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Chances and Challenges of Local Production in Africa

International Conference Local Production and Access to Medicines: Discussion with Stakeholders from International Organizations, Donor Agencies, Pharmaceutical Producers and NGOs
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The World Health Organization (WHO) is the directing and coordinating authority on international health within the United Nations' system. WHO experts produce health guidelines and standards, and help countries to address public health issues. WHO also supports and promotes health research. Through WHO, governments can jointly tackle global health problems and improve people's well-being.

193 countries and two associate members are WHO's membership. They meet every year at the World Health Assembly in Geneva to set policy for the Organization, approve the Organization's budget, and every five years, to appoint the Director-General. Their work is supported by the 34-member Executive Board, which is elected by the Health Assembly. Six regional committees focus on health matters of a regional nature.

WHO ARE OUR PARTNERS IN HEALTH?

WHO and its Member States work with many partners, including UN agencies, donors, nongovernmental organizations, WHO collaborating centres and the private sector. Only through new ways of working and innovative partnerships can we make a difference and achieve our goals.

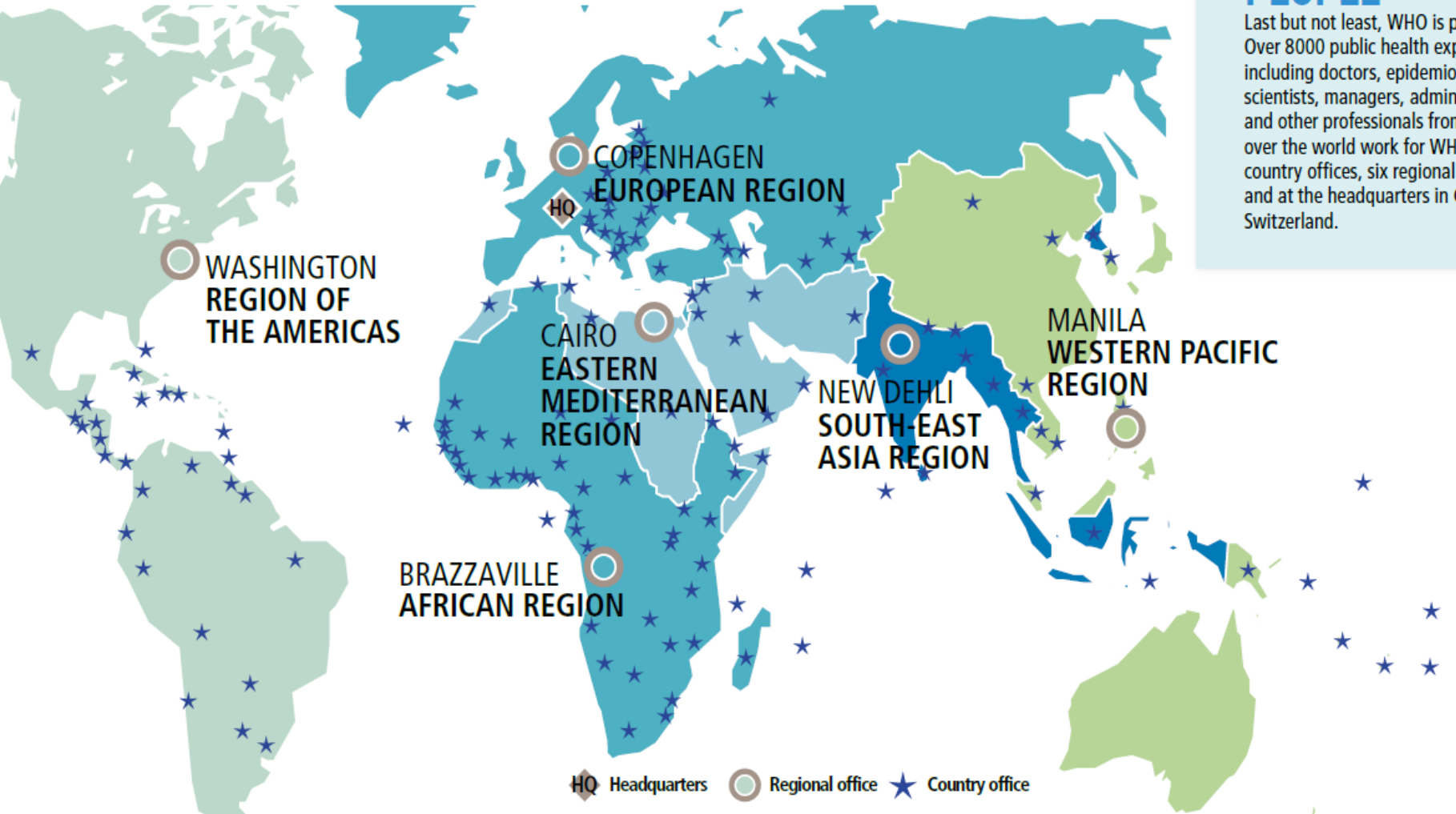
The World Health Assembly. WHO's 193 member countries meet to decide policy for improving health.

More about WHO
www.who.int/about/en/

WHAT IS THE WORLD

PEOPLE

Last but not least, WHO is people. Over 8000 public health experts including doctors, epidemiologists, scientists, managers, administrators and other professionals from all over the world work for WHO in 147 country offices, six regional offices and at the headquarters in Geneva, Switzerland.



HEALTH ORGANIZATION?

WHO activities in the field of health products regulation (medicines incl. biologicals, medical devices)

- Setting policies, norms and standards – for access, rational use, quality, safety and efficacy
- Assessment of national regulatory systems, regulatory support and capacity building
- Promoting regulatory harmonization and information exchange – safety, quality, best practices etc.
- Assuring safety and quality of selected products for United Nations family through prequalification programmes (medicines, vaccines, diagnostics)

Standards and WHO

- WHO is **mandated** to "*develop, establish and promote international standards with respect to food, biological, pharmaceutical and similar products*" *(Article 2, WHO Constitution)*;

- WHO Expert Committee on Specifications for Pharmaceutical Preparations
- WHO Expert Committee on Biological Standardization
  - *Both complimentary to ICH activities*

- Joint FAO/WHO Expert Committee on Food Additives

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Assessing national medicines regulatory systems

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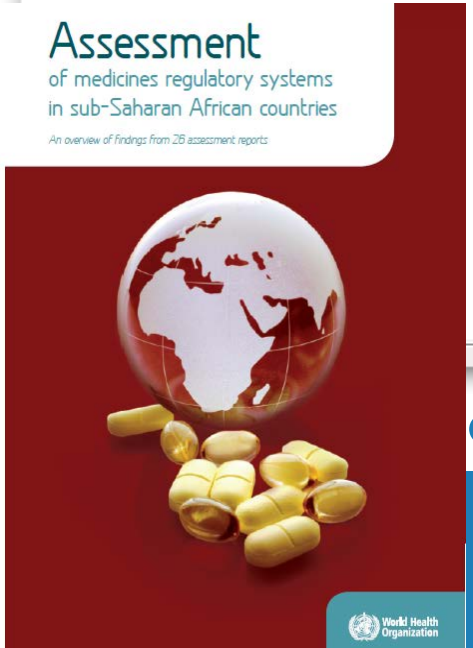
Assessing national medicines regulatory systems National Medicines Regulatory Authorities (MRAs) are responsible for the regulation and control of medical products such as medicines, vaccines, blood products and medical devices. They contribute to promoting and protecting public health by ensuring that:

- medicines are of the required quality, safety and efficacy,
- health professionals and patients have the necessary information to enable them to use medicines rationally,
- medicines are appropriately manufactured, stored, distributed and dispensed,
- illegal manufacturing and trade are detected and adequately sanctioned,
- promotion and adverting is fair, balanced and aimed at rational drug use,
- access to medicines is not hindered by unjustified regulatory work.

Intensification of international commerce and increasing technological complexity of manufacturing and product specifications have created additional challenges for national regulatory authorities and manufacturers, particularly to those of developing countries. This requires that national regulatory capacity is regularly



- http://www.who.int/medicines/areas/quality_safety/regulation_legislation/assesment/en/index.html

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International Conferences of Drug Regulatory Authorities (ICDRA)

- Biennial Global meetings bringing together regulators from around 100 nations
- Promoting information and best practices exchange, cooperation, harmonization and convergence
- Several initiatives started in ICDRA environment
  - ICH initial discussions
  - AMRH initiative initial discussions
  - Reports from various harmonization initiatives

New: Harmonization of pharmacopoeias

- Pharmacopoeial Discussion Group (PDG)
  - ICH parties - US, Japanese and European Pharmacopoeia
  - WHO observer

- Harmonization beyond PDG – WHO took initiative convening all functioning pharmacopoeias for further convergence and harmonization:

- The 1st International Meeting of World Pharmacopoeias, 29 February – 2 March, 2012, Geneva; Switzerland

- The 2nd International Meeting of World Pharmacopoeias, 18-19 April 2013, New Delhi, India

Prequalification programme – powerful engine for facilitating quality manufacture

http://apps.who.int/prequal/

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Dossier assessments
Prequalification of APIs
Inspections
Quality Control Laboratories
Quality Monitoring
Training material, workshops and meetings
Press and media

WHO - Health Systems and Services: Prequalification of Medicines Programme :: Site Map

PREQUALIFICATION PROGRAMME
A United Nations Programme managed by WHO

Vision

Good quality medicines for everyone.

Mission

In close cooperation with national regulatory agencies and partner organizations, the Prequalification Programme aims to make quality priority medicines available for the benefit of those in need.

This is achieved through its evaluation and inspection activities, and by building national capacity for sustainable manufacturing and monitoring of quality medicines.

Strategy

- Apply unified standards of acceptable quality, safety and efficacy.
- Comprehensively evaluate the quality, safety and efficacy of medicinal products, based on information submitted by the manufacturers, and inspection of the corresponding manufacturing

LATEST NEWS

Micro Labs' paediatric lamivudine tablet prequalified

Newly prequalified APIs

New WHO Assessment Report published

Speeding up access to quality medicines in Africa

Prequalification of medicines saves lives

WHO experts give risk rating for urgently needed medicines

Generic antiretroviral therapy is safe and effective

PQP response to claims of sub-standard antimalarials

Essential Medicines*

- Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness.

- Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford.

- Access to essential medicines as human right and as indispensable part of universal health coverage

Access to essential medicines remains a problem*

- In spite of progress, especially with communicable diseases (HIV/AIDS, malaria and TB), the access to essential medicines remains a huge problem
- Chronic diseases—mainly cardiovascular disease, cancer, chronic respiratory diseases, and diabetes—were estimated to cause more than 60% (35 million) of all deaths in 2005; more than 80% of these deaths occurred in low-income and middle-income countries.
- NCDs have negative impact on individuals, and family economic production and wellbeing. For example, estimated loss in national income from heart diseases, stroke and diabetes in 2005 were $18 billions in China, $11 billion in the Russian Federation, $9 billion in India and $43 billion in Brazil.
- Access to medicines for mental disorders remains poor – up 70% may not get treatment in low-income countries

Concept of local production*:
Specific to local production WHO activities

- Project: *Improving access to medicines in developing countries through technology transfer related to medical products and local production.*
- Implemented by the Department of Public Health Innovation and Intellectual Property of the World Health Organization (PHI/HIS/WHO) in partnership with the United Nations Conference on Trade and Development (UNCTAD) and the International Centre for Trade and Sustainable Development (ICTSD) with funding from the European Union (EU).
- Objective of the project: To increase access – especially for the poor in developing and least developed countries – to medicines, vaccines and diagnostics.

Special web site

http://www.who.int/phi/publications/local_production/en/index.html

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Local production for access to medical products

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Technology Transfer

Phase 1 of this project concentrates on identifying the main challenges and obstacles to local production of medical products and related technology transfer in developing countries. The aim of this work was to develop a framework that could bring together and guide policymakers and others from all relevant fields to support the local production of medicines, vaccines and diagnostics in a manner that should improve access maximizing the potential to improve public health.

The project is in the context of the Global Strategy and Plan of Action on Public Health Innovation and Intellectual Property supported with funding from the European Union. The outputs of phase 1 were published at a seminar in the European Parliament on 7 December 2011.

Relevant publications

- Local production for access to medical products: Developing a framework to improve public health, 2011
- Local production for access to medical products: Developing a framework to improve public health, 2011
- Trends in local production of medicines and related technology transfer, 2011
- Pharmaceutical production and related technology transfer: Landscape report, 2011
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- ....

Policy Brief

Local Production for Access to Medical Products
Developing a Framework to Improve Public Health

This briefing paper provides an overview of activities undertaken by WHO and its partners during the first phase of a project on the local production of medical products[1] for improved access in developing and least developed countries (LDCs). This is an action supported with funding from the European Union.[2] The project is in the context of the Global Strategy and Plan of Action on Public Health Innovation and Intellectual Property. The aim of phase 1 was to develop a framework and shared goals that could bring together and guide policy-makers and others from the fields of public health, trade, industrial policy and other relevant sectors (1).

Summary: a coherent, long-term policy approach is needed

- Ensuring access to medical products is a complex undertaking requiring governments, through their relevant policies, to balance the availability of quality assured medical products (supply side) with meeting priority public health needs with products that are acceptable and affordable (demand side).
- Supporting local production is one means by which governments in the developing world may seek to maintain this balance, and this project has reviewed many of these activities in a number of countries – with some demonstrating a real potential to make a difference in the area of improving access.
- Developing countries aspire to build and strengthen their domestic medical product industry. Trends show that local production is growing and diversifying in these countries through national efforts and with support from regional and international initiatives.
- However, the evidence for local production resulting in an improvement in access to medical products is inconclusive. In order to ensure a strong linkage between what is produced locally and what improves access, a comprehensive and system-wide approach is needed. This has to bring coherence between industrial, trade and health policies. From a public health perspective, support for local production should have the explicit intention of improving access to medical products.
- The framework paper and the related reports from phase 1 of this project contribute to the process of identifying the appropriate policy areas and actions that are needed so that governments can ensure that local production of medical products can contribute to the economic development of a country while also meeting its public health needs.
- WHO, working in collaboration with key partners, plans to promote and seek to implement this framework in phase 2 of the project globally, regionally and in a selected number of countries.

Outputs from phase 1 of the project

Phase 1 of the current project concentrated on identifying the main challenges and obstacles to local production of medical products and related technology transfer in developing countries. This work has been presented as a series of reports that are available for free download from the WHO website and includes the framework document.

1. *Local production and access to medicine in low- and middle-income countries: A literature review and critical analysis.*
2. *Trends in local production of medicines and related technology transfer.*
3. *Pharmaceutical production and related technology transfer: Landscape report.*
4. *Local production of pharmaceuticals and related technology transfer: A series of case studies.*
5. *Increasing access to vaccines through technology transfer and local production.*
6. *Increasing access to diagnostics through technology transfer and local production.*
7. *Local production for access to medical products: Developing a framework to improve public health.*

Background and context

Access to medicines remains a challenge in developing countries and it is an important part of the Millennium Development Goals (MDGs).[3] Surveys of medicine prices and availability have shown that public sector availability of a selection of generic[4] medicines is less than 60% across WHO regions (2).

1 In this phase, 'medical products' includes pharmaceuticals, vaccines and diagnostics.

2 This is an action under a European Parliament resolution to support pharmaceutical-related transfer of technology and capacity building for local production of medicines in developing countries, especially in least developed countries. *European Parliament Resolution on the TRIPS Agreement and access to medicines* (B6-0288/2007/Rs_TA (2007)0353).

3 MDG Target 8.e: In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries. See http://www.un.org/millenniumgoals/global.shtml

4 WHO defines generic medicines as: "Pharmaceutically equivalent or pharmaceutically alternative products that may or may not be therapeutically equivalent. Multisource pharmaceutical products that are therapeutically equivalent or interchangeable."

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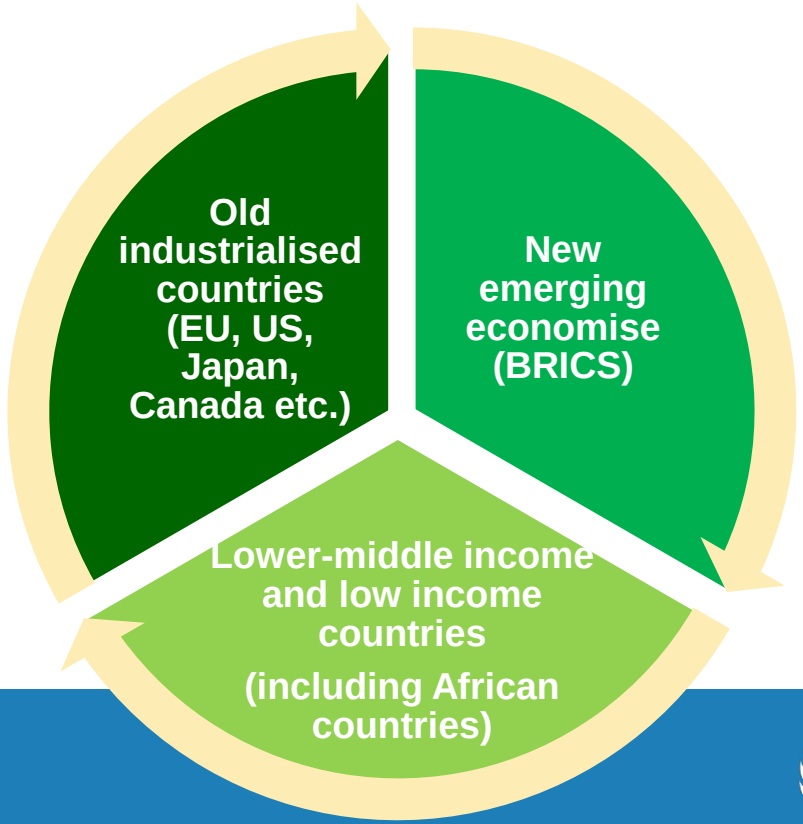
Chances for Developing Countries and Least Developed Countries*

- Old concepts do not hold – three "power centres" for pharmaceutical manufacturing with different logic and interest but – convergence on going



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Old industrialised countries

- Substantial industrial capacity
- Not much dependent on local manufacture, less generic markets
- Base for research based industries - consolidating into few giants with new functions – marketing powerhouses, contracting a lot out
- Generic industries merging and going Global
- Machinery/lab equipment monopoly shifting away – China producing production and lab equipment
- Increasing Globalization and work sharing
  - 80 % APIs from India and China, also a lot of excipients and packing materials
  - Contract manufacturing for FPPs (India)
  - R&D – more and more in "developing world" – clinical trials, basic research slowly following

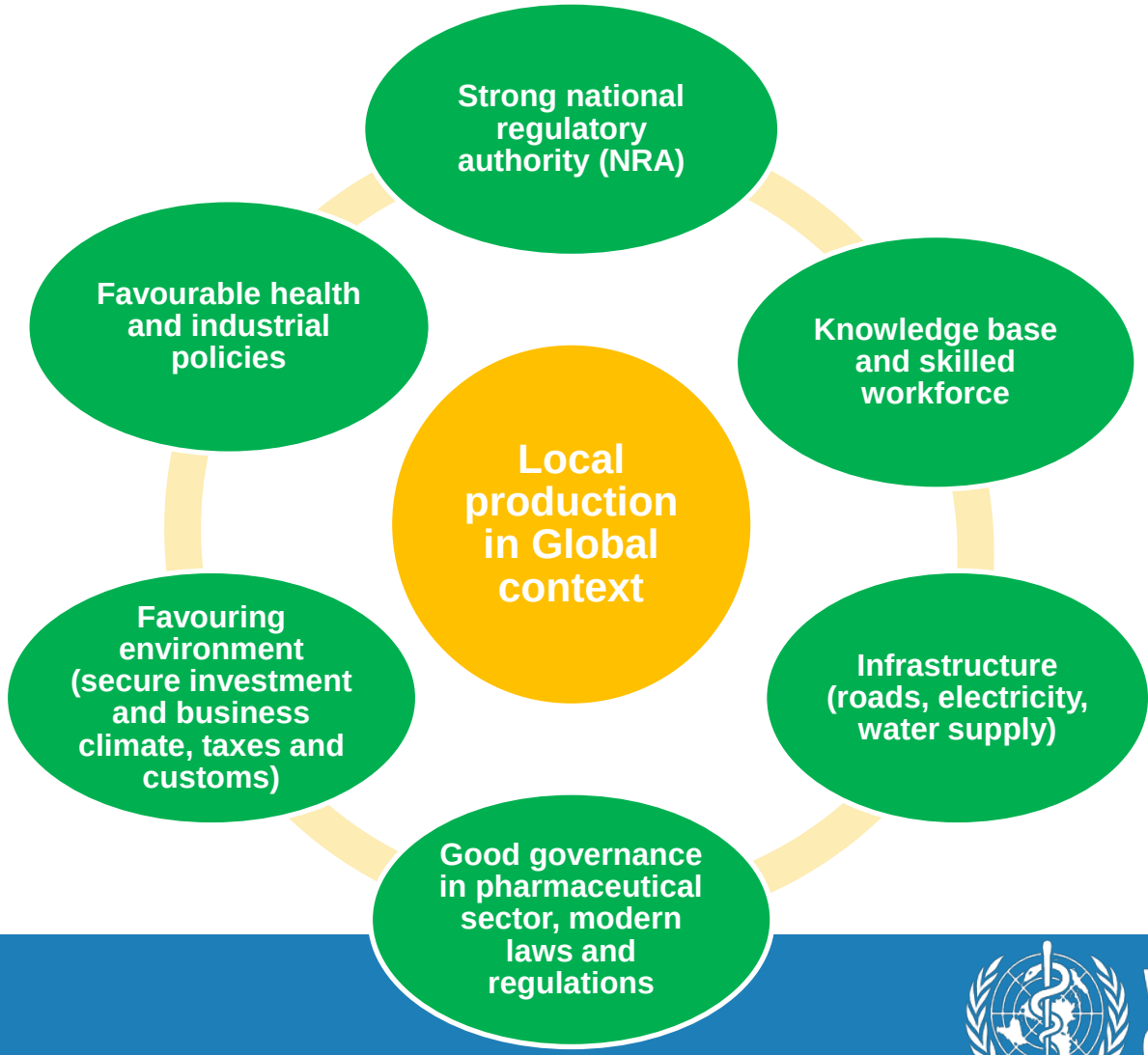
New emerging economies

- Increasing industrial capacity in many areas with needs for new markets, still at large generic markets but with increasing share of originator products
- Increasingly part of work sharing and taking over certain functions
  - API, excipients, packaging materials, machinery production etc.
- Participating in Global R&D
  - Clinical trials increasing, CROs developing, basic research
- Developing its own original R&D for new products
- Generic industries developing and consolidating, going Global reaching out to old industrialised country markets (India) and developing country markets (China)

Lower-middle income and low income countries (including African countries)

- Local manufacture may (?) be more important, mostly generic markets
- Bigger dependence on outside country/region resources (almost 100% for APIs, excipients, packing materials machinery)
- Less part of Global R&D – less clinical trials, in many no CROs, no participation in basic research
- Generic companies small and not reaching further than country or sub-region
- Many have either no or only limited industrial capacity
- Relative lack qualified human resources and knowledge base
- Less business freedom and less attractive investment environment
- Local policies may disfavour local manufacturing
- More problems with good governance in pharmaceutical sector

Sustainable local production in Africa needs favourable environment and … collaboration between countries and access to markets



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WHO position and experiences (particularly in the light of improved access to essential medicines)

- Local manufacturing may facilitate access but is not a goal in its own right
  - Dramatic quality problems have occurred (e.g.Pakistan examples)
  - Locally produced essential medicines may be of lower quality and higher price
  - Health care providers and patients do not care where the medicines come from provided they are safe, of good quality and affordable
- Some products likely more feasible for local production than others e.g. blood products, antivenom sera
- Locally produced medicines must meet **international standards** for Quality, Safety and Efficacy
  - Risk-based step-by-step approach possible, but no compromise on final goal

Concluding remarks (1)

- Local manufacturing is not a "panacea" in its own right but can help to improve access to quality essential medicines
- Governments' commitment to create enabling environment in all of its complexity is important
  - Good Governance principles implemented, especially in pharmaceutical sector, are one of the foundation
- Efficient highly qualified national regulatory authority is a must
- Sub-regional and regional collaboration between governments and regulators is vital to create a predictable harmonized "quality market for quality products"

Concluding remarks (2)

- WHO has promoted regulatory capacity building, collaboration and harmonization long time and will continue to do so being open to new ideas
- Making medicines is not any more a "local" business and the era of only locally operating regulators with different standards starts to end
- The future of medicines regulation is more in collaboration and networking based on harmonized standards; regulators starting to function more as a functional network rather than individual players, and individual players focusing on what they can give the best *added value – e.g. regulating well local manufacturers*

Concluding remarks (3)

- Through its prequalification programme and other technical activities WHO has obtained **unique experience and expertise** about the problems that local manufacturers face.
- WHO has also given substantial technical help to local manufacturers including API manufacturers in China and FPP manufacturers in several regions including Africa.
- In cooperation with all partners and stakeholders, **including national regulators**, it will continue to give assistance for local manufacturers willing to produce quality products meeting international standards.