

Position paper

Eyes on the prize: regional production of medicines to achieve health equity, sovereignty and self-reliance

Health equity and countries' sovereignty and self-reliance must be and remain the core objectives of strengthening regional production of medicines and other health technologies. Wemos calls for a global action plan to achieve these objectives.

Introduction

When you get ill, you want to access the medicines you need. However, this is not self-evident everywhere in the world. The Covid-19 pandemic made once more apparent how dependent low- and middle-income countries are on high-income countries when it comes to access to medicines, vaccines and other health technologies. This power imbalance is morally wrong, hampers the development of countries and has led to avoidable deaths and hardship.

The geographic concentration of vaccine manufacturing is a good example of how unevenly capacity is distributed around the world. Only [1% of all vaccines used in African countries](#) is produced on the continent. To end the dependency on high-income countries, the African Union aims to increase its own production capacity. Its objective is to have 60% of all vaccines used in African countries, be made on the continent by 2040. Other regions around the world face similar challenges.

Many global health actors stress the importance of strengthening regional manufacturing capacity as it can increase countries' sovereignty and self-reliance. During the Covid-19 pandemic, this resulted in new platforms for sharing intellectual property, knowledge and data needed for production, like the [Covid-19 Technology Access Pool \(C-TAP\)](#) and the [mRNA hub](#). Moreover, in 2021, the member states of the World Health Organization (WHO) passed [resolution 74.6](#), committing them to strengthen regional production in order to create equitable access.

In the coming years, it will be determined how, to what extent and under what conditions regional production capacity will be built up. Often, the discussion on increased manufacturing capacity ends up being very technical, lacking focus on the original purpose and what elements are needed to get there. Furthermore, the support and involvement of high-income countries and pharmaceutical companies is good, but also brings along the risk that other interests intrude.

As Wemos we believe that health equity, sovereignty and self-reliance must be and remain the core objectives when discussing policies for strengthening regional manufacturing. When these pillars are at the

foundation of increased production capacity, countries will be able to respond more effectively to health crises and provide better access to pharmaceutical products for their population in general.

In this position paper we elaborate on the objectives of health equity, sovereignty and self-reliance, what is needed to achieve these objectives and the current state of affairs. We also call for a global action plan.

Core objectives of strengthening regional production

Health equity

Populations in low- and middle-income countries do not always have access to pharmaceutical products, even though they have an unmet medical need. With manufacturing sites being more fairly distributed around the world, it is easier for governments to create equitable access that takes into consideration the barriers that certain groups in society may face in accessing these products.

During the Covid-19 pandemic, we have seen that countries with a relatively high burden of disease were often not the first in line to access vaccines or treatments against the virus. Even though high-income countries had already vaccinated a large part of their population, and even had given boosters, low- and middle-income countries often still lacked access to adequate amounts of vaccines. Increased regional manufacturing would facilitate the equitable distribution of medicines around the world, based on the needs of countries and their populations.

Sovereignty

In order to facilitate the autonomous decision-making of governments in times of crisis, countries or regions need to have increased manufacturing capacity within their respective jurisdiction. By being able to directly guide the research and development (R&D), production, pricing and allocation in their country or region, governments can be more flexible to address specific health concerns. Having regional manufacturing capacity in low- and middle-income countries would improve their balance of power with high-income countries. Currently, the latter have a much larger influence on the distribution of pharmaceutical products, especially in times of crisis.

Self-reliance

Equitable distribution of pharmaceutical products does not guarantee that governments have sufficient supplies to meet all medical needs in a country or region, especially in times of global health emergencies. Increased manufacturing capacity should enable governments to be more self-reliant with respects to their needs.

The additional capacity also needs to be financially sustainable, to make sure that the benefits are long-lasting. Increased self-reliance for countries and regions would also reduce their dependency on external factors, like trade restrictions in times of crisis, and therefore mitigate risks. Having parts of the supply and

production chain within a government's jurisdiction, enables a rapid response to increase the manufacturing capacity.

Arrangements needed to achieve health equity, sovereignty and self-reliance

To make sure that the objectives of health equity, sovereignty and self-reliance are met, several barriers need to be overcome. Enforcement of intellectual property rights and lack of access to knowledge and data are known hurdles when setting up new manufacturing sites. These hurdles can be overcome voluntarily through non-exclusive licensing, facilitated by WHO's C-TAP or the Medicines Patent Pool (MPP). Intellectual property barriers can also be overcome through involuntary measures when the desired result is not achieved through voluntary measures. An example of an involuntary measure that a government can take in order to extend the intellectual property rights to third party manufacturers, is a compulsory license.

The public funding of research and development of medicines and other health technologies, should come with strings attached. Conditions tied to public funding could for example make it mandatory for R&D entities to share knowledge and data and enter into non-exclusive licenses with manufacturers around the world.

So-called 'satellite sites', production sites of large pharmaceutical and biotechnology companies which are located abroad, should contribute to increased sovereignty. Local governments should be involved in decision-making processes concerning the destination of manufactured goods. Pharmaceutical companies should also ensure the sharing of intellectual property, knowledge and data to build sustainable manufacturing capacity for the future. Ultimately, increased involvement of low- and middle-income countries in satellite sites will foster their independence, flexibility and development of R&D capabilities.

To achieve these objectives, the global community has to make sure that the financing of regional manufacturing initiatives is sustainable and sufficient. Moreover, the funding should always be based on the needs of the recipients.

Current state of affairs

Progress on WHA resolution 74.6

The WHO is a longstanding advocate of regional manufacturing. The World Health Assembly (WHA) adopted a milestone resolution in 2021 (WHA74.6), but the discussion on this topic within the WHA dates back to the 1970s. While WHO's focus on local manufacturing has always been high, Covid-19 crisis urged bold, immediate measures. With the 74.6 resolution, WHO member states have committed themselves to strengthen regional production in order to achieve more equitable access to pharmaceutical products around the world.

The intention of the WHO is to put words in action, and the resolution goes into the right direction. For example, the resolution calls for concrete actions to boost access to pharmaceutical products, including technology transfer mechanisms such as C-TAP and the use of [TRIPS flexibilities](#) to overcome intellectual property barriers. The resolution also strives for an end-to-end, comprehensive approach that goes beyond the industrial process of manufacturing, encompassing support of R&D, transparency of markets of medicines, a skilled health workforce, regulatory system strengthening, sustainable financing and more.

The WHA resolution 74.6 is a great starting point for governments around the world to improve regional manufacturing capacity, especially for low- and middle-income countries. If well implemented it has the opportunity to improve health equity, sovereignty and self-reliance.

As highlighted by the [first progress report](#) published in April 2023, that will be discussed during the 76th WHA, there is still much work to be done, and further implementation of the resolution will depend on multiple factors: the willingness of member states, their capacity and governance structures, as well as the availability of adequate financial support. A gap of USD 4.60 million was reported for the implementation of the WHA 74.6 resolution in 2021. The total resources required to implement the resolution for 2021-2030 is USD 69.54 million.

To keep track of the progress and facilitate the exchange of information between multi-stakeholders and member states involved in the field of regional manufacturing, the WHO will be convening the second [World Local Production Forum](#), that will take place in the Netherlands in November 2023. The progress report expressly mentions the World Local Production Forum, defined as an initiative to “shape strategies and direction, galvanize collective action, and foster partnerships on sustainable local production”.

Pandemic Accord negotiations

There are several opportunities in the near future to implement the WHA 74.6 resolution and materialise the objectives of health equity, sovereignty and self-reliance. Currently, the negotiations on WHO's Pandemic Accord are ongoing. The proposed text sets out recommendations and obligations for WHO member states to prepare for and respond to future pandemics. In the 'zero-draft' of the Pandemic Accord there is specific attention for technology transfer, regional manufacturing capacity, overcoming intellectual property barriers and transparency. These are all elements that could contribute to health equity, sovereignty and self-reliance.

The proposed text in the Pandemic Accord contains the right elements but is often too ambiguous with regards to the beforementioned topics. Until the 77th WHA, WHO member states will have time to improve the Pandemic Accord text. Wemos' has published an [assessment of the zero-draft](#) as well as [textual suggestions](#).

Global action plan

As mentioned, in November 2023, the WHO is convening a World Local Production Forum in the Netherlands. This event provides a timely opportunity to strengthen political commitment, and agree on actions and funding for manufacturing capacity in low- and middle-income countries. The WHA resolution 74.6 is a good start in terms of setting out objectives and general instruments that are needed. But in order to move from ideas to actions, the world would benefit from a concrete global action plan which sets out financial requirements to facilitate regional manufacturing.

Additionally, the global action plan could set out how high-income countries could contribute to specific ongoing projects for regional manufacturing, like the mRNA hub, with health equity, sovereignty and self-reliance being core objectives. The content and actions of such a plan should be closely aligned with the regional needs, as for instance described under the African Union's and Africa CDC's [Partnerships for African Vaccine Manufacturing Framework for Action](#).

Making a real difference

The world is on a turning point when it comes to increasing countries' self-reliance and sovereignty in access to medicines and other health technologies. Regional production can make a real difference for the independence and development of countries and the health of current and future generations. Let us keep the focus on these objectives and what is needed to achieve them, and avoid distraction by other interests. The time is now.