Interagency Pharmaceutical Coordination Group (IPC)

Informal Sub-Group Meeting on Local Pharmaceutical Production

30 September 2009
Geneva
c/o WHO, Room M 205
Why this meeting?

• Decision at last regular IPC meeting (May 2009).
• Rising interest in topic in recent past:
  – Priority attention on HIV/AIDS, malaria and TB, alongside with international funding initiatives (e.g. GFATM).
  – Advocacy for full use of *TRIPS Flexibilities* favouring DCs/LDCs; extended deadline for TRIPS compliance until 2016 for LDCs specifically (OECD Nordwijk Agenda, WHA).
  – Growing political attention to local/regional manufacturing
    ⇒ AU “Pharmaceutical Manufacturing Plan for Africa” (2007), SADC, COMESA, ECOWAS, etc.
    ⇒ (L)DC country levels
• Views on feasibility of local production: shift to more differentiated assessments.
Why this meeting?

- Revisit international debate on pros & cons and opportunities & limitations of local production support as one means of improving access to medicines.
- Explore scope for improving interagency networking and cooperation towards local production assistance.
- Intermediate step to planned UNIDO/BMZ-GTZ international gathering to take a fresh look at thinking and evidence on stimulating local pharmaceutical production (Apr/May 2010).
- Ideally, advance towards common position for full IPC meeting, Washington, 11-12 Nov 2009 (WB).
Lead questions

**Overall:** How should the UN/IPC members support local pharmaceutical production in DCs/LDCs?

1. What role can the local pharmaceutical manufacturing sector play in DCs/LDCs with regard to access improvements? What are the pros and cons of supporting the development of local pharmaceutical production?

2. How do participating agencies affect (directly or indirectly), or impact upon the operating conditions of, the pharmaceutical manufacturing sector in DCs/LDCs?
   - Stocktaking of interventions (questionnaire)

3. What additional action (including intra-IPC cooperation) can be thought of that would increase the impact of pharmaceutical sector support? Under what conditions, if any, would agencies be willing to support the local production of medicines and how?
ACCESS TO DRUGS “UNIVERSE”
A multitude of players…

BASIC RESEARCH
DISCOVERY/DEVELOPMENT

TESTING
(phase I, II, III, IV)

PRODUCTION

REGISTRATION

PROCUREMENT/DISTRIBUTION

DELIVERY USE/TREATMENT

MeTA Medicines Transparency Alliance
**Objective:** collect baseline information on activities regarding local production by participating agencies.
9 of 14 participating agencies replied: GFATM, IFC, GTZ/BMZ, UNCTAD, UNDP, UNIDO, WHO, WB

**Main results:**
- Agencies are supporting local production directly (UNIDO, GTZ/BMZ, IFC)- WHO PQ - training for local producers
- 2 Agencies are considering to enter into the field (UNDP, WHO)
- UN Agencies affect local production indirectly as (1) a huge market through their procurement of medicines (2) in the field of quality by setting and enforcing standards (3) by working on the business and regulatory environment.
- Consensus on Preconditions for local production: Quality, financial sustainability and holistic approach
- Problems: Regulatory Capacity and quality assurance, market dynamics and technology transfer, IPR
- Topics of interest: varied agenda for further research
Session 1: Supporting the local production of essential medicines in LDCs/DCs – Some considerations and UNIDO’s approach

IPC Sub-Group Meeting on Local Pharmaceutical Production

Geneva, 30 September 2009

Juergen Reinhardt, Project Manager, UNIDO Vienna
Outline

1. Potential Benefits and Challenges Faced
2. UNIDO’s Project
   • Key features
   • Lessons
3. Summing up
1. Potential Benefits and Challenges Faced
THE CASE FOR SUPPORTING LOCAL PHARMACEUTICAL PRODUCTION IN (L)DCs:

- Big three pandemics (HIV/AIDS, Malaria, TB): persisting/growing gap between drug needs and availability – **too little, too expensive**.
- Securing benefits from shorter supply chains: local production could theoretically help to alleviate access problems such as **counterfeit products, weak public distribution networks** and **stock-outs**.
- Opportunity to help increase standards and regulation in sustainable way: prequalification requirements exist for treatments against pandemic diseases, but local producers manufacture other essential drugs without similar regulatory oversight.
- **Strategic importance of local capacity** for pharmaceutical manufacturing e.g. Flu antivirals.
- Opportunity to **combine health agenda with some wider development considerations**, e.g. highly skilled jobs creation, value addition in local economy, retention of donor money in country (longer term import substitution).
- Potential to build **basis for local innovation** for “neglected diseases”.
- **Politics of Public Health**, e.g. the increasing frustration in countries at perceived paternalism and the potential for this to undermine valuable public health initiatives (e.g. AMFm).
KEY CHALLENGES IN DEVELOPING LOCAL PRODUCTION:

- Local production NOT a magic bullet.
- Commercial viability and highest quality standards = must.

At plant level:

- **Affordable financing** for capital intensive investment with long term pay back timeline.
- **Lack of credible market data** can limit the ability to plan and justify investments.
- **Small** domestic and **fragmented** sub-regional **markets** limit scope for scale economies.
- Need to access-develop the **management and technical skills** to upgrade facilities/processes/documentation in companies.
- Requirement to access and develop the **human resources** for the long term running of international standard facilities.
- Viable and sustainable business models **require progress on inputs** (e.g. raw materials, utilities, packaging, etc.) – need to look into entire supply chain.
- **Access to services** (e.g. maintenance of machinery, bioequivalence facilities).
KEY CHALLENGES  (cont)

• No quick fixes: *establishing international quality standards requires viable path* for industry development with some challenging considerations (e.g. timelines to implement upgrades, establishing possibly interim quality standards, road map for sector development).

• Increased *capacity of NRAs* to oversee local production is a multifaceted challenge in itself.

• *Local perspectives on* prescribed *quality* standards vary but can be politically powerful.

• For the potential benefits regarding access to medicines to be fully realized, progress in health system development will be required (human resources, central medical stores, procurement systems etc.).

➔ The breadth of challenges, the interrelationship between issues, the range of perceived benefits and the variety of mandates in this space suggest that *coordination between stakeholders* (both at a local and global level) is *crucial*. 
2. UNIDO’s Project
## CURRENT GLOBAL UNIDO PROJECT

<table>
<thead>
<tr>
<th><strong>Project title</strong></th>
<th>Strengthening the local production of essential generic drugs in developing countries (DCs/LDCs) through the promotion of SMEs, business partnerships, investment promotion and South-South cooperation</th>
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</thead>
</table>
| **Duration**      | 2 phases: 01/2006 – 12/2010  
Further extension likely                                                                                                                     |
| **Budget**        | Euro 3.3 m - Co-funded by Germany (EUR 2.48 m) and UNIDO (EUR 0.82 m)                                                                 |
| **Objective**     | To support the establishment and/or expansion and upgrading of SMEs in 3-4 target (L)DCs for the local manufacturing of essential generic drugs |
| **Focus**         | Medicines against HIV/Aids, malaria and tuberculosis, selected neglected tropical diseases (NTDs)                                                                                           |
| **Guiding criteria** | Commercial viability  
Int’l quality standards (GMP, WHO PQ) |

**Project** positioned at **interface of public health and economic/industrial development.**
RANGE OF PROJECT INTERVENTIONS – POLICY LEVEL

- **Policy advice** (analysis/improvement of business, legal and regulatory environment for production of essential medicines)
  - Needs assessments
  - Sector (competitiveness/performance) analyses

- National multi-stakeholder **public-private dialogue** and consensus-building on pharmaceutical sector development and/or sector strategy formulation

- **Awareness raising/networking** workshops (national/regional)

**LAST NINE MONTHS**

- **Ghana (since Aug 2008):**
  - National pharmaceutical sector roundtable process (PMAG, MOIT);
  - 1st national sector roundtable July 2009;
  - Aim: Agreed sector strategy by end-2009

- **Kenya (since Sep 2009):**
  - National pharmaceutical sector roundtable process (MOI, MOHS)
  - Aim: Agreed sector strategy by Q1/2010
  - Baseline: Pharmaceutical sector study
RANGE OF PROJECT INTERVENTIONS – INSTITUTIONAL LEVEL

- Capacity-building of pharmaceutical manufacturers associations & other private sector-led self-help initiatives

- Quality infrastructure: Support in strengthening/upgrading of medicines regulatory authorities (MRAs), drug testing laboratories or standards institutions/ calibration bodies, etc.

  ➔ Not stand-alone, only to complement project support extended at business level

- Reducing barriers to trade: (sub)regional harmonization support

LAST NINE MONTHS

- Ghana:
  PMAG: advice & capacity building for public-private dialogue.

- Regional:

- Regional/Tanzania:

- WHO/NEPAD/GF/DFID initiative:
  Regional Harmonization of Drug Regulation, Jo’burg mtg, Feb 2009.
RANGE OF PROJECT INTERVENTIONS – COMPANY LEVEL

- Technical and managerial assistance
  - Initial plant-level SWOT assessments/ad-hoc advice
  - Business plan advice and (pre-)feasibility analysis
  - Coaching towards international GMP (e.g. PIC/S) and/or WHO pre-qualification standards
- Partner search assistance (equity, technology/know-how)
  - Brokering of business partnerships between local pharmaceutical SMEs and foreign generics producers
- Prerequisite: submission of sound business concept/plan
  - e.g. UNIDO Company Project Profile (CPP)

**KEY:** Catalytic support only, private/corporate sector lead

**LAST NINE MONTHS**
- Botswana
- Cameroon
- Ghana
- Kenya
- Uganda (-)
- Lesotho (-)
KEY LEARNING/OBSERVATIONS TO DATE

• Policy Level:
  ⇒ Multiple stakeholders and agendas and the realities of “donor-recipient history” require the establishment of strong relationships and investment in consensus building to achieve genuine progress.
  ⇒ Local political will and the prospect of meaningful progress are important for traction to be achieved.

• Institutional Level
  ⇒ Industry associations are alliances of competitors with different business models etc. creating a challenging context for sustainable and united entities.
  ⇒ Human resource development support for the sector by multitude of donors would benefit from an integrated strategy.

• Enterprise Level
  ⇒ Tender markets unlikely to be sufficient to sustain companies – consideration of overall business plan (broader product portfolio).
  ⇒ Large variation between companies in terms of standards.
COMPONENTS THAT UNIDO BRINGS –
THE HEALTH / ECONOMIC DEVELOPMENT INTERFACE

- UNIDO has strong relationships on the ground with the Ministries of Trade and Industry.
- Coordination with other UNIDO programs can lead to accessing mechanisms for longer term strategy implementation.
- We are able to form close relationships with manufacturers without perceived conflicts of interest.
- We can feed the manufacturers’ perspective into the global policy debate.
- UNIDO can act as an ‘honest broker’ between companies and sectors, and agencies with more specific/sensitive mandates.
SUMMING UP:

- There are potential benefits from both health and economic development perspectives in promoting the local production of pharmaceuticals.
- There are substantial challenges that are faced in order to achieve these benefits.
- UNIDO’s organizational mandate and the design of the project means it can operate across the health and economic development interface.
- UNIDO is keen to work with partner organizations, as coordination of efforts is crucial.
Thank you!

Juergen REINHARDT,
Project Manager, PTC/PSD
Phone: +43-1-26026-3405
Fax: +43-1-26026-6864
E-mail: J.Reinhardt@unido.org

Nadine VOHRER,
Associate Expert, PTC/PSD
Phone: +43-1-26026-5089
Fax: +43-1-26026-6864
E-mail: N.Vohrer@unido.org

Alastair WEST,
Senior Technical Advisor, PTC/PSD
Phone: +43-1-26026-3882
Fax: +43-1-26026-6864
E-mail: a.west@unido.org

UNIDO, POB 300, A-1400 Vienna, AUSTRIA
Website: www.unido.org
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- Survey Results -

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IPC survey results

1. Reasons for (renewed) interest in the topic of local production of essential drugs

- Received requests from International Organizations/Regional Economic Communities
- Internal debate in organization (ideological and practical debate)
- Requests from Member States
- WHO Global Strategy and Plan of Action on Public Health, innovation, intellectual property rights, technology transfer, R&D and local production.
- Global Fund: topic remains interesting - no final policy decision by the board
- GTZ/BMZ International program launched by minister
- IFC: requests received from local producers
- UNICEF Local procurement through country offices
IPC survey results

2. Studies/Intelligence available

- **GTZ/BMZ:** Pharmaceutical Sector Studies Bangladesh, Ghana, Tanzania, Feasibility Study for East Africa, Legal aspects of local production Rwanda, The TRIPS Agenda: Access to Knowledge and Technology,
- **UNCTAD:** Advisory studies on IP Ethiopia, Tanzania, Thailand, Uganda, EAC, Reference guide to intellectual property,
- **UNICEF:** GMP inspections of local producers to facilitate local procurement,
- **UNIDO:** Pharmaceutical Sector Studies (partly being revised), Lesotho, Nigeria, Senegal/Mali, Uganda, Zambia, Zimbabwe, Cambodia, Laos, Global Market study on opportunities for producers in LDCs,
- **World Bank (WB):** Exploratory Study on Active Pharmaceutical Ingredient Manufacturing for Essential Medicines,
- **WHO:** Studies underway (project on improving access to medicines in developing countries through tech transfer and local production).
### IPC survey results

#### 3. Activities promoting local production **directly**

| Policy level | GTZ: National Drug Policy TAN, EAC harmonization of patent rights, Support AU manufacturing Plan,  
|              | UNIDO: Pharmaceutical Sector Roundtables GHA, KEN,  
|              | UNCTAD: Research and policy advice on investment framework |
| Institutional level | GTZ- Support QC labs EAC, ET, training facilities ET, TAN and BE center in EAC,  
|                   | Action Medeor: support research lab in TAN,  
|                   | Inwent: Training on TRIPS,  
|                   | UNIDO: Support sector associations in GHA, SADC and training facility in TAN |
| Enterprise level | GTZ- Support 18 companies towards GMP: ETH, KEN, SYR, TAN,  
|                 | Action Medeor: Support companies: TAN-ARVs, KEN-ACTs,  
|                 | IFC, BMZ/DEG: Provide loans and invest equity in local manufacturers,  
|                 | UNIDO: SWOT assessments/ad-hoc advice, business plan advice and (pre-) feasibility analysis, GMP/PQ coaching |

**Considering to enter:** UNDP with focus on South-South cooperation to facilitate access  
WHO research under way to define support of local production
**IPC survey results**

3. Activities *indirectly* affecting local production (1)

<table>
<thead>
<tr>
<th>Markets</th>
<th><strong>UNICEF</strong>: Procurement and supply chain, Global Fund (GF): Procurement ATM - needs defined by recipients, <strong>UNDP</strong>: Procurement – Principal Recipients for GF in 26 countries, <strong>World Bank (WB)</strong>: Procurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality</td>
<td><strong>UNICEF</strong>: Inspections of local producers against WHO GMP, local authorities participate in GMP inspections, <strong>GTZ</strong>: Support for quality infrastructure, <strong>WB</strong>: Dialogue with USP on quality assurance in (L)DCs – anti-counterfeit, <strong>GF</strong>: Participation in trainings</td>
</tr>
</tbody>
</table>
### IPC survey results

3. Activities *indirectly* affecting local production (2)

<table>
<thead>
<tr>
<th>Business and Regulatory</th>
<th><strong>UNCTAD &amp; UNDP:</strong> IP/TRIPS advice to LDCs,</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human Resources</td>
<td><strong>BMZ/Inwent/UNCTAD:</strong> Training on TRIPS</td>
</tr>
<tr>
<td>Finance</td>
<td><strong>IFC:</strong> As lenders and investors</td>
</tr>
<tr>
<td></td>
<td><strong>WB:</strong> Expert advice on health insurance incl. coverage of pharmaceuticals in developing countries</td>
</tr>
<tr>
<td>Distribution</td>
<td><strong>GTZ:</strong> Health sector reform programs in several countries</td>
</tr>
<tr>
<td></td>
<td><strong>WB:</strong> Analyze public procurement agencies and supply chains in select countries.</td>
</tr>
</tbody>
</table>
IPC survey results

4. Important issues and problems with regard to local production

- Regulatory Capacity (National Control Labs) and Harmonization of Regulatory Standards,
- Quality of production (compliance and enforcement),
- Markets dynamics: competition, transparency and costs (esp. role of India for medicines production and role of API market),
- Technology transfer/technical competence for more complex drugs,
- Intellectual property rights (use of TRIPS Flexibilities),
- Neglected diseases (incentives for research),
- Multi-stakeholder approach important.
IPC survey results

5. Preconditions for supporting local production

- **GTZ**: Quality - International GMP, regional market access, policy support,
- **IFC**: Technical competence, financial sustainability, environmental and social criteria,
- **UNIDO**: Quality and commercial sustainability,
- **UNICEF**: Standard WHO GMP guidelines,
- **UNCTAD**: Company level measures flanked by policy support, multi-stakeholder approach,
- **WHO**: Result of ongoing project, several studies and mapping exercise underway.

Preconditions that all agencies seem to subscribe to:

1. Quality (WHO GMP),
2. Financial sustainability,
3. Holistic approach.
IPC survey results

6. Other issues/ Areas of interest for further work

- **GF:** Pricing Policy, national public procurement policies, sustainable markets for local producers,
- **GF:** Quality of essential medicines in general non-ATM drugs and strengthening quality assurance report 2010 - different regimes currently in use,
- **GTZ:** Alternative patent regimes,
- **GTZ:** Reduction of counterfeits as side-effect of local production,
- **WB:** APIs - regulatory capacities, sustainability of API supply markets, API quality assurance and procurement skills for local producers,
- **UNCTAD:** Effect of philanthropic initiatives to promote local production.