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First Coordination Meeting for the Pharmaceutical Industry in the GCC and Yemen
Doha, Qatar, 11 April 2011

Towards a multi-client study on the pharmaceutical industry in GCC and Yemen

Brainstorming & feedback session

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GOIC multi-client study on the pharmaceutical industry in GCC and Yemen

Outline

1. Why this session?
2. Context: supporting local pharmaceutical production (LPP) in developing countries
3. Accelerating pharmaceutical industry growth and upgrading in GCC: key issues
4. What should the multi-client study look into?

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WHY THIS SESSION?

1. GOIC invited UNIDO inputs for study concept note
   - GOIC Pharmaceuticals Vision Report 1999 ⇨ Sector overview
   - ALPEN CAPITAL, GCC Pharmaceuticals Industry, Dec 2010 ⇨ Investors looking for opportunities
2. 2011 study objectives (GOIC proposal)
   - Provide GCC pharmaceuticals industry with intelligence for strategic planning purposes
   - Identification of investment opportunities; investment promotion (FDI & domestic)
   - Increased efficiency and regional/GCC harmonization of drug regulation
3. Joint UNIDO & IMS 'coaching' along exercise to establish interest and precise information, analytical and/or advisory needs that different stakeholders (**you!**) would wish to see addressed in study
   - IMS: Markets, investment, healthcare infrastructure
   - UNIDO: Sector development strategies and policies
4. UNIDO's re-engagement with pharmaceutical industry development
   - Strengthening the local production of essential drugs in developing and least developed countries (DCs/LDCs) ⇨ Focus: sub-Saharan Africa (!)

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CONTEXT: SUPPORTING LOCAL PHARMACEUTICAL PRODUCTION (LPP)

1. **Access to** affordable high quality **drugs** remains **vastly inadequate** globally
   - Regarding both three **big pandemics** (HIV/Aids, malaria, tuberculosis) …
   - … **AND many other communicable & non-communicable diseases**
   - Human tragedy on its own
   - Compromises productive capabilities
   - Most profound in LDCs/sub-Saharan Africa
2. **Challenges** hindering access on both demand and supply side **well documented**
   - Wide range of public health and economic development issues
   - Drug procurement, storage, distribution, pricing, rational use, regulatory issues
   - Low purchasing power, funding constraints, stock-outs, penetration of substandard & counterfeit products
   - Limited human resources for health
3. **Vast majority** of essential medicines is being **imported** into Africa
4. **SSA 2008:** Only 28% from African manufacturers
   - Of which 70% from South Africa and a further 20% combined from GHA, KEN & NIG

CONTEXT: SUPPORTING LPP (cont'd)

5. **Over last decade, much more importance attached to pharmaceutical sector development on international "access to drugs" agenda**
   - **WTO TRIPS** Agreement & **Doha Declaration** on TRIPS and Public Health
     - Interface between IPRs and public health: impact of IPRs on innovation and access to medicines
     - LDC waiver (= exemption until 31 Dec 2005)
     - TRIPS flexibilities: Exceptions, parallel imports, **compulsory licenses** (CL), etc.
     - WTO Members can issue CLs for local production *and* imports ("Para 6 system")
     - "TRIPS Plus" in bilateral trade agreements
   - DCs/LDCs increasingly attest **strategic importance** to sector
     - **Security/continuity of** medicines **supply**
     - Conduit to **combat substandard** and counterfeit **medicines**
     - Knowledge-intensive industry
   - DC/LDC pharma industry keen to get **access to internationally funded drug procurement markets** (tenders), e.g. GFATM, PEPFAR, …

CONTEXT: SUPPORTING LPP (cont'd)

6. **LPP initiatives *include***

- **WHA 2008:** Global strategy and plan of action on public health, innovation and intellectual property
  - Element 4: Transfer of technology and production of health products, including for health-related R&D, through investment, capacity building and partnerships
- **AU:** Pharmaceutical Manufacturing Plan for Africa (**PMPA 2007**)
  - **CAMI 19** (**27-31 March 2011**): Pharmaceutical sector prioritized in AIDA implementation plan (= **A**ccelerated **I**ndustrial **D**evelopment in **A**frica)
- **SADC** Pharmaceutical Business Plan (2007-13)
- **EAC** Regional Pharmaceutical Manufacturing Plan of Action (2010-16)
- **NEPAD** initiatives on the Strengthening of Pharmaceutical Innovation & on Drug Regulatory Harmonization in Africa
- **Country level:** pharmaceutical industry assigned priority status

PHARMACEUTICAL PRODUCTION IN DCs/LDCs – CHALLENGES RELATED TO:

- Human resources as to industrial pharmacy
- Access to technical know-how on plant upgrading
- Access to affordable capital & impact of high interest rates on debt
- Fragmented nature of regional markets and small market size, adversely effecting efficiency prospects
- Import of raw materials (APIs), largely from Asia, and related lead time and working capital requirements
- Reliability & costs of utilities
- Capacity of medicines regulatory authorities to prevent lower standard and counterfeit products
- Intra-government coordination (health, tax, science and industrial policies)
- Sector representation by effective business membership organizations (pharmaceutical manufacturer associations)

KEY CHALLENGE:
„TENSION“ BETWEEN PUBLIC HEALTH AND INDUSTRIAL POLICY

	Public health (PH)	Industrial policy (IP)
Objective	Low-cost supplies of high-quality drugs (quality, safety, efficacy)	Pharmaceutical industry growth (income, jobs, tax revenue, exports)
Views on LP	Drug production venue of no / little importance	Insufficient interest of large-scale global manufacturers in small DC/LDC markets
		Knowledge, education, training
Varied synergies of IP measures on PH objective	• Direct subsidies, loans or tax breaks • Import restrictions or duties for competitor products • Export subsidies • Preferential treatment (public drug procurement, regulatory approvals, pricing decisions) • …	

GRADUAL MAINSTREAMING OF LPP SUPPORT

- Contentious debate about feasibility of LPP in DCs/LDCs has given way to …
- … gradual acceptance of pharmaceutical industry development as valuable contribution to easing access to drugs challenge
- **Fostering production of essential medicines in DCs/LDCs is a complex undertaking** (nature of products & production processes, governance, multiplicity of stakeholders)
- "Natural" tension between industrial development and public health perspectives can be overcome by
  - Showing commercially viable route to quality production
  - Denying any 'need' to reduce or accept reduction of quality standards
- **Need for holistic approach** towards sector development …
- … requires to **overcome disconnects**
  - ***Within governments***/public policy stakeholders (health, industry/trade, science/technology)
  - ***Between public and private sector***

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Accelerating pharmaceutical industry growth in GCC: key issues

POLICY FRAMEWORK

- **Political will** needed to boost pharmaceutical industry by changing institutional and business environment
- Multitude of stakeholders requires **acceptance of need for coordination/cooperation** at varied levels
  - Intra-government (at least, Ministries of Industry & Health)
  - Medicines regulatory body
  - Industry
- Industry incentives (tax, capital, …) – must be evidence based
- Promote manpower/human resource development
- No prescribed, one-size-fits-all strategy
- Interactive/iterative process with core stakeholders

Accelerating pharmaceutical industry growth in GCC: key issues (cont'd)

REGULATION

- Key role of (national) **medicines regulatory authority** (**MRA**) for establishment of, and ensuring adherence to, quality standards (QA/QC)
- Is MRA strong enough to enforce compliance (incl. political backing)?
- Communication lines with manufacturers on GMP (e.g. GMP roadmap with milestones and timelines)?
- Efficiency of granting marketing authorization
- Post marketing surveillance (PMS) – ensure uniform quality standards and their transparent application (level playing field for imports and locally produced drugs)

Accelerating pharmaceutical industry growth in GCC: key issues (cont'd)

REGULATORY HARMONIZATION

- Disparate regulatory systems hamper trade in pharmaceuticals
- Need for medicines legislative framework at national and (sub)regional levels beyond GMP, e.g. GDP, GLP, GCP, other
- Harmonization of medicines registration
- Regulatory harmonization initiatives underway in sub-Saharan Africa (EAC, COMESA, SADC, …) – slow progress

Accelerating pharmaceutical industry growth in GCC: key issues (cont'd)

TRIPS AGREEMENT

- How have TRIPS provisions been translated into national IPR/ patent legislation in GCC countries? Is there a need for GCC countries to make use of TRIPS flexibilities?

Accelerating pharmaceutical industry growth in GCC: key issues (cont'd)

BUSINESS MEMBERSHIP ORGANIZATIONS (BMOs)

- Pharmaceutical (or, specifically, generics) manufacturers association
- National and/or sub-regional (GCC)
- Recent initiatives at sub-regional level SSA
  - Southern African Generics Medicines Association (SAGMA)
  - Federation of East African Pharmaceutical Manufacturers (FEAPM)
  - Western African Pharmaceutical Manufacturers Association (WAPMA)
- Early talks about pan-African body
- Functions: advocacy, service provision

14th Annual International Generic Pharmaceutical Conference

Cape Town International Convention Centre

Save the date

1-3 November 2011

further details to follow

IGPA
INTERNATIONAL GENERIC PHARMACEUTICAL ALLIANCE

International **Generic Pharmaceutical** Conference

Breaking Barriers to Medicine Access

NAPM
National Association of Pharmaceutical Manufacturers

THE CONFERENCE COMPANY

2011 Cape Town **Conference**

www.igpacapetown2011.com

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PARAMETERS OF GCC MULTI-CLIENT STUDY

Starting point	• GCC healthcare needs to rise sharply (growing & ageing population, rising non-communicable 'lifestyle' diseases) • Vast majority of drugs imported • Is the intention to advocate for a larger part of GCC medicines needs to be met from locally produced ones (relative share/absolute numbers?
Information needs to be satisfied	What are the main stakeholders' key information/sector intelligence needs that the study should address? • Policy-makers (industry, trade, health, science & technology) • Manufacturers • MRAs • Other?
Intended use(s), purpose(s)	• Guidance for decisions at company level (strategic planning, investment decisions, …) and at policy level (industrial policy measures, MRA strengthening, regulatory harmonization)? • Key analytical input for development of regional (GCC) pharmaceuticals sector development strategy?
Target audience	Policy-makers, manufacturers, regulators, …?

PARAMETERS OF GCC MULTI-CLIENT STUDY

Which of these questions would you like to see addressed?	• What is the market outlook for major groups of pharmaceuticals in GCC? • Competitiveness of locally-manufactured medicines viz. other regions? What strategies needed to counter foreign competition? • Current challenges for intra-regional trade in pharmaceuticals? • Challenges and opportunities brought about by WTO membership? • MNC Global strategies of MNCs: recent trends and likely future developments • Regulatory hurdles faced by pharma industry in GCC? • Role of CROs in pharma industry and their use by GCC companies • How can GCC companies enhance R&D capabilities? • Trends in global partnerships and licensing deals? Involvement of GCC? Licensing and partnership opportunities with global players? • Likely future investment direction for pharmaceutical industry in GCC and Middle East? **ANY OTHER?**

Thank you!

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ANNEX

UNIDO GLOBAL PROJECT

Advice & capacity-building	Strengthening the local production of essential **generic** drugs in developing countries through the promotion of SMEs, business partnerships, investment promotion and South-South cooperation
Duration	Start: 01/2006 Phase III: 01/2011 – 12/2012
Budget	EUR 4.7 m - Co-funded by Germany (EUR 3.68 m) & UNIDO (EUR 1.02 m)
Objective	Increased capacity for the competitive local manufacturing of essential generic drugs in target (L)DCs
Focus	• Initially, medicines against three pandemics • Meanwhile, essential medicines at large
Levels of intervention	• Policy • Institutions • Sector/plant
Guiding criteria	• Commercial viability • Int'l quality standards (GMP, WHO PQ) ⇨ But : pragmatic approach recognizing realities on the ground

UNIDO PROJECT - MILESTONES

Policy

- Multi-stakeholder pharmaceutical sector roundtable processes & formulation of sector development strategies underway: **GHANA, KENYA**

Institutions

- Coaching towards formal inauguration of **Southern African Generic Medicines Association** (SAGMA), Dec 2009
- Support to pharmaceutical manufacturers associations (strategy building, LP advocacy): **West Africa, Botswana**
- Sponsoring int'l **training course on „Advanced Industrial Pharmacy"**; host: Kilimanjaro School of Pharmacy, Moshi/URT

Sector/plants

- Overall: escorting upgrading process towards int'l c-GMP and/or WHO Pre-qualification (PQ).
- **GHANA:** Coaching/advisory support for two companies (business plan, investor search, mock inspection)
- **CAMEROON:** Inauguration of new plant (Apr 2010)
- **BOTSWANA:** Conceptual study on Greenfield investment

UNIDO PROJECT - MILESTONES

Significant network of contacts:

ALMA, COHRED, NEPAD, SADC, UNAIDS, UNCTAD, UNDP, UNITAID, UNDP, WHO

- Interagency Pharmaceutical Coordination Group (IPC), Chair: WHO
- SADC Pharmaceutical Task Force
- Roll Back Malaria Procurement and Supply Chain Management Working Group (RBM/PSM)
- African Leaders Malaria Alliance (ALMA)

UNIDO'S NICHE: INTERFACE PUBLIC HEALTH / INDUSTRY

- Access-to-drugs challenge addressed by large number of stakeholders
  - UN agencies, DFIs, scientific bodies, CSR-related initiatives, bilateral donor agencies
  - Procurement, distribution, treatment and use; research, discovery, development & testing, regulatory issues

BUT

- Interventions to improve operational environment of pharmaceutical manufacturers or to upgrade towards international quality standards remain few and far between

ENHANCED UNIDO PROGRAMME: PLANNED MODULES

Pharma sector development strategies, policies & programmes

- Value chain approach
- Sector roundtables, multi-stakeholder consultations

Investment facilitation, including matchmaking platform

Technology transfer promotion

- North-South, South-South
- Brokering partnerships (business, public/private, CSR-related)

Research function

- Economics of production
- Scarcity of market data

Expert pool for plant-level guidance

- Technical & business

Human resource development

…[other]

In cooperation with/complementary to others