Submission to the United Nations Secretary General's High Level Panel on Access to Medicines

Other

UNITED NATIONS SECRETARY-GENERAL'S HIGH-LEVEL PANEL ON ACCESS TO MEDICINES

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Section 1: Abstract

Much of the current debate on health care goals, medical innovation and trade rules focuses on the misalignment between the need to provide incentives to innovation – mainly through a tight intellectual property (IPR) regime – and the resulting negative consequences in terms of access to medicines. While this clash is certainly crucial, this contribution focuses on a different aspect of the misalignment between innovation and access, concerning essential drugs and generics rather than brand new, innovative drugs. This contribution argues that the promotion of domestic drug production and innovative capabilities in low and middle income countries, and notably on the Sub-Saharan African subcontinent, can may constitute an important step towards achieving significant improvements in public health – as a human right that includes access to essential medicines. We provide background and evidence for this argument. We then draw out policy implications, arguing that increased policy coherence between health policies for medicines access and public health, and industrial and trade policies for Africa-based pharmaceutical production and innovation, are both feasible and beneficial, generating synergies between improved medicines access and local industrial innovation.

Section 2: Contribution

Proposition

Much of the current debate on health care goals, medical innovation and trade rules focuses on the the misalignment between the need to provide incentives to innovation – mainly through a tight intellectual property (IPR) regime – and the resulting negative consequences in terms of access to medicines. While this clash is certainly crucial, this contribution focuses on a different aspect of the misalignment between innovation and access, concerning essential drugs and generics rather than brand new, innovative drugs. This contribution

argues that the promotion of domestic drug production and innovative capabilities in low and middle income countries, and notably on the Sub-Saharan African subcontinent, can constitute an important step towards achieving significant improvements in public health – as a human right that includes access to essential medicines.

As a consequence, and at the same time, the promotion of learning, technological upgrading and innovation in pharmaceutical production based in these counties becomes a central policy priority. Indeed, obstacles to such initiatives, arising in part from trade policies and procurement rules, are prominent examples of misalignment and incoherence between intellectual property rights, trade rules and public health objectives.

This contribution thus argues that global and local health policies affecting access to medicines and medical devices in low and middle income countries should be redesigned to give a stronger emphasis on their industrial impact; specifically, global and local policies should be revised to support enhanced market access and greater innovation incentives for Sub-Saharan Africa-based producers of pharmaceuticals, diagnostics and medical devices. This will require: further documentation and recognition of the public health benefit of Africa-based producers' track record and capability in supplying medicines to those on low incomes, and their innovative record to date; and redesign of procurement principles and policies to create more coherence between health and industrial policies, to support market access and innovation by Africa-based manufacturers for public health benefit.

Background

There is an increasing body of evidence that local producers of essential medicines are able to meet the needs of rural populations for access to essential medicines significantly better than importers of medicines, whose supply has been shown to suffer from "urban bias" (Mujinja et al 2014). This is increasingly recognised by international aid agencies, as it has long been by domestic government procurement agencies, which use local producers to supplement supply from recognised importers because of the advantages of local production in terms of speed, flexibility and reach.

However, lack of coherence in current policy frameworks both at international and local level generates disincentives for the local production (that is, production based in African countries) of essential medicines. A number of policy initiatives, both at the global and local levels, in the areas of health, trade, intellectual property rights, procurement and industrial development have made it more difficult for important African producers to access the local markets and upgrade their technology successfully (Mackintosh et al 2016). The existing success stories in local production, however, demonstrate that local production can make a difference in fulfilling the human right to access to health for the sections of society that are usually excluded because of existing policy incoherence (Gebre-Mariam et al 2016; Fortunak et al 2016).

The development of domestic capabilities in the manufacturing and distribution of drugs and medical devices in African countries may therefore be considered as part of a broader commitment to sustain industrial growth as well as health, based on learning and innovation. The construction of such capabilities makes it more likely that firms will improve existing

products, adapting them to local conditions and redressing the existing bias towards drugs directed mainly to rich markets. In this respect, policies targeting pharmaceuticals should be explicitly considered as one important element of a broader vision and set of growth oriented, health- and human rights-supporting policies.

It is now widely and increasingly recognized that economic growth and development are essentially based on the accumulation of knowledge and capabilities, both at the levels of individuals and organizations. Such capabilities are learned through education and formally acquired skills but also – and fundamentally – through experience, practice and the acquisition of tacit knowledge. It is also increasingly recognized that – in order to ignite and support these learning processes, active intervention and policies are needed to provide incentives for agents to engage in such activities and to define the basic and complex economic and institutional conditions that allow knowledge to be developed, shared and further improved (Cimoli et al., 2009; Rodrik, 2004 and 2009).

As a consequence, success in pharmaceuticals requires the attainment of a set of organizational and institutional preconditions which are likely to go much beyond the boundaries of this specific industry but impact on the broader ability to grow. The conditions that have to be met in order to successfully promote efficient industrial activities in pharmaceuticals will pave also the way for further growth in different sectors.

Evidence

Several arguments and types of evidence support the proposition that promotion and redesign of global and local health and industrial policies to support Africa-based pharmaceutical production and innovation can act to support African access to essential medicines.

First, current global health policies have stifled innovation and market access by important African producers. For example, the shift to new anti-malarial medication, in the form of artemisinin combination therapy (ACTs), shifted production of the first line of defence against malaria mortality from local producers to Indian exporters; this occurred despite formulation and production capability in African firms, because of the set of subsidy and procurement trading rules implemented by large scale donor-supported procurement agencies, and supported by WHO market regulation interventions (Wangwe et al 2014). Access to the much more expensive new first line anti-malarial medication, in Tanzania for example, now relies on externally subsidised imports, and has been patchy especially in rural areas at some periods, with no local production to fill gaps through domestic procurement. A further example has been international donor pressure, including WHO policy advice, on African countries to remove all tariffs on imported formulations, despite a lack of evidence to date on tariff incidence, and with the effect of disadvantaging local producers paying taxes on imports and opening African markets to unsustainable dumping especially of basic antibiotics (Tibandebage et al 2016). The result has been the undermining of local manufacturing in countries that have implemented this approach and have high donor dependency, such as Tanzania (Tibandebage et al 2016).

Second, despite these pressures, African countries do have (contrary to some perceptions) large, active and innovative pharmaceutical industries and associated scientific activity and expertise (Banda et al 2016; Fortunak et al 2016). Examples of innovative scientific work in pharmaceuticals, and associated industrial investment, in Africa include the development of the first effective treatment for sickle cell disease, Niprisan ™ , refined and tested in Nigeria as a phytomedicine developed from local treatments; also "leap frogging" technological advances such as the use of "green chemistry" and flow chemistry innovations to reduce the cost of manufacture of active pharmaceutical ingredients (APIs) in African conditions (Fortunak et al 2016). In Ethiopia, local scientific work is replacing imported wit local excipients in pharmaceutical production, and a Sino-Ethiopian hard capsule manufacturing plant is competitively supplying a large part of the Eastern and Southern African market (Fortunak et al 2016; Gebre-Mariam et al 2016). Note that these producers actively manufacturing in Sub-Saharan Africa are mainly locally owned, by African private capital, with some joint ventures involving foreign direct investment and/or government shareholding (Banda et al 2016).

Third, as noted in the background section, Africa-based producers have been already shown to display a capability to meet the needs of rural African populations for access to essential medicines that is greater than the capability of importers of medicines. A study in Tanzania showed that a set of essential medicines produced in Tanzania were equally likely to be available in rural as in urban areas, while imported medicines displayed "urban bias", being much more available in urban than rural areas. Local producers of basic essential medicines had effective wide distribution in outlying as well as more easily accessed areas, and furthermore, the largest local firms' branded generics were widely trusted by the population. Importers lacked comparable rural distribution networks (Mujinja et al 2014; Mackintosh and Mujinja 2010).

Fourth, these considerations apply also and crucially to medical devices and diagnostics, which play an increasingly significant role in effective use of medicines in treatment. However, access to appropriate and affordable medical devices has remained an ongoing challenge for most African countries. In May 2012, the 65th World Health Assembly adopted multiple resolutions acknowledging the dire need for medical devices to address the health priorities of low-income populations in African countries. It is widely recognised that addressing public health priorities cannot be achieved without ensuring access to essential medical devices (WHO, 2012). A study shows that most of the African countries depend on the imports of medical devices from advanced countries, creating challenges of affordability and appropriateness (Kale, 2010). Cheng (2007) revealing the 'mismatch' between supply and demand shows that in number of cases imported medical devices are mostly unsuitable for local conditions and endanger lives of patients, health workers and communities. A recent WHO (2010) report shows that more than 50% of devices remain unused in African countries due to structural and cost factors, indicating further widening of the mismatch. Referring the situation in Africa, Miesen (2013) comments that "across Sub-Saharan Africa, "medical device graveyards" litter the empty closets and spare corners of hospital". As such, a wider understanding of factors that influence access to medical devices in African countries, and a

remodelling of existing procurement policies, is essential for resolving challenge of 'medical device graveyards' and achieving the objective of inclusive healthcare.

Finally, it is possible to turn the situation, promoting innovation and development of African pharmaceutical production, using more coherent policies, thus benefitting access to medicines, public health and also industrial growth. Recent Ethiopian experience offers one example: a combination of expanding primary health care; providing some industrial protection for local pharmaceutical producers (through non-zero tariffs on finished formulations and a list of basic medicines for priority local supply); stronger local control of procurement policies through accords with donors; rising local scientific capability feeding into the local industry; and a government promotion of foreign direct investment in joint ventures incorporating technology transfer has generated a sharp increase in local production of medicines.

Implementation and benefits

In summary, the following policies can bring coherence to trade, industrial and public health (access to medicines) policies in the African context, and in other low and middle income countries also.

- Reorient procurement of medicines and medical devices, by government and donors, to support local production and upgrading by African producers through generating market access for those producers;
- Integrate health and industrial strategies both domestically and internationally in order to achieve synergies that will benefit both access to medicines and market access for African producers.
- Put an end to international institutions characterising tariffs on imports of final formulations as a “sick tax”, and replace this policy with shared investigation of appropriate medium term industrial support for local pharmaceutical and medical device production, including support for African governments that ban imports of some basic items where domestic market competition can provide the items effectively at acceptable prices (Chaudhuri and West 2014).
- Strengthen current international support for African scientific and technological upgrading in pharmaceuticals including market access for cost effective innovations.

There is already recognition at UN level of the need for this reorientation towards greater health-industrial policy coherence for Africa in particular (Sidibé et al 2014). Emerging initiatives to be encouraged include the rethinking of global procurement rules to create local tenders of manageable size, rather than constantly enlarging the pooling of tender volumes, which can support local producers at acceptable cost; creating procurement strategies that look to medium term security and diversity of supply in the interests of sustainability rather than focusing only on lowest cost for acceptable quality, thereby generating market access for African producers who can benefit from learning-by doing and reduce their prices over time; and the World Health organisation’s increasingly active support for upgrading by African producers. This rethinking can produce policy coherence between access to medicines and public health on the one hand, and the requirements of industrial development, innovation

and trade in African pharmaceuticals on the other.

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