2nd African Regulatory Conference: KEY TAKE-AWAYS

Engela Dedwith, Eli Lilly

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CONFERENCE TOPICS

1. Regulatory Harmonisation
2. The Global Regulatory Environment
3. The Value of Research and Development in Patient Access to Medicines
4. Regulatory Challenges to Patient Access to Medicines
5. Patient Safety through Pharmacovigilance
6. Product Quality Update, including GMP, Site Inspections, and Anti-counterfeiting Strategies

The African Medicines Registration Harmonisation (AMRH) Initiative

March 2010

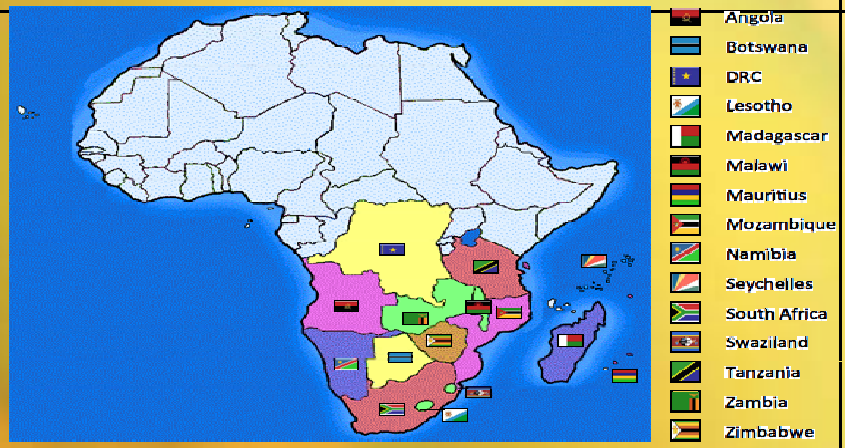
The AMRH Initiative is working to enable and speed up African plans to harmonise medicines registration

Overall aim	**Improve public health by increasing rapid access to safe and effective medicines of good quality for the treatment of priority diseases**
Specific aim	**To reduce the time taken to register priority medicines**
Methodology	▪ **Support the development of regional project proposals to expedite and strengthen medicines registration through regional harmonisation and collaboration** ▪ **Mobilize funding and implementation resources**

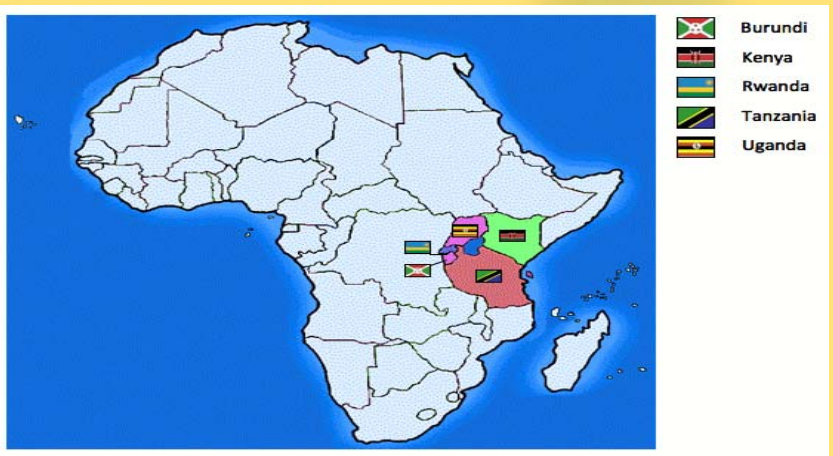
The initiative builds on existing political mandates, plans and progress at continental and regional level

Four regional project proposals are currently in development These proposals involve 75% of African countries

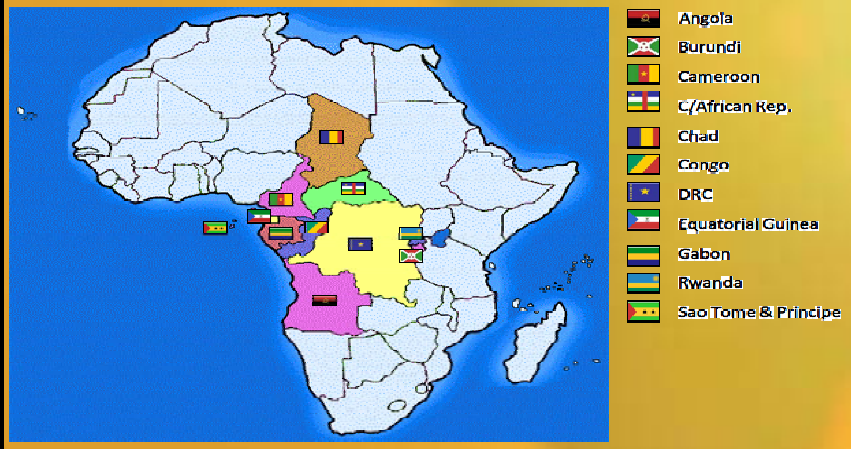
Southern Africa: SADC– 15 member states



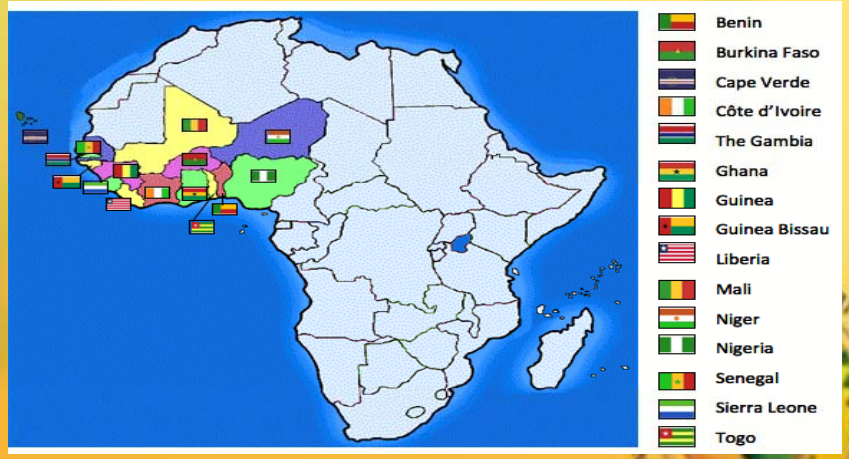
East Africa: EAC – 5 member states



Central Africa: ECCAS and OECAC - 11 combined member states



West Africa: ECOWAS and UEMOA – 15 combined member states



SADC = South African Development Community; EAC = East African Community; ECCAS = Economic Community of West African States; OCEAC = Organisation de Coordination pour la lutte contre les Endémies en Afrique Centrale ; ECOWAS = Economic Community of West African States; UEMOA = Union Economique et Monétaire Ouest Africaine

… promote medicines registration harmonisation

AMRH Regional Project Proposals

Not Harmonised → **Fully Harmonised**

Working independently	Collaborate on selected topics	Harmonised standards and broad collaboration	Recognition of decisions made elsewhere	Centralized regional registration
Member states operate independently and each country has its own technical requirements and format for registration applications	Member states collaborate on selected topics e.g.certain technical guidelines, GMP inspections, information exchange etc.	Member states have common technical requirements and collaborate broadly e.g. sharing assessment and inspection reports, joint evaluations and inspections	National verification based decisions made elsewhere (either within the REC or beyond) and/or mutual recognition agreements	Centralized registration on behalf of participating member states

National sovereignty is respected: medicines registration decisions remaining firmly that of sovereign nations

What makes this initiative different?

Regional harmonisation in Africa has been pursued before, but never with the support, consensus or continental coordination seen today.

The AMRH initiative is achievable because of its focus on:

- **A step-wise approach** that commits to the most logical and realistic steps first (medicines registration, starting with generics, and expanding to encompass other products and regulatory functions at a later date)
- **Enlisting the support of all regions and countries**, as a truly continental effort that will promote and enable inter-REC communication and collaboration
- **Creating a supportive community**, with the right partners already cooperating and a high level of donor interest (the Bill & Melinda Gates Foundation and DFID are committed in principle and Consortium partners are actively engaging other interested donors to solicit their support)

EXAMPLE:

EAST AFRICA COMMUNITY'S MEDICINES REGULATORY HARMONIZATION INITIATIVES

Mr. Apollo Muhairwe
Executive Secretary/Registrar
National Drug Authority of Uganda
Johannesburg, 2nd March 2010

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Milestones for EAC harmonization (1)

- To launch a **regional drug registration website** to make national/regional legislation and guidelines and national lists of registered products publicly and centrally available by December 2010

- To implement a **common document** (format and content) of technical requirements, **common procedures** for implementation of harmonized guidelines, including common evaluator guidelines, and common GMP inspection guidelines by December 2011

Milestones for EAC harmonization (2)

- To **fast track the registration of essential medicines** for priority diseases at national level through the implementations of a regional factory inspections policy and a registration approval pathways policy (using risk-based approaches) by December 2011

- To establish **systems for joint evaluations and inspections** to build capacity and trust within and across Partner States NMRAs by December 2010 and ensure that these are integrated into national decision making processes to expedite the registration of essential medicines for priority diseases and minimise duplication by December 2012

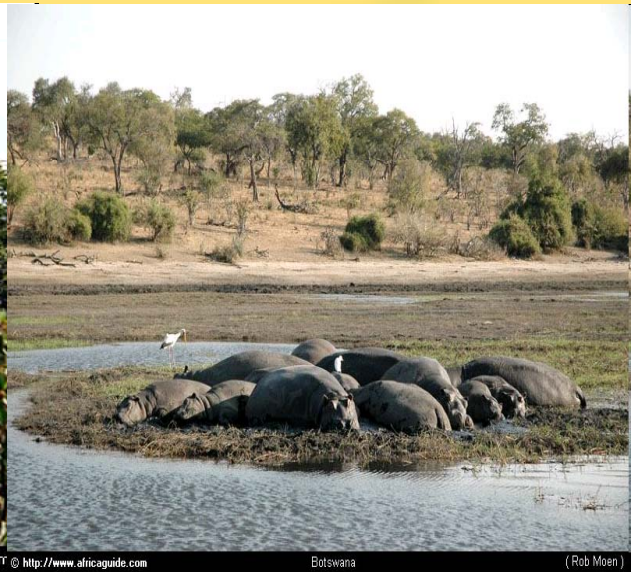
Milestones for EAC harmonization (3)

- To contribute to the **establishment of the East African Community Medicines and Food Safety Commission** through the recruitment of EAC DRH National Focal Points, the EAC Senior Health Officer (Medicines Regulation) and the EAC e-health and informatics officer by January 2010

Industry Involvement: East African Pharmaceutical Industry Association (targeted for mid 2010)

EXAMPLE: SADC MEDICINES REGULATORY HARMONIZATION

JOSEPH MTHETWA



APPROVED GUIDELINES

1. Adverse drug reactions;
2. Registration of Medicines;
3. Licensing of manufacturers;
4. Licensing of wholesalers, dispensaries and pharmacies;
5. Licensing for export / import;
6. Post-marketing surveillance;
7. Donations;
8. Recalls;
9. Validation;
10. Advertising;
11. Clinical trials;
12. Nutritional supplements;
13. Pharmacovigilance Guidelines;
14. Guidelines for Pharmaceutical Wholesale Dealing;
15. Guidelines for Retail Pharmacy;
16. Good Manufacturing Practice

STATUS OF HARMONIZATION

- All Member States have received copies of Guidelines for Registration and Control of Medicines

- Three more guidelines to be developed:
  - Disposal of unwanted Medicines;
  - Control of Illegal and Substandard Medicines
  - Regulation of Traditional Medicines.

New EU Regulatory trends

Truus Janse-de Hoog
Medicines Evaluation Board
Chair Coordinationgroup

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Risk minimisation measures

- **Risk management plans are required for products with new active substances, biologicals** and known substances with **new indications**
- Risk minimisation measures can be agreed at EU level with the granting of a **new marketing authorisation** or with a **variation** of the marketing authorisation
- Implementation at national level
- Information on Risk minimisation and Risk management plans can be found in Annexes of EPARs (Public Assessment Reports on http://www.ema.europa.eu/htms/human/epar/eparintro.htm)

Risk Minimisation Examples

Risk minimisations measures are:

- Pregnancy prevention programme
- Educational material for doctors or patients
- Questionnaires
- Restrictions in legal status

Medicines for children

- Many medicines are used off-label in children
- Paediatric Regulation came into force 1st January 2007
- Applications for New Chemical Entitiescan only be validated if they include Paediatric studies or waiver or deferral
- **A PIP is a Paediatric Investigation plan**
- A PIP has to be approved by Paediatric Committee (PdCo)
- PIPs are also requested if a company applies for a new indication or pharmaceutical form for products that have a patent.

The Management of Variations in Africa

Industry Views and Key Issues

Florence Roizard
Director, Regulatory Affairs
Middle East and Africa
Merck Sharp & Dohme
EFPIA-Africa Regulatory Network Lead

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What is the issue for industry?

Regulations regarding variations are highly varied across countries in Africa

- Requirements
- Timelines

EFPIA Position on Managing variations in CPP-dependent countries

EFPIA Position Paper

Management of Variations in Certificate of Pharmaceutical Product-Dependent Countries

Executive summary

The current processes and timeline related to the management of variations in Certificate of Pharmaceutical Product (CPP)-dependent countries require modification in order to move towards a more unified and simplified system. The goal is to allow a timely implementation of Product Labelling and Quality changes locally, in relation with their approval in the relevant 'reference country'.

➢ **To access this EFPIA position paper, click on:**
http://www.efpia.eu/Content/Default.asp?PageID=559&DocID=7708

EFPIA Position on Managing variations in CPP-dependent countries

Scope

CPP-dependent countries across international areas

Purpose

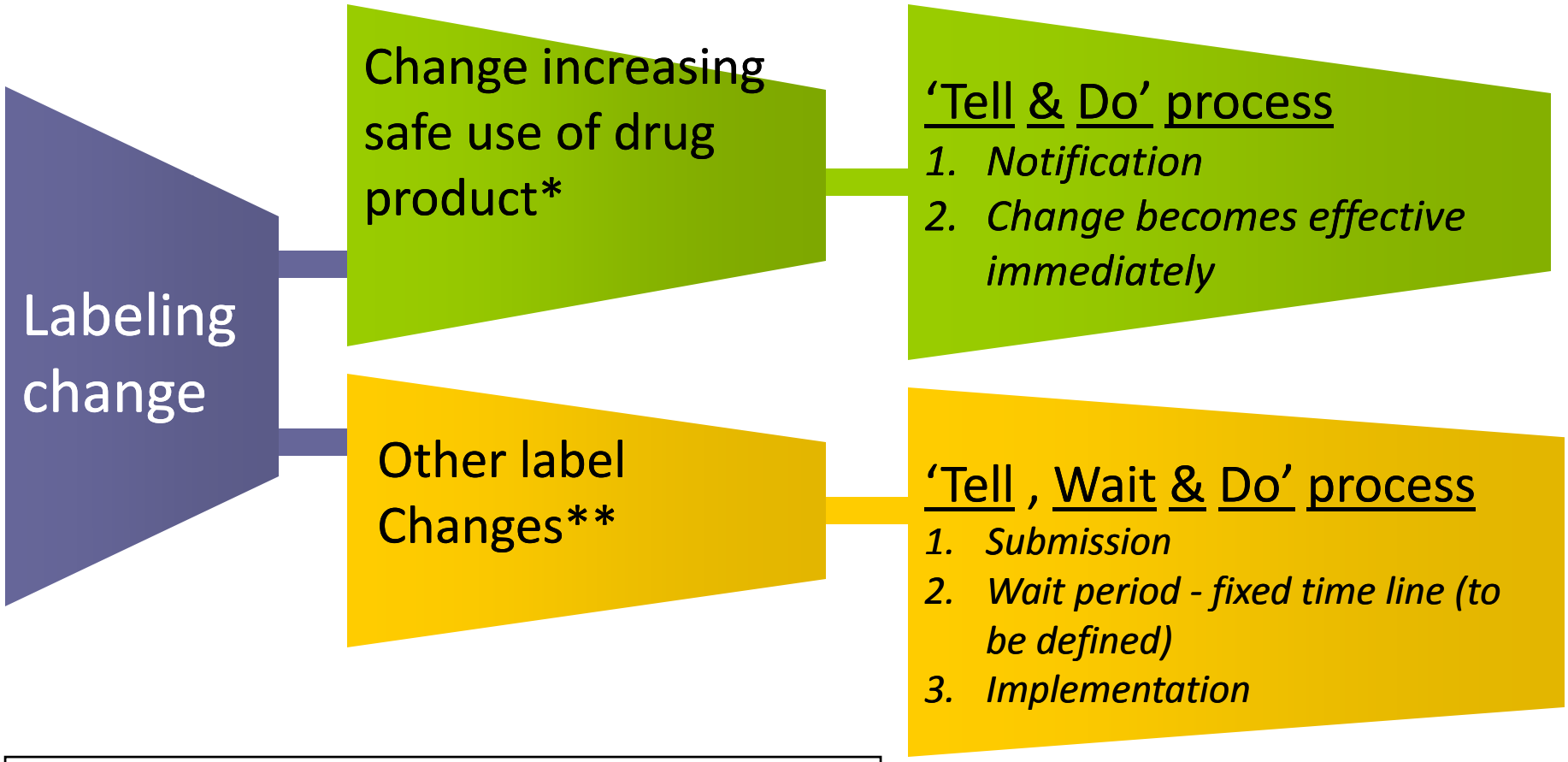
To move towards a more **unified, simplified and predictable system**

In order to allow **timely implementation** of Product Labeling and Quality changes locally, in relation with their approval in the relevant 'reference country'

As per local regulations, a variation should be **approved in a reference country** prior to being processed in CPP-dependent countries

EFPIA Position on Managing variations in CPP-dependent countries

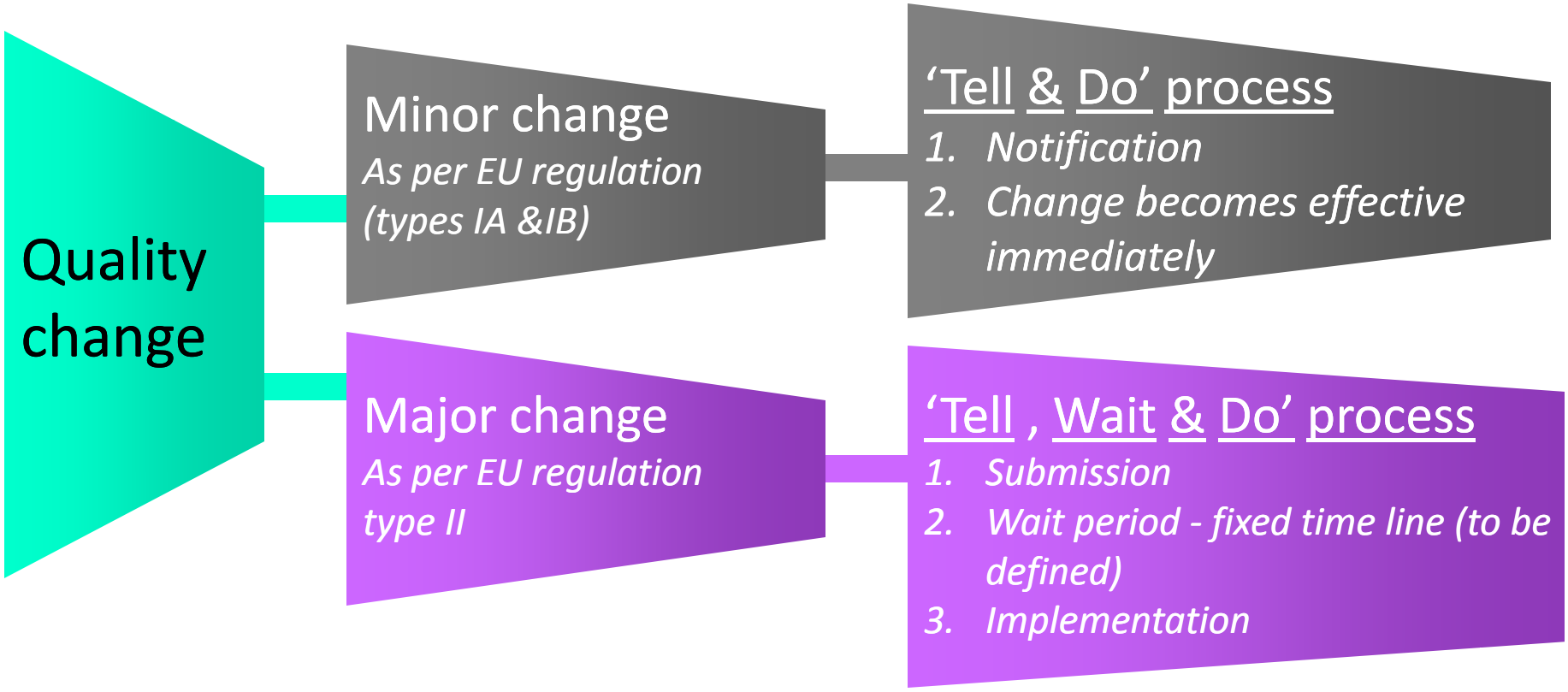
Proposal for managing labeling variations in CPP-dependent countries



* Includes -but not limited to- warnings, contra-indications, interactions
** Includes -but not limited to- indications, dosage and administration in line with approval in reference country.

Proposal for managing quality variations in CPP-dependent countries

whenever change is relevant to locally approved marketing authorization



Conference Conclusions

1.Harmonisation

- **Support the NEPAD initiative** to establish 5 regional centres
- Short Term Steps that can improve efficiency :
  - Establish, SOON, a **common (single) CTD for Africa**
  - **Collaborative GMP inspections**
  - Fast-tracking of reviews of "priority" medicines
  - Leverage the EU system for variations adopt EFPIA proposals
  - Harmonise Definitions of Variations and establish time- lines for review
- Establish "Road Maps" with agreed, realistic time lines
- **Continue to work with / Get involved in ICH GCG**

Conference Conclusions

2. Access

- Regulatory Capacity : Recruitment, TRAINING, retention of skilled regulatory agency staff (including FDAAA II)

3. Pharmacovigilance

- More awareness of all stakeholders and training of MRA staff and share current best practice in Africa

4. Combating Counterfeit Medicines

- Develop “pan Africa” SYSTEMS (transnational movement of goods)

5. “Consultation” and “Partnership”

- Ask the pharmaceutical industry for input when developing policy and processes

6. Follow up Workshops in the regions during 2010/11

THANK YOU TO:

- **SAPRAA Committee for promoting the Conference**
- **SAPRAA Membership for Attendance**