EDCTP consultative meeting, 11 June 2007
Room M105

Vaccine regulatory issues in African countries :

Building & sustaining national capacity

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World Health Organization (WHO)

With input from :
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World Health Organization

Outline of the presentation

1. Issues and challenges met by vaccine regulatory systems in Africa
2. WHO framework to strengthen vaccine regulatory systems
3. Progress, achievements and constraints
4. WHO priorities 2007-2010

Issues & challenges for regulatory systems in Africa

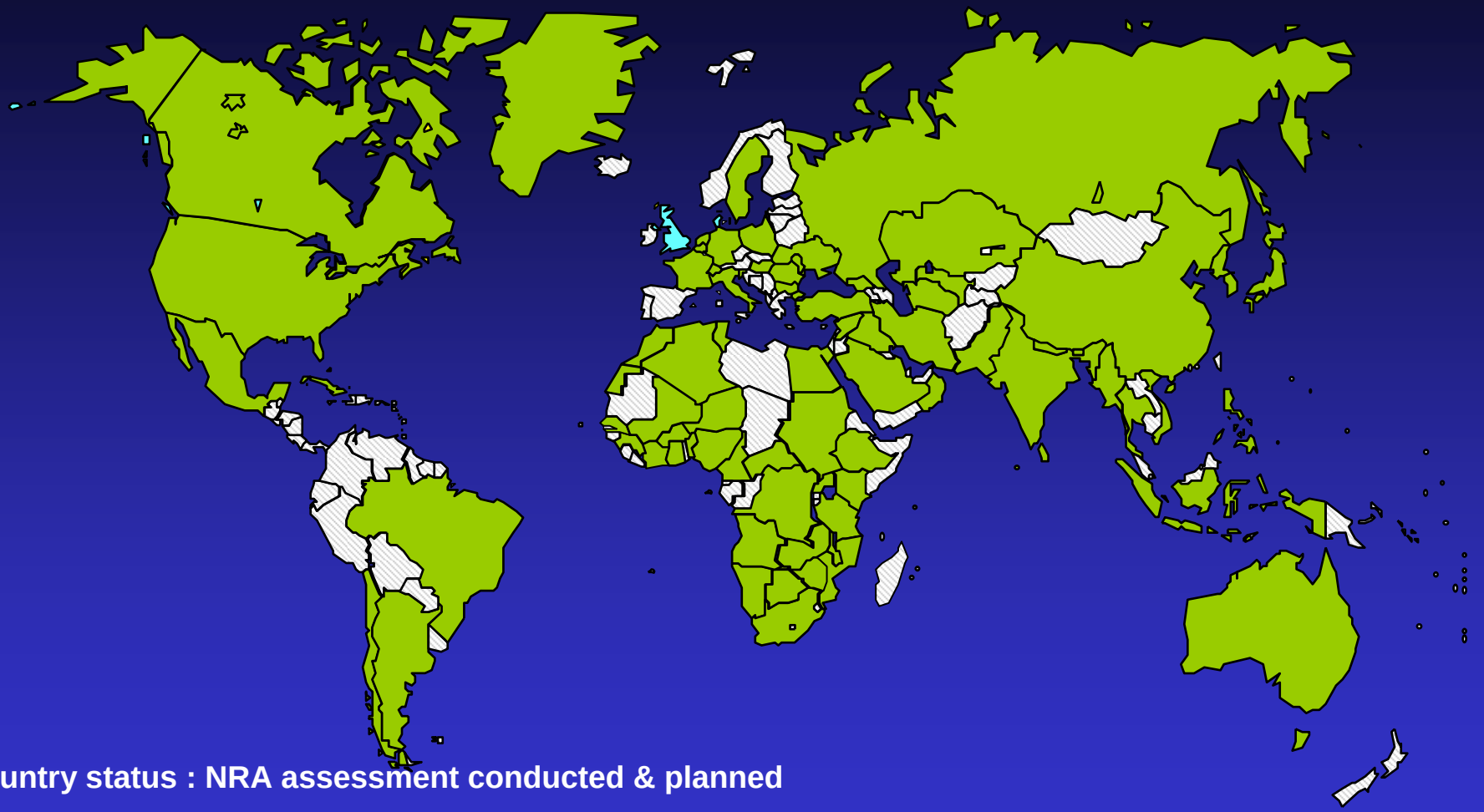
Regulatory issues

- No/weak regulations or not consistent with international standards
- Overlap/conflict of roles/duties among institutions (NRA & Ethics)
- Limited knowledge of foreign sponsored regulations
- Absence of provision for expedite reviews
- National regulation/Guidelines in place require updating (as per article 58, WHO Experts Committees (ECBS) & guidelines)
- No/limited regulatory framework for oversight of clinical trials
- Limited/no Pharmacovigilance & laboratory capacity

Managerial issues

- Limited human resources and expertise in new areas
- Lack of funding to build capacity
- No or limited access to local manufacturing capacity
- Limited exchange/sharing regulatory information to guide decision making
- Sponsors & manufacturers interfere and influence NRAs

INVENTORY OF VACCINE REGULATORY SYSTEMS: 86 NRAs assessed, Oct.1998 - June 2007



Country status : NRA assessment conducted & planned

- NRA assessment conducted
- Not yet conducted
- To be completed in 2007

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National Regulatory Functions recommended to regulate vaccines

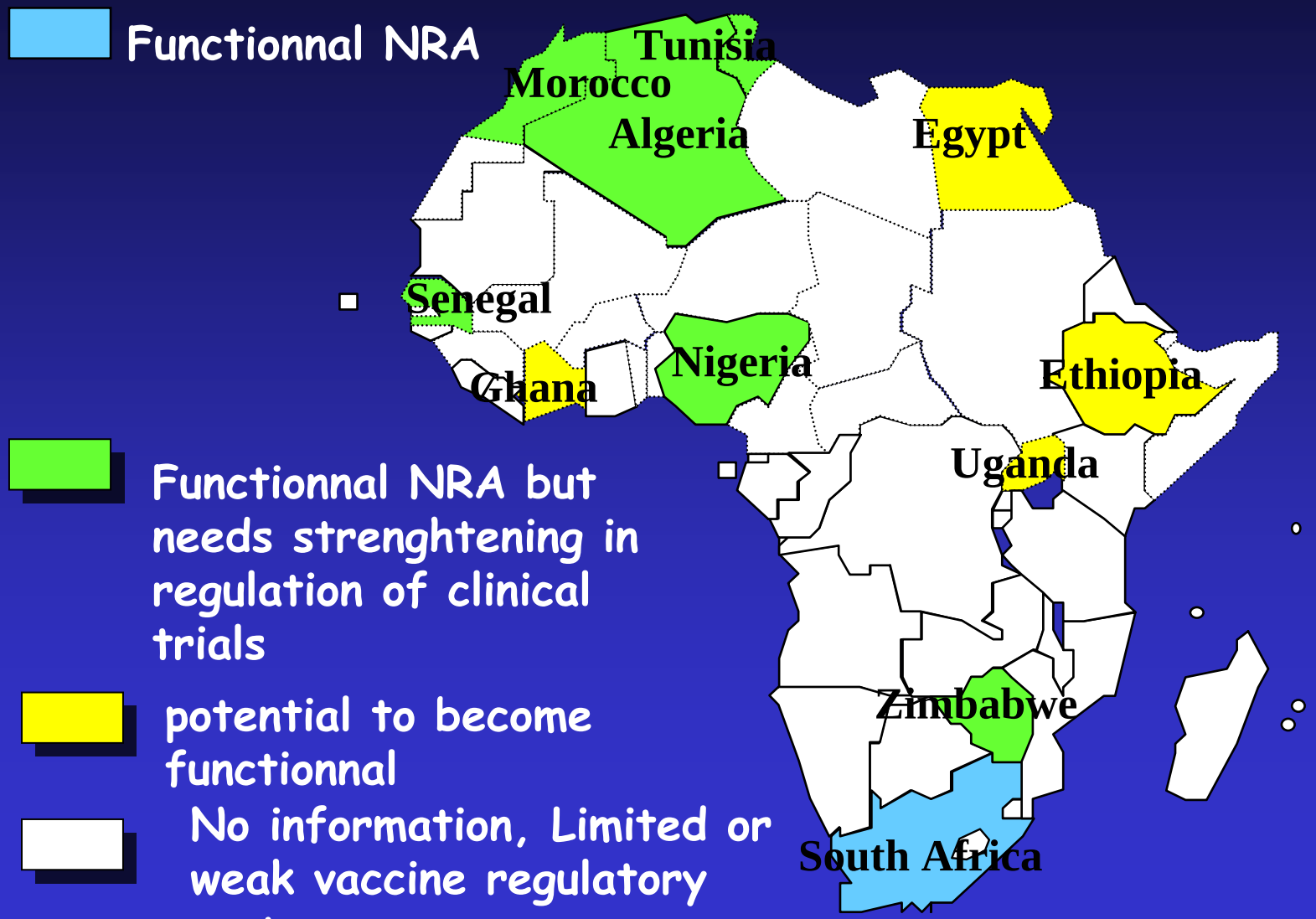
Regulatory functions

Regulatory functions	Source of vaccines: UN agency	Procure	Produce
Regulatory system	26 countries	19 countries	Senegal
Marketing Autorization & Licensing activities	Functions undertaken in producing Countries with functional NRA		
Postmarketing: AEFI			
Lot release			
Laboratory access			
Regulatory inspections			
Authorization & monitoring of CTs	✓	✓	✓

in countries that conduct clinical trials

CTs : Clinical trials, UN: United Nations, AEFI: Adverse Events Following Immunization

FUNCTIONNAL NRA THAT HAVE CAPACITY TO REGULATE VACCINES , AFRICA, July 2006



By end of 2010 : 37 out of 46 COUNTRIES WILL HAVE DEVELOPED APPROPRIATE CRITICAL REGULATORY FUNCTIONS

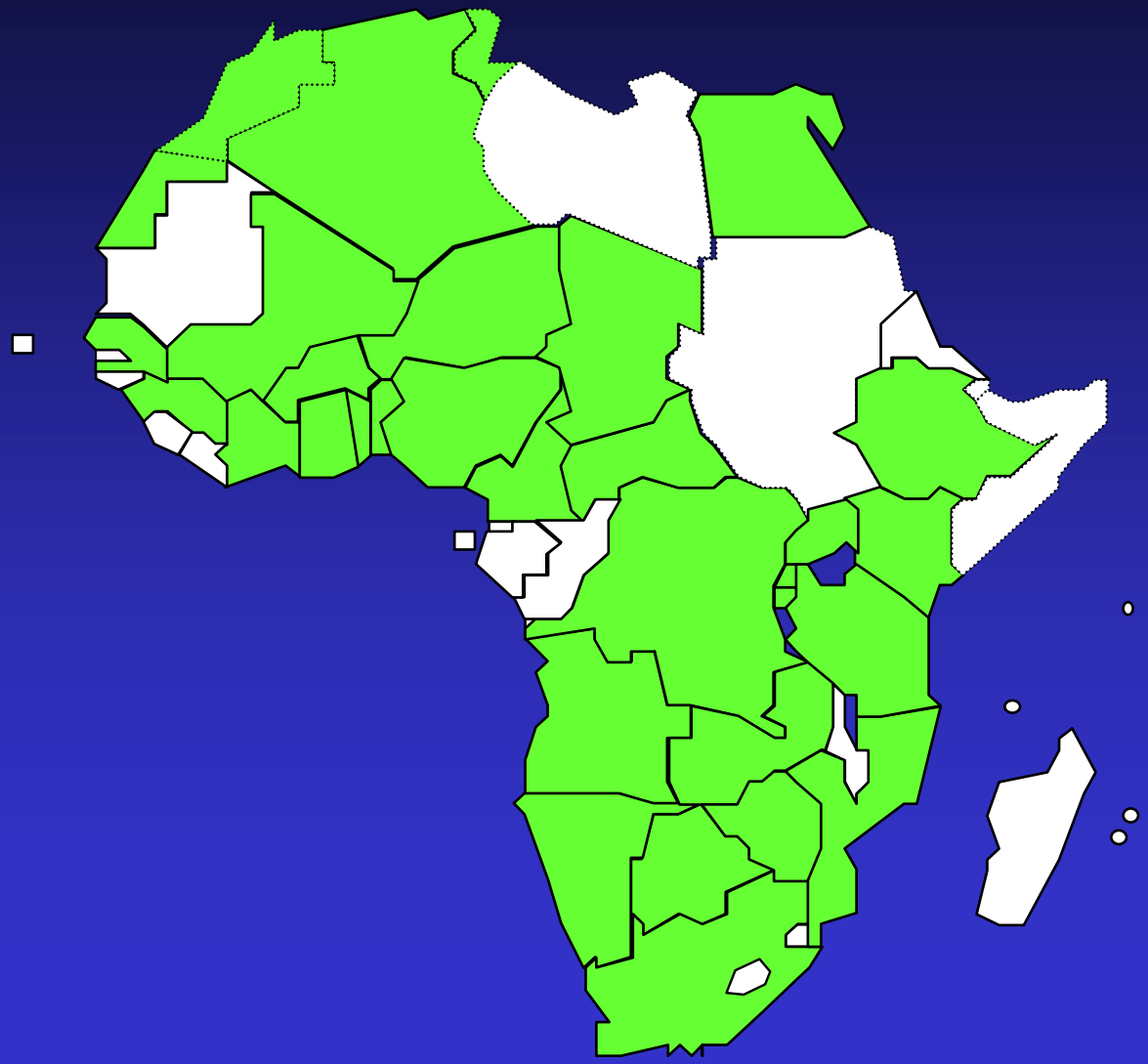
2006: 6 countries

2007: 6 countries

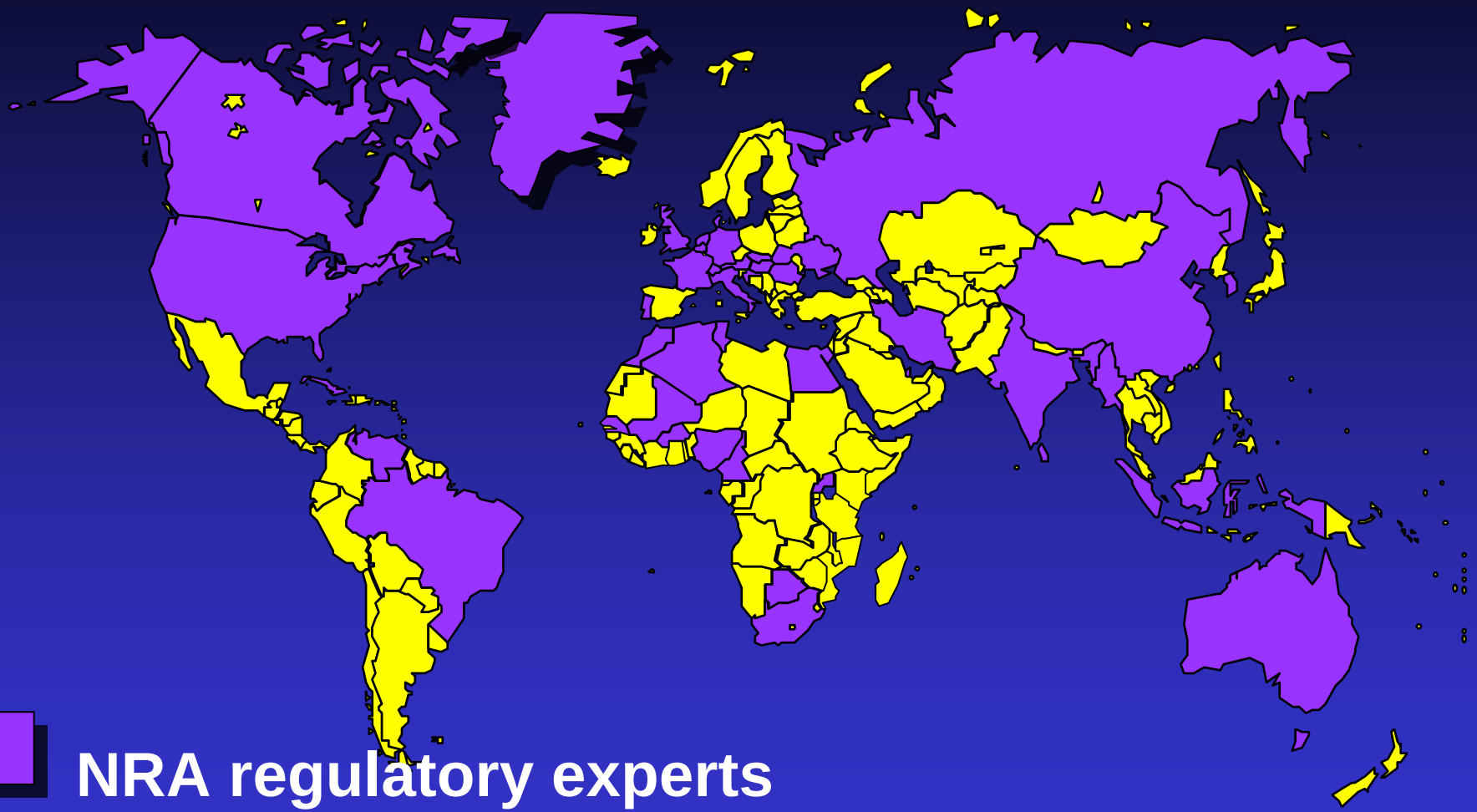
2008: 8 countries

2009: 8 countries

2010: 9 countries



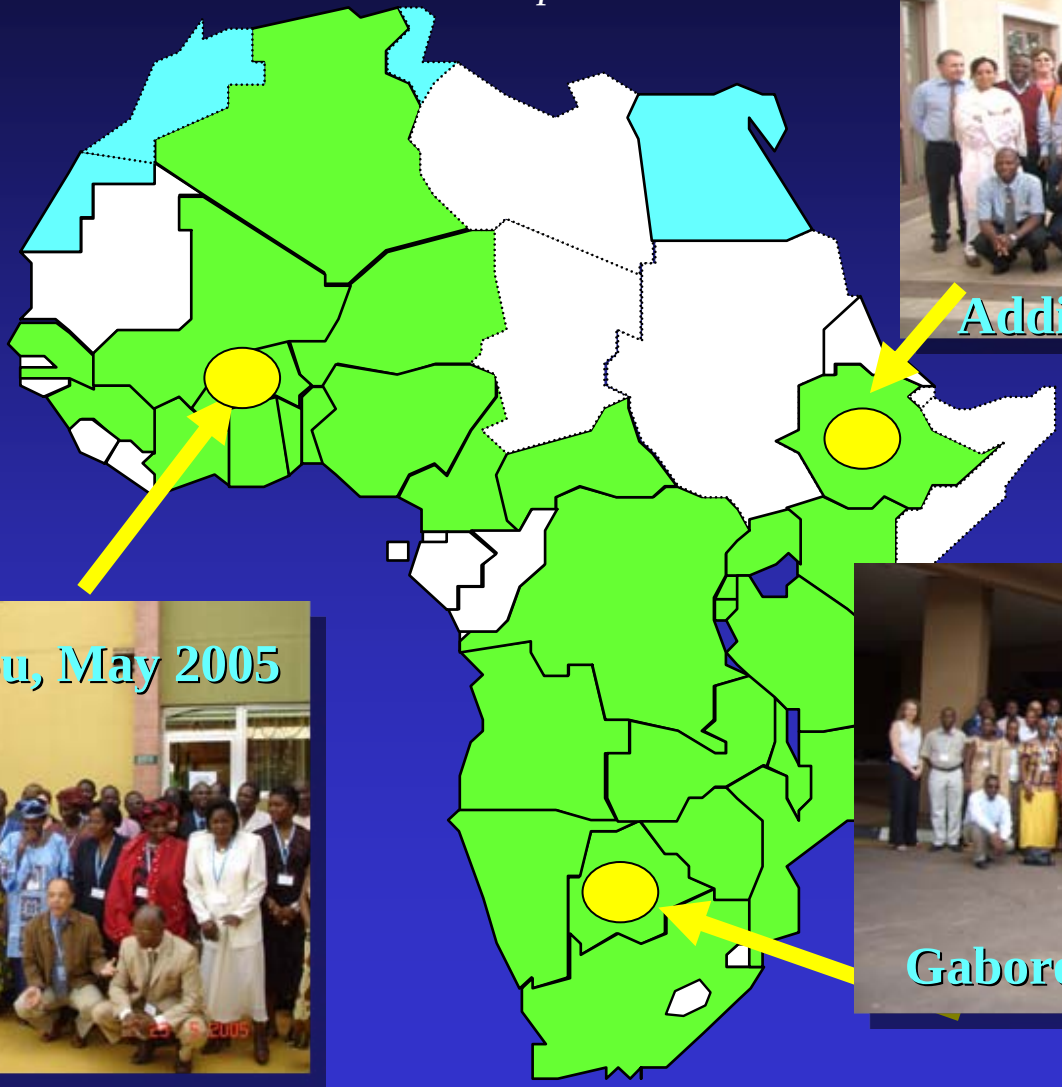
350 regulatory specialists available in the WHO global roster to assist countries to develop regulatory capacity (Oct.1998 – June 2007)



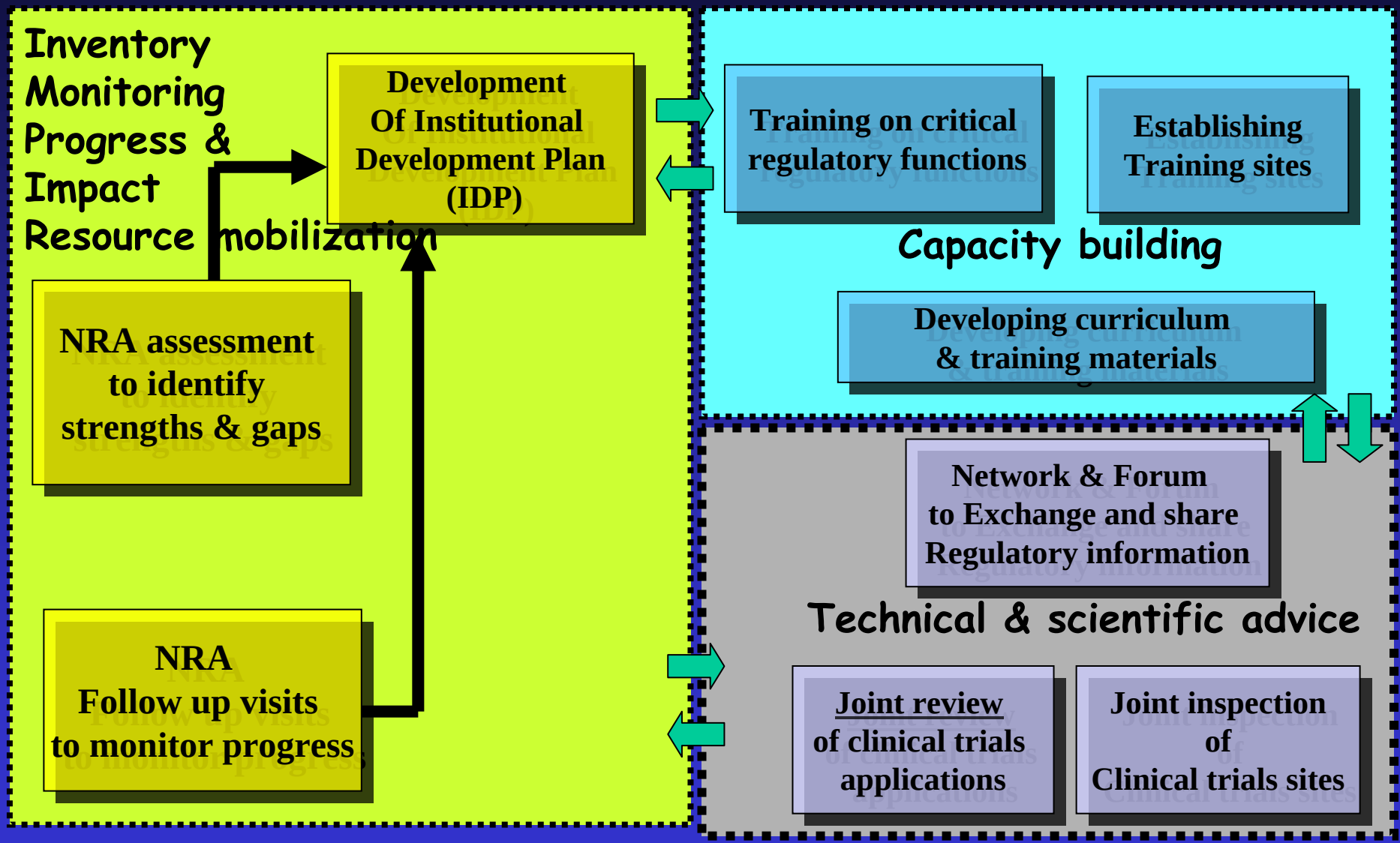
NRA regulatory experts

3 INTERCOUNTRY WORKSOPS CONDUCTED IN 2005 TO DEVELOP DEVELOP INSTIUTIONAL DEVELOPMENT PLAN (IDP) FOR 28 COUNTRIES

1. *Funded by : WHO & AAVP*
2. *EDCTP participated in theGaborone's workshop*



Framework to strengthen vaccine regulatory systems in Africa : Building and sustaining national capacity



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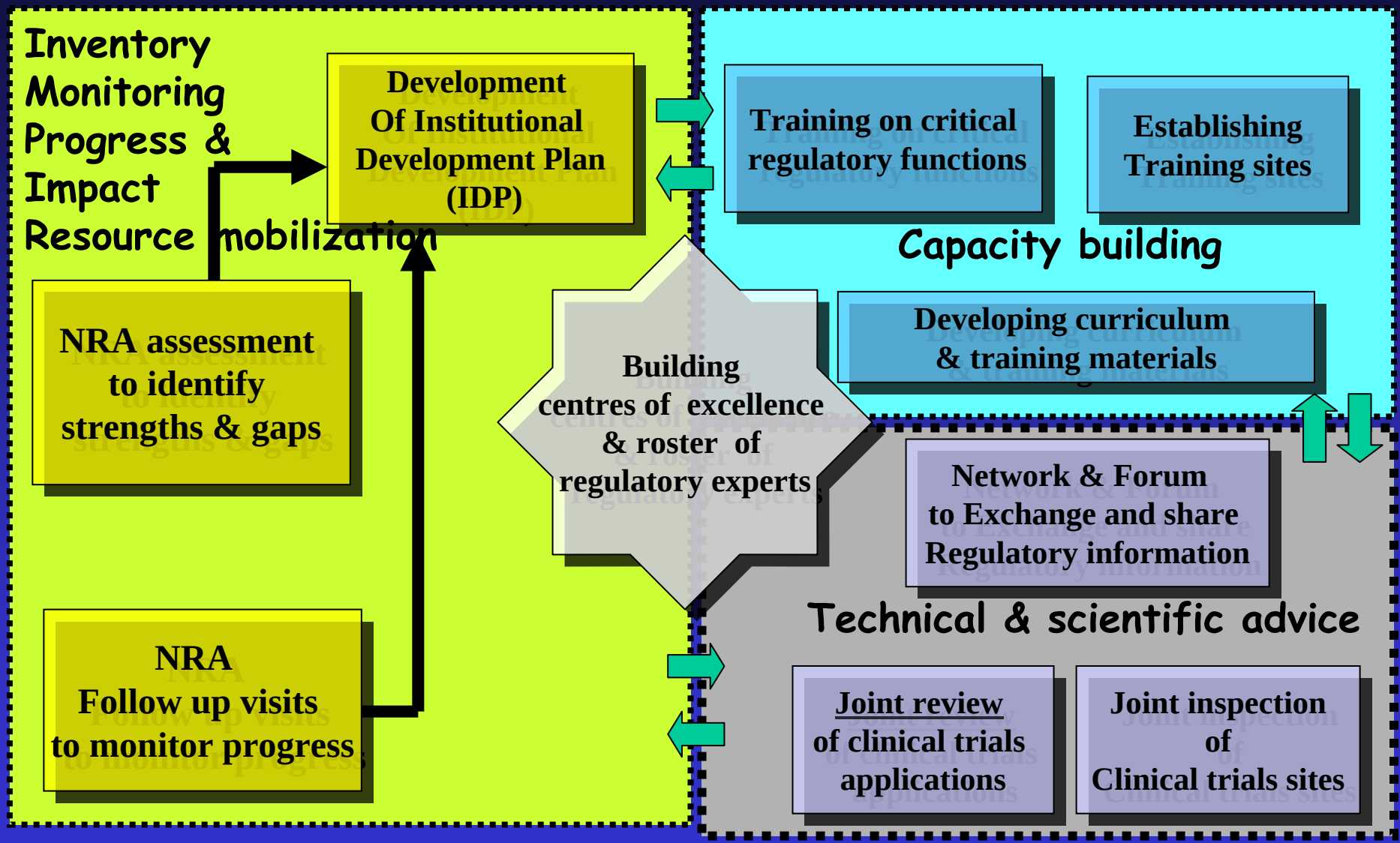
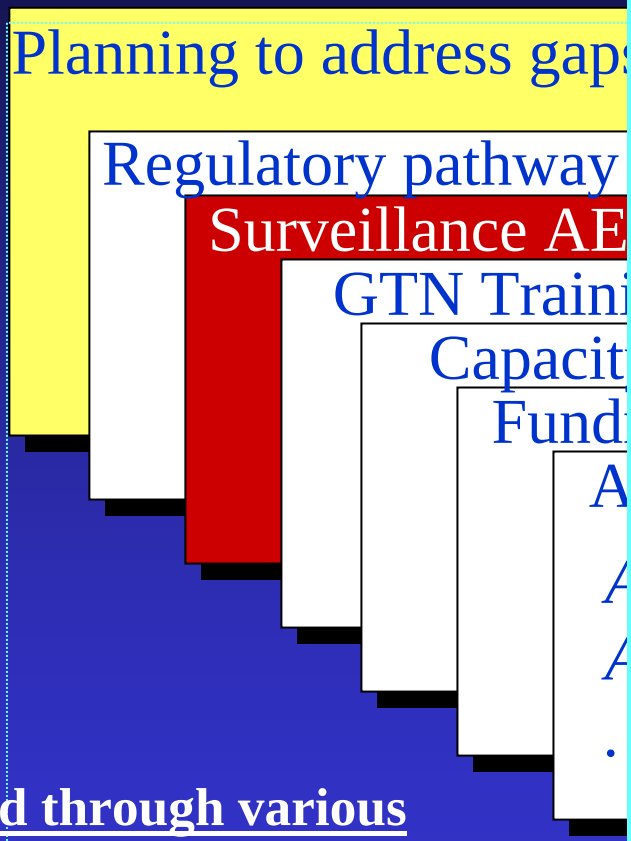


ACTIVITIES TO STRENGTHEN VACCINE REGULATORY SYSTEMS IN AFRICA

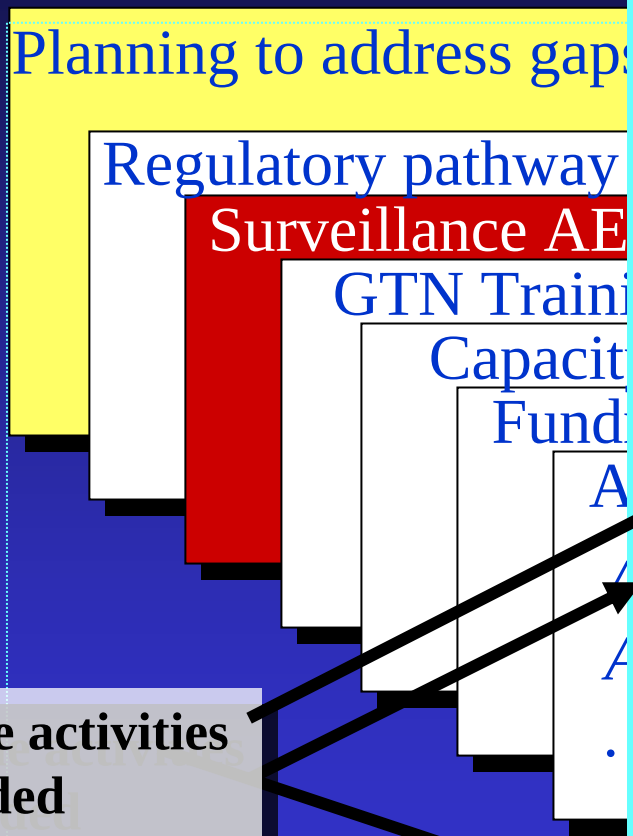


Funded through various Sources: MVP/PATH, WHO, EDCTP, GAVI, CIDA, etc..)

* Institutional Development Plan (IDP)

Activities conducted	Status
1.Ressource mobilization activities: EDCTP, CIDA, Bill Melinda Gates, AFDB, IDB)	Completed with EDCTP, CIDA and B&M.
2. Three NRA planning workshops countries with IDP* for 28 countries	Completed
3. Network meetings: Developing Countries vaccines regulatory network (DCVRN) & AVAREF (African Vaccine Regulatory forum, Accra, Ghana)	Completed
4.Joint review of CTs applications for MeningoA + Workshop on regulatory procedures for clinical evaluation of vaccines+forum for the evaluation of clinical data of rotavirus vaccines for registration purposes	Completed
5. Sensitization/advocacy workshop for all country stakeholders (Uganda & Senegal)	2 out 3 completed
6. GTN training provided to AFR countries on vaccine regulation: CTs (3 training) , AEFI/PMS (1 training), Vaccine regulation (1 training) & Lot release (1 training), Monitoring of CTs (1 training)	18 out of 28 countries completed

ACTIVITIES TO STRENGTHEN VACCINE REGULATORY SYSTEMS IN AFRICA



Activities conducted	Status
3. Network meetings: Developing Countries vaccines regulatory network (DCVRN) & **AVAREF (African Vaccine Regulatory forum, Accra, Ghana)**	Completed
4.Joint review of CTs and joint inspections for MeningoA + Workshop on regulatory procedures for clinical evaluation of vaccines+forum for the evaluation of clinical data of rotavirus vaccines for registration purposes.	Completed
6. **GTN training provided to AFR countries** on vaccine regulation: CTs (3 training) , AEFI/PMS (1 training), Vaccine regulation (1 training) & Lot release (1 training) Inspection of CTs (1 training)	18 out of 28 countries completed

* Institutional Development Plan (IDP)

1st AVAREF meeting, Sept.2006
African Vaccine Regulators Forum

1. Participants: 19 Countries, NRA and Ethics committee + EDCTP.
2. Experienced NRAs: EMEA & US FDA .
3. Product sponsors: GSK,MVPPATH, WRAIR, US NIH.
4. Themes : selected disease of importance : HIV, malaria, Meningo A & Rotavirus, regulators.
5. Funded by: WHO, EDCTP; MVP/PATH , RVP/PATH and AAVP.
6. Issues: Low funding for NRAs, conflict of interest, limited resources, lack of understanding of roles of NRA/Ethics committess, separate institutions, access epidemiological data, laboratory capacity, ADR investigation, information sharing network

Recommendations:

- Need to expand and sustain capacity building in vaccine trials oversight
- Joint review of clinical trial application should be expanded
- Strong interest in conducting joint inspection of clinical trials sites
- Increase training opportunities to develop regulatory capacity
- Develop guidance for clarification roles of NRA & ethics committees
- Pharmacovigilance provision re article 58 should be flexible for implementation
- Develop clinical trials case definition of efficacy for malaria vaccines
- Secretariat 's forum is hosted in WHO/AFRO

CHANGES DOCUMENTED BETWEEN TO IMPROVE REGULATORY OVERSIGHT OF VACCINES

The Gambia
(ongoing)

Senegal

Burkina Faso

Ethiopia

Cameroon

Mali
(ongoing)

Ghana
(ongoing

1. Plan developed and implemented for all countries involved
2. Training planned and conducted for all countries involved
3. Template procedures to evaluate CTs applications
4. Amended regulation to Involve NRA in evaluation of CTs
5. Clarification of roles/responsibilities to authorize CTs
6. Focal point & training requested for staff
7. Guidelines discussed , amended for endorsement by MoH
8. Coordination among NRA/Ethics Committee to authorise CTs
9. 1st African Vaccine regulators forum (Ghana, Accra, Sept.2006
10. Inventory of CTs and plan for registration to WHO registry

Nigeria
(ongoing)

South Africa
(expert's input)

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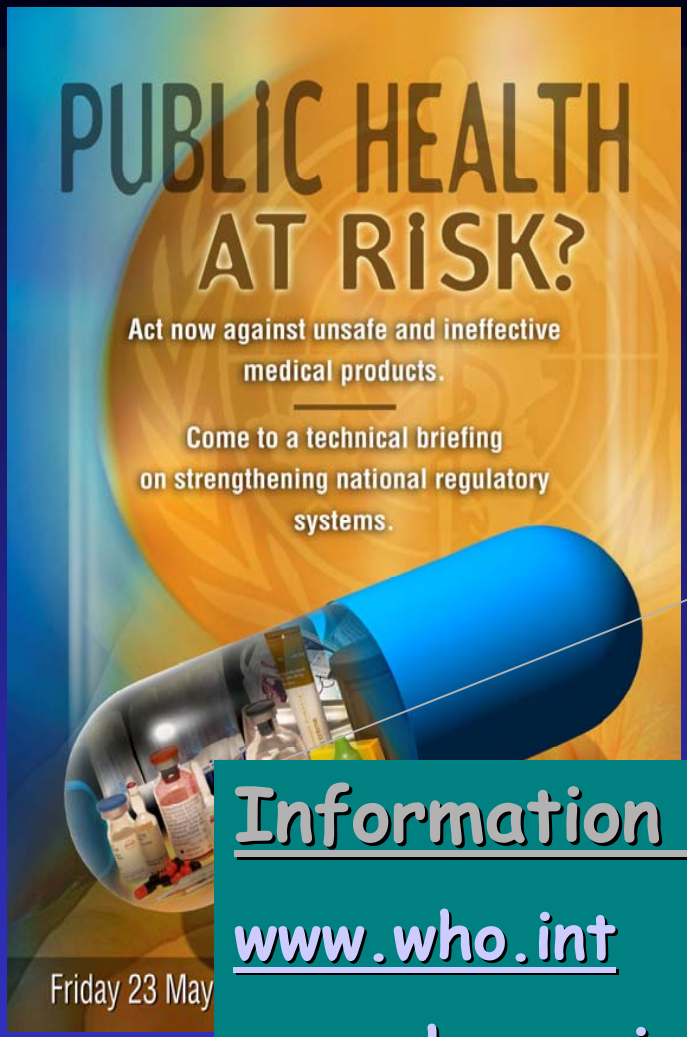
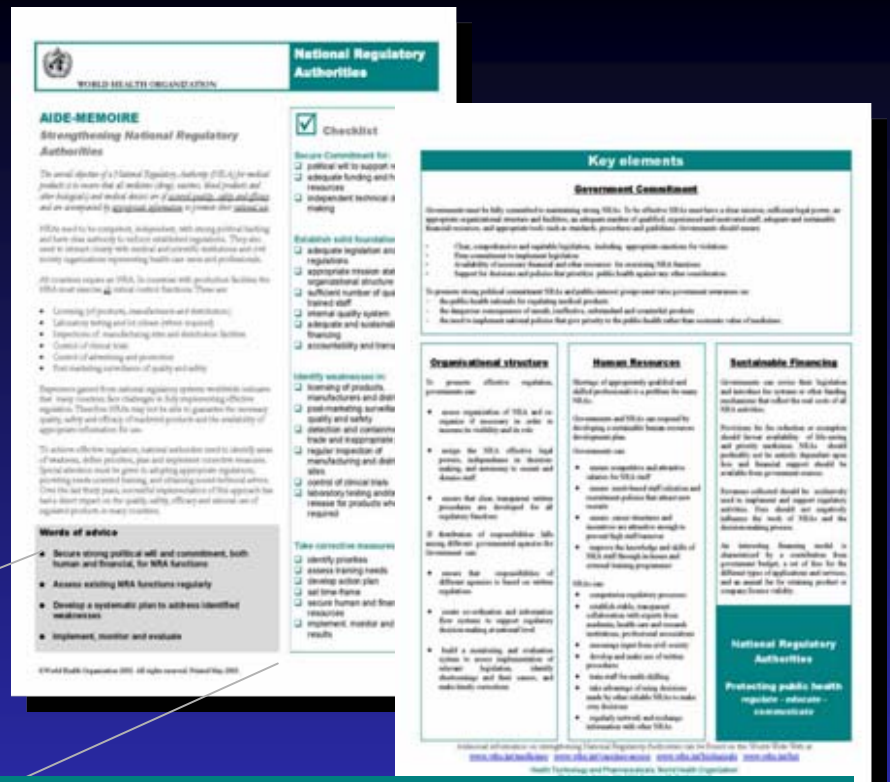
Priorities 2007-2010
Aim: Build and sustain national capacity

1. **AVAREF *meeting to be continued yearly**: it provides a forum for networking, exchange of information, and discussion of questions related to the specific issues involved in regulating trials for vaccines.
2. **Development of Centres of Excellence** to support, between the meetings, the needs identified by AVAREF.
3. **GTN training activities** to be sustained and expanded for African regulatory staff, ethics committee representatives and relevant African scientists involved in vaccine clinical trials.
4. **GTN additional training curriculum** needs to be developed to address the third step of clinical evaluation, which is the evaluation of clinical data for licensing purposes
5. **Regional coordination:** the need to expand the project and to cover a wider range of activities suggests that appropriate staff resources needs to be allocated for regional coordination of the project.

*** AVAREF: African Vaccine Regulatory forum**





Information sources for regulators

www.who.int

www.sharepoint.who.int/ATT (access upon request, used as space to share information with all country participants and partners (eg. EDCTP, UNICEF, NRAs, NCLs, Ethics, etc)