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## Lessons from COVID-19: Pharmaceutical Production as a Strategic Goal

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As often said, major crises bring about challenges but also opportunities. The strategic importance of a local pharmaceutical industry has been growingly recognized as a result of the COVID-19 crisis. Developing countries should take advantage of this opportunity to strengthen their pharmaceutical industry, including biological medicines. Industrial policies would need to be reformulated under an integrated approach so as to expand value added & create jobs while addressing public health needs. South-South cooperation may also play an important role in increasing the contribution of developing countries to the global production of pharmaceuticals.

The impact that COVID-19 will have on the global consumption, production and distribution patterns is still uncertain, but there are some signs that suggest changes in industrial policy that governments can implement to achieve development goals and greater autonomy. A clear example is found in the pharmaceutical sector (including the production of active ingredients and biological products), whose strategic value has been recognized as a result of the crisis triggered by that disease. The imposition of restrictions by several governments on the export of medicines and other medical products. 1 and the shortage of supply caused by the sudden increase in demand, highlighted the dependence of many countries on imports in a critical sector for public health (and the economy). Thus, it has been noted that 80% of the active substances used in medicines marketed in the European Union (EU) are imported, mainly from China and India. The need to reduce this external dependence appeared as a common and urgent objective for the EU, including by granting financial incentives to relocate the production of active pharmaceutical substances to Europe.<sup>2</sup> According to the EU Commissioner for Health and Food Safety, "it is now more evident than ever that we need a strategic approach to limit dependence on manufacturers and countries and that the means to produce essential medicines in the EU must be created". <sup>3</sup> The response to this situation is also reflected in the 'Pharmaceutical Strategy for Europe', one of whose objectives is "to reduce direct dependence on raw materials from non-EU

<sup>&</sup>lt;sup>1</sup> See: South Centre, "Trade Measures Adopted by Countries in Response to COVID-19". Available from <a href="https://www.southcentre.int/covid-19/">https://www.southcentre.int/covid-19/</a>.

<sup>&</sup>lt;sup>2</sup> "La UE busca depender menos de Asia en el rubro medicamentos", *Bae Negocios*, 12 May 2020. Available from <a href="https://www.baenegocios.com/mundo/La-UE-busca-depender-menos-de-Asia-en-el-rubro-medicamentos-20200512-0042.html">https://www.baenegocios.com/mundo/La-UE-busca-depender-menos-de-Asia-en-el-rubro-medicamentos-20200512-0042.html</a>.

<sup>&</sup>lt;sup>3</sup> Ibid.

countries". <sup>4</sup> It is not much different in the United States, where at the height of the COVID-19 crisis, it was observed that Chinese pharmaceutical companies supplied 97% of the US market for antibiotics, over 90% for vitamin C, 95% for ibuprofen, 91% for hydrocortisone, with a global dependence on imported active ingredients of the order of 80%.<sup>5</sup> Similar dependence with respect to India exists in that country for antibiotics, painkillers, hormones, antiviral drugs and vitamins B1, B6 and B12.<sup>6</sup>

The recognition of this overdependence in respect of pharmaceuticals (and other medical inputs) and of the strategic importance of having a local pharmaceutical industry, has arisen in the context of a deeper and more general reconsideration about the proclaimed benefits of the globalization of the economy that has accelerated in the last decades. The COVID-19 crisis has made governments, including those of developed countries, realize the vulnerabilities of a production system based on 'global value chains' - which geographically fragments production processes to exploit economies of scale and lower labor costs in developing

countries -<sup>7</sup> especially in the face of trade disruptions (such as those caused by the trade war launched by the United States against China).

The economic and financial crisis generated by COVID-19 has deepened initiatives - which are not entirely new -8 to sustain local production through a variety of mechanisms aimed at recovering 'strategic autonomy'. This is already clear in the United States (whose government has in recent years encouraged the relocation of productive activities in the US territory and recently granted massive subsidies to the local pharmaceutical industry)<sup>9</sup>, in India (Indian Prime Minister Narendra Modi's statement of 12 May 2020 on a new era of economic self-sufficiency)<sup>10</sup>, in Japan (subsidies for companies that repatriate factories), <sup>11</sup> and in the EU as mentioned above.

The pharmaceutical industry (including biotechnological products) can be one of the axes in this new policy framework oriented to local production. Its strategic importance has been demonstrated by the emergency created by COVID-19. However, not only health reasons explain the revaluation of this industry, but also the contribution it can make to local added value and employment, especially of technical and professional staff. According to the aforementioned EU Strategy, the "European pharmaceutical sector is an important contributor to the EU economy in terms of the creation of highly qualified jobs and investment in innovation". <sup>12</sup> Thierry Breton, the

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<sup>&</sup>lt;sup>4</sup> European Commission, "Pharmaceutical strategy for Europe". Available from <a href="https://ec.europa.eu/health/human-use/strategy">https://ec.europa.eu/health/human-use/strategy</a> en.

<sup>&</sup>lt;sup>5</sup> Yanzhong Huang, "The Coronavirus Outbreak Could Disrupt the U.S. Drug Supply?", *Council on Foreign Relations*, 5 March 2020. Available from <a href="https://www.cfr.org/in-brief/coronavirus-disrupt-us-drug-supply-shortages-fda">https://www.cfr.org/in-brief/coronavirus-disrupt-us-drug-supply-shortages-fda</a>.

<sup>&</sup>lt;sup>7</sup> See: for example, Eduardo Bianchi and Carolina Szpak, "Cadenas globales de valor, comercio internacional y actuación empresaria", *Revista Argentina de Investigación en Negocios* 1 (Abril 2015). Available from <a href="http://ppct.caicyt.gov.ar/index.php/rain/article/view/v1n1a03">http://ppct.caicyt.gov.ar/index.php/rain/article/view/v1n1a03</a>.

<sup>&</sup>lt;sup>8</sup> Aileen Kwa, Fernando Rosales and Peter Lunenborg, "COVID-19 and WTO: Debunking Developed Countries' Narratives on Trade Measures", Policy Brief No. 77 (South Centre, May 2020). Available from <a href="https://www.southcentre.int/wp-content/uploads/2020/05/PB-77-3.pdf">https://www.southcentre.int/wp-content/uploads/2020/05/PB-77-3.pdf</a>.

<sup>&</sup>lt;sup>9</sup> The Biomedical Advanced Research and Development Authority (BARDA) has recently made massive investments in vaccine development for COVID-19: Moderna (\$483 million), Sanofi (\$30 million), Johnson & Johnson (\$456 million), and AstraZeneca (\$1.2 billion). See e.g. Meagan Parrish, "Coronavirus vaccines: The billion dose dash", *pharma Manufacturing*, May 20, 2020. Available from: <a href="https://www.pharmamanufacturing.com/articles/2020/the-billion-dose-dash-for-coronavirus-vaccines/">https://www.pharmamanufacturing.com/articles/2020/the-billion-dose-dash-for-coronavirus-vaccines/</a>.

<sup>&</sup>lt;sup>10</sup> See: Rajesh Roy, "India's Leader Calls for Economic Self-Sufficiency, Promises Relief", *The Wall Street Journal*, May 12, 2020. Available from <a href="https://www.wsj.com/articles/indias-leader-calls-for-economic-self-sufficiency-promises-relief-11589306423">https://www.wsj.com/articles/indias-leader-calls-for-economic-self-sufficiency-promises-relief-11589306423</a>.

<sup>11</sup> See: "Globalisation unwound: Has covid-19 killed globalisation?", *The Economist*, 14 May 2020.

<sup>&</sup>lt;sup>12</sup> Pharmaceutical strategy for Europe, op. cit.

EU Commissioner for the Internal Market observed in this regard: "[o]ur companies, large and small, provide us with jobs, prosperity and strategic autonomy". 13

A United Nations Conference on Trade and Development (UNCTAD) study on Argentina, Indonesia, Thailand, Uganda, Bangladesh, Indonesia, and Colombia, among others, concluded that many of these developing countries were well-prepared "to take on the role of providing cheaper medical products to poor people throughout the developing world. Companies in these countries have achieved the economies of scale required to produce medicines competitively and will expand over the next decade". While this study focused on the formulation of 'generic' chemically synthesized drugs, there are also promising opportunities for the production of active ingredients as well as for the expansion of the production of biotechnology products, such as monoclonal antibodies. It has been noted with respect to the latter that a 'creative imitation strategy' presents important opportunities for "those countries with minimal bioprocess experience and a biotechnology knowledge base to enter as creative imitators by taking advantage of the transitional windows of opportunity of low economies of scale and as yet undefined regulatory frameworks". 15

Taking advantage of these opportunities to strengthen a pharmaceutical/ biotechnology industry may require the reformulation of industrial policies, so as to promote with an integrated approach this sector as a generator of value added, employment and foreign exchange, as well as an instrument for achieving health autonomy to address public health needs. Such an integrated approach implies the deployment of a series of well articulated instruments, as proposed by the concept of 'mission-oriented industrial strategy'. These instruments include, among others, fiscal measures, access to financing, support to research and development (R&D) including of an experimental nature, a regulatory framework that does not create undue obstacles to registration (especially for biosimilars), an intellectual property regime that uses the flexibilities of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) such as compulsory licensing, and a policy of government procurement that provides predictability to local demand. With respect to the latter, UNCTAD has noted that "[t]he strategic application of government support measures to those medicines that are essential to the national public health system helps local drug makers become more competitive in an area where there is demand from the government".<sup>17</sup>

As often said, major crises bring about challenges but also opportunities. One of the lessons of COVID-19 for developing countries is that they can put in place comprehensive industrial policies to enhance their manufacturing capacity in pharmaceuticals - which will be indeed indispensable

<sup>&</sup>lt;sup>13</sup> Alberto López Girondo, "El Covid-19 le hizo ver a la UE su dependencia en la industria farmacéutica", *Tiempo*, 17 May 2020. Available from <a href="https://www.tiempoar.com.ar/nota/el-covid-19-le-hizo-ver-a-la-ue-su-dependencia-en-la-industria-farmaceutica">https://www.tiempoar.com.ar/nota/el-covid-19-le-hizo-ver-a-la-ue-su-dependencia-en-la-industria-farmaceutica</a>.

<sup>&</sup>lt;sup>14</sup> UNCTAD, Local Production of Pharmaceuticals and Related Technology Transfer in Developing Countries: A series of case studies (2011), p. 11. Available from <a href="https://unctad.org/en/Publications">https://unctad.org/en/Publications</a> Library/diaepcb2011d7 en.pdf.

<sup>&</sup>lt;sup>15</sup> Sebastián Sztulwark, Matías Mancini, Santiago Juncal and Pablo Lavarello, "Imitación creativa en países de industrialización tardía: enseñanzas del caso de los biosimilares en Corea e India", in *Explorando el camino de la imitación creativa: La industria biofarmacéutica argentina en los 2000*, Pablo Lavarello, Graciela Gutman and Sebastián Sztulwark, eds. (Libro-CEUR CONICET, 2018), p. 24.

 <sup>16</sup> UCL Commission for Mission-Oriented Innovation and Industrial Strategy, A Mission-Oriented UK Industrial Strategy (2019). Available from <a href="https://www.ucl.ac.uk/bartlett/public-purpose/publications/2019/may/mission-oriented-uk-industrial-strategy">https://www.ucl.ac.uk/bartlett/public-purpose/publications/2019/may/mission-oriented-uk-industrial-strategy</a>.
 17 UNCTAD, Tool Box for Policy Coherence in Access to Medicines and Local Pharmaceutical Production (2017), p.

<sup>&</sup>lt;sup>17</sup> UNCTAD, *Tool Box for Policy Coherence in Access to Medicines and Local Pharmaceutical Production* (2017), p
5. Available from <a href="https://unctad.org/en/PublicationsLibrary/diaepcb2017d2">https://unctad.org/en/PublicationsLibrary/diaepcb2017d2</a>
\_en.pdf.

to supply the products (notably the vaccines) needed to prevent that disease. South-South cooperation may, in fact, play an important role in increasing the contribution of developing countries to the global production of pharmaceuticals. <sup>18</sup>

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<sup>&</sup>lt;sup>18</sup> See, e.g., *Developing National Ecosystems for South-South and Triangular Cooperation to Achieve Agenda 2030 for Sustainable Development* (South Centre-IsDB, 2019). Available from: <a href="https://www.southcentre.int/sc-and-isdb-joint-publication-september-2019/">https://www.southcentre.int/sc-and-isdb-joint-publication-september-2019/</a>.