GVIRF 2018 Plenary 3: Growing Developing Country Vaccine Manufacture	
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Session Outline	**Chair:** Gerd Zettlmeisl (Chairman, Hilleman Laboratories) **Presentations:** *Vaccine Production in Developing Countries: An Economic Evaluation*, Syarifah Liza Munira (Department of Economics, Faculty of Economics and Business, Universitas Indonesia) *Developing Country Vaccine Manufacturers–Access to Immunization*, Lakshminarayana Neti (Biological E. Limited) *Perspectives on Approaches to Take, and Factors to Consider, Towards Sustainable Manufacturing Capacity*, Martin Nicholson (Pharmaceutical Expert, Dept. of Trade Investment and Innovation, UNIDO) *Addressing Patent Barriers to Vaccine Development & Access*, Kate Elder (Vaccines Policy Advisor, MSF Access Campaign)
Objectives of the session	*To discuss:* • Vaccine manufacturing from the developing country perspective • How manufacturers in developing contribute to global coverage • How international agencies can assist these countries in acquiring sustainable manufacturing
Main outcome	• Access to affordable vaccines requires an enabling environment for DCVMs and prices that are sustainable for manufacturers in the long term
Summary	This session identified challenges in the Developing country vaccine manufacturer (DCVM) business model and ways to address them and promote long-term access to affordable vaccines. DCVMs are serving ~110M infants (84% of the world's birth cohort) annually and supplying 60% of UNICEF and PAHO procurement. Out of 145 prequalified (PQ'd) vaccines, 64 are manufactured by DCVMs. Quality standards are the same for all PQ'd products and manufacturers must continually invest in their quality systems maintain compliance. However, LIC and LMIC manufacturers account for only 4% and 8% respectively of global vaccine market revenues and are under intense pressure to supply quality product at the lowest possible prices. For example, UNICEF is now procuring pentavalent vaccine at less than $0.80 per dose: this price may be unsustainable for some manufacturers. UNIDO's Global Pharmaceutical Project provides guidance for companies establishing manufacturing capabilities for human vaccines.[a,b] Facility setup takes longer and is more expensive for vaccine production than for generics: a new vaccine facility could take 3.5 to 10 years and $14M to $225M to establish, depending on capacity and whether it will be fully integrated or limited to formulation and filling. Therefor a robust business case including both technical and market assessments is needed to ensure repayment of upfront investments and sustained commercial viability. National governments and regional bodies can facilitate by establishing strong national regulatory authorities, providing incentives

	and direct investments, fostering a supportive business environment, and building a highly skilled workforce. Business risks include long development timelines and regulatory complexity that extend time to market; lack of demand predictability, which leads to poor capacity utilization and high fixed costs; diverse procurement mechanisms that in some cases promote monopolies; pressure for unsustainably low prices; and limited markets for regional vaccines that make it difficult to achieve economies of scale. An economic evaluation found that, while vaccines have high fixed costs, these costs can be offset by multi-vaccine facilities and large volumes. At volumes over 20 million doses, variable costs become the main driver. In addition, for viability in domestic markets manufacturers need sustainable and reliable production and suitable vaccine technologies. For export markets, they also need a fully-functioning national regulatory authority and prequalified vaccines. For these reasons, it is important to establish a strong domestic presence prior to expanding into export markets. Patent restrictions can create barriers for DCVMs, limiting competition that contributes to vaccine affordability.[c] Patent barriers are found throughout the vaccine development process, and while manufacturers can address them by in-licensing the necessary technology, designing around patents (when feasible), or challenging them, many companies lack the capacity to do so. The global community can contribute by promoting transparency in the intellectual property landscape with an open patent database, improving laws and policies, strictly applying patentability criteria and challenging unmerited patents, building robust access conditions into licensing and other agreements, and through capacity building and guidance. For DCVMs to continue supplying affordable vaccines, the "healthy markets framework"[d] must ensure sustainable prices that factor in their cost drivers and business risks.
Key references or quotes	a. VMPA Study: Vaccine Manufacturing and Procurement in Africa, 2017. https://www.unido.org/sites/default/files/files/2017-12/VMPA-Study-ebook.pdf b. Establishing Manufacturing Capabilities for Human Vaccines, 2017. https://www.unido.org/sites/default/files/files/2017-12/Establishing-Manufacturing-Capabilities-for-Human-Vaccines-ebook.pdf c. A Fair Shot for Vaccine Affordability: Understanding and addressing the effects of patents on access to newer vaccines, 2017. https://www.msfaccess.org/sites/default/files/VAC_report_A%20Fair%20Shot%20for%20Vaccine%20Affordability_ENG_2017.pdf d. Healthy Markets Framework, developed jointly by the Bill & Melinda Gates Foundation, Gavi, and UNICEF, 2016. https://www.gavi.org/library/gavi-documents/supply-procurement/healthy-markets-framework--public-overview/