

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

Draft resolution proposed by China, Eswatini, Ethiopia, Ghana, Kenya, Namibia, Rwanda, South Africa, Sudan, Togo and Zimbabwe

The Executive Board,

Having considered the report on the global strategy and plan of action on public health, innovation and intellectual property,¹

(PP1) 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 the quality, safe, effective and affordable medicines and other health technologies;²

(PP2) 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;

(PP3) Recalling also United Nations General Assembly resolution 74/30 (2020) and resolution WHA73.1 (2020) on the 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-responsive, with full respect for human rights;

(PP4) 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;

(PP5) Recalling further the 2030 Agenda for Sustainable Development and its aim of ensuring that no one is left behind;

¹ Document EB148/10.

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

[(PP5 bis) Recalling [the WTO Doha; add] Declaration on the TRIPS Agreement and Public Health ([WTO; add]; delete] Doha Declaration), adopted on 14 November 2001; add; delete; retain]

[(PP5 bis alt) Recalling the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), which provides flexibilities for the protection of public health and [the promotion of; add] [promotes; delete] access to medicines for all, in particular for developing countries [and least-developed countries, as affirmed by; add] [, and; delete] the Doha Declaration on the TRIPS Agreement and Public Health, which recognizes that intellectual property protection is important for the development of new medicines. (Source: A/RES/74/20 (OP29) GHFP – previous resolution on TRIPS and public health); add; delete/reserve]

[(PP5 bis alt alt) Reaffirming the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) as amended, and also reaffirming the 2001 WTO Doha Declaration on the TRIPS Agreement and Public Health, which recognizes that the TRIPS Agreement 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, [which recognizes that intellectual property protection is important for the development of new medicines; reserve] [, including considering [as appropriate; add] time limited waivers of some specified provisions related to COVID-19 products and technologies; add; reserve; no objection]; add and replace PP5bis, PP5bis alt and request removal of mention of TRIPS IP in PP8bis, OP1.10, OP2.9; support PP5bis alt alt]

(PP6) 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 (e.g. Goals 3, 8 and 9);

[(PP6 bis) Recognizing that some countries face problems in accessing medicines, vaccines and other essential health technologies, [such as [the overwhelming demand; delete/move], low manufacturing capacity, high prices, among others, [condition; delete] [can affect; add] access; add] and that such problems are exacerbated in times of pandemic [and/or overwhelming demand; add] such as COVID-19. [The overwhelming demand, low manufacturing capacity, high prices, among others, [condition; delete] [can affect; add] access; move]; add; reserve; question on source of language]

(PP7) Recalling WHO's roadmap for access to medicines, vaccines and other health products 2019–2023 as part of comprehensive support for access, and strategic local production, while considering regional plans and initiatives such as the Pharmaceutical Manufacturing Plan for Africa;

(PP8) [Considering that there is a need to emphasize; delete] [Emphasizing; add] the possibility of [realizing; delete] [promoting; add] access to [quality-assured; add] [safe, effective and affordable; add] medicines and other health technologies through building capacity for local production, especially in LMICs, [effective technology transfer [on voluntary and mutually agreed terms; add; reserve] and cooperation, [development of patent pools[, and promoting generic competition; add] [in order to promote generic competition,; delete]; delete]; add; delete] [based on; delete] [in line with; add] WHO's road map for access to medicines, vaccines and other health products 2019–2023 as comprehensive support for access;

[(PP8 bis) Recognizing [that; delete] intellectual property protection [has a significant role in the pharmaceutical industry; add; reserve; delete] [is important for the development of new medicines; delete] [while also [recognizing that public health-sensitive intellectual property rules and mechanism can help address the misalignment between profit driven innovation models and public health priorities; add; reserve; delete] [recognizing the need to ensure the financial sustainability of health systems;

delete]; delete] [and also recognizes the concerns about its effect on prices; add]; add; reserve; reserve on first part] [delete entire PP8bis]

[(PP8 ter) Mindful of concerns about the current patent system, especially as regards access to medicines in developing countries and reaffirming that public health interests are paramount in both pharmaceutical and health policies; add; reserve; delete PP8ter]

(PP9) Recognizing that integration of local production into overall health systems strengthening can contribute to sustainable access to quality-assured, safe, effective and affordable medicines, help prevent or address medical product shortages, achieving universal health coverage and strengthening national health security;

(PP10) 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;

(PP11) 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;

[(PP11 bis) 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; add; reserve]

(PP12) Noting that the local production of medicines and other health technologies can provide for greater [security; question; delete] [sustainability; add] of supply chains, especially in public health emergencies;

(PP13) Noting that the inter-agency statement on promoting local production signed by the six organizations (The Global Fund, UNAIDS, UNCTAD, UNICEF, UNIDO and WHO) calls for a holistic approach, close partnership, inter-ministerial 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;

(PP14) Recognizing the work of the inter-agency pharmaceutical cooperation group hosted by the WHO and the role of Unitaid and the Medicines Patent Pool to help countries enhance [their local production capacities; delete] [the access to medicines particularly for HIV/AIDS, tuberculosis and malaria, etc.; add], strengthen their regulatory systems and help producers meet pre-qualification standards;

(PP15) Recalling also the launch of the Access to COVID-19 Tools (ACT) Accelerator [and C-TAP; add; delete], which is a global collaboration that seeks to accelerate development, production, and equitable access to COVID-19 tests, treatments, and vaccines;

(PP16) Noting that, with globalization and the variety of country contexts, there is no “one size fits all” approach in promoting local production;

(PP17) Recognizing that conditions in the challenges faced by Member States are suitable for embarking on local production as a strategy to improve access to safe, effective, quality and affordable vaccines, medicines and other health technologies;

(PP18) Recognizing that the small economic size of some Member States' economies poses a challenge for local production, which could be addressed by regional market integration;

(PP19) 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;

(PP20) Recognizing that an effective regulatory system is a necessary component to ensure the quality, safety and effectiveness of medicines and other health technologies; [propose to delete]

[(PP20 bis) Recognizing [the relevance of exercising; delete] [the Doha Declaration, which affirms that; add] the TRIPS [Agreement can and should be interpreted in a manner supportive of WTO members' right to protect public health and promote access to medicines for all, and reaffirms the right of WTO members to use, to the full, the provisions of the TRIPS Agreement, which provides; add] [flexibilities; delete] [flexibility for this purpose; add] [in order to promote research and development as well as local production; delete]; add; reserve] [propose one mention in document in PP5bis alt alt; propose one para in PP and in OP; propose one para in PP; propose mention in OP; delete]

[(PP 20 bis alt) Recognizing the need to promote access to medicines and other health technologies for all, including through the use of the TRIPS flexibilities, recognizing the importance of protection of intellectual property for the development of new medicines as well as the concern[s; add] about its effect on prices; add; delete]

(PP21) Noting that the benefits and sustainability of local production is dependent on 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 use and prevent inappropriate use;

(PP22) Acknowledging with appreciation the many existing national, regional and global efforts, as well as the achievements made by the Member States, to quality and sustainable local production of safe, effective and affordable medicines and other health technologies to benefit public health needs;

(PP23) Noting that local production can contribute towards achieving the triple billion goals of WHO's Thirteenth General Programme of Work;

(PP24) 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 need and health security,

(OP1) URGES Member States, where appropriate, based on the national context:¹

(OP1.1) to strengthen their leadership, commitment and support in promoting to establish and strengthen quality and sustainable local production of medicines and other health technologies that follows good manufacturing practices;

(OP1.2) to align their national and regional policies and strategies related to local production, and to leverage regional economic integration and coordination platforms to agree upon support for products with sizeable regional demand to expand access to markets and enhance sustainability of local production;

(OP1.3) to develop evidence-based holistic national and regional policies, financing mechanisms, strategies and plans of action, in collaboration with stakeholders, for strengthening the local production of quality-assured medicines and other health technologies;

(OP1.4) to explore the mechanism to establish [a; delete] national/regional pooled fund[s; add] to [ensure; delete and propose “facilitate”; support] sustainable support for the implementation of the national/regional strategies for local production; [question on OP1.4; suggest to integrate into OP1.3; delete OP1.4; retain but can also merge with OP1.3] [reserve/delete; retain]

[(OP1.4 alt) to explore appropriate mechanisms to support the sustainable implementation of the national/regional strategies for local production [, which may include national/regional pooled funds; add; reserve]; add]

(OP1.5) to enhance inter-ministerial policy coherence and to create incentives and an enabling business environment for local production to be quality-assured and sustainable;

(OP1.6) to apply a holistic approach in strengthening local production by considering, for example, promoting research and development, price transparency, regulatory systems strengthening, access to sustainable and affordable financing, development of skilled human resources, access to technology [on voluntary and mutually agreed terms; add; delete] for production and needs-based innovation [and/or in line with international and multi-lateral frameworks; add; delete]; the aggregation of national and regional demand; appropriate incentives for private-sector investment; and [procurement decisions based on quality and not only lowest cost [and following good manufacturing practice; add]; delete], particularly in the context of achieving universal health coverage;

(OP1.7) to engage in global, regional and subregional networks related to promoting quality and sustainable local production of quality, safe, effective and affordable medicines and to further enhance multistakeholder collaboration;

(OP1.8) to further engage in North–South and South–South development cooperation, partnerships and networks to build and improve the transfer [and localization; add] of technology related to health innovation [[on [voluntary and; add] mutually-agreed terms; delete] and/or in line with [international [and multi-lateral; add] frameworks; reserve]; add]

¹ And, where applicable, regional economic integration organizations.

(OP1.9) to promote [sustainable; add] local production of [safe and effective [and evidence-based; add]; add] [knowledge-based; add] traditional medicines as alternative source of medicines especially through research and manufacturing of local herbal medicines [according to national contexts and priorities; add]; [delete OP1.9; retain OP1.9]

[(OP1.10) to [fully; add] use the flexibilities [provided in; delete] [embedded in the TRIPS Agreement and; add] [affirmed by the Doha Declaration [on TRIPS and Public Health; add], which affirms that; add] the TRIPS Agreement [[in order to promote local production; delete], [generic competition; delete; retain] and access to medicines.; delete] [can and should be interpreted in a manner supportive of WTO members' right to protect public health and promote access to medicines for all, and reaffirms the right of WTO members to use, to the full, the provisions of the TRIPS Agreement, which provides flexibility for this purpose; add]; add; reserve]

[(OP1.10 alt) to acknowledge the possibility to use in urgent cases the flexibilities provided in the TRIPS Agreement in order to ensure access to medicines.; propose OP1.10alt or delete OP1.10] [delete OP1.10 and in other OP related to TRIPS; delete OP1.10; propose para mentioned once in document]

(OP2) REQUESTS the Director General:

(OP2.1) to continue to support Member States by strengthening actions related to resolutions WHA61.21, WHA66.22 and WHA67.20;

(OP2.2) to strengthen the WHO's role in providing leadership and direction in promoting the strategic use of quality, accessible and affordable and sustainable local production of medicines and other health technologies, by using a holistic approach and following good manufacturing practices;

(OP2.3) to raise awareness of the importance of sustainable local production of safe, effective, quality and affordable medicines and other health technologies in improving access;

(OP2.4) to continue to support Member States, upon their request, in promoting quality and sustainable local production of active pharmaceutical ingredients, medicines and other health technologies, including, as appropriate, by:

(OP2.4.a) providing technical support to Member States in developing and/or implementing national policies and evidence-based comprehensive strategies and plans of action for local production;

(OP2.4.b) supporting Member States to foster strategic and collaborative partnerships, particularly for research and manufacturing;

(OP2.4.c) building the capacity of Member States towards policy coherence and creating an enabling business environment; [agreed to retain as it is under OP2.4; will propose text; propose to merge with OP2.4a]

(OP2.4.d) building the capacity of governments and other stakeholders to strengthen local production towards quality assurance, regulatory approval and WHO prequalification as appropriate; [text agreed but will propose new text]

(OP2.4.e) strengthening regulatory system and regional regulatory collaboration;

(OP2.4.f) supporting Member States in [facilitating; add] [research and development and; delete; retain] technology transfer [[on voluntary and mutually agreed terms; delete; retain] [and/or in line with international and multi-lateral frameworks; add; delete/retain, retain] add] for local production of [quality-assured; add] prioritized medicines and other health technologies to [prevent and; add] address shortages and/or specific local public health needs [to continue to support Member States in the exchange and transfer of technology and research findings, in the context of paragraph 7 of the Doha Declaration which promotes and encourages technology transfer; add; delete];

(OP2.4.g) exploring a mechanism for collecting and disseminating local production-related market intelligence; [question; retain]

(OP2.5) to encourage greater participation on the part of Member States in existing regional and global initiatives for collaboration and cooperation, in line with WHO principles and guidelines;

(OP2.6) to foster and coordinate with relevant international intergovernmental organizations in promoting local production in a strategic and collaborative approach;

(OP2.7) [to [establish a; delete; retain] [leverage existing; add; delete]; delete] [to leverage existing and, if needed, establish new; add] global platforms to promote need-based transfer of technology [on voluntary and mutually agreed terms; add; delete] [and/or in line with international and multi-lateral frameworks; add; delete] and local production under North–South and South–South cooperation;

(OP2.8) to allocate sufficient resources to carry out activities under this resolution at all three levels of the Organization;

[(OP2.9) to [continue to support the application of; delete] [affirm the right of WTO Members to use; add] TRIPS flexibilities in order to [protect public health and, in particular; add] promote [local production, [generic competition; delete] and; delete] access to medicines [for all; add]; add; reserve] [delete OP2.9; propose mention this type of para once]

[(OP2.9 alt) [to continue to [support; delete] [recognize; add] the application of TRIPS flexibilities in [urgent cases to ensure; add] [order to promote local production, generic competition and; delete] access to medicines; add; reserve]; add]

[(OP 2.9 bis) to continue support transparency of prices and cost of medicines (including the supply chain) in order to promote access and affordability; add]

[(OP2.10) to report [on progress in the implementation of this resolution; add] [back; delete] to the World Health Assembly [yearly from 2023–2027; add] [in 2023; delete], through the Executive Board [and to ensure that strengthening local production is included as part of regular reporting on access to medicines.; add] [, on WHO efforts to support the strategic use of local production of medicines and other health technologies, including the consideration of factors such as quality standards and cost; delete]; add]

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