**The draft resolution:**

**Strengthening Local Production of Medicines and Other Health Technologies to Improve Access**

PP 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 the quality, safe, effective and affordable medicines and other health technologies[[1]](#footnote-0);

PP 2. Recalling resolution WHA61.21 (2008), decision WHA 71(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;

PP 3. Recalling also UNGA resolution A/74/L.92 (2020) and WHA A73/CONF./1Rev.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-responsive, with full respect for human rights;

PP 4. Recalling also the Human Rights Council resolution RES/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;

PP 5. Recalling further the 2030 Agenda for Sustainable Development and its aim of ensuring that no one is left behind;

[PP 5 bis Recalling [the WTO Doha; Canada add] Declaration on the TRIPS Agreement and Public Heath ([[WTO; Canada add]; Canada delete] Doha Declaration), adopted on 14 November 2001. Argentina add; USA delete; Argentina, South Africa, Brazil, Mozambique, Indonesia, Mexico, Zambia, Zimbabwe, Togo, Namibia, Eswatini, India, China, Thailand, Russia retain]

[PP 5 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; Canada add] [promotes; Canada delete] access to medicines for all, in particular for developing countries [and least-developed countries, as affirmed by; Canada add] [, and; Canada 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); Australia, EU, Norway, UK add; USA delete/reserve]

[PP 5 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; Egypt reserve] [, including considering [as appropriate; EU, Russia add] time limited waivers of some specified provisions related to COVID-19 products and technologies; South Africa add; USA, Canada, Japan, UK, Switzerland reserve; EU no objection]; USA, Australia, EU, Switzerland add and replace PP5bis, PP5bis alt and request removal of mention of TRIPS IP in PP8bis, OP1.10, OP2.9; Canada, Switzerland, UK, EU, Japan, Australia support PP5bis alt alt]

PP 6. Acknowledging Member States’ commitment to achieve the Sustainable Development Goals including those which relate to local production of medicines and other health technologies in various ways (e.g. SDG3, SDG8, SDG9);

[PP 6 bis. Recognizing that some countries face problems in accessing medicines, vaccines and other essential health technologies, [such as [the overwhelming demand; Brazil delete/move], low manufacturing capacity, high prices, among others, [condition; EU delete] [can affect; EU add] access; Australia add] and that such problems are exacerbated in times of pandemic [and/or overwhelming demand; Australia add] such as COVID-19. [The overwhelming demand, low manufacturing capacity, high prices, among others, [condition; EU delete] [can affect; EU add] access; Australia move]; Argentina, South Africa, Russia, China, Brazil, Costa Rica, Mexico, Indonesia add; USA reserve; EU, Australia, Russia, Norway, Australia, UK question on source of language]

PP 7. Recalling WHO’s roadmap for access to medicines, vaccines and other health products 2019-2023[[2]](#footnote-1) 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;

PP 8. [Considering that there is a need to emphasize; Ecuador delete] [Emphasizing; Ecuador add] the possibility of [realizing; USA, Switzerland delete] [promoting; USA, Switzerland add] access to [quality-assured; USA, Australia add] [safe, effective and affordable; Brazil, Australia add] medicines and other health technologies through building capacity for local production, especially in LMICs, [effective technology transfer [on voluntary and mutually agreed terms; USA, Switzerland, Australia, Canada add; South Africa, Egypt reserve] and cooperation, [development of patent pools[, and promoting generic competition; Canada add] [in order to promote generic competition,; Canada delete]; USA delete]; Argentina add; Switzerland delete] [based on; USA delete] [in line with; USA add] WHO’s road map for access to medicines, vaccines and other health products 2019–2023 as comprehensive support for access;

[PP 8 bis. Recognizing [that; Argentina delete] intellectual property protection [has a significative role in the pharmaceutical industry; Argentina add; Norway, Australia, USA, EU, Canada, Switzerland reserve; Switzerland, UK delete] [is important for the development of new medicines; Argentina 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; Argentina add; Norway, Australia, USA, EU, Canada, Switzerland reserve; Switzerland, UK delete] [recognizing the need to ensure the financial sustainability of health systems; Argentina delete]; Canada delete] [and also recognizes the concerns about its effect on prices; Canada add]; EU add; USA reserve; South Africa reserve on first part] [USA delete entire PP8bis]

[PP 8 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; Zimbabwe add; EU, UK, Norway, Canada reserve; Canada, UK, Norway delete PP8ter]

PP 9. Recognizing that integration of local production into the 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;

PP 10. 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;

PP 11. 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; Argentina add; USA, UK, Switzerland reserve]

PP 12. Noting that the local production of medicines and other health technologies can provide for greater [security; Russia question; Secretariat delete] [sustainability; Secretariat add] of supply chains, especially in public health emergencies;

PP 13. Noting that the interagency statement on promoting local production[[3]](#footnote-2) 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;

PP 14. 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; Ethiopia, Zimbabwe delete] [the access to medicines particularly for HIV/AIDS, tuberculosis and malaria, etc.; Ethiopia, Zimbabwe add], strengthen their regulatory systems and help producers meet pre-qualification standards;

PP 15. Recalling also the launch of the Access to COVID-19 Tools (ACT) Accelerator [and C-TAP; Costa Rica add; Switzerland delete], which is a global collaboration that seeks to accelerate development, production, and equitable access to COVID-19 tests, treatments, and vaccines;

PP 16. Noting that, with globalization and the variety of country contexts, there is no “one size fits all” approach in promoting local production;

PP 17. 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

PP 18. 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;

PP 19. 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;

PP 20. Recognizing that an effective regulatory system is a necessary component to ensure the quality, safety and effectiveness of medicines and other health technologies; [EU, Egypt propose to delete]

[PP 20 bis. Recognizing [the relevance of exercising; Canada, Argentina delete] [the Doha Declaration, which affirms that; Canada, Argentina 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; Canada, Argentina add[ [flexibilities; Canada, Argentina delete] [flexibility for this purpose; Canada, Argentina add] [in order to promote research and development as well as local production; Canada, Argentina delete]; Argentina add; USA, Switzerland reserve] [USA, Japan propose one mention in document in PP5bis alt alt; Egypt propose one para in PP and in OP; EU propose one para in PP; South Africa propose mention in OP; Brazil 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; Australia add] about its effect on prices; Norway, EU add; Brazil delete]

PP 21. Noting that the benefits and sustainability of local production is dependent on a functioning pharmaceutical value chain: from research & 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;

PP 22. 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;

PP 23. Noting that local production can contribute towards achieving the Triple Billion goals of the WHO 13th General Programme of Work;

PP 24. 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.

1. Urge Member States[[4]](#footnote-3):

OP 1. Where appropriate, based on the national context,

OP 1.1. to strengthen their leadership, commitment and support in promoting to establish and strengthen quality and sustainable local production of medicines and other health technologies which follows good manufacturing practices;

OP 1.2. to align their national and regional policies and strategies related to local production and 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;

OP 1.3. 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;

OP 1.4. to explore the mechanism to establish [a; South Africa delete] national/regional pooled fund[s; South Africa add] to [ensure; USA delete and propose “facilitate”; Ethiopia, South Africa support] sustainable support for the implementation of the national/regional strategies for local production; [USA question on OP1.4; Norway, Brazil suggest to integrate into OP1.3; EU, Australia, UK delete OP1.4; Egypt retain but can also merge with OP1.3] [USA reserve/delete; South Africa, Ethiopia, Thailand, Zimbabwe retain]

[OP 1.4 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; Ethiopia, Egypt add; EU, Australia reserve]; Egypt, EU, UK add]

OP 1.5. to enhance inter-ministerial policy coherence and to create incentives and an enabling business environment for local production to be quality-assured and sustainable;

OP 1.6. 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; Switzerland, USA, EU add; Egypt, Argentina, Indonesia delete] for production and needs-based innovation [and/or in line with international and multi-lateral frameworks; Bangladesh, Switzerland, Egypt add; USA 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; EU add]; Egypt, Thailand delete], particularly in the context of achieving universal health coverage;

OP 1.7. 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 multi-stakeholder collaboration;

OP 1.8. to further engage in North–South and South–South development cooperation, partnerships and networks to build and improve the transfer [and localization; Egypt add] of technology related to health innovation [[on [voluntary and; USA, EU add] mutually-agreed terms; Argentina delete] and/or in line with [international [and multi-lateral; Bangladesh, Switzerland add] frameworks; USA reserve]; Canada, Switzerland add]

OP 1.9. to promote [sustainable; Canada add] local production of [safe and effective [and evidence-based; Russia add]; UK add] [knowledge-based; Canada, Thailand add] traditional medicines as alternative source of medicines especially through research and manufacturing of local herbal medicines [according to national contexts and priorities; Russia add]; [USA, EU, Norway delete OP1.9; Ethiopia, Thailand, Brazil, Indonesia, Eswatini retain OP1.9]

[OP 1.10. To [fully; Egypt add] use the flexibilities [provided in; Canada, Egypt delete] [embedded in the TRIPS Agreement and; Egypt add] [affirmed by the Doha Declaration [on TRIPS and Public Health; Egypt add], which affirms that; Canada add] the TRIPS Agreement [[in order to promote local production; Japan, Canada delete], [generic competition; Canada, Australia delete; Egypt retain] and access to medicines.; Canada 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; Canada add]; Argentina add; USA 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.; Norway propose OP1.10alt or delete OP1.10] [USA, Japan delete OP1.10 and in other OP related to TRIPS; Switzerland delete OP1.10; Canada propose para mentioned once in document]

1. Request the Director General:

OP 2.1. To continue to support Member States by strengthening actions related to WHA61.21, WHA66.22 and WHA67.20;

OP 2.2. 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;

OP 2.3. to raise awareness of the importance of sustainable local production of safe, effective, quality and affordable medicines and other health technologies in improving access;

OP 2.4. 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:

OP 2.4.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;

OP 2.4.b. assisting Member States to foster strategic and collaborative partnerships, particularly for research and manufacturing;

OP 2.4.c. building capacity of Member States towards policy coherence and creating an enabling business environment; [Egypt agreed to retain as it is under OP2.4; EU will propose text; Russia propose to merge with OP2.4a]

OP 2.4.d. building capacity of governments and other stakeholders to strengthen local production towards quality assurance, regulatory approval and WHO prequalification as appropriate; [text agreed but Egypt will propose new text]

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

OP2.4.f. supporting Member States in [facilitating; Norway, Switzerland add] [research and development and; Norway, Switzerland delete; Brazil, Egypt retain] technology transfer [[on voluntary and mutually agreed terms; Argentina, Egypt delete; Canada, EU, Japan retain] [and/or in line with international and multi-lateral frameworks; Bangladesh, Switzerland add; USA delete/reserve, Egypt retain] USA, Switzerland add] for local production of [quality-assured; USA add] prioritized medicines and other health technologies to [prevent and; USA 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; Zimbabwe add; USA delete];

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

OP2.5. to encourage greater participation of Member States in existing regional and global initiatives for collaborations and cooperation in line with WHO principles and guidelines;

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

OP2.7. [to [establish a; Canada delete; Ethiopia retain] [leverage existing; Canada add; Ethiopia delete]; Norway delete] [to leverage existing and, if needed, establish new; Norway add] global platforms to promote need-based transfer of technology [on voluntary and mutually agreed terms; USA, Switzerland add; Argentina delete] [and/or in line with international and multi-lateral frameworks; Bangladesh, Switzerland add; USA 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; Canada delete] [affirm the right of WTO Members to use; Canada add] TRIPS flexibilities in order to [protect public health and, in particular; Canada add] promote [local production, [generic competition; UK delete] and; Canada delete] access to medicines [for all; Canada add]; Argentina add; USA reserve] [USA, Switzerland delete OP2.9; Canada propose mention this type of para once]

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

[OP2.10. To report [on progress in the implementation of this resolution; Ethiopia add] [back; Ethiopia delete] to the World Health Assembly [yearly from 2023-2027; Ethiopia add] [in 2023; Ethiopia delete], through the Executive Board [and to ensure that strengthening local production is included as part of regular reporting on access to medicines.; Ethiopia 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; Ethiopia delete]; USA add]

1. Medicines and other health technologies includes pharmaceuticals, vaccines, biopharmaceuticals, medicals devices etc. [↑](#footnote-ref-0)
2. <https://apps.who.int/iris/bitstream/handle/10665/330145/9789241517034-eng.pdf?ua=1> [↑](#footnote-ref-1)
3. 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. [↑](#footnote-ref-2)
4. And, where applicable, regional economic integration organizations. [↑](#footnote-ref-3)