**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); Brazil add] WHA63.12 (2010), WHA65.17 (2012), WHA65.19 (2012), [WHA66.22 (2013); Argentina add], WHA67.20 (2014), WHA67.21 (2014), WHA67.22 (2014), WHA68.7 (2015), WHA71.8 (2018), [WHA72.8 (2019); South Africa, Brazil add; USA reserve] 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), [; USA, Norway, Switzerland delete] [USA, Norway, Switzerland delete], decision WHA 71(9) (2018), and document A71/12 (2018), [; USA delete] [insofar as they address; USA add] 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 3bis. Recalling the United Nations Secretary General’s High Level Panel on Access to Medicines (2016), calls on governments to negotiate global agreements on the coordination, financing and development of health technologies to complement existing innovation models~~;Argentina add; Australia, UK, Norway, USA, Switzerland delete]

**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[; [Norway delete]

[PP5bis 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]

[PP5bis 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]

[PP5bis 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, and notes the need for appropriate incentives in the development of new health products; USA, Australia, EU, Switzerland add and would replace PP5bis, PP5bis alt and would request removal of mention of TRIPS IP in PP9bis, OP1.10, OP2.8]

**PP 6.** Acknowledging Member States’ commitment to achieve the Sustainable Development Goals [including those; EU, Norway add] 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 [~~and the lack of a global mechanism~~; Australia question; Argentina delete], 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 [USA reserve highlight]. The overwhelming demand, low manufacturing capacity, high prices and the lack of a global allocation mechanism, among others, [condition; EU delete] [can affect; EU add] access; Argentina, South Africa, Russia, China, Brazil, Costa Rica, Mexico, Indonesia add; EU, Australia, Russia, Norway, Australia, UK question on source of language]

**PP 7.** ~~Considering the Pharmaceutical Manufacturing Plan for Africa (PMPA) that aims to strengthen local pharmaceutical manufacturers in Africa to produce quality, affordable essential medicines to improve health outcomes, and to realize direct and indirect economic growth;~~

[USA, Norway, UK, Australia reserve; suggest by South Africa for Secretariat to check other regions/resolutions] [USA reserve deletion of PP7]

**PP 8.** ~~Considering also the commitment of [African Union; Australia add] Heads of State and Government at their 19th Ordinary Assembly in 2012 to consolidate their efforts for local production and strengthening regulatory oversight in Pillar II of the [African Union; Australia add] Roadmap on shared responsibility and global solidarity on AIDS, TB and Malaria (ATM), which also underscores the need to accelerate access to affordable and quality-assured medicines and health-related commodities~~; [Norway, UK, Australia reserve][USA reserve deletion of PP8]

[PP8.alt. Recalling WHO’s roadmap for access to medicines, vaccines and other health products 2019-2023[[2]](#footnote-1) as [part of; USA add] comprehensive support for access [, and [strategic local production while; USA add] considering regional plans and initiatives such as the Pharmaceutical Manufacturing Plan for Africa; Norway, EU, UK, South Africa add to replace initial PP7 and PP8]; EU add to replace initial PP8]

**PP 9.** [Considering that there is a need to emphasize; Ecuador delete] [Emphasizing; Ecuador add] the possibility of [realizing; USA, Swtizerland 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 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;

[PP9bis. Recognizing [that; Argentina delete] intellectual property protection [has a significative role in the pharmaceutical industry; Argentina add] [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] [recognizing the need to ensure the financial sustainability of health systems; Argentina delete]; Canada delete]; EU add; USA reserve; Canada suggest using language from Doha Declaration; South Africa reserve on first part] [and also recognizes the concerns about its effect on prices; Canada add] [UK, Norway, Canada, Australia, Switzerland, USA, EU reserve on Argentina addition] [USA delete] [Switzerland request to delete the additions to PP9bis introduced by Argentina]

[PP9ter. 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 prefer to delete] [Norway not in position to support this text]

**PP 10.** Recognizing that[, in the right regulatory and policy environment,; USA add; South Africa, Argentina question on “right”; Zimbabwe, South Africa delete] integration of local production into [the; USA delete; Zimbabwe retain] overall [initiatives for; USA add; Zimbabwe delete] health systems strengthening can contribute to sustainable access to quality[-assured; USA add] [safe, effective; EU add] and affordable medicines, [help prevent or address; USA add] medical product shortages, achieving universal health coverage and [strengthening; USA add] national [health security; Russia reserve on last 2 words];

[~~PP10bis. Noting that the term “local production” can apply to finished pharmaceutical products, active pharmaceutical ingredients, excipients and starting materials, and/or fill-finishing and packaging intended for domestic markets and/or export based on national, regional and/or global demand and suitability of Member States for local production may vary among these product types~~; USA add; Zimbabwe ask source; Argentina, Brazil, Zimbabwe, South Africa, Zambia delete]

**PP 11.** Recognizing also that local production can contribute to other national development goals, such as catalysing local capacity in innovation, strengthening [expertise in the health workforce; USA delete] [human capital and expertise; USA add] and building a knowledge-based economy;

[PP11bis. 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; Zimbabwe, South Africa add]; EU, USA, Switzerland add]

[PP11 BIS BIS. Recognizing the importance of promoting competition to improve availability and affordability of health technologies consistent with public health policies and needs, [inter alia,; EU add] through the production and introduction of generic versions, in particular of essential medicines, in developing countries; Argentina add; USA, UK, Switzerland reserve].

[PP11ter. Noting that the local production of medicines and other health technologies can provide for greater security of supply chains, especially in public health emergencies; USA add]

**PP 12.** [Recalling; Zimbabwe delete] [Noting; Zimbabwe, South Africa add] that the [first; EU delete] interagency statement on promoting local production[[3]](#footnote-3) signed by the [top leadership of; South Africa delete] the six organizations (The Global Fund, UNAIDS, UNCTAD, UNICEF, UNIDO and WHO) calls for a holistic approach, close partnership, inter-ministerial and [multi-; Zimbabwe, South Africa delete] [relevant; Zimbabwe, South Africa add] stakeholder cooperation, and global synergy in promoting [the high; USA add; UK, South Africa delete] quality and sustainable local production of [quality-assured,; USA add; UK, South Africa delete] [safe, effective[, quality; UK, South Africa add] and affordable; Brazil add] medicines and other health technologies;

[PP12bis. 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; EU add; Ethiopia question on the role of inter-agency pharmaceutical cooperation group, Unitaid & Medicines Patent Pool on enhancing local production capacity specifically] [Zimbabwe ask for information on how Unitaid & MPP promote local production]

**PP 13.** Recalling also the launch of the Access to COVID-19 Tools (ACT) Accelerator [and C- TAP; Costa Rica add; Switzerland delete], which is a [ground-breaking; Zimbabwe delete; Brazil, South Africa, Norway find different wording] global collaboration [that seeks; USA add] to accelerate development, production, and equitable access to COVID-19 tests, treatments, and vaccines. [Brazil, South Africa, Norway prefer original text]

**PP 14.** Noting that, with globalization and the variety of country contexts, there is no “one size fits all” approach in promoting local production;

**PP 15.** Recognizing that [not all; Zimbabwe delete] [conditions in; USA add] [the challenges faced by; Zimbabwe add] Member States are suitable for embarking on local production as a strategy to improve access to [quality-assured; UK delete] [, safe, effective; EU add] [[quality; UK add] and affordable; Brazil add] [vaccines,; Brazil add] medicines and other health technologies [and that locally produced products may sometimes have higher prices than imported versions; USA, UK add; South Africa, Zimbabwe, Brazil, Ethiopia, Zambia delete]; [Zimbabwe, Ethiopia delete PP15]

**PP 16.** Recognizing [that; USA delete] the small [economic; USA delete] size of some Member States [economies; USA add] poses a challenge for local production, which could be addressed by regional market integration;

**PP 17**. Emphasizing that the quality of locally produced medicines and other health technologies [cannot; USA delete] [should not; USA add] be compromised [and that manufacturing and regulatory systems should be in place to ensure that products meet appropriate regulatory standards; USA add]; [Zimbabwe propose deletion of original PP17]

[PP17bis. Noting that the local production of medicines and other health technologies can provide for greater security of supply chains, especially in public health emergencies; USA add]

**PP 18.** Recognizing that an effective regulatory system is a necessary component to ensure the quality, safety and effectiveness of medicines and other health technologies;

[PP18bis. Recognizing [the relevance of exercising; Canada delete] [the Doha Declaration, which affirms that; Canada 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 add[ [flexibilities; Canada delete] [flexibility for this purpose; Canada add] [in order to promote research and development as well as local production; Canada delete]; Argentina add; USA reserve] [Switzerland reserve]

[PP18bis. 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 of its effect on prices

**PP 19.** Noting that the benefits and sustainability of local production is dependent on a functioning pharmaceutical value chain: from research & development, manufacturing [and USA add][ Secretariat delete] regulation through to pricing and reimbursement, supply chains and [prescribing,; USA add] [and; Secretariat add] dispensing [by medical professionals as well as stewardship to ensure judicious use and prevent inappropriate use; USA add];

**PP 20.** Acknowledging with appreciation the many existing national, regional and global efforts, as well as the achievements made by the Member States, to promote [the high; USA add] quality and sustainable [safe, effective and affordable; Argentina add] local production of medicines and other health technologies to benefit public health needs;

**PP 21.** Noting that local production can contribute towards achieving the Triple Billion goals of the WHO 13th General Programme of Work;

**PP 22.** Noting with concern that Member States still face many challenges in establishing and strengthening sustainable local production of quality[-assured; USA add], safe, effective and affordable medicines and other health technologies to benefit public health need and health security,

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

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

**OP1.1.** to strengthen their leadership, commitment and support in promoting [to establish and strengthen; Bangladesh add] [the high; USA add] quality and sustainable local production of medicines and other health technologies;

**OP1.2.** to align [their; USA add] national [and regional; USA add] policies and[/or; USA delete] strategies related to local production [with regional policies and/or strategies; USA delete], and leverage [on; USA delete] regional economic integration [and coordination platforms to agree upon support for products with sizeable regional demand; USA add] to expand access to markets and enhance sustainability of local production;

**OP1.3.** to develop evidence-based holistic national [and regional; Norway add] policies, [financing mechanismes,; Norway add] strategies and plans of action in collaboration with stakeholders for strengthening [the; USA add] local production of [quality-assured; USA add] medicines and other health technologies;

**OP1.4.** to explore the mechanism to establish a national/regional pooled fund to ensure sustainable support for the implementation of the national/regional strategies for local production; [USA question on OP1.4; Norway suggest to integrate into OP1.3; EU delete OP1.4]

**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,; Argentina add] regulatory systems strengthening, access to sustainable and affordable financing, development of skilled human resources, access to technology [on voluntary and mutually agreed terms; Switzerland propose this text here] for production and needs-based innovation [[on voluntary and mutually agreed terms; Switzerland propose to move this text] [and/or in line with international and multi-lateral frameworks; Bangladesh, Switzerland add]; the aggregation of national and regional demand; appropriate incentives for private-sector investment [South Africa question on private-sector investment]; and procurement decisions based on quality and not only lowest cost, particularly in the context of achieving universal health coverage; USA add]; [Norway add text later]

**OP1.7.** to engage in global, regional and subregional networks related to promoting [high; USA add] [safe, effective and affordable; Argentina add] quality and sustainable local production, and to further enhance multi-stakeholder collaboration;

**OP1.8.** to further engage in North–South and South–South development cooperation, partnerships and networks to build and improve transfer of technology related to health innovation [on mutually-agreed terms and/or in line with international [on mutually-agreed terms and/or in line with international [and multi-lateral; Bangladesh, Switzerland add] frameworks; Canada, Switzerland add]

**OP1.9.** to promote [sustainable; Canada add] local production of [safe and effective; UK add] [knowledge-based; Canada add; Bangladesh question; Secretariat will check the language used] traditional medicines as alternative source of medicines especially through research and manufacturing of local herbal medicines; [USA, EU, NOR delete OP1.9; Ethiopia retain OP1.9]

[OP1.10. To use the flexibilities [provided in; Canada delete] [affirmed by the Doha Declaration, which affirms that; Canada add] the TRIPS Agreement [in order to promote local production, generic competition 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] [USA delete] [Switzerland delete]

[OP1.10. To [acknowledge the possibility to; Norway add] use [in urgent cases; Norway add] the flexibilities provided in the TRIPS Agreement in order to [promote local production, generic competition and; Norway delete] ensure access to medicines.; Argentina add; USA reserve]

1. **Request the Director General:**

[OP2bis. To continue to support Member States by strengthening actions related to WHA61.21 and WHA66.22; Argentina add]

**OP2.1.** to strengthen the WHO’s role in providing leadership and direction in promoting [the strategic use of high; USA add] quality[, accessible and affordable; Argentina add] and sustainable local production of medicines and other health technologies by using a holistic approach;

**OP2.2.** to raise awareness of the [potential; USA add] importance of [the high; USA add] quality [accessible and affordable; Argentina add] and sustainable local production of medicines and other health technologies in improving access[, when used strategically in appropriate contexts; USA add];

**OP2.3.** to continue to support Member States upon their request in promoting [the high; USA add] quality [accessible and affordable; Argentina add] and sustainable local production of [active pharmaceutical ingredients,; USA add] medicines and other health technologies, including, as appropriate, by:

**OP2.3.a.** providing technical support to Member States in developing and/or implementing national policies and evidence-based comprehensive strategies and plan of action;

**OP2.3.b.** assisting Member States to foster strategic and collaborative partnerships;

**OP2.3.c.** building capacity of Member States towards policy coherence and creating an enabling business environment;

**OP2.3.d.** building capacity of industry, governments and other stakeholders to strengthen local production towards quality-assurance, [regulatory approval; USA add] and WHO prequalification as appropriate;

**OP2.3.e.** promoting regulatory system strengthening and regional regulatory [collaboration and; Norway add] harmonization [, collaboration and cooperation; Norway add; Norway delete];

**OP2.3.f.** supporting Member States in [facilitating; Norway, Switzerland add] [research and development and; Norway, Switzerland delete] technology transfer [on voluntary and mutually agreed terms [and/or in line with international and multi-lateral frameworks; Bangladesh, Switzerland add] 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; [Zimbabwe propose to insert 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]

**OP2.3.g.** exploring [the] a mechanism for collecting and disseminating local production-related market intelligence; [USA question on OP2.3.g.; Ethiopia retain as LMICs need WHO support with market intelligence for local production]

**OP2.4.** to encourage greater participation of Member States in existing regional and global initiatives for collaborations and cooperation in line with WHO principles and guidelines;

**OP2.5.** to foster and coordinate with relevant international intergovernmental organizations to promoting local production in a strategic and harmonised approach;

**OP2.6.** to [establish a; Canada delete; Ethiopia retain] [leverage existing; Canada add; Ethiopia delete] global platform[s; Canada add] to promote need-based transfer of technology [on voluntary and mutually agreed terms [and/or in line with international and multi-lateral frameworks; Bangladesh, Switzerland add] USA, Switzerland add] and local production under North-South and South-South cooperation;

**OP2.7.** to continue its support in local production through dedicated staff and sufficient resources to carry out activities under this resolution [at all three levels of the organization; Zimbabwe add].

[OP2.8. 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 and; Canada delete] access to medicines [for all; Canada add]; Argentina add; USA reserve] [Switzerland delete]

[OP2.8. 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]

[OP 2.8 bis To continue support transparency of prices and cost of medicines (including the supply chain) in order to promote access and affordability; Argentina add]

[OP2.9. 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-3)
4. And, where applicable, regional economic integration organizations. [↑](#footnote-ref-4)