministry of health of Egypt
Egypt	Mahmoud	El Mahdawy	Ministry of health of Egypt
Egypt	Asmaa	Yousry	Ministry of health of Egypt
Egypt	Jilan	Ezzat	Ministry of Health of Egypt
Egypt	Bassant	Hassan	Ministry of Health of Egypt
Egypt	Mahfouz	KASSEM	Ministry of Health of Egypt
Egypt	Mohamed	Elarbi	National Research Center
Egypt	Sanaa	Haroon	National Research Center
Egypt	Sayed	M	National Research Center
Egypt	Osama	El Shabrawy	National Research Center
Egypt	Sally	mohamed Ibrahim	National Research Center
Egypt	Ahmed	ZAGHLOL	Ministry of Health of Egypt
Ethiopia	Mamadou	DIALLO	African Union Commission
Ethiopia	Janet	BYARUHANGA	African Union Commission
Ethiopia	Benjamin	DJOUDALBAYE	African Union Commission
Ethiopia	Mohamed	ZEIN KASIM	Ministry of Health of Ethiopia
Ethiopia	Shifraw	HABTE	Nared General trading Ethiopia
Kenya	Solomon	MUNYUA MUNCHINA	IGAD - Nairobi
Kenya	Christopher Humphrey	WANGA	IGAD - Nairobi
Libya	Anwar	Massoud Allag	CEN SAD
Libya	Khadra	LASWED	Ministry of Health Libya
Sudan	Ahmed	AL SHAFIE	Almadinal Medical company
South Africa	Margareth	NDOMONDO-SIGONDA	NEPAD
South Africa	Mercy	FOMUNDAM	NEPAD
South Africa	Seke	LUKOVI	NEPAD
South Africa	Nancy	NGUM	NEPAD
South Africa	Leonard	KAMWANJA	NEPAD
South Africa	Abolade	AWOTEDU	NEPAD
South Africa	Fute	ISKARI	NEPAD
USA - Seattle	James	PLATTS	Bill and Melinda Gates Foundation
USA - Seattle	Vincent	AHONKHAI	Bill and Melinda Gates Foundation
Egypt	Mohamed	BIN SHAHNA	World Health Organization - EMRO
Switzerland	Alain	PRAT	World Health Organization HQ

Annex 2

Day 1: December 13th

8.30 – 9.00am	***Registration of participants***	
	SESSION 1: OPENING CEREMONY	
9.00am- 10.00am	**Statement**: Bill and Melinda Gates Foundation **Statement**: WHO **Statement**: African Union Commission **Statement**: NEPAD Agency **Official Opening:** Minister for Health, Egypt	
	Group Photo	
10.00 – 10.30	Coffee Break	
10.30-13.00	**SESSION 2- Chair: Egypt**	
10.30 – 11.00	An overview of African Medicines Registration Harmonization initiative & Objectives of the meeting	NEPAD Agency
11.00 – 11.40	Presentations from RECs on ongoing medicines regulation harmonization initiatives in the region Discussions	CEN-SAD IGAD
11.40 – 13.00	Industry perspective presentations Discussion	Algeria, Egypt, Sudan, Djibouti, Somalia and Ethiopia
13.00– 14.00	**Lunch Break**	
14.00– 15.30 `	**SESSION 3 - Chair: Algeria**	
	Presentations from National Medicines Regulatory Authorities (NMRA) Discussions	Algeria, Egypt, Ethiopia, Libya, Comoros
15.30 – 15.45	**Tea Break**	
15.45– 17.15	Breakout sessions Recommended next steps for day 2 & 3	Groups (RECs, NMRA, Industries)
19.00	Group Dinner (Bus to leave at 18h30 Ramses Hilton Hotel to the Nile Cruse)	

Day 2: December 14th

8.30-12.20	**SESSION 4**	
8.30 – 10.30	Summary of Day 1 Focus Group Discussion	REC, NMRAs & Industries NEPAD Agency Consultants on Situation Analysis
10.30 – 11.00	**Coffee Break**	
11.00-12.30	Focus Group Discussion Summary of Day 1	REC, NMRAs & Industries NEPAD Agency Consultants on Situation Analysis
12.30– 14.00	**Lunch Break**	
	SESSION 5 – Chair : CEN-SAD	
14.00 – 15.30	Plenary session	
15.30 – 16.00	**Coffee Break**	
16.00 – 17.30	Plenary session Continue	

Day 3: December 15th

	SESSION 6 - Chair: Ethiopia		
8.30 – 10.30am	Summary of Day 2		
	A Proposed Approach for Supporting Medicines Registration Harmonization in North/North Eastern Africa Discussion		The Consortium
10.30 – 11.00am	**Coffee Break**		
11.00 – 12.30	Recommended Next Steps	RECs, NMRA , Industry	
12:30pm-1.00pm	Wrap-up and close	All	
1.30pm – 2.30pm	**Lunch**		

Annex 3

NEPAD CEO's Speech

Address of Dr. Ibrahim Assane Mayaki
The Chief Executive Officer **of the Planning and Coordination Agency of New Partnership for Africa's Development (NEPAD) to mark the opening of the North/North-Eastern Africa Medicines Regulatory Harmonization (AMRH) Consultation Meeting**

13-15 December 2010, Cairo, Egypt

I extend to you the warm greetings of the* Chief Executive Officer *of the NEPAD Agency, HE Dr. Ibrahim Assane Mayaki, who could not be present due to other important meetings he is attending outside the continent. He has asked me to read those notes on his behalf…

Dr. Hatem Mostafa El-Gabaly, Minister of Health and Population of the Republic of Egypt

Ladies and Gentelmen, representatives of North and North-East Africa: The Regional Economic Communities The national medicines regulatory authorities, The representatives of national pharmaceutical Associations

As you know, the 14th African Union (AU) summit decided a year ago to create the NEPAD Agency as the technical arm of the AU with a mandate to:
• Facilitating and coordinating the implementation of programs and projects of regional priority
• Mobilizing the resources and partners in the service of these programs
• Defending and disseminating the vision of the AU and NEPAD, their missions, principles and values.
During the past year, the entire machinery of the NEPAD Agency has been devoted to achieving the specific objectives of this phase:
• The NEPAD secretariat was transformed into a Planning and Coordinating Agency of NEPAD through which the 2010-2013 strategy and the 2010-2014 Business plan were prepared
• The Executive Director of the agency was in continuous contact with the AUC to align the programs of both organizations, defining the specific functions of the Agency in tandem with that of the AUC and to strengthen collaboration
• The administrative and financial processes of transition to the regulations of the AU were well underway
• As part of their duties, the directorates of the NEPAD agency, in synergy with the AUC, have developed their action plans by building on prior progress to meet the mandate of the agency.
The major change that is taking place during the transition from the former NEPAD secretariat to the current NEPAD agency is at the level of the program design, the level of perception of the outcome and in the structures and processes that carry them. In particular, the approach to implementing the programs will no longer be guided by sectors in isolation but will achieve strategic objectives within thematic frameworks. This vision targets the obtainment of tangible results, and will equally use resources efficiently to maximize the impact.

Five (5) thematic areas were selected for the new generation of programs in the Agency:
• Agriculture and food security
• Climate change and natural resources management
• Regional integration and infrastructure
• Human development
• Economic and Corporate Governance

From now on, the agency's performance will be evaluated through:
• The number and quality of the regional programs made available to countries and to RECs by the NEPAD Agency
• Improving the mechanisms for the mobilization of internal and external resources to support these programs
• The contribution of these programs to improve the capacity of the agency, of the countries and the RECs in the implementation and monitoring

Distinguished Guests, Ladies and Gentlemen,

Africa is entering the 21st century with a vision rooted in the values of pan-Africanism, accountability and transparency, professionalism, and effective delivery of results. The NEPAD agency, through the alignment of its strategy with that of the AUC, is committed to these values and will play its role under proper governance. Under the new structure, the RECs are full members of the Steering Committee of the NEPAD Heads of State and Government Orientation Committee. They will have a decisive role so that the Agency delivers its mandate. Indeed, the RECs are the pillars of economic integration of Africa, and the Agency will continue more than ever before to work with them to identify and develop programs, and to monitor and evaluate them.

The objectives of the NEPAD Agency in the area of Health, as mentioned in the African Action Plan, are focused around strengthening health systems to reduce diseases, and the acceleration of progress towards achieving the Millennium Development Goals. The Agency's objectives are also designed to facilitate the extension of the results achieved towards regional and intergovernmental structures. The corollary of the implementation of the African Action Plan is the collaboration of the health sector with other sectors, and improving the socio-economic and political environment.

Despite the progress achieved to attain the Millennium Development Goals for the health (MDGs 4, 5 and 6), the progress remains below the original targets, which are:
• Reducing infant mortality by two thirds between 1990 and 2015, and by three quarters the maternal mortality rate,
• Stopping the spread of AIDS and offering treatment to all those who need it to combat this disease,
• Stopping the spread of malaria and other major diseases

To make progress in achieving its commitments and its programs in the field of health, Africa forged partnerships with major international and regional bodies. And it is in the context of such a vision that the initiative " African Medicines Regulatory Harmonization " was conceived and incubated in 2008 and its implementation started in 2009.

This initiative faces the notorious disparity among African countries regarding their health systems and the multiple regulatory frames in terms of production, importation, registration and distribution of drugs. The African Medicines Regulatory Harmonization initiative (AMRH) was then launched to assist countries and Regional Economic

Communities (RECs) in Africa to meet the challenges mentioned above. It is thus intended to support RECs and countries for the medicines reguatory harmonization and provide an appropriate framework to donors interested in supporting Africa as well as the concerned parties wishing to take part in the action.

The AMRH initiative has already made a great stride. After the consultation meeting held in February 2009, a comprehensive action plan adopted by concensus offered several RECs a framework for preparing and submitting projects. Even if the initiative emphasizes short-term harmonization of medicinesregistration, its ultimate goal is to extend the action to cover other health products and other regulatory functions. Even if the initiative –in the short term- aims to develop regional projects, it will target in the longer term to coordinate the actions of the RECs on a continental scale in order to avoid duplication, minimize costs and optimize the use of resources for coherent and consistent actions.

The AMRH program was designed to be managed under the auspices of a consortium composed of several parties. The consortium is made up of African political partners (African Union Commission (AUC), NEPAD and Pan African Parliament (PAP)) and international development partners (WHO and its regional branches EMRO, AFRO, Department for International Development-DFID) and two major U.S. foundations (Bill & Melinda Gates Foundation-BMGF, and Clinton Foundation Health Access Initiative-CHAI).

Within the consortium, the NEPAD agency works in collaoboration in with other AU organs , (PAP and AUC), a coordination and advocacy role, in the service of the entities that will implement the initiative, namely the RECs, the national governments through their National Medicines Regulatory Authorities (NMRAs) and the Pharmaceutyical Manufacturing sectors.Progress made to date explains the recent involvement of the World Bank in the management of a fund to support the program.

Distinguished Guests, Ladies and Gentlemen,

The NEPAD Agency notes with satisfaction that several RECs and regional organizations operating in the field of health are already involved in the AMRH initiative and contribute to this continental mechanism. Such is the case of the East African Community (EAC), the Organization for Coordination in the Control of Endemic Diseases in Central Africa (OCEDCA), the Economic Community of Central African States (ECCAS), Economic Community of West African States (ECOWAS), the West African Economic and Monetary Union (UEMOA), the Southern African Development Community (SADC)
The meeting that you are holding today is intended to involve other regional economic communities, namely: The Common Market for Eastern and Southern Africa (COMESA),Intergovernmental Agency for Development (IGAD), Community of Sahel-Saharan States (CEN-SAD) and Arab Maghreb Union (AMU), as well as National Medicines Regulatory Authorities from North and North-East Africa to actively get involved in Medicines Regulatory Harmonization. Your meeting also involves important and active economic agents in the production and distribution of basic medicines who will be our future partners in this sector in the continent.

The NEPAD Agency today aknowledges the progress made by the AMRH initiative and thank you all for taking the trouble to come to continue to enhance and own the initiative. it. The Agency will not let this opportunity pass by without thanking the Bill & Melinda Gates Foundation (BMGF) that we have the great pleasure of having among us today.

We are deeply grateful for the significant financial support allocated by this foundation. The Agency extends its gratitude to other consortium members; especially the WHO, and its branches AFRO and EMRO that operate directly in the continent, for their unwavering support for this program.

Distinguished Guests, Ladies and Gentlemen,

To conclude, I would like to extend my thanks to the Executive/General Secretaries of the RECs, the ministers of the departments which are represented by the National Medicines Regulatory Authorities, and the directors and National Associations of Pharmaceutical manufacturers that have come and, for the importance that they attached to this initiative.

I would not finish without thanking the Egyptian authorities for their support to all the activities of the NEPAD Agency. Whenever NEPAD asked for their support and assistance, their response has always been positive. This is not surprising since Egypt is firmly committed to Africa. To this through:

- His Excellency Ambassador Dr. Ibrahim Hassan, representative of His Excellency President Hosni Mubarak to the Steering Committee of Heads of State and Government on NEPAD (NEPAD HSGOC);
- Dr. Ashraf Bayoumi, personal representative of the Minister of Health and Population
- Dr. Osama El Shabrawy, representing the National Research Center and the contact with the NEPAD Agency Who have greatly assisted the NEPAD Agency in the preparation of this meeting

Finally, I thank the NEPAD Agency team led by Margareth Sigonda who has worked for months to prepare for this meeting.
I wish your meeting a great success and the AMRH program itself a long life and integration into all NEPAD programs.

At the end, I urge you to seize the opportunity of your stay here to discover a little bit about Cairo, this magnificent capital of a great country, Egypt, aptly qualified to be the "Mother of the World".

Thank you for your attention!

Annex 4

African Medicines Regulatory Harmonization (AMRH)

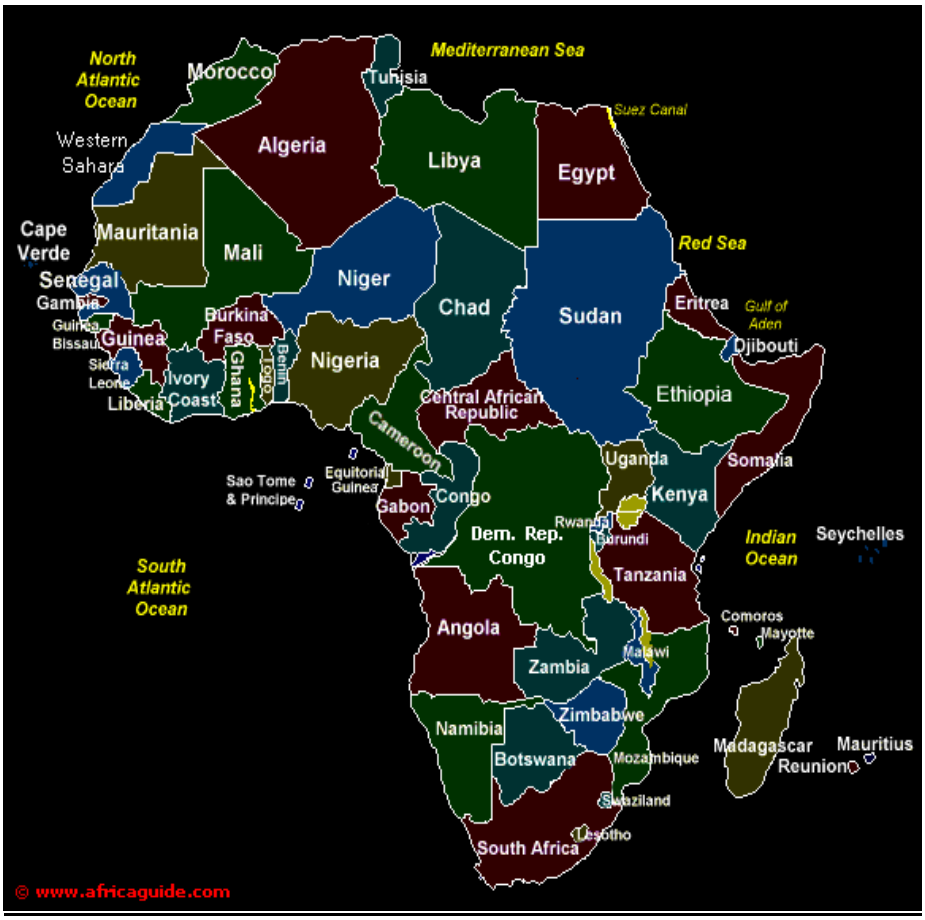
Dr. Ashraf Bayoumi

Head of Pharmaceutical Affairs

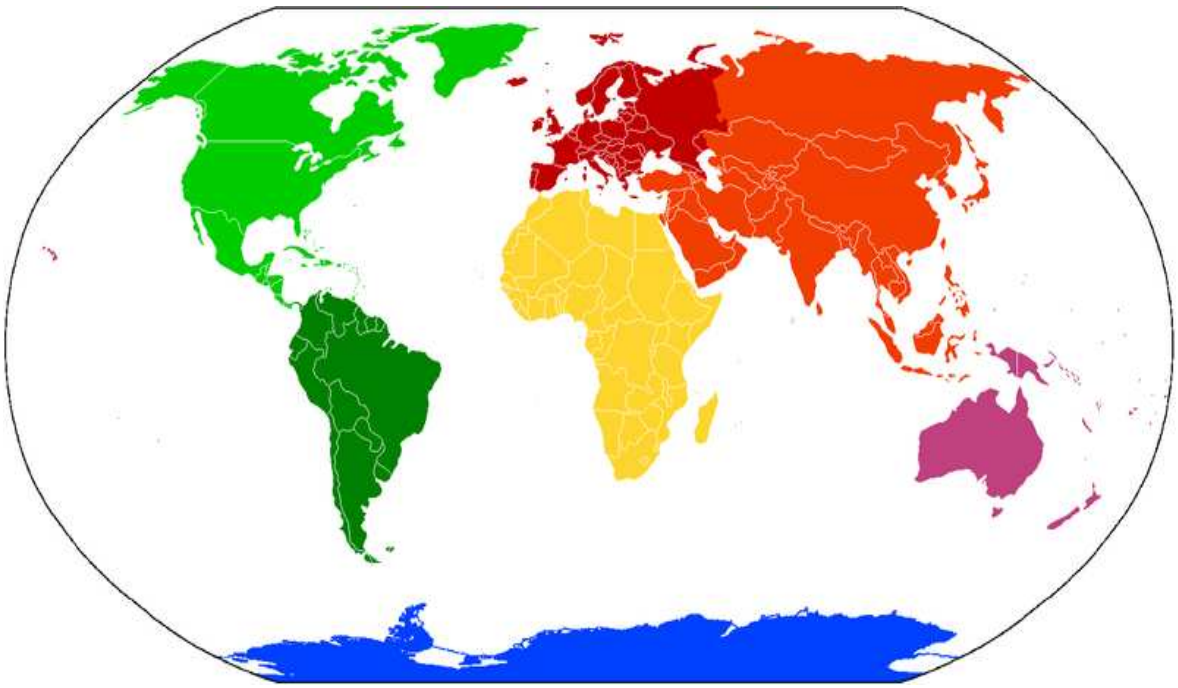
13th- 15th December 2010 - Ramsees Hilton

Welcome to Egypt

African Harmonization



Global Harmonization



The world continents

Continent	% Landmass	Population	% population
Asia	29.5%	3,879,000,000	60%
Africa	20.4%	922,011,000	14%
North America	16.5%	528,720,588	8%
South America	12%	382,000,000	6%
Antarctica	9.2%	1,000	0.00002%
Europe	6.8%	731,000,000	11%
Australia	5.9%	22,000,000	0.5%

African Medicines Regulatory Harmonization (AMRH)

- Has become a mandatory requirement to be able to compete with the new pharmaceutical associations as EU, USA, Japan and South-East Asian Nations (ASEAN)

- It's not that easy step; it requires numerous meetings, technical discussions, reviews and complex negotiations to resolve differences of scientific opinion as well as national sovereignty issues.

Harmonization

- The process of adjusting differences and bringing them into agreement.

- Strengthen efforts for capacity building to develop a common technical documents and requirements.

- Provide a mechanism for sharing on-going regional harmonization activities and provide technical assistance to member countries when needed.

Purpose

- Improve health status of the public

- Increasing access to safe, effective, affordable medicines for treatment of priority diseases

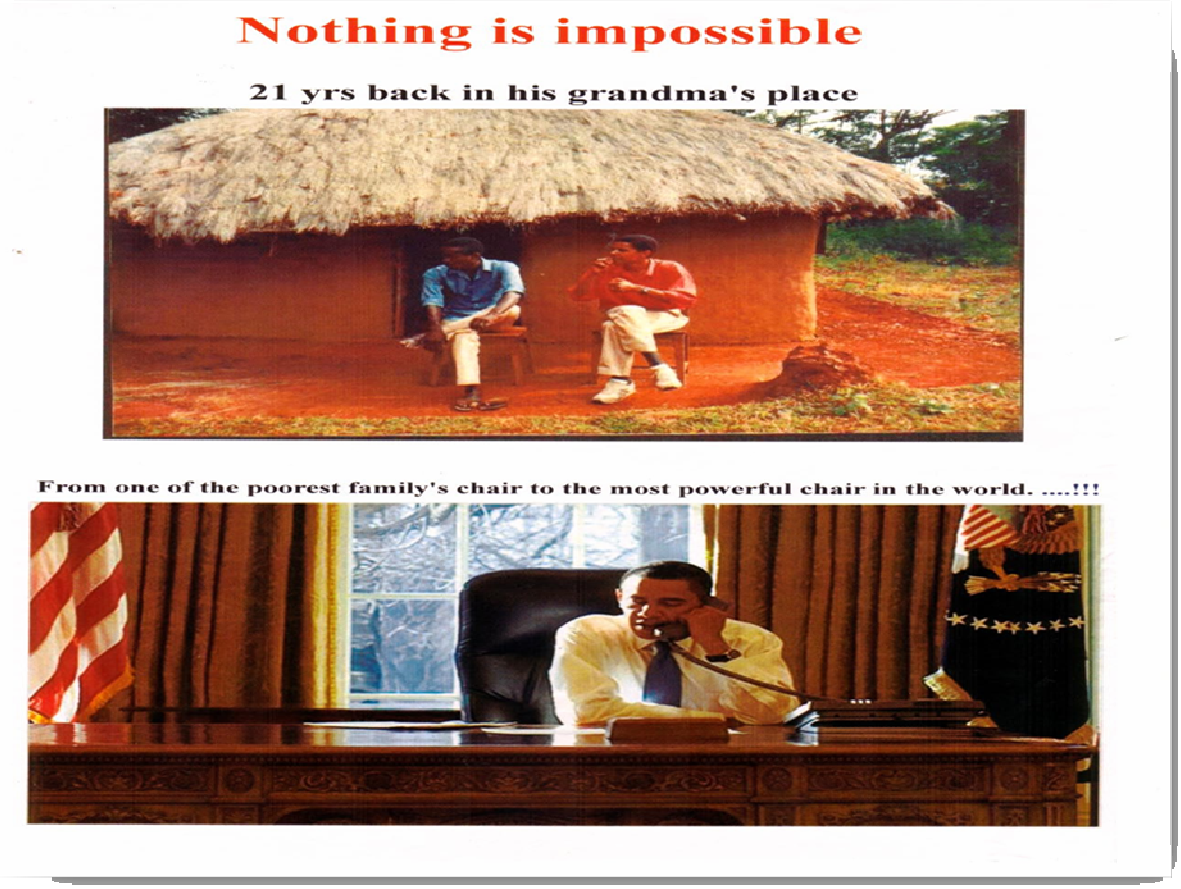
Provide a protected electronic platform for regulators to share information and experience on specific regulatory topics of common interests.
Obstacles

- Insufficient resources

- Exchanging information (Logistics)

- Funding

- Plans are too broad



Why?

- Cooperation between countries, since not every country can have all the capacity needed to achieve growth
- Ensures consistency and adherence to international standards
- Need to meet public expectations by minimizing delay in making safe and effective drugs available to patients in need

League of Arab States: Future Plan with Arab country

- ❖ Finalize the draft for CTD on June 2010.
- ❖ The Final CTD will be signed in March 2011.
- ❖ eCTD will start after the approval of CTD.

Conclusion

- In this conference are country experts with different perspectives, backgrounds, experiences & skills.
- We are all resources for each other during and after this meeting.

Annex 5

Closing Remarks: Mohamed Elarbi Aouani
Director of NEPAD/NABNet

North/North-Eastern Africa Medicines Regulatory Harmonization (AMRH)
Consultation Meeting
13-15 December 2010, Cairo, Egypt

Ladies and Gentlemen,

Our meeting for North and North East Africa on the African Medicines Regulatory Harmonization (AMRH) is nearing its end. This meeting allowed us to have various intense and fruitful discussions on a very important program that touches on a vital domain for Africa.

The meeting was intended to bring together 4 RECs and 12 countries of the Northern and North Eastern shores of Africa. The 12 countries should have been represented by their National Medicines Regulatory Authorities as well as their representatives from the National Associations for pharmaceutical manufacturers.. The major objective of this meeting resided in the initiation of a process of preparation of project proposals through which North and North East Africa would contribute in the AMRH initiative.

It is clear that the meeting has only brought together half of the RECs targeted (CEN-SAD and IGAD), one third of the representatives of the regulatory authorities (Algeria, Ethiopia, Libya, Comoros) and one fourth of the industry sector (Algeria, Ethiopia and Sudan). This fact has deprived the meeting of a debate that would have otherwise captured the all the concerns of the entire region.

However, the quality of participants, the organizers' efforts to adapt a modified agenda at the request of the audience, and the support and contributions of all members of the consortium; have all turned this meeting into a significant step in the initiation of AMRH in the North and North-East region of the continent.

I would very much like to thank all the participants for their contribution to the intense discussions that were often not easy because of the unavailability of a basic analysis of the situation, and because of the complexity of the issues under discussion and the difficulty of the choices that must be made.

In view of the continued effort exerted for the aim of involving this region in the AMRH, allow me to summarize the major directions that emanated from the meeting, which deserve the attention of the AMRH coordinators as follows:

1) It is imperative that the AMRH program coordinators involve the targeted entities in the region who were absent at this meeting, by sharing with them the recommendations and by actively involving them at the earliest in the ongoing debate and the implementation of the program.
2) Increase the interaction between the parties concerned to continue the analysis of the situation and to identify the appropriate approaches to begin the development of the project proposal involving them.
3) strengthen the interaction with the WHO and its branches EMRO and AFRO as well as the multiple skills and resources of the region to capitalize on their ability to benefit the initiative.

4) Ensure that the available resources are harnessed for the launch, via the direct supervision of the NEPAD Agency, through a process leading to the leadership of the RECs and the significant involvement of the Medicines Regulatory Authorities and the most active industrial partners.

Ladies and Gentlemen,
I would like to thank:
1) the Egyptian authorities for their support in the holding of this meeting
2) BMGF for its financial support and the backstopping in the implementation of the project including through advices and encouragements
3) The WHO and its branches for the support in the implementation process

On the other hand, I would like to congratulate the AUC and the NEPAD Agency for the holding of this meeting:
1) I congratulate the AUC for hoisting the meeting by its presence, through an important delegation which provided a significant contribution to the revival of AMRH with more efficiency and coherence with the existing governance
2) I congratulate the team of the NEPAD Agency, including its consultants, for their success in inaugurating the AMRH process in a a very wide, diversified and complex region.

I would finally like to thank the team of translators who have perfectly done their job.

Keep it up!