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**UNIDO support in fostering local pharmaceutical
industry in developing countries, with special regard to
essential health products**

UNIDO support in fostering local pharmaceutical industry in developing countries, with special regard to essential health products

Report by the Director-General

The present document provides information on UNIDO activities in fostering local pharmaceutical industry in developing countries, with particular regard to essential health products.

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I. Introduction

1. The previous decade witnessed significant increases in the supply of life-saving essential medicines in developing countries. Notwithstanding this development, the gap between the drugs needed and those available remains profound. This gap is most apparent with regard to three of the most significant pandemic diseases — HIV/AIDS, malaria and tuberculosis. At the same time insufficient access to quality assured essential drugs to treat other diseases remains a major burden for developing and least developed countries (LDCs).

2. In recent years, the potential role that pharmaceutical manufacturers in the developing world could play as a means of easing the access-to-drugs challenge has received renewed and increasing attention, with particular emphasis on Africa. The local production of medicines has for instance been identified as an important development objective by the African Union (AU) through its 2007 Pharmaceutical Manufacturing Plan. At the subregional level, fostering pharmaceutical production features as one component in the Southern African Development Community's (SADC) Pharmaceutical Business Plan (2007-2013), and a Regional Pharmaceutical Manufacturing Plan of Action is at an advanced stage of preparation within the East African Community (EAC). In addition, the domestic pharmaceutical industry has also been earmarked as a priority sector in a number of countries, including Botswana, Ghana, Kenya and United Republic of Tanzania.

3. Beginning in 2006, with funding from Germany, UNIDO has been rendering advisory and capacity-building support under a global project that seeks to strengthen the local production of essential generic drugs in developing countries. Specific emphasis has been placed on the promotion of small and medium enterprises (SMEs), business partnerships, investment and South-South cooperation. The Organization's role in this area has since been recognized by a number of international bodies including the United Nations General Assembly, in its resolution 63/231 (paragraph 17), which welcomed UNIDO support to the AU Pharmaceutical Manufacturing Plan. Furthermore, the "Global strategy and plan of action on public health, innovation and intellectual property" adopted by the sixty-first World Health Assembly in May 2008 mentions UNIDO as a partner for promoting transfer of technology and the manufacture of health products in developing countries. At its substantive session of 2010, ECOSOC, in its resolution 2010/24 (paragraph 23) urged, inter alia, UNIDO to support the efforts of Member States to build national capacity that can make full use of the provisions contained in the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)¹ and the subsequent Doha Declaration on the TRIPS Agreement and Public Health.² The latter extended the deadline for LDCs for TRIPS compliance until 2016, thereby offering a window of opportunity for LDCs to increase their domestic production of generic drugs.

¹ See *Legal Instruments Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, done at Marrakesh on 15 April 1994* (GATT secretariat publication, Sales No. GATT/1994-7).

² World Trade Organization, document WT/MIN(01)/DEC/2. Available from <http://docsonline.wto.org>.

4. Operationally, UNIDO has provided guidance and insights to a number of public health entities and regional bodies to help them further the positive impact that local production can have. The Organization has joined the SADC Pharmaceutical Task Force, contributes to the Roll Back Malaria Procurement and Supply Chain Management Working Group and is collaborating with a core group led by the African Leaders Malaria Alliance (ALMA) to help address local production shortfalls for malaria products on the continent.

5. Given the insights gained during project implementation, UNIDO is taking stock of achievements and reflecting on possible ways and means to further expand the outreach, effectiveness and impact of assistance geared towards commercially viable production of quality assured essential health products in developing countries. This enhanced support of public health and industrial development agendas, would help to address a distinct niche on the broader access-to-drugs issue, while taking full account of the mandates and responsibilities of a multitude of development agents involved. Such a strengthened UNIDO programme would potentially also lead the way for a more visible contribution to the health-related Millennium Development Goals (MDGs), notably Goals 4 (Reduce child mortality), 5 (Improve maternal health), 6 (Combat HIV/AIDS, malaria and other diseases) and 8 (Target 8.E: In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries).

6. The present report highlights the dimensions of the access-to-drugs challenge, followed by a brief account of the contribution that pharmaceutical producers in developing countries can play in improving access to drugs. It then provides an overview of the recent UNIDO experience in furthering the local production agenda in selected countries. Reflections on the possible scope and direction of an enhanced programme towards the manufacture of essential health products conclude the report.

II. Improving access to essential drugs: the role of pharmaceutical producers in developing countries

The access challenge

7. Access to high-quality essential drugs is a critical determinant of health outcomes in developing countries. A lack of access significantly compromises the ability of people to be economically productive and thus leads to a vicious circle that enforces the poverty trap.

8. The magnitude of the access-to-drugs shortage remains alarming even though recent years have witnessed a dramatic mobilization of resources to specifically tackle the pandemic diseases (HIV/AIDS, malaria and tuberculosis) in the developing world. Significant funding for public drug procurement through entities such as The Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) has contributed to distinct progress in the provision of life-saving drugs for affected people. Other features of these developments include:

(a) At the end of 2009, according to estimates from the World Health Organization (WHO), about 5.2 million people in low and middle-income countries

were receiving antiretroviral medications (ARVs).³ While this marks a more than twelvefold increase over a six-year period, by 2008 only an estimated 42 per cent of patients in need of ARV treatment had access to it. The profound gap between the demand and availability of medicines is set to grow as the disease progresses, with around 2.7 million new infections added in 2008 to the estimated year-end total of 33.4 million HIV positive patients worldwide;

(b) The endemic nature of malaria means that unless control initiatives prove to be effective, the long-term demand for products to treat this disease will also be substantial, especially for the recommended treatment with artemisinin combination therapies (ACTs). It is estimated that in 2008 there were about 200 million cases of malaria in Africa resulting in 800,000 deaths, 88 per cent of which were of children under the age of five;⁴

(c) In 2008, the global prevalence of tuberculosis (TB) was estimated to be over 11 million with nearly four million cases occurring in Africa. Given the impact of the AIDS pandemic on rates of TB infection, the demand for treatment can also be expected to rise;⁵

(d) Chronic diseases are also a major cause of death and disability worldwide. Non-communicable diseases (NCDs), including cardiovascular diseases, diabetes, obesity, cancer and respiratory ailments, now account for 59 per cent of the 57 million deaths annually and 46 per cent of the global disease burden.⁶ According to World Bank estimates, NCDs will by 2015 become the leading cause of death also in low-income countries.⁷ As chronic diseases require continuous treatment, the demand for medicines is thus set to increase further and a stable supply becomes ever more important.

9. The challenges hindering universal access to medicines on both the demand and supply sides are well documented. They include low purchasing power in resource-strapped environments, weak health systems (ranging from drug procurement to storage and distribution, rational use, regulatory issues and drug pricing), limited human resources for health and funding constraints. The access-to-drugs problem is further aggravated by stock-outs and a significant penetration of substandard and counterfeit drugs.

10. Stock-outs occur for a variety of reasons. Frequently long lead times are required for products to be delivered from distant manufacturing sites. In addition, sudden increases in global demand and temporary capacity constraints in global supply can mean that relatively small markets in Africa do not receive the products that they have ordered. For example, Botswana was forced to import replacement ARVs at significant cost as the products that it had originally ordered were diverted to other markets.

³ World Health Organization (WHO) news release “More than five million people receiving HIV treatment”, dated 19 July 2010.

⁴ *World Malaria Report 2009*, World Health Organization (WHO). Available from www.who.int.

⁵ *WHO Fact Sheet No. 104* on tuberculosis, March 2010, issued by the World Health Organization (WHO).

⁶ Information available from www.who.int.

⁷ Olusoji Adeyi, Owen Smith and Sylvia Robles, *Public Policy and the Challenge of Chronic Non-communicable diseases* (Washington, D.C., World Bank, 2007) pp. 17-21.

11. At the same time, according to a recent survey in three African countries by the United States Pharmacopeia (USP)⁸ up to 40 per cent of malaria products on the market were substandard. The quality issues that emerged have serious implications including possibly accelerating the resistance to important drugs (e.g., ACTs) as well as reduced efficacy in many products (e.g., sulphadoxine pyrimethamine which is recommended by WHO for intermittent preventative treatment during pregnancy).⁹

12. According to the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) of WHO, in Africa and many parts of Asia, more than 30 per cent of drugs can be counterfeit. While not exclusive to developing countries, the limited regulatory oversight frequently observed as well as other structural challenges such as erratic supply and unaffordable prices, mean that the penetration of such products is more pronounced in these countries.¹⁰ WHO also states that at the same time, more than three-quarters of all substandard products reported were in developing countries and LDCs.

Pharmaceuticals: patterns of production

13. The geographical distribution of pharmaceutical production venues is markedly uneven. The bulk of production takes place in high-income countries, alongside India as a major manufacturing hub for generic products and China as a key source of active pharmaceutical ingredients (APIs). More than four-fifths of pharmaceuticals sold globally — totalling about \$773 billion in 2008 — are geared towards satisfying the needs of the high-revenue markets of North America, Europe and Japan. Overall, the industry is undergoing a distinct transition due to a lower number of new and innovative products reaching the market, intense price competition and the fragmentation of markets into generic medicines and specialty products. Trends surrounding mergers and acquisitions in recent years reveal less distinction between originator brands and generics as well as between pharmaceutical and biotech industries.¹¹ As the industry is looking for new growth opportunities, “pharmerging markets” receive increasing attention since they are seen as one of the main drivers of growth for the next few years.¹² Against this background, it may be opportune to support smaller companies to establish themselves in hitherto neglected markets and explore the potential for North-South and South-South partnerships to this effect.

⁸ The United States Pharmacopeia (USP) is a non-governmental, public standards setting authority for prescription and over-the-counter medicines and other health-care products manufactured or sold in the United States of America.

⁹ United States Agency for International Development (USAID) and USP, *Survey of the Quality of Selected Antimalarial Medicines circulating in Madagascar, Senegal and Uganda*, November 2009.

¹⁰ IMPACT (International Medical Product Anti-Counterfeiting Taskforce), *Counterfeit Drugs Kill*, May 2008.

¹¹ Frost and Sullivan, “Dynamics in the Pharma and Biotech Industry”, February 2010.

¹² “Pharmerging markets” is a term coined by IMS Health (a private sector corporation specializing in providing market research analysis of the pharmaceutical industry) to describe fast-growing markets for pharmaceuticals in countries such as Brazil, China, India, Mexico, Russian Federation, South Korea and Turkey. See IMS Health, *Pharmerging shake-up*, 2010.

14. As of 2005, WHO reported that 37 countries in Africa had some drug production capacity. While South Africa has the strongest sector, significant production activity also occurs in other countries, including Nigeria with more than 200 pharmaceutical companies, as well as Ghana and Kenya with about 20 and 40, respectively. Other locations such as Uganda and United Republic of Tanzania have a handful of active manufacturers with even smaller numbers reported elsewhere (such as Cameroon, Côte d'Ivoire, Democratic Republic of the Congo and Malawi). Despite the existence of these companies, the majority of pharmaceutical products are imported. A study conducted for the International Finance Corporation (IFC) in 2007 by McKinsey and Company estimated that the total pharmaceutical market in sub-Saharan Africa was worth \$3.8 billion in 2006. Of this, only 28 per cent originated from African manufacturers, almost 70 per cent of which was accounted for by South Africa alone. A further 20 per cent was represented by three countries combined — Ghana, Kenya and Nigeria. With an export share of 35 to 45 per cent of total production, only Kenya showed a distinct exposure to regional markets.¹³ With the partial exception of South Africa, production in sub-Saharan Africa is generally limited to final formulations, characterized by non-complex, high-volume essential products, encompassing basic analgesics, simple antibiotics, anti-malarial drugs, and vitamins.

15. Donor-funded drugs procured for the pandemic diseases represent a significant segment of the overall pharmaceutical market in Africa. Producers in sub-Saharan Africa have essentially been unable to enter into this segment, largely due to the prerequisite that each individual product needs to be pre-qualified by WHO in advance. Achieving pre-qualification requires companies to satisfy a wide range of specifications related to production facilities, staff and the product itself. This implies having suitable facilities and equipment that are validated in conjunction with detailed processes and procedures. Staff must be trained on these procedures and adequate skills for quality control with sufficiently qualified and experienced personnel in certain key posts are indispensable. Finally, the bioequivalence of the product needs to be ascertained. None of these issues is trivial, and satisfying the standards for production plants that were not originally designed to meet these requirements is a challenging endeavour in terms of capital investment, know-how and human resources. So far, only four companies in sub-Saharan Africa have managed to obtain pre-qualification for one or more products (three in South Africa and one in Uganda).¹⁴

16. However, the vast majority of medicines listed on the WHO Model List of Essential Medicines, which includes about 250 products, are not covered by the pre-qualification scheme. Regulatory oversight for these products is provided by national regulatory authorities, which in Africa have particularly limited resources and capacity, one factor that enables substandard and counterfeit products to enter the markets. Consequently, stricter regulatory oversight by the national regulatory authorities is a means by which the quality of drugs on the market can be increased.

¹³ IFC, *The Business of Health in Africa. Partnering with the private sector to improve people's lives* (Washington, D.C., 2007).

¹⁴ Two of the companies in South Africa are affiliates of multinational firms, while the company in Uganda is a manufacturing site of a generics producer from India.

The case for manufacturing medicines in developing countries

17. Since the mid-1990s, there has been intense debate as to whether local production of pharmaceuticals was desirable in developing countries, with some commentators of the opinion that it was not viable to produce high-quality products competitively in many of these countries.¹⁵ Proponents of local production frequently apply a broader perspective to development issues, factoring in the wider economic development benefits that local pharmaceutical manufacturing can deliver. Others suggest that short-term compromises would be an acceptable necessity to achieve the long-term benefit that local production could help generate. This impasse has been described in the African Union Pharmaceutical Manufacturing Plan as a “tension between industrial policy and health policy”.

18. Recently there has been a more differentiated discussion with many actors recognizing that under the right circumstances local production in developing countries has a valuable role to play. This pragmatic perspective has led a number of stakeholders to seek an approach by which public health improvements and industrial development benefits can both be achieved at the same time.

19. Accommodating a public-health perspective would mean that high-quality and affordable local production could help address some dimensions of the access-to-drugs challenge through:

(a) Shortening the supply chains and thereby limiting opportunities for counterfeits to penetrate markets;

(b) Allowing for enhanced regulatory oversight thereby helping to reduce the amount of substandard products in the market place;

(c) Acting as a buffer where sharp increases in demand or supply restrictions limit the availability of products.

20. Many developing countries see a substantial future liability in providing drugs for their populations once donor funding has plateaued or even subsided. Donor fatigue, or the fallout from the financial crisis, is already affecting the resources available for procurement of treatments. For example, the United States President’s Emergency Plan for AIDS Relief (PEPFAR) has reduced its funding for ARVs in both 2009 and 2010, the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) faces a critical replenishing round and the UNITAID/Clinton Health Access Initiative (CHAI) is phasing out its funding of HIV drugs and commodities.¹⁶

21. Given current sources of products, the long-term liability represents a huge potential drain on foreign currency and therefore also a threat to the sustainability of treatment. This is another factor that has led to countries and subregions within Africa wishing to develop local manufacturing as a strategic asset in the health arena.

¹⁵ For example, Warren A. Kaplan and Richard Laing, “Local Production of Pharmaceuticals: Industrial Policy and Access to Medicines”, World Bank HNP Discussion Paper, January 2005. Available from www.worldbank.org.

¹⁶ Médecins Sans Frontières: “No time to quit: AIDS treatment gap widening in Africa”, May 2010.

22. While there is wide agreement that the local production of pharmaceuticals in developing countries is not a panacea that will solve all the access-to-drugs issues, it has the potential to deliver public health benefits that make a meaningful difference to health outcomes. The development of this sector as a knowledge intensive industry, and access to the substantial international donor markets funded by, for example, GFATM and PEPFAR, will provide associated economic development benefits such as employment and tax revenues in conjunction with the principal objective of improving health outcomes.

Meeting the challenge

23. There are significant challenges in realizing the potential of local production. The critical issues are affordability and quality, the latter of which carries significant cost related issues. At present there is a disparity in the quality standards in manufacturing production across Africa. There are certainly examples of companies that aspire to international standards. For instance, Quality Chemical Industries Ltd. in Uganda has recently qualified a product under the WHO system (though as an additional manufacturing site of its Indian partner Cipla Ltd.), and companies such as Cosmos in Kenya have achieved certification in line with the Pharmaceutical Inspection Cooperation Scheme (PICS).¹⁷ Other companies are also making concerted efforts to achieve the requisite standards and there are enough examples to suggest that high-quality production in Africa is a realistic target.

24. However, outside the international markets, the lack of enforced requirements for high-quality production mean that standards are often less satisfactory. This is in part an issue of pricing in a specific market, with producers in developing countries often arguing that companies cannot afford to invest in upgrading quality standards and remain competitive in a market environment that includes substandard products as well as a high level of counterfeit products. Given that locally produced drugs could provide inherent benefits for both health and economic development, the question arises as to how universal high-quality competitive production can be achieved in a way that does not require short-term compromises.

25. The development of a strong pharmaceutical industry in India offers some suggestions as to how to build a high-quality manufacturing industry. Detailed quality requirements with a firm timeline for adherence to these standards were established. Companies also received time-limited incentives such as working capital credits, interest subsidies and export incentives, which enabled them to invest in the necessary upgrades while remaining competitive. Adopting such a two-pronged approach with firm quality requirements in place, a timeline for adherence, credible regulators that will enforce these, and incentives to enable companies to meet these obligations, is part of the solution.

26. Obviously, countries in Africa face a different context to that which India had when it set out to develop its industry. Among other things, India had a sizeable pool of skilled human resources, a large domestic market, and capabilities to produce many of the inputs within the country. Therefore, the development of the

¹⁷ The Pharmaceutical Inspection Cooperation Scheme consists of 37 participating authorities. It works towards the international development, implementation and maintenance of harmonized good manufacturing practice (GMP) standards and quality systems of inspectorates of medicinal products.

pharmaceutical sector in Africa will require a holistic approach that tackles a range of interrelated challenges in a coordinated fashion. The challenges and deficiencies that need to be addressed vary by country and (sub)region, but in general relate to:

- (a) Human resources with the required skills and experience in industrial pharmacy;
- (b) Access to the technical know-how required to design and implement plans to upgrade manufacturing to international standards;
- (c) Access to affordable capital and the impact of high interest rates on debt given a general reliance on debt financing;
- (d) Fragmented nature of regional markets and the relatively small size of domestic markets which diminish the prospects for efficient production;
- (e) Import of raw materials, primarily from Asia and the related lead time and working capital requirements;
- (f) Reliability and cost of utilities;
- (g) Capacities of regulatory authorities to prevent lower standard and counterfeit products exerting downward price pressure from entering the market;
- (h) Coordination between government entities responsible for health, tax and industrial policy to form a coherent policy on pharmaceutical production;
- (i) Representation of the pharmaceutical sector by business membership organizations (notably, pharmaceutical manufacturer associations) that engage in the political process.

III. Supporting pharmaceutical industry in developing countries: recent UNIDO experiences

27. The UNIDO global project geared at promoting the local manufacture of essential generic medicines in developing countries started in 2006. Rendering combinations of advisory and capacity-building support, the interventions endeavour to address key constraints at policy, institutional and production plant levels as well as acting as a catalyst for industry development. Credible commercial viability prospects and a commitment to international quality standards serve as key criteria guiding individual activities. Geographically, the focus has been on sub-Saharan Africa (though not exclusively), where the impact of the pandemic diseases is most profound, and where the access-to-drugs challenge is most severe.

28. Initial activities focused on fact-finding and the generation of evidence so as to fine-tune further activities. To that end, regional workshops were conducted in United Republic of Tanzania (January 2006), Thailand (February 2007), Senegal (October 2007) and Zambia (November 2008), gathering representatives from a wide range of stakeholders from the public and private sectors. The project has also conducted detailed analyses of the pharmaceutical industry in eight developing and least developed countries, and commissioned a study by IMS Health to characterize the supply and demand of a range of products that represent good options for local production.

29. At the policy level, the project has been rendering support towards compiling a development strategy for the pharmaceutical sector in Ghana and Kenya. UNIDO is facilitating a multi-stakeholder consultative process to this effect in each country. Once finalized, UNIDO will further assist in the implementation of these strategies.

30. At the institutional level, the successful inauguration of the Southern African Generic Medicines Association (SAGMA) in December 2009, constituted a milestone achievement towards strengthening the private sector's voice within SADC. This association is the first of its kind in the subregion. Capacity-building assistance has also been rendered to the West African Pharmaceutical Manufacturers' Association (WAPMA) and the Pharmaceutical Manufacturers' Association of Ghana (PMAG) at the national level.

31. Given the need to develop the human resources for pharmaceutical manufacturing, the project has been assisting the St. Luke Foundation in United Republic of Tanzania, which provides an advanced industrial pharmacy training course that is conducted in conjunction with the Howard and Purdue Universities in the United States of America. The project has enabled participants from the public and private sectors to gain expert knowledge in this modular course, with the first 13 trainees graduating in August 2010.

32. In order to demonstrate the viability of high-quality production of pharmaceuticals in Africa to a wider audience, the project has been supporting a number of companies to move towards their stated goal of achieving pre-qualification. The assistance provided has included training on technical aspects of production, guidance as to the requirements to meet international good manufacturing practice (GMP) standards, assistance in developing business plans, and restructuring internal business procedures (e.g. cost accounting), as well as facilitating the search for investors.

33. With a view to exchanging know-how and experience, UNIDO through this project has increasingly engaged in an intense interaction with relevant stakeholders in the international community. In September 2009, together with WHO, it has, for instance, co-chaired a meeting of the Interagency Pharmaceutical Coordination Group (IPC),¹⁸ which was devoted specifically to the local pharmaceutical production theme.

IV. Bridging public health and industrial development agendas: towards an enhanced UNIDO programme

UNIDO niche

34. Corresponding with the multiple dimensions of the access-to-drugs challenge described above, a large number of stakeholders, including United Nations agencies, development finance institutions, scientific bodies, corporate social responsibility-related initiatives, bilateral donor agencies have long since been active in

¹⁸ Formed in 1996 and chaired by WHO, the IPC gathers technical staff of GFATM, UNITAID, UNDP, UNICEF, UNFPA, UNAIDS, WHO and the World Bank. Regular, yet relatively informal meetings, serve to achieve greater inter-agency consistency in the technical advice and other assistance pertaining to pharmaceutical policies.

drug-related areas. These include in particular issues like drug procurement, distribution, use and treatment, research and drug discovery, development and testing, or drug regulatory issues, such as drug registration/market authorization, compliance with quality and related standards or patents. In turn, interventions geared at improving the operational environment of pharmaceutical manufacturers or at facilitating production plants to upgrade towards international quality standards remain few and far between.

35. The insights gained since 2006 have identified a clear and important niche for UNIDO at the interface between public health and economic development. To achieve public health objectives requires the incorporation of an industrial development component in an overall approach as among other things, there is a need to mobilize investment, facilitate technology transfer, and to implement industrial policy initiatives to support and provide incentives for investment in quality production. Aspiring to assist in these efforts successfully calls for the holistic approach pursued to date by UNIDO and confirmed as decisive by the recently completed independent evaluation of the UNIDO global project.¹⁹ Whenever possible, this approach seeks to tackle constraints at the policy, institutional and sector levels simultaneously.

36. Targeting a clear niche for UNIDO implies a need to recognize the domains of other agencies in adjacent areas within the access-to-drugs context and to maximize synergies through collaboration. For instance, WHO fulfils a key normative role by hosting the *International Pharmacopeia* and operating the pre-qualification programme. Concerning the institutional environment, the pharmaceutical sector's development is highly dependent on enhanced regulatory oversight, an area where close cooperation is also warranted with an ongoing initiative by the New Partnership for Africa's Development (NEPAD), WHO and the Bill and Melinda Gates Foundation (BMGF) to move towards harmonized registration requirements in the different regional economic communities in Africa. This is a good example where UNIDO could work with partner organizations to facilitate universal high-quality production of pharmaceuticals in Africa.

Possible programme components of enhanced UNIDO assistance

37. Improving access to medicines by developing the pharmaceutical sector in developing countries is an enormous task that requires targeted and well synchronized advisory and capacity-building support during time periods that frequently exceed established durations of individual projects. An enhanced UNIDO programme would enable the Organization to avoid attempting to cover too many distinct areas too thinly as it seeks to respond to many different needs and expand to additional regions and product groups as requested. Being firmly aligned with the Organization's established three thematic priorities (poverty reduction through productive activities, trade capacity-building, energy and environment), such an enhanced programme would, however, depend on broadening the existing resource base.

¹⁹ UNIDO Evaluation Group, Independent mid-term evaluation "Strengthening the local production of essential generic drugs in least developed and developing countries", 2010.

38. An expanded programme with a corresponding increased funding base, would enable UNIDO to augment the outreach and sustainability prospects of its interventions and hence raise the impact in terms of public health and economic development. In addition to subsuming a number of ongoing activities already contributing to health-related MDGs, such as the production of malaria nets in Rwanda and the work of the UNIDO/International Centre for Science and High Technology (ICS) in Trieste on computer-aided drug design, an enhanced programme would also provide synergies with initiatives such as Labnet, a global laboratory network operational under the auspices of UNIDO and the World Association of Industrial and Technological Research Organizations (WAITRO).

39. An enhanced programme would also explore the scope for extending the UNIDO approach to other health products, including biological commodities, diagnostic products, vaccines, medical devices and other products. UNIDO is already liaising with WHO on its initiative to increase access to some of those products. Promoting the commercially viable production of natural health products (based on medicinal plants or traditional medicines) may likewise warrant attention.

40. While further exploratory work and analyses on the desirable scope and modalities of such an initiative are required, an enhanced UNIDO programme would seek to leverage the Organization's expertise in established service areas. For instance this could mean adapting investment promotion and trade capacity-building support to the specifics of developing pharmaceutical and other health products industries. An enhanced approach would likely adopt a modular format with a number of components addressing major problem areas. Such modules could include:

(a) Advisory services towards the formulation, implementation, monitoring and regular updating or adjustment of pharmaceutical sector development strategies, policies and programmes, applying a value chain approach that seeks to increase the local/regional supply of inputs. This could include packaging, labelling and where viable, the production of APIs and other intermediates;

(b) A module to facilitate investment in the sector. This would build on the UNIDO capabilities in investment promotion. It would involve working with companies and national/subregional sectors to develop their plans and contexts in order to become attractive destinations for capital. It would also entail a matchmaking platform to bring together investors and companies;

(c) An associated module focusing on promoting technology transfer from both North-South and South-South. This would build on the UNIDO established expertise in this area and involve the brokering of mutually beneficial business arrangements between technology providers and recipients. This could become part of a UNIDO pharmaceutical production partnership platform to respond in a systematic manner to Target 8.E of the MDGs;²⁰

(d) An expert pool to provide plant level guidance on technical and business requirements for achieving sustainable high-quality production, including their

²⁰ Goal 8, Target 8.E: In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries.

readying on a larger scale for successfully gaining international quality certifications;

(e) A module focused on developing human resources for the sector as a critical requirement for the long-term sustainability of local production;

(f) A research function to provide analytical output to support the work on the strengthening of local production. For example, research into the economics of production would inform the development of policy tools and objectives that countries could consider. Other work would address the scarcity of market data which, among other effects, compromises the ability of companies to plan and leads to uncertainty on behalf of investors who might otherwise enter the sector;

(g) Expert long-term representation in the field will enable UNIDO to guide the development and execution of strategies to develop the sector and implement the solutions that the programme will have developed (such as appropriate industrial policy, investment promotion, technology transfer).

41. Delivering on a mandate on local production of pharmaceuticals and other health products will require UNIDO to work with partner organizations such as WHO in areas such as developing the regulatory capacity in countries and on harmonization of regulatory requirements to create less fragmented markets. Efforts still in their infancy to strengthen pharmaceutical innovation in developing countries will likewise necessitate close mutual exchanges.²¹ UNIDO will also work with regional organizations such as the AU and SADC to implement their vision and partner with other international organizations and programmes, such as UNAIDS, on the long-term goal of a sustainable provision of essential medicines. As such a central management function will, among other things, build on the relationships that have already been established and look to develop shared workplans with such organizations so that the individual mandates and expertise of the various organizations can be leveraged towards improving health outcomes by strengthening the local manufacture of essential generic drugs and other health products.

V. Conclusions

42. The local production of essential drugs in developing countries has the potential to improve health outcomes in Africa by providing a reliable source of quality assured high-quality pharmaceuticals across the range of essential generic medicines. It has been demonstrated that international standard pharmaceutical production can be achieved in sub-Saharan Africa. An enhanced programme would enable UNIDO to work with its public health partners to improve regulatory oversight, industrial policy initiatives, strategic programmes (for example on human resource development), investment mobilization and technology transfer. In this way, sustainable high-quality manufacturing of pharmaceuticals can be achieved in order to realize both public health and economic development benefits.

²¹ See, for instance, Michael Berger et al., "Strengthening Pharmaceutical Innovation in Africa". Council on Health Research for Development (COHRED), New Partnership for Africa's Development (NEPAD), 2010.

XI. Action required of the Board

43. The Board may wish to take note of the information provided in the present document and provide guidance.

Abbreviations used in this document

ACT	artemisinin combination therapy
ALMA	African Leaders Malaria Alliance
API	active pharmaceutical ingredient
ARV	antiretroviral medication
AU	African Union
BMGF	Bill and Melinda Gates Foundation
CHAI	Clinton Health Access Initiative
EAC	East African Community
ECOSOC	United Nations Economic and Social Council
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GMP	good manufacturing practice
ICS	International Centre for Science and High Technology
IFC	International Finance Corporation
IMPACT	International Medical Products Anti-Counterfeiting Taskforce
IPC	Interagency Pharmaceutical Coordination Group
LDC	least developed country
MDG	Millennium Development Goal
NCD	non-communicable disease
NEPAD	New Partnership for Africa's Development
PEPFAR	United States President's Emergency Plan for AIDS Relief
PICS	Pharmaceutical Inspection Cooperation Scheme
PMAG	Pharmaceutical Manufacturers' Association of Ghana
SADC	Southern African Development Community
SAGMA	Southern African Generic Medicines Association
SME	small and medium enterprise
TB	tuberculosis
TRIPS	Trade-Related Aspects of Intellectual Property Rights
USP	United States Pharmacopeia
WAITRO	World Association of Industrial and Technological Research Organizations
WAPMA	West African Pharmaceutical Manufacturers' Association
WHO	World Health Organization