



## **Médecins Sans Frontières Comments on the WHA74 Local Production Resolution Final Negotiation Text (28 April 2021 version)**

Médecins Sans Frontières (MSF) welcomes the timely presentation of the draft World Health Assembly 74 resolution, “Strengthening local production of medicines and other health technologies to improve access.”<sup>1</sup>

For a long time, the proliferation and control of intellectual property, know-how and technologies among a small number of multinational pharmaceutical corporations has contributed to the failure to deliver equitable and timely access to sufficient medicines, vaccines and diagnostics. Further, the geographic concentration of production and supply by these corporations crowds out local manufacturers in low- and middle-income countries (LMIC). The COVID-19 pandemic has highlighted these structural issues and the urgent need for World Health Organization (WHO) member states to advance the local production agenda.

The draft resolution clearly recognises the importance of enhancing local production capacities in LMICs as an integral strategy to achieve the United Nations Sustainable Development Goals. It also recognizes the critical role of local production in ensuring sustainable supply chains during public health emergencies. As part of the agenda item on the Global Strategy and Plan of Action on Public Health Innovation and Intellectual Property (GSPOA), the draft resolution unequivocally supports price transparency, showing a growing consensus of member states following the WHA72 resolution on transparency.<sup>2</sup>

The resolution includes a number of positive elements as mentioned above, but it also falls short in three ways.

### **1. The draft resolution misses the opportunity to incorporate new options to facilitate local production in a pandemic and beyond, including the proposed TRIPS waiver for COVID-19.**

The draft resolution positively notes the role of TRIPS flexibilities in promoting access to all medicines and medical tools. However, preambular paragraph 5 *ter alt* (PP5 *ter alt*) represents

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<sup>1</sup> Draft resolution: Strengthening Local Production of Medicines and Other Health Technologies to Improve Access. KEI. [https://www.keionline.org/wp-content/uploads/Draft-Resolution-on-Local-Production\\_26042021\\_clean-PDF.pdf](https://www.keionline.org/wp-content/uploads/Draft-Resolution-on-Local-Production_26042021_clean-PDF.pdf)

<sup>2</sup> WHO. WHA78.2 Improving the transparency of markets for medicines, vaccines, and other health products. 2019 May 28. [https://apps.who.int/gb/ebwha/pdf\\_files/WHA72/A72\\_R8-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_R8-en.pdf)

a missed opportunity to link “innovative options to enhance the global effort” to the ongoing process at the World Trade Organization (WTO) for a temporary waiver from certain TRIPS provisions. The waiver would enable member states to take quicker and uninterrupted actions in leveraging production capacity and diversifying supply options.

In the past seven months, the negotiation process<sup>34</sup> of the draft resolution on local production mirrors the process at the WTO concerning the TRIPS waiver proposal. The same group of countries who are opposing the waiver proposal at WTO are reportedly also blocking the explicit reference to this waiver in the WHO local production resolution negotiation.

As a result, PP5ter alt contains vague and compromised text which only hints at the WTO process. This fails to recognize the additional challenge of realising local production in a pandemic when existing TRIPS flexibilities are critical but not sufficient to overcome the barriers to ensure uninterrupted global production and supply to meet access challenges.

**Recommendation:** Given the recent positions of the United States and other countries committing to engage in formal negotiation in support of the TRIPS waiver proposal, WHO member states should reflect this historical development in the final text of the draft resolution before its adoption.

## **2. The draft resolution does not recognise the limitations of relying on voluntary mechanisms to facilitate local production and technology transfer.**

While the draft resolution recognises the positive role of TRIPS flexibilities under OP1.10 for member states and OP2.8 for the Director General, the structure of the text has not articulated clearly that the use of TRIPS flexibilities should be treated as an integral strategic option to facilitate local production. Instead, OP1.6, 1.8 and 2.3.f have only referred to the “voluntary and mutually agreed terms” as the main approach to facilitate transfer of technologies for local production.

The draft resolution’s insistence on voluntary measures ignores lessons of the past and stands in contrast with MSF’s experience and analysis of voluntary licensing efforts, which can often come with restricted terms and conditions limiting or prohibiting supply by producers in developing countries for local health needs.<sup>5</sup>

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<sup>3</sup> KEI. Negotiations on the 74th World Health Assembly (WHA) resolution on local production. <https://www.keionline.org/negotiations-on-the-74th-world-health-assembly-wha-resolution-on-local-production>

<sup>4</sup> KEI. Fissures on intellectual property, C-TAP and transparency emerge in WHO local production negotiations. 2021 Apr 8. <https://www.keionline.org/35873>

<sup>5</sup> MSF. Voluntary licenses and access to medicines. 2020 Oct. <https://msfaccess.org/voluntary-licenses-access-medicines>

More than one year into the COVID-19 pandemic, it is also evident that voluntary measures led by pharmaceutical corporations have not been a solution to equitable access. Companies have mostly engaged in a limited contract manufacturing model of technology transfer, in which they retain all control over IP, production and supply. These non-transparent and time-limited contract manufacturing agreements do little to support long-term independence and growth of local production capabilities in LMICs. The contract manufacturing agreement signed between Johnson & Johnson and Aspen Pharmacare in South Africa is an example of this dynamic. While Aspen has received a technology transfer and will produce 300 million doses in 2021, the control over supply and future use of the platform technology remains with Johnson & Johnson.

The draft resolution should be more ambitious in recognising the inherent limitation of voluntary mechanisms, and instead emphasise the critical role of TRIPS flexibilities and other government-led measures that can facilitate local production.

By looking at voluntary mechanisms as the main mechanisms for technology transfer, the draft resolution also fails to recall the obligation for high-income countries to promote technology transfer to UN-classified Least-Developed Countries under the TRIPS Agreement. For over two decades, the implementation of this TRIPS obligation has been unsatisfactory, especially concerning pharmaceutical technologies. While the obligation itself contains limitations, it remains a critical obligation that requires concrete actions.

**Recommendation:** The resolution should clearly recognise the inherent limitation of voluntary measures in technology transfer and recognize the use of TRIPS flexibilities and other government-led measures as critical to ensure transfer of technology. Member states should also recall the need to enhance concrete implementation of technology transfer obligations of high-income countries, including under the TRIPS Agreement.

### **3. The draft resolution lacks recognition of the important role of public production facilities and public investment as essential elements to ensure local production serves public health objectives.**

The draft resolution, while containing commitments to strengthen local production, fails to point to the pivotal role public investments, public facilities and political support can have to ensure sustainable supply of essential medicines, diagnostics and vaccines.

During the COVID-19 pandemic, public investment into research, development and local manufacturing has been employed successfully by countries at all income levels. For instance, one analysis finds that governments spent over €93 billion on research, development, manufacturing and advanced purchase of vaccines and therapeutics.<sup>6</sup> Countries such as Brazil

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<sup>6</sup> Hoecklin M. €93 Billion Spent By Public Sector On COVID Vaccines and Therapeutics in 11 Months, Research Finds. Health Policy Watch. 2021 Jan 12. <https://healthpolicy-watch.news/81038-2/>

have relied almost entirely on their public manufacturers to supply COVID-19 vaccines, as well as diagnostics through non-profit public production facilities, like Bio-Manguinhos (Fundação Oswaldo Cruz). In India, public producers of vaccines have stepped up to support private manufacturers in manufacturing and supplying vaccines during a time of national crisis. In Senegal, the non-profit production facility DiaTropix – supported by Institut Pasteur Dakar and the UK-based social enterprise Global Access Diagnostics – manufactures rapid tests for COVID-19 while several other tests for outbreak diseases are in the pipeline.

Beyond the COVID-19 pandemic, public-sector manufacturers in many middle-income countries play a crucial role in providing domestic access to health products to address the country's needs. For example, manufacturers in Brazil and Thailand supply critical HIV treatments. Brazil's Bio-Manguinhos also produces about six million reagents annually for the diagnosis of HIV and neglected diseases.

A strategic objective of the draft resolution is to treat local production as an integral part of health system strengthening. To achieve this, local production needs to be operationalized with a clear vision of producing and supplying essential medicines, vaccines and diagnostics as public goods, moving away from a purely market-based paradigm.

**Recommendation:** The draft resolution should recognise public investment and production as essential elements to ensure local production serves public health objectives, with the vision of developing, producing and providing essential medicines, vaccines and diagnostics as public goods.

Finally, member states must ensure that the spirit and commitments made in this resolution are translated into concrete national and regional policies and implemented expeditiously. A resolution that is not implemented will do nothing to support local production of essential health tools globally. The final resolution, therefore, should come with concrete implementation plans to ensure effectiveness.