

## Concept Note

# WHO Resolution on Strengthening Local Production of Medicines and Other Health Technologies to Improve Access

## Background

Attaining the highest standard of health is a fundamental right for all. Access to quality-assured, safe, effective, and affordable medicines and other health technologies for all is a specific component of the Sustainable Development Goals target 3.8<sup>1</sup> and in achieving universal health coverage.

Access to medicines and other health technologies continues to be a global concern. In 2018, an estimated 70% of the people worldwide living with HIV are in the African Region with only 64% receiving antiretroviral treatment, which leaves 9.4 million people living with HIV without access to treatment. Though the coverage of tuberculosis treatment increased globally in 2018, the treatment coverage in the African and Eastern Mediterranean Regions were below the global estimate (70%) at only 56% and 65%, respectively. Non-communicable diseases, many of which are chronic conditions and need long-term treatment, are on the rise with the availability of medicines and other health technologies still problematic in some countries. Furthermore, the supply chain system in many countries remain weak, which lead to stock outs and an increasing number of substandard and falsified products entering the supply chain.

Shortages of medicines and other health technologies have also been increasing in recent years and affects all countries. Shortages are due to various reasons: a limited number of manufacturers of the finished medical product, active ingredient or necessary component/part; low volume markets; low profitability of the medicines and other health technologies; poor forecasting of the demand; prohibitive regulatory requirements (e.g. too costly); interruptions in manufacturing coupled with weak supply systems. Medical product shortages could result in the inability to deliver needed medicines and other health technologies and the penetration of substandard and falsified medicines and other health technologies into the market especially for countries with weak regulatory oversight.

Some countries or regions largely rely on importation of medicines and other health technologies to meet the public health need, which put their health security at risk should importation be interrupted. For instance, in Africa, more than 80% of the demand for essential medicines are imported.

The COVID-19 pandemic has presented an unprecedented challenge to health systems causing complete disruption of the global supply chain of vital medicines and other health products. Many countries imposed restrictive measures during the COVID-19 pandemic to secure adequate

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<sup>1</sup> Sustainable Development Goals target 3.8: Achieve universal health coverage, including financial risk protection, access to quality essential health care services and access to safe, effective, quality and affordable essential medicines and vaccines for all.

access to certain critical medicines and medical products. These restrictive measures including export restrictions, export authorization, restrictions on movement and lockdowns, especially in countries that are the largest producers, has resulted in significant market gaps in many vulnerable countries. The crisis underscored the risk of overreliance on international health supply chains, imported medicines and other health technologies and donor support.

Local production of medicines and other health technologies has been a subject of intense discussion in international, regional and national fora since the 1970s. Within the last two decades, there has been greater emphasis on issues of local production and related technology transfer in the context of access to medicines and other health technologies, leading to critical developments beginning with WHO Resolution WHA 61.21 on the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI)<sup>2</sup>. The GSPA-PHI is a landmark global strategy adopted in 2008 to improve treatment for poverty-related and neglected diseases disproportionately affecting developing countries by simultaneously stimulating innovation to find new medicines and other health technologies for these diseases and improving access to existing products. Element 3 of the GSPA-PHI highlights investment in building innovative capacity in key areas such as science and technology, and local production of pharmaceuticals. Element 4 emphasizes North-South and South-South development cooperation, partnerships and networks to facilitate transfer of technology related to health innovation. In 2014, the top leadership of UNAIDS, UNCTAD and WHO<sup>3</sup> called for renewed investment in strengthening local production in Africa through partnerships to build Africa's capacity to meet shortages in essential medicines and other health technologies, reduce the dependency on imports and ensure health security in the continent. In 2016, the UN General Assembly declared the next decade to be the third industrial development decade for Africa (IDDA III), identifying the pharmaceutical industry as a priority under IDDA III. In 2018, the 71<sup>st</sup> World Health Assembly adopted decision WHA 71(9), in which it requested the Director General "to implement the recommendations of an overall programme review panel addressed to the Secretariat as prioritized by the review panel, in an implementation plan, consistent with the global strategy and plan of action on public health, innovation and intellectual property" and "to report on progress made in implementing this decision."<sup>4</sup> One recommendation from the overall programme review panel is to promote technology transfer as part of local health technology production programmes in developing countries in line with country needs. Moreover, at the 71<sup>st</sup> WHA, Member States highlighted the importance of local production in the context of the global shortage of, and access to, medicines and vaccines<sup>5</sup>.

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<sup>2</sup> See document WHA61/2008/REC/1, resolution WHA61.21 and Annex

<sup>3</sup> Sidibé M, Li Y, Chan M. Commodities for better health in Africa – time to invest locally. *Bull World Health Organ* 2014;92:387-387A (doi: <http://dx.doi.org/10.2471/BLT.14.140566>, accessed 17 Jan 2020)

<sup>4</sup> See document WHA71/2018/REC/1, decision WHA71(9)

<sup>5</sup> See document A71/12

At the regional level, African Heads of States endorsed the African Union Pharmaceutical Manufacturing Plan for Africa (PMPA) in 2007 and the PMPA Business Plan for implementation of the PMPA in 2012 to guide African countries in developing local pharmaceutical manufacturing capacity to address their needs. Regional plans for pharmaceutical manufacturing development were also launched, such as in the East African Community (EAC)<sup>6</sup> and the Economic Community of West African States (ECOWAS)<sup>7</sup>, to tailor the development of a regional pharmaceutical manufacturing industries. In 2018, the WHO Regional Committee for South-East Asia adopted the Delhi Declaration on improving access to essential medicines and other health technologies in the region and beyond.

Since the adoption of the WHO Resolution WHA 61.21, the WHO Secretariat, in collaboration with partners and stakeholders, has been supporting Member States in promoting quality and sustainable local production. With the support of different donors, WHO conducted the landscape analyses of local production and technology transfer of different medicines and other health technologies (including medicines, vaccines, biologicals, medical devices, in vitro diagnostics and blood products) in different regions and countries, and various capacity building for quality assurance. A policy coherence framework was developed for policy makers to achieve both health and industrial policy goals while promoting local production. WHO organized holistic training workshops to build capacity of manufacturers, regulators and other stakeholders to cultivate and leverage on key enabling factors to strengthen local production towards quality assurance and sustainability in different regions. The international community has also been engaged in supporting Member States in strengthening local production to improve access. In 2017, WHO convened an interagency consultation on local production where it was identified that the benefits and viability of local production is dependent on a functioning pharmaceutical value chain: from research & development, manufacturing, regulation through to pricing and reimbursement, supply chains and dispensing. At the 72<sup>nd</sup> World Health Assembly, WHO led the development and launch of the first interagency statement on promoting local production<sup>8</sup> signed by the top leadership of the six organizations (The Global Fund, UNAIDS, UNCTAD, UNICEF, UNIDO and WHO). The statement signaled their commitment in aiming to work in a holistic, strategic and collaborative manner in partnership with governments and other stakeholders in promoting local production. The statement calls for a holistic approach and government commitment to enable manufacturers to comply with international quality standards, be competitive and engage in sustainable manufacturing.

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<sup>6</sup> 2<sup>nd</sup> EAC Regional Pharmaceutical Manufacturing Plan of Action 2017-2027 (<http://eacgermany.org/wp-content/uploads/2018/04/2nd-EAC-Regional-Pharmaceutical-Manufacturing-Plan-of-Action-2017%E2%80%932027.pdf>, accessed 17 Jan 2020)

<sup>7</sup> The Economic Community of West African States (ECOWAS) Regional Pharmaceutical Plan. WAHO, 2014 ([https://www.unido.org/sites/default/files/2016-01/ECOWAS\\_Regional\\_Pharmaceutical\\_Plan\\_0.pdf](https://www.unido.org/sites/default/files/2016-01/ECOWAS_Regional_Pharmaceutical_Plan_0.pdf), accessed 17 Jan 2020)

<sup>8</sup> [https://www.who.int/phi/implementation/tech\\_transfer/Interagency-statement-on-promoting-local-production.pdf](https://www.who.int/phi/implementation/tech_transfer/Interagency-statement-on-promoting-local-production.pdf) (accessed 20 Jan 2020)

The current interest in local production of medicines and other health technologies by Member States is significant as a strategy to improve access to quality-assured affordable medicines and other health technologies, achieve universal health coverage and reduce dependency on imports to strengthen national health security, as well as to catalyze local capacity for innovation, strengthen capacity of the health workforce and stimulate a knowledge-based economy and social development. It is important to note that improved access can be attained not only by a reduction in price, but also by, for example, reducing lead time to the supply chain, and adapting existing products (such as developing heat-stable formulations) or transferring technology to build local production capability to meet specific local needs. Local production can cater to the demand of medicines and other health technologies to treat diseases that disproportionately affect low- and middle-income countries (LMICs), such as neglected tropical diseases and malaria.

Some of the benefits in promoting local production has been evident among Member States; for instance, China has demonstrated certain progress and success with implementing their strategies to promote local production. China's local pharmaceutical manufacturing industry not only benefitted national universal health coverage but has also grown to become the world's leading producer and exporter of active pharmaceutical ingredients by volume and accounted for ~20% of the total global API output. In Bangladesh, local pharmaceutical manufacturers supply ~98% of the local demand for medicines and export to 145 countries worldwide. In 2007, India and Thailand embarked on a project to develop capacity in local production of influenza vaccines through technology transfer due to concerns of the lack of reliable access to a sufficient number of doses via importation in the event of a pandemic. By 2015, local production capacity of pandemic influenza vaccine in India and Thailand reached 20 million and 1.5 million doses, respectively. In 2018, Indian vaccine manufacturers supplied the majority of procured vaccines by volume (> 65%) in all regions except the European Region. As of January 2020, Indian vaccine manufacturers attained WHO prequalification of 50 vaccines and Thai vaccine manufacturers attained 1 WHO-prequalified vaccine.

Indeed, local production could cater to local/regional needs. In Brazil, where the presence of schistosomiasis, leishmaniasis and other neglected tropical diseases is among the highest in the Region of the Americas (e.g. over 1.5 million people requiring preventive chemotherapy annually for schistosomiasis in 2018), the local manufacturer (Immunobiological Technology Institute) supplies the public sector with reagent kits for diagnosis of AIDS, leptospirosis, leishmaniasis, Chagas disease, and schistosomiasis. In the case of malaria, where an estimated 200 million cases of malaria (about 92% of the global cases) were in the African Region, one manufacturer in the United Republic of Tanzania produces long-lasting insecticidal bednets and supplies locally and within Africa via procurement supported by The Global Fund.

Experience has shown that a holistic national strategy is important in developing local production. Some Member States, such as Brazil<sup>9</sup>, Russia<sup>10</sup> and Vietnam<sup>11</sup>, have announced strategies to further develop their local pharmaceutical industry. Ethiopia developed and launched, with support from WHO, the National Strategy and Plan of Action for Pharmaceutical Manufacturing Development in Ethiopia 2015-2025 (NSPA-Pharma) in July 2015, the first translation of the AU PMPA at the national level. Under the NSPA-Pharma, significant accomplishments have been achieved, such as the launch of a holistic incentive package to attract local and foreign investment to support local production and the construction of an industrial park dedicated to pharmaceutical manufacturing.

Progress has been made in promoting local production to benefit public health need, but there are still many challenges in strengthening local production towards quality assurance and sustainability to achieve this goal. Member States, especially LMICs, lack a holistic strategy, sufficient funding and human resources to support the development of local production. Policy incoherence and fragmented markets hamper the business environment from being conducive. Major barriers in quality and sustainable local production also include but not limited to: weak regulatory oversight; lack of skilled local workforce; lack of reliable market intelligence to inform investment decisions; no access to technology for transfer; lack of capacity to receive technology; difficulty in reaching and maintaining international quality standards; lack of sustainable and affordable financing mechanism to sustain local production.

International organizations, including WHO, have been supporting Member States in promoting local production to improve access but the resources available have not been commensurate with the support requested by Member States to deliver impact. Limited resources have also limited efforts in multi-partner collaboration and poses challenges to materialize the 1<sup>st</sup> interagency statement on promoting local production into a concrete and holistic action plan.

Member States require continued support in building capacity to cultivate enabling legal, investment and technical environments for quality and sustainable local production.

Thus, the resolution is to call for a holistic, collaborative approach in addressing the current and future challenges in promoting sustainable local production to improve access to quality, safe, effective and affordable medicines and other health technologies.

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<sup>9</sup> Brazil's Growth Acceleration Plan and Greater Brazil Plan [<http://www.pharmaceutical.com/manufacturing/articles/untapped-opportunities-brazil%E2%80%99s-most-promising>, accessed 19 April 2017]

<sup>10</sup> Russia's Pharma 2020 Strategy [<https://decisionresourcesgroup.com/drg-blog/pharma-2020-russia-marching-towards-self-sufficiency/>, accessed 19 April 2017]

<sup>11</sup> Vietnam's Socio-Economic Development Strategy 2011-2020 [<http://www.economica.vn/portals/0/maubieu/1d3f7ee0400e42152bdcaa439bf62686.pdf>, accessed 19 April 2017]

## **The draft resolution:**

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

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

Recalling resolution WHA61.21 (2008), regional resolutions AFR/RC49/R5 (1999) and SEA/RC71/R2 (2018), decision WHA 71(9) (2018), and document A71/12 (2018), all of which highlight the role of technology transfer and local production of medicines and other health technologies in improving access;

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;

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

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

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;

Considering also the commitment of AU 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 AU 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;

Considering that there is a need to emphasize the possibility of realizing access to medicines and other health technologies through building capacity for local production, especially in LMICs,

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<sup>12</sup> medicines and other health technologies includes pharmaceuticals, vaccines, biopharmaceuticals, medicals devices etc.

based on WHO's road map for access to medicines, vaccines and other health products 2019–2023<sup>13</sup> as comprehensive support for access;

Recognizing that integration of local production into the overall health systems strengthening can contribute to sustainable access to quality and affordable medicines, addressing medical product shortages, achieving universal health coverage and strengthen national health security;

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 and building a knowledge-based economy;

Recalling that the first interagency statement on promoting local production signed by the top leadership of the six organizations (The Global Fund, UNAIDS, UNCTAD, UNICEF, UNIDO and WHO) calls for a holistic approach, close partnership, inter-ministerial and multi-stakeholder cooperation, and global synergy in promoting quality and sustainable local production of medicines and other health technologies;

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

Recognizing that not all Member States are suitable for embarking on local production as a strategy to improve access to quality-assured medicines and other health technologies;

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

Emphasizing that the quality of locally produced medicines and other health technologies cannot be compromised;

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

Noting that the benefits and sustainability of local production is dependent on a functioning pharmaceutical value chain: from research & development, manufacturing, regulation through to pricing and reimbursement, supply chains and dispensing;

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 medicines and other health technologies to benefit public health needs;

Noting that local production can contribute towards achieving the Triple Billion goals of the WHO 13<sup>th</sup> General Programme of Work;

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<sup>13</sup> <https://apps.who.int/iris/bitstream/handle/10665/330145/9789241517034-eng.pdf?ua=1>

Noting with concern that Member States still face many challenges in promoting sustainable local production of quality, safe, effective and affordable medicines and other health technologies to benefit public health need and health security,

### **1. Urge Member States<sup>14</sup>:**

Where appropriate, based on the national context,

- (1) to strengthen their leadership, commitment and support in promoting quality and sustainable local production of medicines and other health technologies;
- (2) to align the national policies and/or strategies related to local production with regional policies and/or strategies, and leverage on regional economic integration to expand access to markets and enhance sustainability of local production;
- (3) to develop evidence-based holistic national policies, strategies and plans of action in collaboration with stakeholders for strengthening local production of medicines and other health technologies;
- (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;
- (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;
- (6) to apply a holistic approach in strengthening local production by considering, for example, regulatory systems strengthening, access to sustainable and affordable financing, development of skilled human resources, access to technology for production and needs-based innovation;
- (7) to engage in global, regional and subregional networks related to promoting quality and sustainable local production, and to further enhance multi-stakeholder collaboration;
- (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;
- (9) to promote local production of traditional medicines as alternative source of medicines especially through research and manufacturing of local herbal medicines;

### **2. Request the Director General:**

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<sup>14</sup> And, where applicable, regional economic integration organizations.



- (1) to strengthen the WHO's role in providing leadership and direction in promoting quality and sustainable local production of medicines and other health technologies by using a holistic approach;
- (2) to raise awareness of the importance of quality and sustainable local production of medicines and other health technologies in improving access;
- (3) 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 plan of action;
  - (b) assisting Member States to foster strategic and collaborative partnerships;
  - (c) building capacity of Member States towards policy coherence and creating an enabling business environment;
  - (d) building capacity of industry, governments and other stakeholders to strengthen local production towards quality-assurance, and WHO prequalification as appropriate;
  - (e) promoting regulatory system strengthening and regional regulatory harmonization;
  - (f) supporting Member States in research and development and technology transfer for local production of prioritized medicines and other health technologies to address shortages and/or specific local public health needs;
  - (g) exploring the mechanism for collecting and disseminating local production-related market intelligence;
- (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;
- (5) to foster and coordinate with relevant international intergovernmental organizations to promoting local production in a strategic and harmonised approach;
- (6) to establish a global platform to promote need-based transfer of technology and local production under North-South and South-South cooperation;
- (7) to continue its support in local production through dedicated staff and sufficient resources to carry out activities under this resolution.