



UNITED NATIONS
INDUSTRIAL DEVELOPMENT ORGANIZATION



SUSTAINABLE DEVELOPMENT GOAL 9
INDUSTRY, INNOVATION AND INFRASTRUCTURE

International Business and Investment Forum: “Mobilizing investment, technology and partnership opportunities for Africa’s pharmaceutical industry”
UN Campus Bonn, Germany - 1-2 March 2018

Promoting health and industrial development: UNIDO support to local pharmaceutical production



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OUTLINE:

Local pharmaceutical production (LPP)

- Context and current status

UNIDO'S global project

- Select work streams
- Highlights 2017-18



UNIDO AT A GLANCE

UNIDO WAS ESTABLISHED IN 1966
AND IN 2016 CELEBRATED ITS

50th ANNIVERSARY

THE ORGANIZATION BECAME
A SPECIALIZED AGENCY OF THE
UNITED NATIONS IN 1985

UNIDO EMPLOYS

638

STAFF MEMBERS

(as at 31 December 2016)

THE PORTFOLIO OF PROJECTS
AND PROGRAMMES IN HAND

\$503.5

MILLION

\$210.1

MILLION

NET VOLUNTARY
CONTRIBUTIONS IN 2016

AS AT 31 DECEMBER 2016,
THE ORGANIZATION HAS

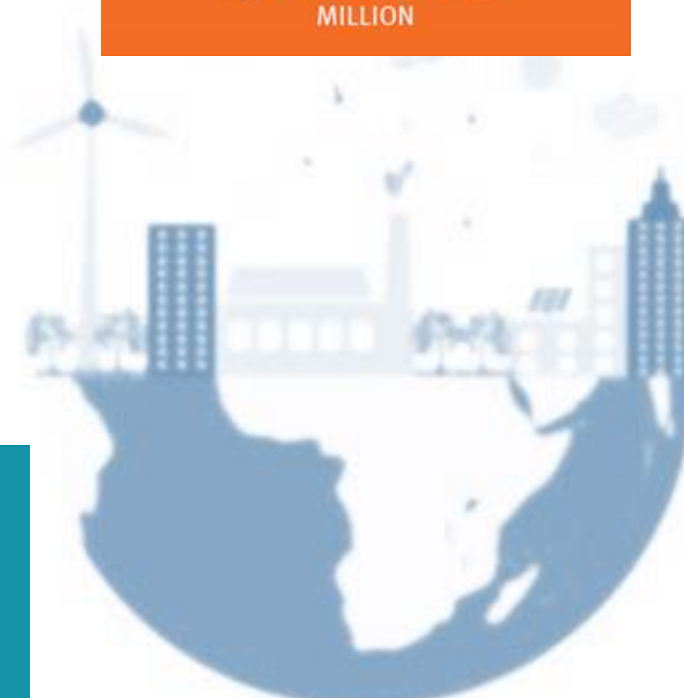
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MEMBER STATES*

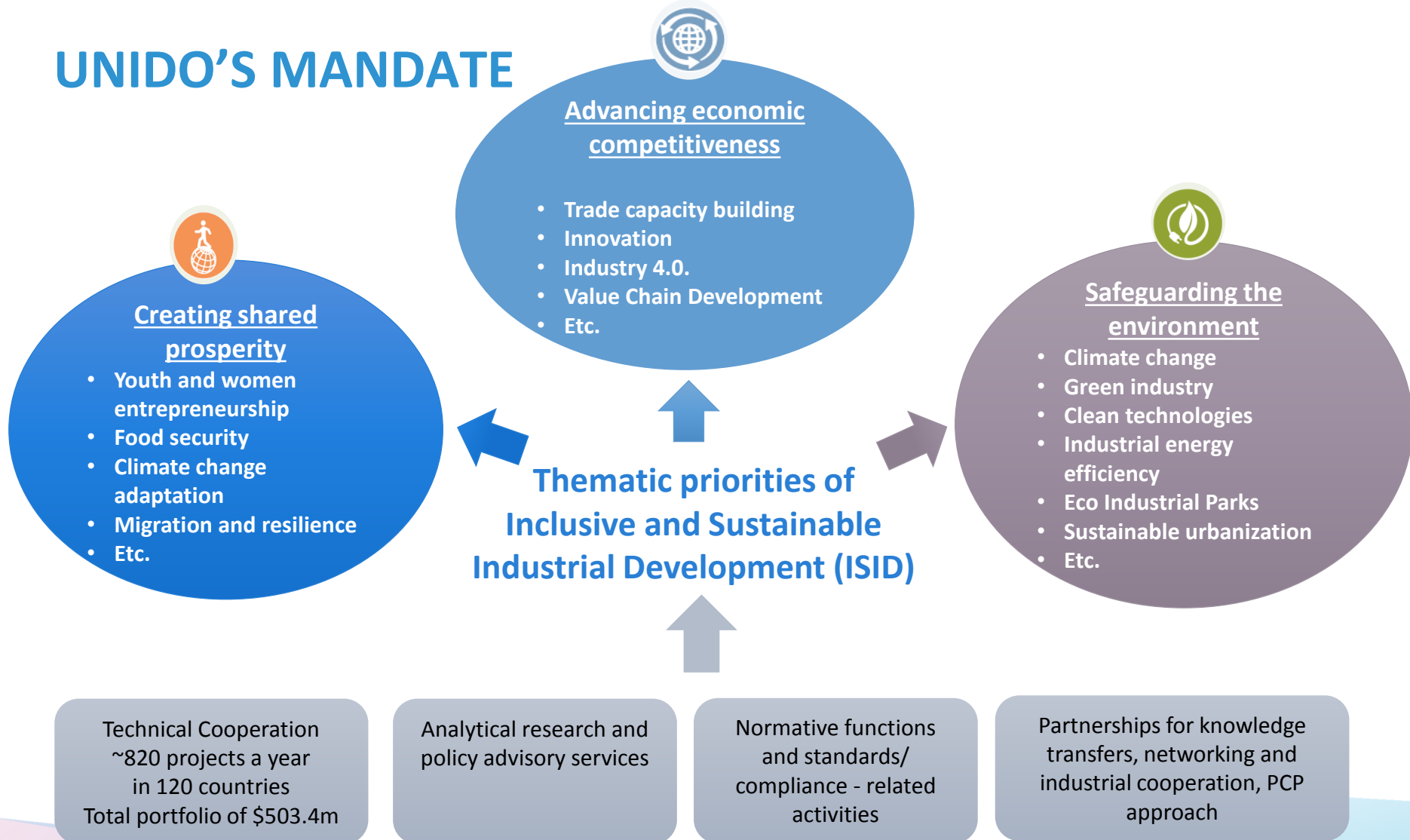
THE DIRECTOR GENERAL OF UNIDO

LI Yong

(CHINA)



UNIDO'S MANDATE





LOCAL PHARMA PRODUCTION IN AFRICA: IN CONTEXT

- In spite of progress over last decade **‘access to medicines’ remains a major global (development) challenge**
- **Dissatisfaction with prevailing production and trade patterns**
 - Sub-Saharan Africa: 70-100% of medicines needs satisfied through imports
 - African pharma effectively shut out from donor-funded drug procurement
- **Potential LPP benefits widely agreed:**
 - Facilitation of regulatory oversight & QA \Rightarrow combat substandard & counterfeit medicines
 - Continuity of supply (shorter supply lines/lead times) \Rightarrow mitigate stock-outs & ad-hoc procurement
 - Reduced dependence on imports (including beyond ‘era of donations’)
 - Broader economic gains: jobs, income, forex, spillovers (of knowledge-intensive industry)



LOCAL PHARMA PRODUCTION IN AFRICA HAS MUCH TO OFFER

- **Promoting LPP is a vital part of a sustainable solution** for access to medicines challenge ...
- ... and thus **strategically important for both public health and economic development** objectives
- Consequently, **significant political attention and bold initiatives by African leaders** at national, regional & continental levels
 - AU Pharmaceutical Manufacturing Plan for Africa (PMPA) 2007
 - UN GA Declaration: Third Industrial Development Decade for Africa (IDDA III) 2016-2025
 - 2nd EAC Regional Pharmaceutical Manufacturing Plan of Action (RPMPOA) 2017-2027
 - ECOWAS Regional Pharmaceutical Plan (ERPP) 2014-2020 ... and others
- However..... no simple solution – no quick fixes – no one size fits all



FOCUS ON QUALITY OF MEDICINES IS OF CENTRAL IMPORTANCE AND REQUIRES COORDINATED ACTION ON VARIOUS FRONTS

- Requires **compliance** by pharmaceutical manufacturers **with international GMP** (Good Manufacturing Practices) standards
 - WHO GMP = prerequisite for supplying int'l markets (donor-funded and stringent regulatory export markets)
- **Transition** from no/low compliance to full compliance **not possible overnight**
- Requires investment (premises/infrastructure, robust QMS, HR)...
- ... and various support measures from government and other players



UNIDO GLOBAL PROJECT

Title	Strengthening the local production of essential medicines in developing countries through advisory and capacity-building support
Duration	Start: 01/2006 Phase 6 ongoing
Objective	Increased capacity for the competitive local manufacturing of safe, efficacious and affordable medicines in target (L)DCs
Approach	<ul style="list-style-type: none"> - Improving the operating environment of pharmaceutical manufacturers - Direct/indirect support to company activities - LPP advocacy/global forum work
Premise	<ul style="list-style-type: none"> - Quality and commercial viability - Contribute to favourable public health (PH) <u>and</u> industrial development (ID) outcomes (interface PH/ID) – SDGs 3, 8 & 9
Focus	From three pandemics initially to essential medicines at large





LPP DEVELOPMENT: CORE COMPONENTS OF A HOLISTIC STRATEGY

GMP Roadmap

Application of GMP roadmap for industry upgrading

Incentives

Guidance on time-limited incentives to support the transition of the pharmaceutical industry

Regulatory strengthening

Assistance to improve regulatory capacity

Policy coherence

Support to adjust policy framework for the industry across govt. actors

Market opportunities

Supporting defragmentation (reg. harmonization) & enhanced pharma market data transparency

Key guiding criteria:

- Quality
- Commercial viability

Governance

Functional, sustainable governance structures including Government and key stakeholders

Know-how/technology transfer

Supporting partnerships and business linkages to access know-how and technology

Human resources

Strengthening and upgrading human resources

Product portfolios

Helping GMP-compliant companies to expand their portfolios with generics of particular importance to public health

Investment

Facilitating access to affordable long term finance to enable upgrading



COMPONENTS TARGETED AT THE BONN MEETING

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SELECT WORK STREAMS

Pharma industry development strategies

- Formulation & implementation
- Country, regional & continental levels
- GHA, KEN, VN, ZIM
- AU PMPA BP

Advocacy/awareness-raising

Meetings, conferences, workshops, collaborations

- Expert Advisory Group (EAG) for the UN SG's High-level Panel on Access to Medicines, New York (2015/16)
- Interagency Pharmaceutical Coordination Group (IPG)

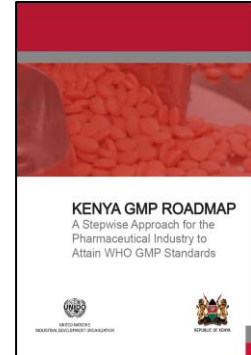
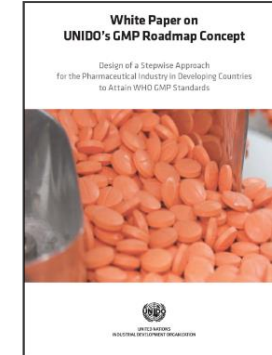
Tools/methodologies

- Strategy development
- GMP Roadmap approach
- Pharmaceutical market intelligence

Industry support

Workshops, trainings, coaching/mentoring:

- Upgrading processes (GMP, WHO PQ) & CAPA preparation; Operational Excellence (OPEX), Lean Six Sigma (LSS) and production efficiencies
- Planning and execution of large and small projects
- Partnership building and linkage platform (PBLP) – facility improvement expertise
- ...



GMP Roadmap work

- KEN, GHA, ETH,
- > 90 company GMP assessments (soon to be 100)

Institutional support

- Pharmaceutical manufacturer associations (national, regional & continental levels)
 - FEAPM, **FAPMA**, **SAGMA**, WAPMA
- IPAT (SLF/KSP Moshi/Tanzania)
- NMRA trainings



WAHO/UNIDO COLLABORATION: REGIONAL GMP ROADMAP FRAMEWORK FOR WEST AFRICA

- Initiated in early 2017, due to complete in 2018
- Project involves all 15 countries in the ECOWAS region, and is divided into three phases
- GMP assessments are being performed and involve companies in all countries where manufacturing occurs
- Outputs include:
 - A regional GMP roadmap framework
 - Training, support and guidance for existing companies in the region to help them to develop towards international standards
 - Country level guidance documents to support the establishment of manufacturing facilities up to international (WHO) GMP standards
- Ongoing discussions regarding continuation of the collaboration - implementation of roadmap framework and industry upgrading with requisite technical cooperation

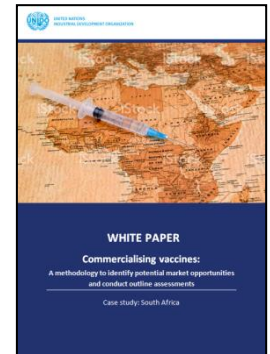
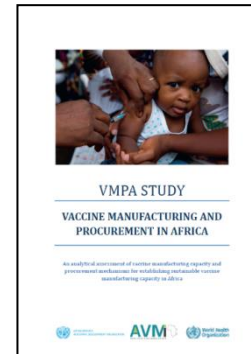


EAC/GIZ/UNIDO COLLABORATION: REGIONAL PHARMACEUTICAL MARKET INFORMATION PROJECT

- Project involves 4 EAC countries in EAC, and 5 Medicines Regulatory Authorities (MRAs)
- Comprehensive assessment made of sources and quality of available primary pharmaceutical data by market component, i.e. commercially imported/donated/(re)exported medicines
- Outputs include:
 - Compilation of database of 18,000+ medicines registered by MRAs in EAC, duly classified
 - Development and deployment of integrated Pharmaceutical Market Information System (iPMIS), allowing
 - direct upload by local manufacturers of production/sales data, never captured before for region
 - market data queries by diverse user groups through Query/Search tool
 - User training on iPMIS for staff of MRAs and local companies, as part of change management

HIGHLIGHTS 2017/18

- Expanding work on **vaccine production**
 - Vaccine Manufacturing and Procurement in Africa (VMPA) study - 2017
 - Establishing Manufacturing Capabilities for Human Vaccines - 2017
 - Commercialising Vaccines: Case Study South Africa – 2018
- **Strategy formulation**
 - Pharmaceutical Sector Development Strategy **Ghana** (update)
 - Under preparation in 2018: Zambia, Panama
- Partner of GFATM/FAPMA 2017 African Pharma Manufacturers Conference, Addis Ababa
 - **GFATM ready to increase procurement from African pharma**
- Focus on **tech. transfer, investment and access to affordable finance, incentive packages**
 - EGM “Improving access of African pharmaceutical manufacturers to investment capital” - 2017
 - **Bonn event : “Mobilizing Investment, Technology and Partnership Opportunities for Africa’s pharmaceutical industry” – March 2018**
 - Guidance document
- **Biosimilars**, in collaboration with ICGEB Trieste (pipeline):



CONCLUSION / WAY AHEAD

- Macro environment is positive for LPP promotion (mainstreaming)
 - Overall socio-economic fundamentals intact for pharma growth
 - Procurement entities: GF, UNICEF – strong desire to diversify supply base & procure from African producers
 - Pharma business activity stepping up of late
- LPP agenda = unfinished for years to come
 - Current medicines procurement practices not sustainable
 - How realistic are donations ad infinitum? Do we want to put up with (increasing) donor dependence? Unmet need for medicines today and tomorrow likely to grow
 - LPP build-up & expansion time-consuming
 - Indispensable: need for African govts. to provide more resources
- Need for coordination across mandates, collaboration and multitude of partnerships
 - BMZ/GIZ, UN (UNAIDS, UNCTAD, WHO), Global Fund, AUC/NEPAD, etc.
 - Business partnerships - need for more!!!
- UNIDO commitment to last
 - Firmly positioned: provider of technically sound, yet pragmatic solutions
 - Access to technology and finance: facilitator/honest broker



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Thank You

For more information, please contact:

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