Speaking notes of Deputy Commissioner Hardin Ratshisusu for the session - "Equitable Access to COVID-19 Healthcare"

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What should be the role of competition law and policy in enhancing access to healthcare, in general, and access to COVID-19 vaccines and drugs, in particular?

Case for competition law in healthcare

Competition law and policy has an important role to play in enhancing access to healthcare. It is even more important when we talk about access to COVID-19 vaccines and drugs.

South Africa realised the significance of competition law in promoting access to healthcare early on in a settlement with GSK and BI on an ARV excessive pricing complaint. GSK and BI agreed amongst other commitments to 1) grant licences to generic manufacturers, 2) permit the licensees to export the relevant ARV medicines to sub-Saharan African countries, 3) where the licensee did not have manufacturing capability in South Africa, permit the importation of the ARV medicines for distribution in South Africa only, provided all the regulatory approvals were obtained and other required measures.

In 2016, the UNITED NATIONS SECRETARY-GENERAL'S high-level panel on access to medicines affirmed the need to promote competition and access to health technologies. For instance, the high-level panel projects that the global economy would lose about USD100 trillion worth of economic output by 2050 if antimicrobial drug resistance is not tackled.

The TRIPS agreement places an obligation on WTO members to protect and enforce intellectual property, but there are key flexibilities that are permitted in order to meet human rights and public health objectives. These include:

1. the ability to determine patentability criteria
2. issuing of compulsory licences,
3. parallel importation
4. general exceptions
5. application of competition laws to limit and remedy the abuse of intellectual property rights in domestic legislation

Though these flexibilities exist, there have some challenges to implement these, largely for developing countries, as the high-level panel noted:

> *The Doha Declaration reaffirmed the rights of WTO Members to utilize flexibilities available under the TRIPS Agreement for the purpose of promoting the right to health and public health objectives. Despite these pronouncements, the sovereign right to*

issue compulsory licenses provided for by TRIPS has been stymied by threats of retaliation from governments and corporations against countries who have followed the prescribed process set out in TRIPS. The ensuing cloud of controversy, intimidation and legal incertitude associated with compulsory licenses have weakened the bargaining position of many WTO Members. It has also impeded the possibility of creative arrangements between governments and corporations with respect to strategies for the production and distribution of health technologies.

These challenges affirm the need to support the steps taken by India and South Africa in the WTO calling for the suspension of the protection of the IP related to COVID-19 health products for equitable access to healthcare and acceptable pricing practices for pharmaceuticals.

UNDP in its flagship publication on competition policy - *Using Competition Law to Promote Access to Health Technologies: A guidebook for low- and middle-income countries* – which is one of the flexibilities in TRIPS highlights the need for competitive outcomes in health technologies markets. An instructive example for benefits of competition is the dramatic reduction in the cost of HIV treatment from USD10,000 per year to just over USD100 per patient per year, which was a result of allowing generic competition for ARVs early on.

Recently CUTS International (2020) has proposed a Toolkit on Competition Policy and Access to Healthcare, which is a timely reminder of the need for nations for adopt measures to improve access to healthcare and affordability

The toolkit advocates for the adoption of uniform rules that ensure firms do not abuse intellectual property rights and stifle competition, but more pertinently, it recognizes that –

"to keep the market competitive, competition law enforcement alone may not be sufficient. First thing that is needed is an enabling policy environment that promotes competition in the market, including removal of entry barriers and market distortions, and inducing ease of doing and running businesses" (CUTS International, 2020: 2).

South Centre (2020) issued a research paper "Designing Pro-health Competition Policies in Developing Countries and has urged "developing countries to enact or revise competition laws and policies to effectively address issues relating to access to pharmaceuticals, having in view their local conditions and specificities including local production capacity, level of competition, average prices, and size of population"

Challenges for competition authorities

1. Lack for enabling legislative frameworks within and across borders

2. Limited resources allocated to competition regulation which hinders effective enforcement of competition laws
3. Unmet capacity building needs particularly for younger competition agencies
4. Lack of cooperation between competition agencies to tackle anti-competitive practices at regional and global level. UNCTAD identified some obstacles for international cooperation, namely:
    - Lack of mutual trust and understanding
    - Lack of focal point at foreign authorities

Conclusion

At the UNCTAD IGE on Competition Law and Policy in 2019, South Africa presented a "Discussion on Competition in Healthcare Markets: Access and Affordability" which empathized key interventions, that are still relevant today:

1. Healthcare must continue to be a priority to policy-makers, sector regulators and competition law regulators
2. Need to prioritize competition issues in pharmaceuticals and healthcare markets
3. Cooperation among competition regulators will enable better and effective enforcement, an essential role in the ecosystem of ensuring that pricing of healthcare remains affordable
4. Competition policy is an important tool to enable access to pharmaceuticals and treatment, at the lowest cost possible, whilst the interests of investment and innovation are also safeguarded

However, competition law as well as other flexibilities under TRIPS may also have limitations, thus necessitating other targeted measures such as the proposed TRIPS waiver, especially in a time of a pandemic like the present.

Finally, as agreed at the 2021 IGE, UNCTAD is expected to prepare reports and studies as background documentation for the twentieth session of IGE on **rethinking competition law enforcement: lessons learnt from the COVID-19 pandemic, especially in socially important markets - challenges and opportunities for an effective response during the pandemic and the economic recovery in the post COVID-19 period**. I hope the deliberations in this session will be amongst those informing this very important debate next year.