World Health Organization

Report of the interagency consultation on local production of essential medicines and health products

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Introduction and background

On 25 April 2017, the World Health Organization (WHO) convened an informal interagency consultation to discuss local production of essential medicines and health products. The meeting was held at the Chateau de Penthes in Geneva, and was attended by representatives of 14 international agencies and by members of the WHO secretariat (Annex A). A number of presentations were made regarding WHO's and other stakeholders' work with relevance for this area), and there was a wide ranging discussion of the challenges faced, opportunities and how best to proceed in the future. This document summarizes a brief, overview of the proceedings.

Access to quality-assured essential medicines and health products remains a challenge, particularly in low- and middle-income countries. The Sustainable Development Goals (SDGs) highlight the importance of access to medicines for achieving universal health coverage. Local production has been a subject of discussion in the World Health Assembly (WHA) since the 1970s and the adoption of Resolution WHA 61.21 in 2008 on a Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI), sharpened the focus on the issue as having potential for promoting innovation, building capacity and improving access.

In this context, a project to explore ways in which local production and technology transfer could be strengthened in a number of low- and middle-income countries was launched in 2009 with the support of the European Commission. The project, titled "Improving access to medicines in developing countries through technology transfer related to medical products and local production" concluded in September 2016. The first phase of the project served to provide an understanding of the landscape of local production and technology transfer for different medical products (medicines, vaccines, biologicals, medical devices, including in vitro diagnostics) in different regions and countries; to identify challenges and obstacles; and to make evidence-based recommendations for promoting local production. The key achievement in this phase was the development of a policy coherence framework that could be used to achieve both public health and industrial goals as well as to provide guidance for efforts for strengthening the local pharmaceutical industry. A second phase of the project focused on: policy analysis, global resource generation, advocacy for a framework for local production and specific capacity-building activities.

Local production has also been the subject of discussion in other international organizations, and has resulted in various resolutions, including the European Union Parliament Resolution on the TRIPS Agreement and Access to Medicines, the Noordwijk Medicines Agenda, and the African Union's (AU) Pharmaceutical Manufacturing Plan for Africa (PMPA) and its Business Plan (PMPA-BP). Also of note in this regard is the African Vaccine Manufacturing Initiative, and the Developing Countries Vaccine Manufacturing Network. WHO and other development partners have been actively supporting the African Union Commission (AUC) and the New Partnership

for Africa's Development (NEPAD) Planning and Coordinating Agency in implementing the PMPA-BP as well as the African Medicines Regulatory Harmonisation (AMRH) Initiative.

Individual Member States have also shown interest in strengthening local production of essential medicines with the purpose of not only improving access, but to benefit from the economic impact of a stronger and sustainable local pharmaceutical industry. WHO has worked with the Ethiopian government on developing and launching the National Strategy and Plan of Action for Pharmaceutical Manufacturing Development in Ethiopia (NSPA-Pharma). The experiences gained in supporting its development and implementing the NSPA-Pharma strategy could be used as an example for other countries that aim to develop and strengthen local production.

Purpose of the interagency consultation

The purpose of the interagency consultation was to review work carried out over the past years and assess what has been useful with respect to local production and access to quality assured medicines with a view to considering an inter-agency strategy for collaboration that would articulate the roles played by the various partner organizations. Within that overall aim, WHO convened the meeting in order to get feedback on a preliminary draft document on Local Production of Essential Medicines and Health Products and to explore the way forward.

Presentations/discussions

WHO update, based on draft discussion paper[1]

The potential benefits of local production were suggested as:

- Improved and sustainable access to quality, efficacious, safe and affordable products;
- Increased national health security (through strengthening of the national regulatory; system and providing un-interrupted supply of medicines and health products);
- Health workforce capacity building;
- Increased focus on needs-based innovation and R&D;
- Progress towards other national goals such as economic development, industrialization and advancing technological capacity and capability; and
- Contributing to progress towards Universal Health Coverage and to the achievement of the Sustainable Development Goals.

[1] The draft discussion paper is under finalization and is planned for publishing in 2017

The various challenges to the development of local production include, in particular the need to develop a fully functioning pharmaceutical value chain (Figure 1). Developing local production goes beyond manufacturing capacity, requiring capacity development across a range policy, regulatory, implementation and coordination activities. The importance of good governance and robust regulation was emphasized.

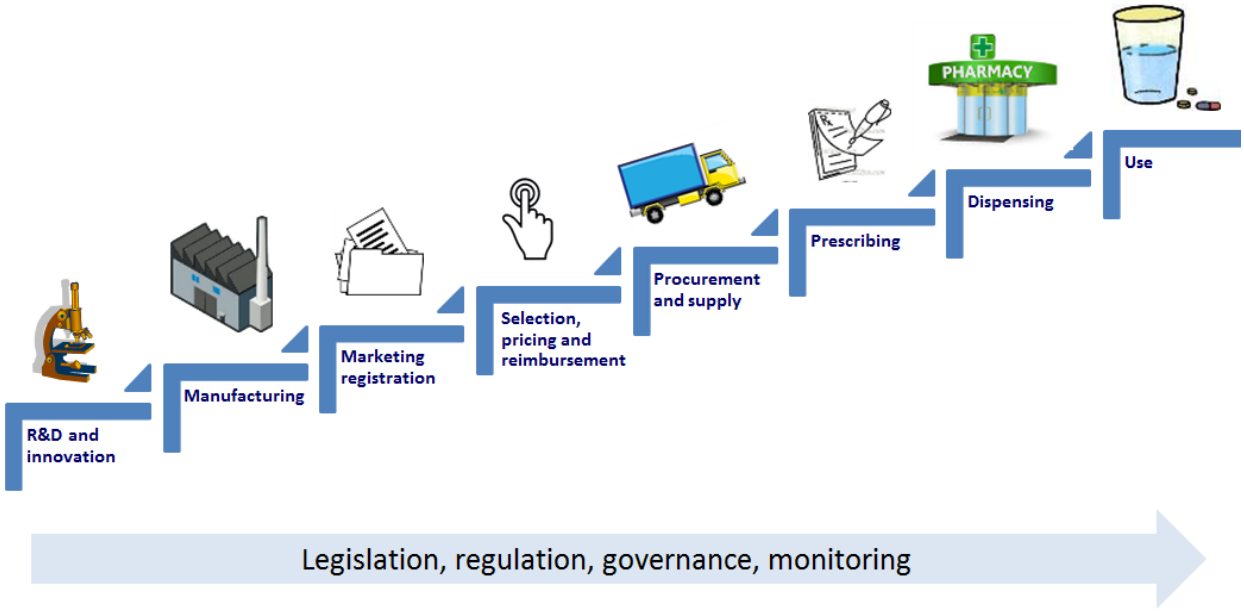

Figure 1. The pharmaceutical system value chain

The Ethiopia experience

The WHO was invited to support the Ethiopian government to develop the "National Strategy and Plan of Action for Pharmaceutical Manufacturing Development in Ethiopia (2015-2025)" (NSPA-Pharma). The NSPA-Pharm has been referred to as a flagship initiative by the Prime Minister of Ethiopia during its launch, indicating high-level commitment and support. The NSPA-Pharma has 8 strategic objectives including regulatory systems capacity building and medicines quality assurance. After the launch of the strategy, progress included the set-up of project governance structures, revitalization of the national Good Manufacturing Practice (GMP) roadmap, development of a method to prioritize local production of essential medicines, assessment of the readiness and feasibility for local active pharmaceutical ingredient manufacturing and the readiness and feasibility for local production of entecavir.

A number of organizations have become involved in the implementation of NSPA-Pharma in 2016 and ensuring effective collaboration has become a priority. An ongoing initiative is the development of an interagency framework of collaboration on promoting the current and future implementation of NSPA-Pharm to improve access of quality medicines in Ethiopia. There are two stakeholder meetings on the project in Addis Ababa in May: 1)2016 NSPA-Pharma Implementation Review Conference, 9-10 May 2017; and 2) Workshop to Establish a Regional Bio-equivalent Centre (RBEC), 11 May 2017.

Other activities
Other WHO activities include work on regulatory system strengthening, monitoring and evaluation of markets, support for technology transfer, and prioritisation strategies for manufacturing. WHO's commitment to interagency collaboration was emphasized.

Discussion on key challenges

- A robust regulatory framework is of paramount importance.
- While it may be feasible to develop local production initially, commercial sustainability remains a challenge when the medicines and health products produced through local production can be more expensive than the commercially available alternatives including imported products.
- There is a need to upgrade manufacturing capacity generally, including upgrades required to reflect changes in manufacturing technology.
- Efforts need to focus on ensuring a competent health workforce to support local production (including the training of regulators, pharmacists, chemists etc.).
- Improving access to medicines through local production requires strengthening of the pharmaceutical system across all areas of the value chain.
- There is a high level of interest in and demand for local production. It was noted for example that the Ethiopian government is in high level discussions with the governments and industry of China and India to establish an industrial park with the goal of attracting over 50 pharmaceutical companies (including finished product production, packaging and active pharmaceutical ingredients (API) manufacturing. Managing and channelling enthusiasm for local production (and the various agendas that drive it) is a major challenge, and will require the development of a coherent strategy that ensures that the regulatory systems are equipped to provide the necessary independent oversight of local production.

Participant updates (Annex B and C) and discussion

The presentations covered the many different ways in which the organizations represented address local production either directly as part of a development agenda or as purchasers of medicines. They also identified the many areas in which the organizations already collaborate, and suggested areas in which future collaboration and/or integration may be possible in the future.

The importance of regulation
The manufacturing facility is only part of the value chain (see figure 1 above.). There was general agreement that an initial focus on regulatory systems might be the best 'entry point' for supporting development of local production recognizing that if uncertainties existed about the quality of products all subsequent efforts would not be successful. WHO's work in this area and key role in supporting regulatory system strengthening (RSS) was noted. Regulatory capacity was judged to be the number one issue for the medicines sector at the European Union (EU)-Africa Summit 2014.

Several participants cited country examples where local production has been developing very fast, making it difficult to regulate. A recent benchmark assessment with the regulatory authority in one country was also described, noting various challenges. It was suggested that properly organized local production (i.e. local production supported by robust regulation) might help regularize such situations.

The issue of corruption was also discussed, with several stakeholders offering examples of how illicit payments can impact local production. The risk of corruption in the pharmaceutical system was judged to be high in some countries reinforcing the need for strong regulatory oversight and good governance. The issue of substandard and falsified (SF) medical products was also discussed, with robust and effectively enforced regulation as an important part of the required response.

Where to prioritize efforts

- Enthusiasm for local production (or the business opportunities that local production presents) is such that in some cases there is a disconnect between political ambition and the capacity and resources needed to support local production. Part of the challenge faced in supporting local production is ensuring that ambition aligns with capacity, taking into account market conditions. Supporting countries in the development of local production will require commitment of resources and time, and it will therefore be important to focus on those environments that appear most favourable.
- Regional approaches offer opportunities for concentration of resources and attainment of the excellence required to ensure quality. Regional approaches can also result in economies of scale (the high cost of national level local production was a recurring theme). It was noted that a number of countries are trying to carve out a place as regional medicines producers.
- Several participants suggested that it might be useful to prioritize specific medicines. The WHO Model List of Essential Medicines (EML) was proposed as a good starting point, partly because significant manufacturing capacity for these products (including know how and experience) is already in place.

Managing expectations

Several participants pointed out that many governments commit resources to local production in the expectation that it will result in lower medicines prices. It is therefore important to understand that not only is local production of quality essential medicines hard to achieve, in many cases the products manufactured will cost more. How local production is to be financed thus becomes a key question, since it should not be the patient who pays the extra costs. Local producers need access to credit, but national banks may not always be willing to provide funds or funds at affordable rates.

Despite these challenges, participants were keen to emphasise the potential benefits of local production. Thailand's efforts in regard to local production of influenza vaccines were presented as an example of what can be achieved. Other benefits of local production discussed

included capacity building, notably through technology transfer, and industrial development, and the concomitant creation of jobs.

The scope for collaboration between the participants
There are many areas around local production in which the participants are already working together; several participants expressed an interest in working together on local production-related areas in the future.

UNCTAD's different activities relating to local production include promoting investment in domestic industry to upgrade capacity, but also to support legal and policy frameworks and coherence. UNCTAD also works to encourage foreign investment and technology transfer and to create political momentum. UNCTAD is working with WHO on how Ethiopia could use TRIPS flexibilities in the context of the NSPA-Pharma in Ethiopia (2015-2025).

UNDP is focused on policy and regulatory environment initiatives, some of which impact on local production. For example, UNDP is supporting work on the reform of national intellectual property (IP) legislation. UNDP is also offering capacity development assistance in IP protection and public health to national legislators, government offices and civil society. Notable in this area is their authoring and commissioning of analyses, reports, position and policy papers on knowledge development in IP and access to medicines. They also monitor and analyse TRIPS-plus IP commitments on essential medicine prices and access. UNCTAD and UNDP work together in some areas, but they acknowledged that there are also areas of overlap.

Key activities from UNIDO include the Programme for Country Partnership), a country-owned mechanism to operationalize Inclusive and Sustainable Industrial Development (ISID), a core UNIDO policy package/initiative. Africa is a significant focus of their work, notably in collaborative projects with the African Union Commission (AUC) and the above-mentioned NEPAD. They foster partnerships with other UN entities as appropriate. The UNIDO representative pointed out that the pharmaceutical industry is a priority under the Third Industrial Decade for Africa (IDDA3), an initiative designed to promote the acceleration of sustainable industrial development in Africa.

UNIDO’s multiple collaborations include: partnering with the AUC for PMPA-BP implementation