

Third report of Committee A

(Draft)

Committee A held its tenth and eleventh meetings on 29 May 2021, chaired by Dr Adriana Amarilla (Paraguay).

It was decided to recommend to the Seventy-fourth World Health Assembly the adoption of the attached resolution relating to the following agenda item:

Pillar 1: One billion more people benefitting from universal health coverage

13. Review of and update on matters considered by the Executive Board

13.4 Global strategy and plan of action on public health, innovation and intellectual property

One resolution entitled:

- Strengthening local production of medicines and other health technologies to improve access

Agenda item 13.4

Strengthening local production of medicines and other health technologies to improve access

The Seventy-fourth World Health Assembly,

Having considered the consolidated report by the Director-General;¹

Recalling resolutions WHA60.20 (2007), WHA61.21 (2008), WHA62.16 (2009), WHA63.12 (2010), WHA65.17 (2012), WHA65.19 (2012), WHA66.22 (2013), WHA67.20 (2014), WHA67.21 (2014), WHA67.22 (2014), WHA68.7 (2015), WHA71.8 (2018) and WHA72.8 (2019), all of which encompass aspects of the need to promote access to quality, safe, effective and affordable medicines and other health technologies;²

Recalling resolution WHA61.21 (2008), decision WHA71(9) (2018) and document A71/12 (2018), insofar as they address the role of technology transfer and local production of medicines and other health technologies in improving access;

Recalling also United Nations General Assembly resolution 74/306 (2020) and resolution WHA73.1 (2020) on comprehensive and coordinated response to the coronavirus disease (COVID-19) pandemic, which call for intensified international cooperation and solidarity to contain, mitigate and overcome the pandemic and its consequences through responses that are people-centred and gender-sensitive, with full respect for human rights;

Recalling also the Human Rights Council resolution 12/24 (2009) on access to medicine in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health;

Recalling further the 2030 Agenda for Sustainable Development and its aim of ensuring that no one is left behind;

Recalling also the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) as amended, and recalling the 2001 Doha Declaration on the TRIPS Agreement and Public Health, which affirms that the TRIPS Agreement can and should be interpreted and implemented in a manner supportive of the right of Member States to protect public health and, in particular, to promote access to medicines for all, and recognizes that intellectual property protection is important for the development of new medicines and also recognizes the concerns about its effects on prices;

Noting the discussions in WTO and other relevant international organizations including on innovative options to enhance the global effort towards the production and equitable distribution of COVID-19 medicines and other health technologies through local production;

¹ Document A74/9.

² Medicines and other health technologies includes pharmaceuticals, vaccines, biopharmaceuticals and medical devices.

Acknowledging Member States' commitment to achieve the Sustainable Development Goals including those that relate to local production of medicines and other health technologies in various ways (for example, Goals 3, 8 and 9);

Recognizing that some countries face problems in accessing medicines, vaccines and other essential health technologies due to factors such as low manufacturing capacity and high prices, among others, and that such problems can be exacerbated in times of public health emergencies and/or overwhelming demand, such as during the COVID-19 pandemic;

Recalling WHO's road map for access to medicines, vaccines and other health products 2019–2023¹ as part of comprehensive support for access and strategic local production, while considering regional plans and initiatives;

Emphasizing the need to improve access to quality, safe, effective and affordable medicines and other health technologies, inter alia, through building capacity for local production, especially in low- and middle-income countries, technology transfer on voluntary and mutually agreed terms, cooperation with, support to and development of voluntary patent pools and other voluntary initiatives, such as the WHO COVID-19 Technology Access Pool (C-TAP) and the Medicines Patent Pool, and promoting generic competition in line with WHO's road map for access to medicines, vaccines and other health products 2019–2023;

Recognizing that integration of local production into overall health systems strengthening can contribute to sustainable access to quality-assured, safe, effective and affordable medicines and other health technologies, and can help to prevent or address medical product shortages, achieving universal health coverage and strengthening of national health emergency preparedness and response and minimizing public health hazards;

Recognizing also that local production can contribute to other national development goals, such as catalysing local capacity in innovation, strengthening human capital and expertise and building a knowledge-based economy;

Recognizing further that the COVID-19 pandemic has highlighted the critical need to prepare for potential disruptions of the supply chain for essential medicines and other health technologies, including through the strengthening of local production;

Also recognizing the importance of promoting competition to improve availability and affordability of health technologies consistent with public health policies and needs, inter alia through the production and introduction of generic versions, in particular of essential medicines, in developing countries;

Noting that the local production of medicines and other health technologies can provide for greater sustainability of supply chains, especially in public health emergencies;

Noting that the inter-agency statement on promoting local production² signed by six organizations (the Global Fund to Fight AIDS, Tuberculosis and Malaria, UNAIDS, UNCTAD, UNICEF, UNIDO

¹ <https://apps.who.int/iris/handle/10665/330145>.

² Interagency statement on promoting local production of medicines and other health technologies. https://www.who.int/phi/implementation/tech_transfer/Interagency-statement-on-promoting-local-production.pdf?ua=1, accessed 7 January 2021.

and WHO) calls for a holistic approach, close partnership, interministerial and relevant stakeholder cooperation, and global synergy in promoting quality and sustainable local production of safe, effective, quality and affordable medicines and other health technologies;

Recognizing the work of the Interagency Pharmaceutical Coordination Group hosted by WHO and the role of Unitaïd and the Medicines Patent Pool to help countries to enhance their access to medicines particularly for HIV/AIDS, tuberculosis and malaria;

Recalling the launch of the Access to COVID-19 Tools (ACT) Accelerator, which is a global collaboration that seeks to accelerate development, production, and equitable access to COVID-19 diagnostics, therapeutics, and vaccines, and which is supported by the health systems connector;

Noting that, with globalization and the variety of country contexts, there is no “one size fits all” approach in promoting local production;

Recognizing that the small size of some Member States’ economies poses a challenge for local production, which could be addressed by regional market integration;

Emphasizing the need to ensure the quality, safety, efficacy, effectiveness and affordability of locally-produced medicines and other health technologies including through effective manufacturing and regulatory systems;

Noting that the benefits and sustainability of local production are dependent on, among others, a functioning pharmaceutical value chain: from research and development, manufacturing and regulation through to pricing and reimbursement, supply chains, and prescribing and dispensing by health workers as well as stewardship to ensure judicious and appropriate use;

Acknowledging with appreciation the many existing national, regional and global efforts, as well as the achievements made by the Member States, to promote quality and sustainable local production of safe, effective and affordable medicines and other health technologies to benefit public health needs;

Noting that local production can contribute towards achieving the triple billion goals of WHO’s Thirteenth General Programme of Work, 2019–2023;

Noting with concern that Member States still face many challenges in establishing and strengthening sustainable local production of quality-assured, safe, effective and affordable medicines and other health technologies to benefit public health systems and public health needs,

1. URGES Member States,¹ where appropriate, based on the national context:
 - (1) to strengthen their leadership, commitment and support in promoting the establishment and strengthening of quality and sustainable local production of medicines and other health technologies that follows good manufacturing practices;
 - (2) to align their national and regional policies and strategies related to local production, and to leverage regional economic integration and coordination platforms to support products with

¹ And, where applicable, regional economic integration organizations.

sizeable regional demand to expand access to markets and enhance sustainability of local production;

(3) to develop evidence-based holistic national and regional policies, financing mechanisms, strategies and plans of action, and to explore appropriate mechanisms to support the sustainable implementation of national/regional strategies for local production in collaboration with stakeholders for strengthening the local production of quality, safe, effective and affordable medicines and other health technologies;

(4) to enhance interministerial policy coherence and to create incentives and an enabling business environment for local production to be quality-assured and sustainable;

(5) to apply a holistic approach in strengthening local production by considering, for example, promoting research and development, transparency of markets for medicines and other health technologies, regulatory systems strengthening, access to sustainable and affordable financing, development of skilled human resources, access to technology transfer on voluntary and mutually agreed terms for production and needs-based innovation, the aggregation of national and regional demand, and appropriate incentives for private-sector investment, particularly in the context of achieving universal health coverage;

(6) to engage in global, regional and subregional networks related to promoting sustainable local production of quality, safe, effective and affordable medicines, and to further enhance multistakeholder collaboration;

(7) to further engage in North–South and South–South development cooperation, partnerships and networks to build and improve the transfer of technology related to health innovation on voluntary and mutually agreed terms and in line with their international obligations;

(8) to take into account the rights and obligations in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), including those affirmed by the Doha Declaration on the TRIPS Agreement and Public Health, in order to promote access to medicines and other health technologies for all;

2. REQUESTS the Director-General:

(1) to continue to support Member States by strengthening actions related to resolutions WHA61.21 (2008), WHA66.22 (2013) and WHA67.20 (2014);

(2) to strengthen WHO's role in providing leadership and direction in promoting the strategic use of quality and sustainable local production of medicines and other health technologies by using a holistic approach and following good manufacturing practices;

(3) to raise awareness of the importance of sustainable local production of safe, effective, quality, and affordable medicines and other health technologies in improving access;

(4) to continue to support Member States upon their request in promoting quality and sustainable local production of medicines and other health technologies, including, as appropriate, by:

- (a) providing technical support to Member States in developing and/or implementing national policies and evidence-based comprehensive strategies and plans of action for sustainable local production;
 - (b) supporting Member States to foster strategic and collaborative partnerships, including research and manufacturing;
 - (c) building capacity of Member States towards policy coherence and creating an enabling environment;
 - (d) building capacity of governments and other stakeholders to strengthen local production towards quality assurance, regulatory approval and WHO prequalification, as appropriate;
 - (e) strengthening regulatory systems and regional regulatory collaboration;
 - (f) supporting Member States in facilitating research and development and technology transfer on voluntary and mutually agreed terms and in line with their international obligations for local production of quality-assured, prioritized medicines and other health technologies to prevent and address shortages and/or specific public health needs;
 - (g) exploring a mechanism for collecting and disseminating local production-related market intelligence including on the impact of local production measures on availability, accessibility, affordability and prices of local health technologies in collaboration with other relevant international organizations and agencies;
5. to encourage greater participation of Member States in existing regional and global initiatives for collaboration and cooperation;
6. to foster, and coordinate with relevant international intergovernmental organizations in promoting, local production in a strategic and collaborative approach;
7. to leverage existing and, if needed, establish new global platforms to promote transfer of technology on voluntary and mutually agreed terms and in line with international obligations and local production under North–South and South–South cooperation;
8. to continue to support local production by dedicating staff and sufficient resources to carry out activities under this resolution at all three levels of the Organization;
9. to continue to provide technical support, as appropriate, upon request, in collaboration with other competent international organizations, in particular WIPO and WTO, including to policy processes and to countries that intend to make use of the provisions contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), including the flexibilities affirmed by the Doha Declaration on the TRIPS Agreement and Public Health in order to promote access to pharmaceutical products;
10. to continue to support transparency of prices and economic data along the value chain of medicines, including locally produced medicines, and other health technologies (including the supply chain) in order to promote access and affordability;

11. to report on progress in the implementation of this resolution to the Health Assembly biennially from 2023 to 2027.

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