**An Interagency Statement on Promoting Local Production of Medical Products: the progress made and way forward.**

***Preamble***

There is great interest by low- and middle-income countries (LMICs), particularly in Africa, to invest in the local production of medical products as seen within the public domain (1-7). The value of local production is its potential to improve access and protect national health security. Improving access to quality-assured medical products contributes to universal health coverage (UHC) and improved health outcomes. Local production also has potential value to support other national goals, such as economic development, industrialization and advancing technological capacity and capability. Thus, promoting local production of quality-assured medical products is regarded as a strategy to contribute to multiple SDG targets.

Local production has been the subject of discussions internationally. At the World Health Assembly in 2008, the adoption of Resolution WHA61.21 on the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property brought a new focus on local production as a means of contributing to the overall goals of improving access, improving innovation and building capacity. The African Union (AU) Heads of States and Governments endorsed the Pharmaceutical Manufacturing Plan for Africa (PMPA) in 2007 and the Business Plan (PMPA-BP) in 2012. The top leadership of UNAIDS, UNIDO and WHO highlighted the potential of local production and the importance for collaborative action to improve public health and sustainable development in Africa (8). And recently, a report by the WHO Director-General that was presented at the 71st World Health Assembly highlighted that strategic and sustainable local production of quality-assured medical products is a component towards improving access (9).

Significant progress has been made in past years. For instance, at a regional level, the AUC and NEPAD Agency implemented the African Medicines Regulatory Harmonization Programme with support from a consortium of partners and stakeholders to contribute to the AU PMPA and facilitate access to quality-assured medicines. Also, the East African Community Regional Pharmaceutical Manufacturing Plan for Action (2012-2016) was developed with multi-stakeholder engagement and development partner support to serve as a roadmap to guide the EAC towards building a regional pharmaceutical manufacturing industry. At a national level, the Ethiopian government, with support from WHO and other partners, developed and launched the National Strategy and Plan of Action for Pharmaceutical Manufacturing Development for Ethiopia (2015-2025) (NSPA-Pharma). The NSPA-Pharma combines the objectives of health and industrial policies to improve access to quality, efficacious, safe and affordable medicines and to grow the sector and economy.

Promoting local production is a cross-cutting endeavour, which requires *inter alia* political commitment and policy coherence, a long term vision, sustainable and affordable finance, human resource development, a robust regulatory system, adequate infrastructure and an intellectual property system with consideration of the flexibilities in the TRIPS Agreement. As a result of this complexity, challenges still remain for LMICs and international partners and expectations need to be managed as further investment in local production of medical products continues. For instance, the success of industrial development experienced in larger countries is difficult to replicate in smaller markets. In some settings, the economic and development agendas are overwhelming the health agenda and the capacity of the health system, particularly the countries’ national regulatory authority capability to respond effectively. In other cases, countries have committed resources into local production with expectations of lower prices for medicines but in fact, may have resulted in higher prices for the locally produced medicines.

***Progress made***

***Discussion points:***

* *Should the content be arranged by organization, by subject or by product type (pharmaceuticals, biologics, medical devices, in-vitro diagnostics)?*
* *And starting from when, e.g. 2015 to the present or the last ten years?*

*Examples of progress made:*

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| ***Organization*** | ***Subject*** | ***Activity to strengthen/promote local production, 2015 to present*** |
| GIZ | National/Regional development | * Supported the EAC Secretariat with implementation of the Regional Pharmaceutical Manufacturing Plan of Africa * Gap analyses of 30-35 companies to facilitate achievement of WHO GMP standards |
| Capacity building | * Capacity building & developing guidance on improving policy coherence on access to medicines   Kenya:   * Training of GMP inspectors |
| Guidelines & tools | * Toolbox for Policy Coherence in Access to Medicines and Local Pharmaceutical Production in collaboration with UNCTAD |
| UNCTAD | Policy analyses | * Case studies on local production and technology transfer on 8 countries in collaboration with WHO |
| National development | * National IP policy and access to medicines in South Africa (2016, 2017) |
| Capacity building | Ethiopia:   * Multi-stakeholder training on IP policy (2016)   Senegal:   * Regional workshop on Transfer of Technology and Public Health (Apr 2017)   Vietnam:   * National capacity building workshop on patent examination (2016) |
| Guidelines & tools | * Toolbox for Policy Coherence in Access to Medicines and Local Pharmaceutical Production in collaboration with GIZ |
| UNICEF | Market development | * Active policy to procure locally where local supplier meets UNICEF quality standards * Actively looking for local suppliers of medicines in Africa * For local bids, international bidders are excluded * For international bids, landed cost and lead time are evaluated in favour of local manufacturers * UNICEF has established 5 local suppliers of finished pharmaceuticals in 5 African countries |
| Collaboration linkages | * Is a PIC/S associated partner organization |
| UNIDO | National development | * Developed and applying a GMP roadmap approach in Kenya, Ghana and ECOWAS (future) |
| Capacity building | * Market data initiatives for Ghana and EAC |
| Collaboration linkages | * Is the lead technical agency to the AUC for PMPA-BP implementation * Collaborations with WHO, UNAIDS, UNCTAD, GIZ, USP, IFC, etc. |
| WHO | Policy analyses | * Published framework for policy coherence for local production * Policy analyses for policy coherence conducted in Africa and in Ethiopia, Ghana and Kenya, Ghana in collaboration with UNCTAD * 3 published country case studies on promoting local production to protect public health in China, Cuba and India * 8 published landscape analyses on local production of medical products, including vaccines, MDs, IVDs and blood products, and in 8 countries around the globe |
| National development | * Supported development, launch & implementation of Ethiopia’s NSPA-Pharma * Revitalized Ethiopia’s national GMP roadmap |
| Capacity building | Ethiopia:   * Building regulatory capacity of EFMHACA GMP inspectors * Training to Ethiopia on how to take advantage of flexibilities in TRIPS |
| Collaboration linkages | * Developed an interagency framework of collaboration for NSPA-Pharma implementation * Convened interagency consultations on local production |
| Guidelines & tools | * Developing a risk assessment tool * Developing an assessment tool for the feasibility & readiness for sustainable local production |

***Lessons learned***

***Discussion points:***

*Can agencies/institutions provide examples of lessons learned, with evidence, which has promoted or hampered local production?*

*Examples of lessons learned:*

* Government commitment is critical to promoting sustainable quality local production:
  + In Cuba, long-term commitment towards policy coherence and integration yielded social and economic impacts, including: health indicators and a human development index comparable to developed countries; access to medicines and other health technologies; novel scientific results with high visibility and IP rights.
  + In Ethiopia, the government provides incentive packages for establishing manufacturing facilities in industrial parks, e.g. Kilinto Industrial Park for pharmaceutical manufacturing.
* Long-term vision and strategy is important: e.g. AU PMPA Business Plan, EAC Regional Pharmaceutical Manufacturing Plan for Action, NSPA-Pharma.
* Human resource development for pharmaceutical manufacturing should include other requisite professionals, e.g. microbiologists, engineers and statisticians.
* Manage expectations

***Future challenges***

***Discussion point:***

*What are the future challenges in promoting local production?*

*Examples:*

* Low production standards
* Lack of a robust regulatory framework
* High costs of finance and the lack of access to appropriate and sustainable finances
* Commercial sustainability when locally produced products can be more expensive than available products, including imports
* Lack of collaborative linkages and policy coordination between ministries and institutions
* Lack of coherent strategies
* Managing countries’ expectations
* High level of interest and demand, resulting in increasing requests from countries
* Transitioning countries

***Way forward***

***Discussion point:***

*How do we overcome the challenges and drive impact?*

*Examples:*

* Focus on priority areas: e.g. policies, regulatory system strengthening , quality assurance, health workforce capacity building, access to finances and incentive packages
* Prioritize product types for local production
* Partnerships: global application of the interagency framework of collaboration for NSPA-Pharma implementation

***Conclusion***

***Discussion point:***

* Summarize the different elements
* Articulate the midterm and long term outcomes

***References***

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**PROPOSED ROADMAP and discussion points**

For the development of an interagency statement on the progress and way forward in promoting local production, a roadmap is proposed to structure the process:

***Discussion points:***

* *Which agency/institution would like to participate?*
* *What are the target audiences for the interagency statement?*
* *What would be the mode of publishing the interagency statement? E.g. website, organization publications (such as the WHO Drug Information), industry journals*
* *What would be the process for drafting the interagency statement? For instance, will agencies/institutions contribute content on the progress made and then consolidate into a single document?*
* *Which agency/institution will be responsible for which task?*
* *What would be the timelines?*
* *Are there clearance procedures from participating agencies/institutions that need to be observed?*

**PROPOSED ROADMAP**

Conceptualization phase

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| ***Steps*** | ***Timeline*** |
| Discuss the development of the interagency statement through the discussion points | During the meeting |

Drafting phase

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| ***Steps*** | ***Target Timeline*** |
| Provide content from the participating agencies/institutions to WHO | 2 months |
| Draft the statement (version 1) and then circulate to the participating agencies/institutions for comments | 2 months |
| Provide comments on version 1 to WHO | 1 month |
| Revise the statement based on comments received (version 2) and then circulate to the participating agencies/institutions for final comments | 1 month |
| Provide final comments to WHO | 2 weeks |
| Finalize the statement and start the publication phase | 2 weeks |

Publication phase

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| ***Steps*** | ***Target Timeline*** |
| Edit and format the final version accordingly (refer to discussion points) and then circulate to the participating agencies/institutions for comments | 4 weeks |
| Provide comments to WHO | 2 weeks |
| Finalize the statement | 2 weeks |
| Publish the statement |  |