A new geography of medicines: preliminary comments on local pharmaceutical production in Africa

Maurice Cassier
CNRS

« Global drugs » and local production

- It can be used descriptively, to refer to the development of medicine production for domestic use, as opposed to production targeting regional or international market
- But it also has methodological significance in the sociology and anthropology of science, in relation to the local creation of knowledge and know-how underpinning any industrialization process

Local production and pharmaceutical policies

- The notion of local production can also refer to national medicine production policies to achieve technological and industrial autonomy and to meet domestic health needs in order to fight epidemics or endemics
- It can be referred to a process of "nationalization" of the pharmaceutical technology

Local production and Essential medicines Policies

- Local production in developing countries, through the creation of formulation laboratories, was part of the policy of access to essential medicines.
- WHO archives show that in the early 1980s, the WHO delegated several missions in East African countries to assess local production capacities. However the international pharmaceutical federation did not wish to make local production an immediate priority.

The hostility of the World Bank in 2005

- World Bank experts advised against the development of local production in developing countries, particularly in the poorest countries, arguing that production costs are too high and that the quality is uncertain : « The authors conclude that in many parts of the world, producing medicines domestically makes little sense economically. In fact, local production may even limit access to medicines if economies of scale are lost in the process » (Local Production of Pharmaceuticals, The World Bank, january 2005).

Local production in Africa

- Cycles of development of local pharmaceutical production can be observed in Africa, particularly in the context of post-colonial independence and economic development policies : Egypt under Nasser, public pharmaceutical production in Algeria, creation of public labs in Tanzania in the sixties and seventies
- A new cycle of pharmaceutical production development can now be witnessed in Africa, with technical support and investments from Chinese and Indian companies over the last 10 years in the context of their global expansion : joints venture, directs investments, importation of raws materials from Asia, circulation of technicians

Clusters of national producers and few implantations from multinational firms

- There are also groups of privately-owned national producers, in Morocco, Tunisia, Egypt, Ghana, Nigeria, Kenya and South Africa, and to a lesser extent Côte d'Ivoire, Tanzania and Uganda
- A few multinationals have local development strategies in Africa. Sanofi, for instance, has seven production facilities
- the Brazil-Mozambique collaboration to produce essential medicines in Africa (2003-)

Political Initiatives to develop local pharmaceutical production in Africa

- Pharmaceutical Manufacturing Plan for Africa (PMPA) adopted by the African Union at a summit in Accra in July 2007
- In the field of intellectual property, it recommends to extend patentability exceptions beyond 2016 for low-income countries, to afford them the possibility to copy new therapies, which no longer exists in India since it adopted medicine patents
- In the field of regulation, drug agencies must promote the improvement of local companies' production standards and harmonize their requirements for registration to constitute wider markets.

organization of local producers

- The East African Community (EAC: Burundi, Tanzania, Kenya, Rwanda and Uganda) decided to support the Federation of East African Pharmaceutical Manufacturers (FEAPM)
- This strategy is designed primarily to produce generic medicines which India can no longer copy due to its new law on intellectual property.

Economic studies on local production in Tanzania

- Indian economist Sudip Chaudhuri has shown the strong presence of Indian medicines on the Tanzanian market (40% of registered medicines), while local production accounts for only 8% of registrations but supplies 1/3 of the market, both private and public
- Investments have been made over the last few years to meet Manufacturing Best Practice standards or to obtain a prequalification from the WHO, with the assistance of external agencies: the Belgian Investment Company for Developing Countries, the DNDI and the OTECI to produce Asaq

the Brazil-Mozambique collaboration to produce essential medicines in Africa

- An economic study was recently undertaken on the pharmaceutical manufacturing company built in Mozambique with the help of the Brazilian government
- One of the major obstacles to the growth of this local production may relate to the fact that the main ARV funders in Mozambique, the Global Fund and PEPFAR, mainly source prequalified generic medicines from India

An invention from humanitarian medicine : Asaq

- Asaq was developed at the MSF's initiative from 2002, in the framework of the FACT, an international consortium of universities and scientific organizations from the North and the South
- The development of this fixed-dose combination was complicated and was carried by a collective of university laboratories and French start-ups around Bordeaux.
- to the academics' disappointment this technology was not patented, as expressly requested by MSF and the DNDI - Drugs and Neglected Diseases Initiative- that control the dissemination of the technology

A « global commons » policy

- "By relinquishing the patent on this medicine and applying differential prices that can extend as far as the 'no loss/no gain' model for the public sector and large international health organizations, Sanofi and the Drugs for Neglected Diseases initiative (DNDi) have reached a decisive stage that has improved access to antimalarial treatment" (source: Sanofi).

Economic model of DNDI-Sanofi asaq

- An original partnership between a humanitarian organization and a multinational firm
- the medicine's non-patentability and the non-exclusivity of its industrial exploitation
- price commitments by Sanofi, at least for the medicine's distribution in the public sector
- the deployment of a policy of access to the medicine which the Sanofi group can advertise in partnership with a humanitarian organization, to treat an epidemic hitting low-income countries in Africa
- the WHO's pre-qualification of Sanofi's Asaq from 2008 to access international markets

« local production » of Sanofi-Asaq in Morocco

- "This desire for proximity with patients can be seen through a few examples: The production of ASAQ Winthrop in Morocco: an antimalarial medicine manufactured in the heart of the African continent" (source : Sanofi group).
- Since 2014, Sanofi -Maphar uses semi-synthetic artemisinin produced by Sanofi in Italy
- Sanofi-Maphar distributes Asaq-Winthrop in 30 african countries

The dissemination of asaq production in Tanzania

- From 2010, while Sanofi was already producing Asaq in Morocco, the DNDI began to investigate establishing production in other African countries. This intention to spread Asaq production across several laboratories and in several countries is part of the DNDI's policy of non-exclusivity to prevent a monopoly on this medicine
- DNDI chose a laboratory in Tanzania -Zenufa- that could access the market for prequalified generic medicines financed by the Global Fund and international programmes

The spread of production in Asia

- production of Asaq by Indian and Chinese manufacturers who duplicated or developed the technology themselves and obtained pre-qualifications from the WHO. This dissemination is the result of Asaq's non-patentability; a part of it is organized and controlled by the DNDI and the rest is free.
- 3 of them are WHO pre-qualified (IPCA, Cipla, Guilin)

Some ways to acquire asaq technology for an african producer

- a transfer towards new laboratories organized by the DNDI
- The implantation of a new Sanofi laboratory, which would require the agreement of the DNDI
- a transfer organized by an Indian or Chinese generic medicine manufacturer
- the DNDI's reverse engineering of the Asaq technology or the development of another technology by an African laboratory, using its own resources or collaborating with academics

Which standards of production ?

- As we have seen, the DNDI favours the field of WHO prequalification and the market of large international organizations, which for the moment excludes many laboratories in Africa
- Another path also exists, which can be followed alongside WHO prequalification: certifications issued by a national drug agency

Local production : how to overcome the barriers of standards ?

- Through international collaboration promoted by the WHO, european or french medicines agencies, governemental cooperation agencies, or NGOs - as DNDI in Tanzania
- Through the strengthening of national medicines agencies, the creation of bioequivalence centers, the education and employment of pharmacists and chemists
- National agencies can offer and provide technical assistance to local producers to improve their standards of production

Developing the local production using the flexibilities of Intellectual Property

- Least developed countries are allowed to use exemptions from patentability until 2016 january (TRIPS agreement); however, some countries havent use theses flexibilities ; they also could use compulsory licences in order to set up local production of generics

Which markets for local production ?

- We could observe local production supplying domestic markets or regional markets and normally or eventually certified by national authorities
- Very few african producers can presently access the international market of WHO prequalified medicines ; but a selection of them are currently involved in a procedure of pre-qualification by WHO

Local production and public health policies

- Local production of ARVs or ACTs are eventually driven by health needs to fight epidemics or endemics : creation of a public factory for ARVs in Mozambique, factories localized with the aim of producing antimalarials in endemic region (Tanzania)
- But international agencies are frequently disconnected from local producers : how the two parties could cooperate ? Which role for national authorities ?