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Regulatory and Ethics Environment, Difficulties and Challenges

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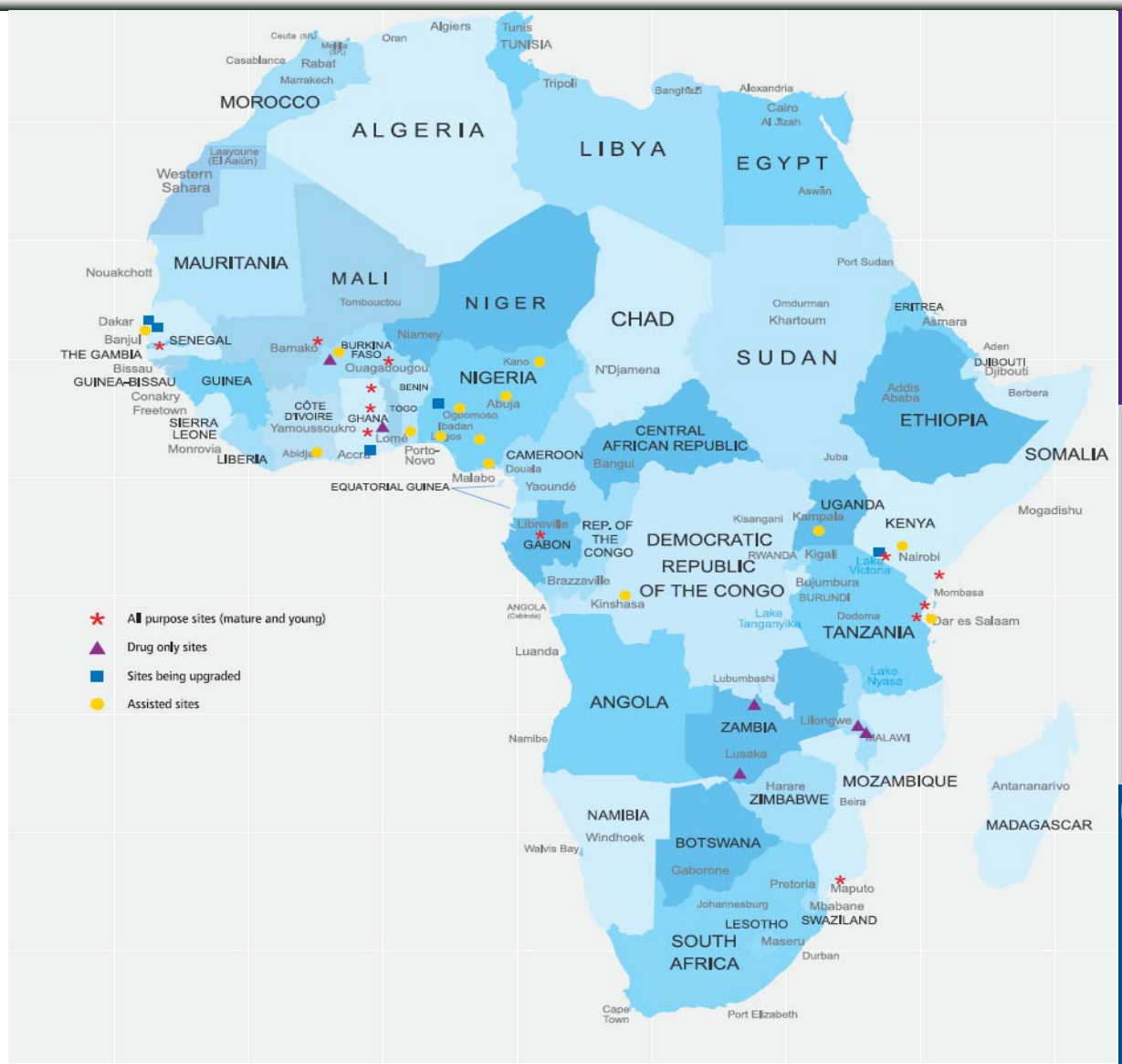
Preamble

- Increased funding for R&D on diseases of poverty in Africa
- Subsequent increased need for functional regulatory and ethical reviews
- Substantial improvements in the ethical framework
- Regulatory environment largely remaining weak
- Unprecedented and changing trends pose a challenge for products primarily not intended for the developed world.



6 MATURE ALL-PURPOSE SITES

1. US Army Medical Research Project-Kenya (USAMRU-K), Kisumu (Kenya)
2. Wellcome Trust/KEMRI, Kilifi (Kenya)
3. Malaria Research and Training Centre (MRTC), Bancoumana, Bandiagara, Doneguebougou (Mali)
4. Centro de Investigação em Saúde da Manhiça (CISM), Manhiça (Mozambique)
5. Bagamoyo/Ifakara Health Research & Development Centre (IHRDC), (Tanzania)
6. Medical Research Council (MRC): Basse, Banjul/Fajara, Farafenni (The Gambia)

6 YOUNG ALL-PURPOSE SITES

1. Hospital Albert Schweitzer (HAS): Lambarene, Libreville (Gabon)
2. Agogo Clinical Trial Centre, Kumasi Centre for Collaborative Research (KCCR) in partnership with the School of Medical Sciences (SMS), Kumasi (Ghana)
3. Kintampo Health Research Centre (KHRC), Kintampo (Ghana)
4. National Institute for Medical Research (NIMR), Tanga (Tanzania)
5. Navrongo Health Research Centre, Navrongo (Ghana)
6. Centre National de Recherche et de Formation sur le Paludisme (CNRFP), Oubritenga/Ouagoudougou (Burkina Faso)

6 DRUG-ONLY SITES

1. Centre de Recherche en Santé de Nouna (CRSN), Nouna (Burkina Faso)
2. Blantyre Malaria Project Research Clinic, Ndirande, Blantyre (Malawi)
3. QE Hospital Malawi-Liverpool- WellcomeTrust Research Programme (MLW), (Malawi)
4. Malaria Institute at Macha, Choma (Zambia)
5. Tropical Diseases Research Centre (TDRC), Ndola (Zambia)
6. Komfo Anokye Teaching Hospital (KATH), Kumasi (Ghana)

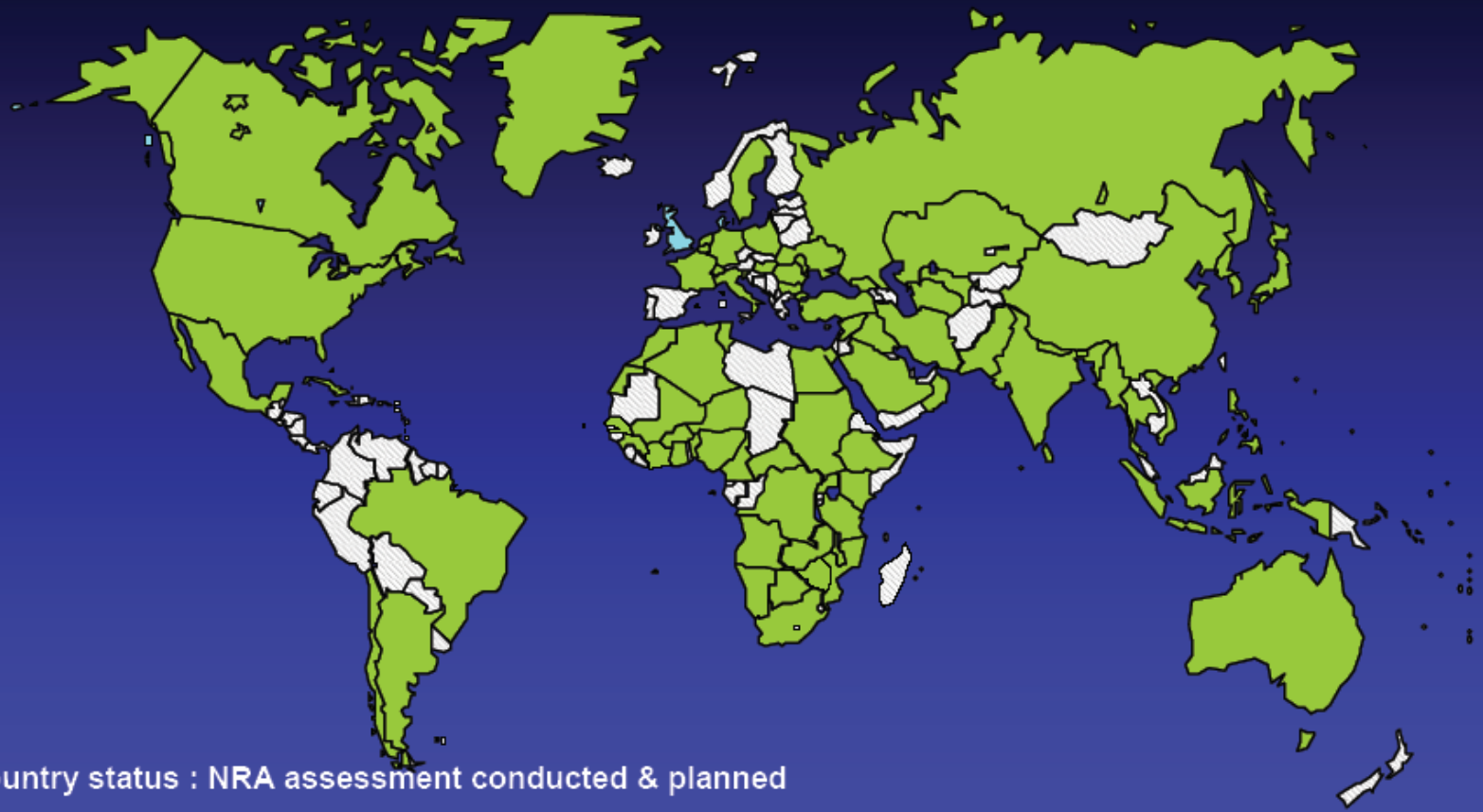
THE MALARIA PRODUCT PIPELINE: PLANNING FOR THE FUTURE

HEALTH POLICY DIVISION
THE GEORGE INSTITUTE FOR INTERNATIONAL HEALTH

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

World Health Organization, HTP/IVB/ATT. LBelgharbi

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



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World Health Organization, HTP/IVB/ATT. LBelgharbi

Ethical Review Capacity in Africa

- A study in early 2000 showed that 36% of WHO member countries did not have ERCs/IRBs
- AMANET conducted African ERC/IRB Needs Assessment Survey: probably the biggest survey of Africa to date
- 28 committees surveyed across Africa; analysis in progress
- AMANET Survey covers
  - Availability of resources for the committees
  - Training needs of ERC/IRB members
  - Availability of SOPs
  - Data Management and archiving systems
- To address the needs, US$50,000 capacity strengthening grants to be given to 21 Ethics Committees

Issues

Regulatory

- Product registration and marketing traditionally hrough colonial lines
- Few NRAs formally exist
- In Africa, 53% of NRA's - limited or no capacity, 37% - basic capacity and only 10% moderate capacity (WHO, 2006)
- Registration processes outdated
- Unapproved and unregulated products circulating on markets (WHO2005; 30% in Kenya)
- Inadequately monitored and un approved clinical trials
- Inadequate pharmacovigilance
- Emerging regulations - article 58 EU

Ethics

- Frameworks improving but generally below expected international standards
- Inadequate training of Ethics Committee members
- Limited professional and educational diversity in the committees
- Limited experience and knowledge of reviewing and monitoring complex clinical trials
- Cumbersome paper-based data management and archiving system
- Generally, resource-constrained
- Various positions regarding standard of care issues; during and post-study

On going efforts

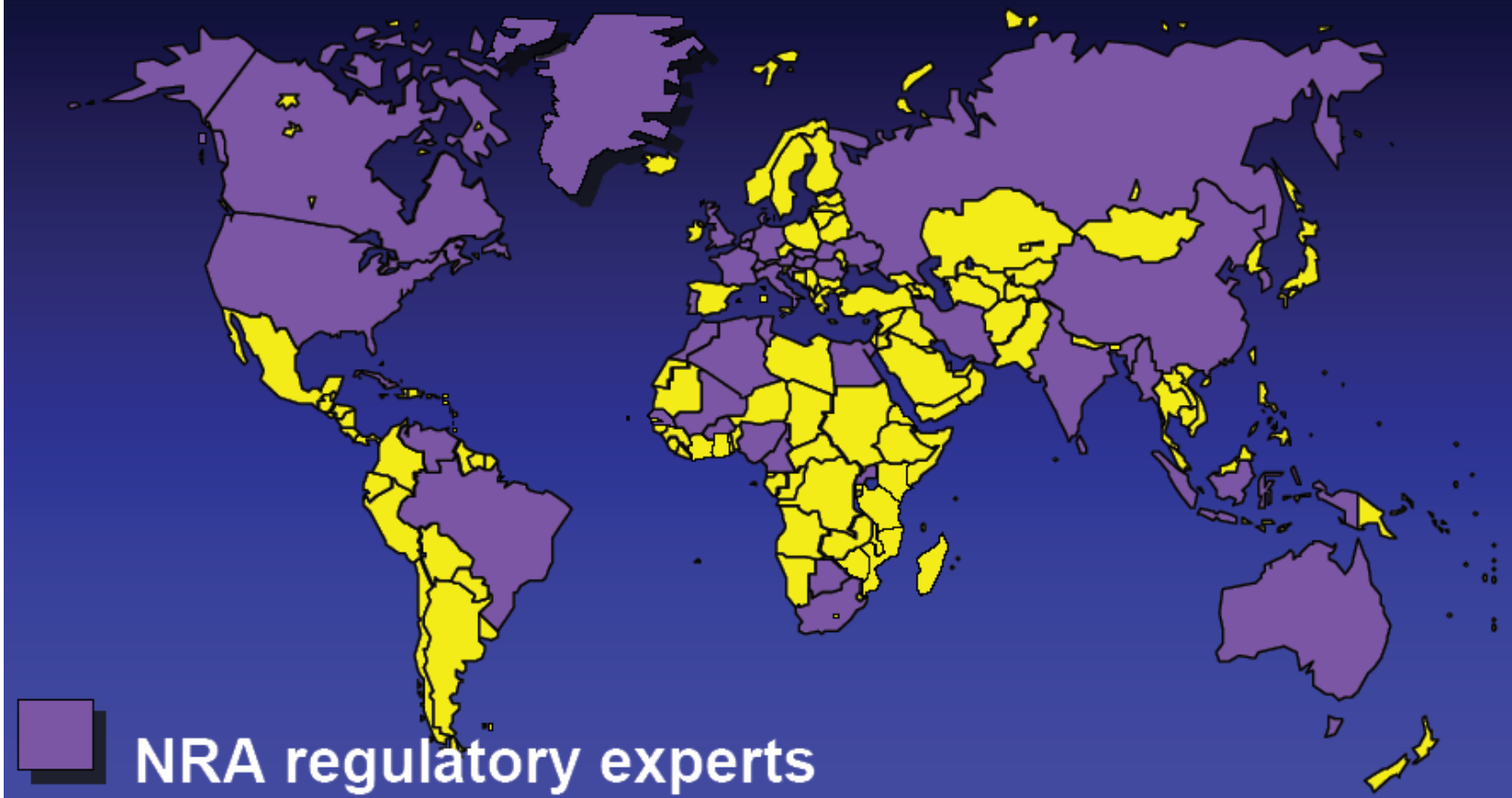
Regulatory

- Joint reviews
- AVAREF
- Global Training Network
- Regional harmonisation of guidelines – SADC
- DCVRN

Ethics

- EDCTP
- On going AMANET survey + capacity building project
- PABIN
- SARETI-South African Research Ethics Training Initiative

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



NRA regulatory experts

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

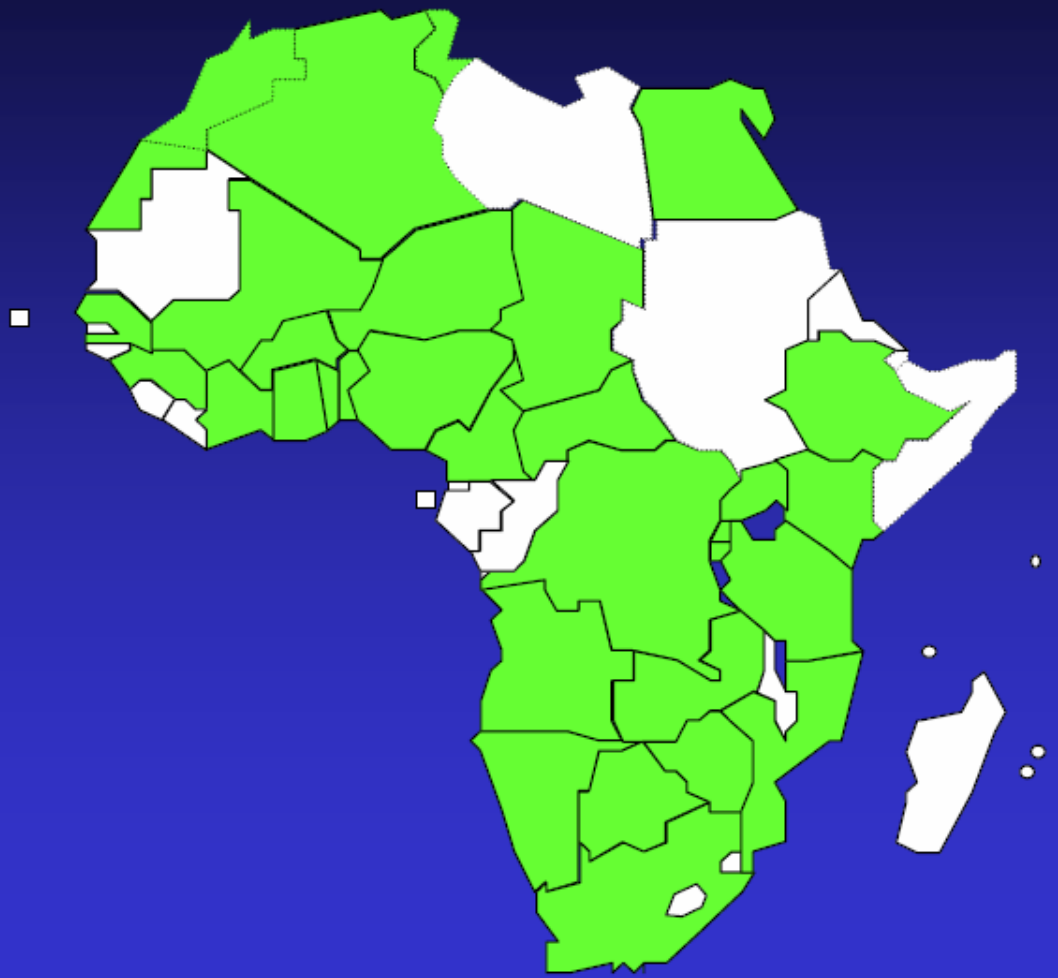
2006: 6 countries

2007: 6 countries

2008: 8 countries

2009: 8 countries

2010: 9 countries



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Competing challenges

Capacity issues

- Weak/No regulations
- Lack of skilled human resources for review of IDD dossiers
- National Regulations needs to be updated in response to emerging international regulations (Process of articulating applicable laws by governments)
- Development of pharmacovigilance systems by local Authorities
- Regulatory Pathway for IND***
- Process of regional harmonization of regulation

Managerial/Operational

- Inadequate staff
- Minimal solicitation from external expertise (42%, WHO 2006)
- Most financed from state budget with revenues generated paid in public treasury
- Sponsors & manufactures ("unintended")interference and influences

Recommendations

- Continue support Networks…
- Development and Harmonization of SOPs/Guidelines for Ethics Committees and NRAs in Africa is crucial

- Accelerated Regulatory Pathway
  - better synergy, option for parallel and reduction in duplication between article 58 procedures and PQ,
- Its unethical to restrain life saving products only because of bureaucratic procedures

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Thank You