

## Appendix 2. Compilation of Definitions of “Local Production” Used

From a search of publicly available documents relating to the local production of medical products, there is no common definition of “local production” which, in part, may be due to the different meanings of “local” and “production” when used in the context of the manufacture of medical products<sup>1</sup>.

- For “local”, the term can have a “jurisdiction” or territorial context (e.g. taking place within a country and subject to a national jurisdiction, regardless of whether nationals or foreigners own the business) or an “ownership” context (e.g. owned by nationals in full or in part as a majority).
- For “production”, there is a wide range of manufacturing activities which a company can undertake – it can be just one activity, such as packaging the finished medical product, or several activities, such as formulating, producing and packaging the finished product. Thus, the activities which can be considered as “production” may vary, depending on the context of its use.

The table below summarizes descriptions of “local production” in publicly available documents to enable comparison and facilitate discussions for harmonizing the definition of “local production”.

No	Publication Title	What is “Local”			What is "Production"
		Description	Jurisdiction	Ownership	
1	<i>Pharmaceutical Production and Related Technology Transfer</i>	<i>“For the purposes of this study, “local” is defined as any production of drugs taking place in low-, lower-middle- and upper-middle-income countries, regardless of the ownership structure.”</i>	✓	✗	<i>“‘Production’ is defined as any stage of the drug manufacturing process from production of active pharmaceutical ingredients (APIs) to formulation or packaging.”</i>
2	<i>Trends in Local Production of Medicines and Related Technology Transfer</i>	For the purpose of the document, both viewpoints are implied: <i>“the definition of ‘local production’ was <u>not limited to manufacturing facilities owned by nationals of a host country.</u>”</i>	✓	✓	There is <b>no</b> description of what “production” encompasses.
3	<i>Local Production and Access to Medicines in Low- and Middle-Income Countries: A literature review and critical analysis</i>	<i>“If production occurs within a country to produce one or more of the materials listed [...], this is regarded as ‘local production’.”</i>	✓	✗	<u>Pharmaceutical products</u> : primary, secondary and tertiary manufacturing. <u>Vaccines</u> : specific for each product but includes isolating viral particle isolation, seed production & polyvalent vaccine assembly. <u>Medical devices</u> : product component is complex.
4	<i>Local Production for Access to Medical Products: Developing a Framework to Improve Public Health</i>	<i>“For the purposes of Phase 1 of this project, the territorial/jurisdictional basis of describing production has been used, ...”</i>	✓	✗	3 levels of manufacturing are described: primary (API, intermediates, excipients), secondary (finished product), tertiary (packaging).

<sup>1</sup> Trends in Local Production of Medicines and Related Technology Transfer. Geneva; WHO; 2011.

5	<i>Local Production and Technology Transfer to Increase Access to Medical Devices: Addressing the barriers and challenges in low- and middle-income countries</i>	<i>“For the purpose of this report, local production categorizes any manufacturer that is located within a national jurisdiction, regardless of whether it is national or internationally owned.”</i>	✓	✗	The 3 levels of manufacturing for pharmaceuticals is the same for medical devices, i.e. primary, secondary and tertiary, “... to describe a range of value-added activities from assembling pre-made parts, to developing devices from raw materials, to a combination of the two.”
6	<i>2013 Survey on Development of Appropriate, Affordable, Quality Medical Devices for Low-Resource Settings</i>	<i>“Local production is defined for the purposes of this survey as ‘domestic production of medical devices by international or national industries to solve a local public health need’”.</i>	✓?	✗	There is <b>no</b> description of what “production” encompasses.
7	<i>Investment in Pharmaceutical Production in the Least Developed Countries: A Guide for Policy Makers and Investment Promotion Agencies</i>	<i>“Local production shall mean the manufacture of pharmaceuticals in a developing country, whether by a locally owned firm, by a joint venture or by a foreign firm.”</i>	✓	✗	<i>“... pharmaceutical manufacturing encompasses a wide range of activities from drug development – R&amp;D – to the packaging and distribution of the final product, that is, the medicine.”</i>
8	<i>Local Production of Pharmaceuticals: Industrial Policy and Access to Medicines An Overview of Key Concepts, Issues and Opportunities for Future Research</i>	6 categories of companies (uni-/multi-national) are described to show what “local” means but all of them having activities <u>within the country</u> , e.g. sales, R&D and/or manufacturing or establishing a headquarters.	✓	✗	Four classifications of production are described: <ul style="list-style-type: none"> <li>▪ Packaging of already formulated medicines and small-scale local production of sterile or non-sterile formulations such as IV fluids.</li> <li>▪ Formulation of drugs in final dosage form and some production from imported intermediates.</li> <li>▪ Production from imported intermediates and manufacture of some intermediates from local materials.</li> <li>▪ Production of active substances and processing to produce the required pharmaceutical dosage forms.</li> </ul>
9	<i>Local production of pharmaceuticals and health system strengthening in Africa: An Evidence Brief</i>	<i>“By ‘local’ manufacturing, throughout this Brief, we mean manufacturing geographically located in low- and middle-income countries, and specifically in SSA, independent of ownership.”</i>	✓	✗	There is <b>no</b> description of what “production” encompasses.
10	<i>Local production of medical technologies and its effect on access in low and middle-income countries: a systematic review of the literature</i>	<i>“We use a jurisdictional, not an ownership definition. If production takes place in-country to produce biomedical products, this is local production”.</i>	✓	✗	<u>Pharmaceutical products</u> : primary, secondary and tertiary manufacturing. <u>Vaccines</u> : specific for each product but includes isolating viral particle isolation, seed production, bulk manufacture & polyvalent vaccine assembly. <u>Medical devices</u> : product component is complex.

## References

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