Local Production and Access to Medicines in Low- and Middle-Income Countries

A literature review and critical analysis

Intellectual Property and Trade

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ICTSD
International Centre for Trade and Sustainable Development

World Health Organization

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List of abbreviations

API	active pharmaceutical ingredient
ARV	antiretroviral
CQS	chloroquine-sensitive
CQT	chloroquine tablets
FDI	foreign direct investment
FTA	free trade agreement
GNI	gross national income
GTZ	Deutsche Gesellschaft fuer Technische Zusammenarbeit,
HAART	Highly active antiretroviral therapy
IPR	intellectual property rights
LDC	least-developed countries
LMIC	low- and middle-income countries
LP	local production
MOH	ministry of health
NEML	national essential medicines list
NGO	nongovernmental organization
OECD	Organization for Economic Co-operation and Development
OTC	over-the-counter
PAHO	Pan-American Health Organization
PPP	public–private partnership
R&D	research and development
SEC	Securities and Exchange Commission
TB	tuberculosis
UN	United Nations
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Programme
UNIDO	United Nations Industrial Development Organization
WHO	World Health Organization
WHO/PHI	World Health Organization Department of Public Health Innovation and Intellectual Property
WTO	World Trade Organization

1. Introduction

1.1 Balancing industrial and health policies

For the pharmaceutical sector, policy-makers around the world continually struggle to balance health policy objectives (e.g., access to affordable and essential medicines) with those of industrial policy in the pharmaceutical sector (e.g., promoting innovation and local research and development (R&D) activity).[1] Tensions particularly arise over pricing and reimbursement. Limited health care budgets – and competing demands for scarce resources – force governments to set limits on which medicines to provide or subsidize, for whom and at what price. What ministries of health and/or health plans view as necessary to maintain equitable access to medicines, industry may view as detrimental to R&D and innovation.

1.2 Purpose of this report

This report explores the interface between industrial and health policies. Based on a literature review in the field, the report summarizes previous theoretical and empirical work on local production (LP) of biomedical products, and its potential impact on access to medicines. By 'products' we mean medicines and devices, including diagnostics. The report:

- Assesses to what extent the linkages between LP and access were explored in previous studies;
- Critically analyzes whether the methods employed in the literature were sufficient to suggest a robust relationship between LP and access;
- Evaluates whether results obtained could be directly applied to LP conditions in low- and middle-income countries (LMICs).

It is not primarily a review of LP, nor is it an extensive policy discussion on improving LP in LMICs.

1.3 Definitions

1.3.1 'Local production'

Jurisdictional component

Local production can take several forms:

1 As an example of the balancing required, Australia has implemented a range of generic programmes and policies to promote, attract and support domestic investment in R&D. Key components of the industry development agenda include direct government support for basic science, research infrastructure and higher education through a combination of grants, tax concessions, venture capital and import/export programmes. Between 1988 and 1999, the government allowed medicine manufacturers undertaking new R&D or value-added production in Australia to receive premium prices under their reimbursement scheme (PBS). Premiums were to be valued at a maximum of 25% of the additional research or production activity. Between 1999 and 2004, firms were required to undertake additional manufacturing and R&D activity in Australia in exchange for higher prices for medicines listed on the PBS (Morgan et al., 2008).

1. Local subsidiary of, or joint venture with, a multinational pharmaceutical company selling branded medicines in local and regional markets (i.e. Glaxo Smith-Kline, Pfizer, etc.);
2. Generic manufacturer producing medicines for the local and global markets (i.e. Ranbaxy, Cipla, etc.);
3. Generic manufacturer producing medicines for predominantly the local market; and
4. Locally–owned, small-scale manufacturers serving a portion of the domestic market (Mercurio 2009).

Some manufacturers cut across more than one of the categories, as branded medicine companies now operate their own generic companies and successful, large-scale generic companies are also developing branded medicines. For the purposes of the current review a jurisdictional definition has been adopted, rather than one based on ownership. If production occurs within a country to produce one or more of the materials listed below (see *Product component*), this is regarded as 'local production'. Most foreign direct investment (FDI) in low-income countries remains in the non-productive sectors. Hence, this form of multinational corporation subsidiary activity will tend to be minimal in the case of LMICs.

Product component

The focus of this review is on biomedical products including pharmaceutical products, vaccines and medical devices, for example. With regard to pharmaceuticals, primary LP is the manufacture of active pharmaceutical ingredients (APIs) and intermediates from basic chemical and biological substances. Secondary LP includes the production of finished dosage forms from raw materials and excipients (inactive substances). Tertiary LP is limited to packaging and labelling finished products, or repackaging bulk finished products. In relation to vaccines and LP, many vaccines are currently derived from viral particles developed in eggs. Technology is specific for each vaccine product and may include isolating viral particles, producing vaccine 'seed' viruses, bulk manufacture, and assembling polyvalent vaccines. With regard to medical devices, the product component can be extraordinarily complex as a medical 'device' can be anything from a bed to a magnetic resonance imagery machine.