

Draft Concept Note

2nd Interagency consultation for local production of essential medicines and health products

Background

Access to quality-assured essential medicines and health products still remains to be a challenge, particularly in low- and middle-income countries (LMICs). Improving access is recognized as an important part of achieving universal health coverage and other cross-cutting health targets embedded in the Sustainable Development Goals. The African Union Heads of States and Governments endorsed the Pharmaceutical Manufacturing Plan for Africa (PMPA) in 2007 and Business Plan (PMPA-BP) in 2012 to strengthen the ability in Africa to produce high quality, affordable essential medicines in order to improve health outcomes. In 2008, the adoption of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property in Resolution WHA 61.21 sharpened the focus of local production as a means to promote innovation, build capacity and improve access to essential medicines and health products.

LMICs has shown great interest in promoting local production as a strategy towards universal health coverage and improved access. Subsequently, with support from development partners, LMICs have made progress on several fronts. However, many barriers remain, such as inadequate regulatory systems and pharmaceutical value chains, low production standards, unavailable skilled workforce and lack of appropriate and sustainable financing. Past experiences in promoting and strengthening local production also demonstrated the need for collaboration.

In order to help address these challenges, WHO convened an informal interagency consultation on local production on 25 April 2017 in Geneva, wherein UN agencies and international partners discussed local production and access to quality-assured medicines with a view towards considering an inter-agency strategy for collaboration that would articulate partners' roles and explore the way forward. Outcomes of the meeting included consensus on the need to develop strong regulatory systems, for providing guidance to countries in setting priorities and for managing expectations in local production. Refer to Appendix 1 for the meeting report from the 1st inter-agency consultation on local production.

In the spirit of the 1st interagency consultation, which highlighted the importance of collaboration, WHO supported the Ethiopian government in adopting an interagency framework for collaboration for the implementation of the NSPA-Pharma¹ that aims to assist Ethiopia to

¹ National Strategy and Plan of Action for Pharmaceutical Manufacturing Development in Ethiopia (2015-2025)

strengthen coordination, synergize partners' competitive advantages and expertise and reduce duplication. The interagency framework also provided a model for collaboration and coordination at a country level which could be expanded to a global level.

Local production was also discussed at the Interagency Pharmaceutical Coordination (IPC) Group meeting in Copenhagen in December 2017, with a call from the participants for further discussion and collaboration in promoting local production to improve access. Areas of action for local production and next steps were identified, including consideration for a standing IPC subcommittee on local production as a platform for regular information sharing and an interagency statement on the progress and way forward of local production. The importance for collaborative linkages in promoting local production to improve access was further highlighted in a report by the WHO Director-General² that was presented at the 142nd session of the WHO Executive Board in January 2018.

Following on the recommendations of the IPC, WHO is convening the 2nd interagency consultation on local production to continue the dialogue and momentum on local production of essential medicines and health products.

Objectives

The objectives of the meeting are to:

- a. provide an update on recent activities in promoting local production from partners;
- b. develop a harmonized definition for "local production" (refer to Appendix 2 for a compilation of definitions of local production used);
- c. discuss a roadmap for the development of an interagency statement on the progress and the way forward in promoting local production (refer to Appendix 3 for a compilation of public statements);
- d. establish a standing IPC subcommittee on local production.

² World Health Organization Executive Board, 142nd session. Addressing the global shortage of, and access to, medicines and vaccines: Report by the Director-General. Geneva: World Health Organization; 2018 (http://apps.who.int/gb/ebwha/pdf_files/EB142/B142_13-en.pdf, accessed 28 March 2018).

Expected outcomes

The expected outcomes of the meeting include:

- a. a proposed common term and definition for “local production”;
- b. a roadmap for developing an interagency statement on the progress and way forward in promoting local production;
- c. establishment of a standing IPC subcommittee on local production;
- d. recommendations for the way forward.

Proposed agenda

The proposed agenda for the meeting is attached as Annex 1.

Participants

The list of participants is attached as Annex 2.

Date and venue

The 2nd interagency consultation on local production is scheduled to take place on 18 June 2018 in Geneva, Switzerland. The meeting will take place at WHO Headquarters in Room M605 in the M Building.

List of Appendices

1. Report of the interagency consultation on local production of essential medicines and health products. In: WHO/Essential medicines and health products [website]. Geneva: World Health Organization; 2017
(http://www.who.int/medicines/publications/report_interagency_consultation_local_prod_essential_meds_hp/en/, accessed 28 March 2018).
2. Compilation of definitions of “local production” used.
3. Compilation of public statements on local production.

Annex 1. Draft agenda

2nd Interagency consultation for local production of essential medicines and health products

Geneva, 18 June 2018

Venue: Room M605, M Building, WHO Headquarters

Draft Agenda

<i>Time</i>	<i>Programme</i>	<i>Presenter</i>
8:00 – 8:30	Welcome coffee / Registration	
<i>Morning Session Chair: Emer Cooke / Mike Ward</i>		
8:30 – 8:50	Opening & Welcome	<i>Dr Mariângela Simão</i> Assistant Director-General Access to Medicines, Vaccines and Pharmaceuticals (MVP) <i>Dr Suzanne Hill</i> Director Essential Medicines and Health Products (EMP)/MVP <i>Ms Emer Cooke</i> Head Regulation of Medicines and other Health Technologies (RHT)/ EMP/MVP
8:50 – 8:55	Review and adoption of the Agenda	<i>Dr Jicui Dong</i> Programme Manager for Local Production Regulatory Systems Strengthening (RSS)/RHT/ EMP/ MVP
8:55 – 10:10	Updates from partners (5 minutes for each)	
10:10 – 10:40	Coffee break	
10:40 – 10:50	Presentation 1: Compilation of definitions of local production used	WHO
10:50– 12:20	Discussion 1: Elements for the working definition of local production	
12:20 – 13:30	Lunch Break	
<i>Afternoon Session Chair: Mike Ward / Jicui Dong</i>		
13:30 – 13:45	Presentation 2: Draft roadmap and outline for interagency statement on the progress and way forward	WHO
13:45 – 14:45	Discussion 2: Roadmap for interagency statement on the progress and way forward	

14:45 – 15:15	Discussion 3: Assessment tool on feasibility and readiness for sustainable local production	WHO, UNIDO, UNCTAD
15:15 – 15:45	Coffee Break	
15:45 – 16:45	Discussion 3: Local production of condoms Any other topics	UNFPA
16:45 – 17:15	Discussion 4: Establishment of IPC subcommittee Recommendations and the way forward	
17:15 – 17:30	Discussion 5: Reporting to the IPC	
17:30	Closing remarks	<i>Mr Mike Ward</i> Coordinator of RSS/RHT/EMP/MVP

Annex 2. List of Participants

List of Participants

<i>Organization</i>	<i>Participant</i>	<i>Email</i>
GAVI	Ms Marion Menozzi-Arnaud	mmenozziarnaud@gavi.org
Global Fund	Mr. Lin Li	Lin.Li@theglobalfund.org
Global Fund	Ms Melisse Murray	Melisse.murray@theglobalfund.org
GIZ	Ms Corinna Heineke	corinna.heineke@giz.de
MPP	Mr. Esteban Burrone	eburrone@medicinespatentpool.org
Stop TB	Ms Brenda Waning	brendaw@stoptb.org
UNAIDS	Dr. Joy Backory	BackoryJ@unaids.org
UNCTAD	Mr. Ermias Biadgleng	Ermias.Biadgleng@unctad.org
UNCTAD	Mr. Christoph Spenneman	Christoph.Spennemann@unctad.org
UNFPA	Ms Seloï Mogatle	mogatle@unfpa.org
UNHCR	Mr. Javier Utande	utande@unhcr.org
UNICEF	Dr. Akthem Fourati	afourati@unicef.org
UNICEF (remote)	Hitesh Hurkchand	hhurkchand@unicef.org
UNIDO	Mr. Alastair West	A.West@unido.org
UNITAID	Mr. Jan Akko Eleveld	eleveldj@unitaid.who.int
UNITAID	Ms Katherine Hencher	hencherk@unitaid.who.int
UNITAID	Dr. Cherise Scott	cscott@unitaid.who.int
USAID (remote)	Ms Helen Petach	hpetach@usaid.org
World Bank	Dr. Ana Holt	aholt@worldbank.org
WHO	Dr. Mariângela Simão	simaom@who.int
WHO	Dr. Suzanne Hill	hills@who.int
WHO	Ms Emer Cooke	cookee@who.int
WHO	Mr. Mike Ward	wardmi@who.int
WHO	Dr. Jicui Dong	dongj@who.int
WHO	Mr. David Woo	wood@who.int
WHO	Ms Noëlle Mendy	mendyn@who.int
WHO	Dr. Bernadette Abela-Ridder	abelab@who.int
WHO	Dr. Adham Rashad Ismail Abdel Moneim	ismaila@who.int
WHO	Ms Tania Cernuschi	cernuschit@who.int
WHO	Mr. Boniface Dongmo Nguimfack	dongmonguimfackb@who.int
WHO	Dr. Martin Friede	Friedem@who.int

WHO	Dr. Daniel Low-Beer	lowbeerd@who.int
WHO	Ms Claudia Nannei	nanneic@who.int
WHO	Ms Silvia Schwarte	schwartes@who.int
WHO	Dr. Klara Tisocki	tisockik@who.int
WHO	Dr. Socorro Zarate-Escalante	escalantes@who.int