Pharmaceutical manufacturing capacities in the post-pandemic era: sustainable industrial policies and practices

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As the COVID-19 pandemic diffuses beyond borders, national governments are on mission mode to support stretched health systems and implement redistributive policies. As all of us are facing this hard-hitting planetary disaster, we must address it collectively. However, the nationalism wave is soaring globally. The pandemic emerged as the biggest crisis humanity has ever faced after the World Wars. We need to anticipate and address its after-effects carefully. Now, would we care to step together for post-pandemic recovery? Though the nature of the world after the pandemic remains to be fully understood, we explore the policy options that we can latch on to through the pandemic lessons.

The COVID-19 crisis has evidently showcased the fragility of our healthcare system and multilateralism, along with a lack of political will in addressing inequalities. United Nations (UN) Secretary-General António Guterres aptly pointed out that "… we passed the science test. But we are getting an F in Ethics …" (76th UNGA, 2021). We can see that economic conditions started recovery but that too largely in the cases of developed nations only. Now is the time to reduce the inequalities and gaps between rich and poor, developed and developing countries, and producers and consumers. The most important lesson that humankind should learn from the COVID-19 pandemic is the socio-technical interdependence of our societies. Many of the least developed and developing countries queue for vaccine dosages and depend on technologically advanced nations. On the other hand, the fully vaccinated populations of the advanced nations are equally vulnerable to the novel coronavirus strains that originated in the countries with unvaccinated people. Even the pharmaceutical manufacturing facilities of developed countries depend on the supply of raw materials manufactured in developing countries. Such interdependence is inevitable. Hence, the countries hoarding the COVID-19 vaccines dosage and its technological know-how must realise the need of the hour. With great power comes great responsibility.

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1. Large-scale transformations in biopharma sector: Use case of India

Large-scale industry-wide transitions have not been smooth sailing and do not occur overnight. They take decades, history teaches. Emulating

the positive development and experience of countries like India will need a sustainable and strategic outlook in policy implementation. Countries desiring large-scale transformation in their biopharma sector will need to address the technology gaps at various levels. Necessary technology advancement will depend not only on consumption demands but also on research and development efficiency and quality. Policymakers and regional leaders need to understand that such a technology gap will persist for a long time. It results from the accumulation of technological knowledge among technologically advanced nations that continue to innovate due to the availability of resources.

Awareness of interdependence and promotion of self-sufficiency: a case of biopharma sector in India

Over the decades, the Indian pharmaceutical sector has strengthened and competed fiercely to reduce the monopoly of western counterparts. The world has also moved on from the United States and European Union (Sworn, H., 2021). The power redistribution can also be seen with the advent of India and China in the case of COVID-19 vaccine development. They have achieved many milestones even without an IP waiver from the WTO. The least developed countries or countries in the TRIPS transition period should explore India's progress on domestic intellectual property policies, research and development culture in the biopharma industry, national drug policies, and human resource training system.

After independence, India put forward careful steps to nurture its biopharma ecosystem with strategic amendments in the Indian Patent Act and policy positions in the international arena of access to medicines. The Indian patent policies continue to uphold Article 21 of the Indian Constitution dedicated to the right to life and the right to personal liberty, as well as Article 47, which accords the responsibility to the Indian State to improve public health. This is evident through the amendments of the Indian Patent Act 1970, through 2005, the adoption of TRIPS flexibilities, and India's recent stance about TRIPS waiver in coronavirus pandemic.

India first repealed the British-era Patents and Design Act 1911, constituted two expert committees, and two Joint Parliamentary Committees for adopting forward-looking patent acts. The Indian version of the Act imposed special restrictions on patenting substances related to chemicals, food, and medicines, until the expiration of the TRIPS transition period. This policy was resourceful for ensuring adequate access to medicines. It resonated with the generic pharma industries. However, it was contrary to innovator pharma lobbies and received stiff opposition. With this, generic manufacturers could synthesise the medicines, raw materials, or active pharmaceutical ingredients with their own synthesis protocols.

While amending the patent act in the post-TRIPS transition period, India also adopted stringent patent eligibility requirements to refrain from evergreening patents by excluding the minor improvements of drug candidates in Section 3d. The patent act retained the pre-grant opposition and included post-grant opposition on similar grounds to struct down the patents that should not have been granted. This gives the generic biopharma industry a breathing space. Even India carefully addressed the compulsory licensing request of Natco Pharma against the Bayer Corporations drug Nexavar. This decision of the Indian Controller General of Patents, Designs, and Trade Marks was further challenged to and upheld by the Intellectual Property Appellate Board (IPAB) and the Supreme Court of India. This decision also highlighted the need for 'working of patents' in India to meet the unmet needs of access to medicines and advocated for voluntary licensing measures. The voluntary requirement was again endorsed in the latter case when BDR Pharmaceuticals requested a compulsory license on Bristol-Myers-Squibb's cancer drug Dasatinib, which was rejected because the applicant has not made enough efforts to obtain a voluntary license.

2. Insights for nourishing policy architecture of LDCs and countries in TRIPS transition

With similar strategies, various least developed countries (LDCs) or countries with TRIPS transition periods should take advantage of TRIPS flexibilities. This year Bangladesh's Beximco Pharmaceuticals could launch the 1st generic version of Pfizer's COVID-19 treatment Paxlovid (BPL, 2021). This antiviral drug is a

combination of nirmatrelvir and ritonavir tablets with the 90% efficacy of preventing hospitalisation and death of high-risk patients amidst the soaring Omicron-led wave. This shows the importance of extending the TRIPS transition period for LDCs until 2034. Unfortunately, the developed countries did not support the request of LDCs to extend the transition period until graduation of the respective LDCs from this category. Its necessity depends on the fact that the LDCs will face obstacles in achieving technological advancement until they overcome this status.

The least developed countries can take leads from the policy practices of their Indian and Chinese counterparts. As the policy and markets continuously drive the Chinese economic growth with the critical role of foreign investment, it is interesting to explore their market entry and pricing frameworks, market structure with the lens of competition and exclusivity, and intellectual property policy implementation. The rise of the generic biopharma sector in China arouses the interest of international communities in historical developments, including expansion of industrial scale manufacturing, improvement in industrial capacity building, the opening of the market, the role of multinationals in promoting the Chinese pharma sector, and administrative faculty of pharmaceutical industries in China.

Firstly, the LDCs need to leverage the TRIPS exceptions and flexibilities thoroughly as India could take such advantage in nurturing its generic biopharma industry during a transition period. On the other hand, as China amended its patent act in 1992 after the negotiations with the United States on extending patentable subject matter, China could not take benefits of such exception after it signed up for WTO in 2001. Second, LDCs need to train their human resources in legal and regulatory affairs. India had a long tradition of legal professionals who understood and analysed western laws for a long time; hence, India could take the lead at GATT, promote inclusion of intellectual property stream in GATT, and establish WTO. Until very recently, Indian technologists and enterprises took the lead in understanding the regulatory processes of the Western world, which eventually helped them internationalise their biopharmaceutical enterprises, seek quality certifications, and extend the purview of local contract research organisations (CROs). Finally, LDCs should develop a conducive environment by promoting the research and development of generic drugs. This will eventually build the technological capacities for innovator drug development. There is a need for establishing domestic infrastructure and leveraging the benefits of lower labour costs.

Paradoxical policy positions of UN-led agencies on developing manufacturing capacities in developing countries

The production of necessary vaccines and medicines is still inadequate to fulfil the needs of the world population stuck in the COVID-19 crisis. The galvanisation of international communities in securing public health equality is absolutely necessary. It's a human rights issue. However, the 12th Ministerial Conference of the WTO got postponed when the proposal for intellectual property waiver was to be presented. That's the case when the world witnesses the organisation of significant sporting events like the Tokyo Olympics. Conditions globally could have been better with adequate manufacturing facilities in developing countries and LDCs.

Over the past three decades, the World Health Organisation's (WHO) position on developing local manufacturing capacities remains either unclear or in contrast to the other UN agencies such as the United Nations Industrial Development Organization (UNIDO) and the United Nations Conference on Trade and Development (UNCTAD). In 2005, Richard Laign of WHO's Essential Drugs and Medicines Program along with Warren Kaplan argued in the World Bank Meeting that "… if a developing country with manufacturing facilities is able to finish off bulk active ingredients sourced from developed or other countries at high costs, such manufacture may have no impact whatever on patient access to needed medicines …" (Kaplan and Laing, 2005). They suggest that – there is no reason to produce medicines domestically as it makes little economic sense; local productions are often not reliable; it may be possible for small country markets to be coordinated; state-owned productions are "ill-advised," and they need to be efficient to avoid losses as the profit margins are lower; and foreign exchanges savings might be smaller to import technology, raw materials, and lab equipment. Another

WHO review published in 2011 supports the above argument by citing the relative lack of econometric and time series studies linking local production and access to medicinal products (WHO, 2011). In 2017, the report of interagency consultation on local production of essential medicines concluded that the local productions might be feasible initially; however, it challenged commercial viability and argued that the local productions might be expensive than alternatives available, including imported goods (WHO, 2017).

On the contrary, UNCTAD promotes the local pharmaceutical production and ensures coherence among seemingly unrelated policies, including drug regulations, research and development, trade, and intellectual property. They further present parallel case studies from various countries (UNCTAD, 2011; UNCTAD, 2017). Similarly, UNIDO provided technical cooperation and advisory services to promote local pharmaceutical production in developing countries. They advocated that such facilities can primarily help vulnerable and rural populations by providing access to medicines (Velásquez, G., 2020; UNIDO, 2020).

With the above discussion, it can be concluded that the COVID-19 has proved the necessities of local biopharmaceutical production facilities in the wake of national priorities. Developing countries need to play a cohesive role in establishing local facilities to ensure adequate access to medicines with standard quality. United Nations-led agencies should provide coherent guidance on facilitating the local production capacities. Developing countries should take these challenges as opportunities to step towards self-sufficiency.

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