WORLD HEALTH ORGANIZATION
REGIONAL OFFICE FOR AFRICA

ORGANISATION MONDIALE DE LA SANTE
BUREAU REGIONAL DE L'AFRIQUE

ORGANIZAÇÃO MUNDIAL DE SAÚDE
ESCRITÓRIO REGIONAL AFRICANO

REGIONAL COMMITTEE FOR AFRICA **AFR/RC55/10**
17 June 2005

Fifty-fifth session
Maputo, Mozambique, 22–26 August 2005 **ORIGINAL: ENGLISH**

Provisional agenda item 8.4

LOCAL PRODUCTION OF ESSENTIAL MEDICINES, INCLUDING ANTIRETROVIRALS: ISSUES, CHALLENGES AND PERSPECTIVES IN THE AFRICAN REGION

Report of the Regional Director

EXECUTIVE SUMMARY

1. World medicine production is on the increase but is concentrated in a few industrialized countries. Despite the growth observed in global medicine production over the years, studies indicate that Africa's share of world medicine production continues to decline.

2. With a view to strengthening regional local production capacity and improving access to essential medicines, the Regional Committee for Africa formerly adopted resolutions AFR/RC38/R19, AFR/RC49/R5 and AFR/RC54/R5. These pertain to local production of essential drugs in the Region; a situation and trend analysis of essential drugs in the Region; and improving access to care and treatment for HIV/AIDS, The 3 by 5 Initiative.

3. Most production of medicines in the Region is limited to compounding and packaging, repacking, and processing bulk medicines into dosage forms using imported raw materials. The majority of the production facilities are privately-owned. Mainly generic medicines are produced, and they satisfy only a small proportion of national requirements. The viability of local production is influenced primarily by the size of the market; existence of other production capacity in the Region; size and procurement preferences, especially of public sector market, physical infrastructure and human resources.

4. This document examines issues, challenges and perspectives and advises governments on the way forward with local production of essential medicines, including antiretrovirals, in the African Region.

5. The Regional Committee is requested to review and adopt the orientations contained in this document.

CONTENTS

INTRODUCTION

1. World medicine production is on the increase, but it is concentrated in a few industrialized countries. Despite the growth observed over the years, studies indicate that Africa's share of world medicine production continues to decline, and low-income countries account for 2.6% of global output.[1]

2. It is estimated that about half of the population in the African Region lack regular access to essential medicines[2] while 90% of the medicines used are imported.[3] Essential medicines are those that satisfy the priority health-care needs of the population and are absolutely necessary for health care. Lack of regular access to essential medicines jeopardizes the credibility of health-care systems.

3. Access to health care is a fundamental human right.[4] Access to essential medicines constitutes an important element in the fulfilment of the right to health and is one of the most cost-effective elements of modern health care. The Millennium Development Goals include access to essential medicines as one of the health-related indicators.[5]

4. HIV/AIDS has exacerbated the problem of access to medicines. Out of the 6 million people living with HIV/AIDS who need antiretroviral treatment, 4.4 million are in the African Region and only 8% have access to antiretrovirals.[6]

5. Previously, the Regional Committee for Africa adopted various resolutions: AFR/RC38/R19, on local production of essential drugs in the Region; AFR/RC49/R5, regarding a situation and trend analysis on essential drugs in the Region; and AFR/RC54/R5, on improving access to care and treatment for HIV/AIDS, The 3 by 5 Initiative. The Executive Board, at its one-hundred-and-fourteenth session, discussed the manufacture and challenges of antiretrovirals in developing countries. The Board highlighted that policy decisions about whether to import essential medicines from reputable sources or to promote local manufacture should be based on careful situation analysis and realistic appraisal of the feasibility of domestic production.[7]

6. Production of generic medicines has become an important economic activity. Pharmaceutical production takes place at three levels. Primary level production includes the manufacture of active pharmaceutical ingredients and intermediates from basic chemical substances. The secondary level includes the production of finished dosage forms from raw materials; tertiary production is limited to packaging of finished products or repackaging of bulk finished products.[8]

7. Issues pertaining to promoting and sustaining local production capacity introduce a complex combination of health, social and economic considerations. Policy decisions on local medicine production should be based on the feasibility of economic sustainability of local production and the achievement of social and health objectives.

---

[1] WHO, *The world medicines situation*, Geneva, World Health Organization, 2004.
[2] WHO, *The world medicines situation*, Geneva, World Health Organization, 2004.
[3] WHO, *Intensified essential drugs programme for the African Region*, Harare, World Health Organization, Regional Office for Africa, 1998 (unpublished).
[4] United Nations, Universal Declaration on Human Rights, adopted and proclaimed by General Assembly resolution 217 A (III) of 10 December 1948.
[5] http://milleniumindicators.un.org (accessed 16 November 2004).
[6] UNAIDS/WHO, *"3 by 5" progress report*, Geneva, World Health Organization, 2004.
[7] WHO, Manufacture of ARVs in developing countries and challenges for the future, Geneva, World Health Organization, 2004 (EB114/15).
[8] WHO, How to develop and implement a national drug policy, second edition, Geneva, World Health Organization, 2001.

8. The aim of this document is to examine issues, challenges and perspectives and advise governments on the way forward with local production of essential medicines, including antiretrovirals, in the African Region.

SITUATION ANALYSIS

9. The Regional Committee for Africa adopted resolutions AFR/RC49/R5 and AFR/RC38/R19 which emphasize essential medicines, local production of essential medicines and traditional medicine in the WHO African Region. In response to these, the following salient activities have been undertaken:

(a) Funds to support implementation of essential medicine programmes in countries were mobilized and national professional officers were recruited in 11 countries. Policy-makers were briefed on the impact of WTO/TRIPS agreements on pharmaceuticals and public health. With WHO support, some countries reviewed and implemented their national medicine policies, patent laws and legislation; strengthened their medicine regulatory authorities, undertook price surveys, and prepared to undertake bulk purchasing. Assessment of local production facilities were undertaken in some countries, and preliminary discussions between WHO, AU and UNDP were initiated to foster mechanisms to promote intercountry collaboration on local production of generic essential medicines at subregional or regional level.

(b) A regional strategy on promoting the role of traditional medicine in health systems was developed. It addresses research and development of local production of traditional medicines; countries are articulating policies to enhance implementation of the strategy. Some countries in the Region have embarked on production of various plant-based traditional medicines on a pilot scale for the treatment of some communicable and noncommunicable diseases. For example, Madagascar is producing a medicine for diabetes and Nigeria for sickle-cell anaemia; Burkina Faso and Tanzania have started producing malaria medicines from locally-cultivated medicinal plants.

10. Of the 46 countries in the African Region, 38 have pharmaceutical industries; 35 have secondary level production and 25 have tertiary production (some countries having both secondary and tertiary production). Eight countries[9] have no such industry.[10] South Africa performs all types of local production, including primary production of chemicals and limited local production of generic active (pharmaceutical) ingredients.[11] Generally, the majority of the production facilities are privately-owned; locally-produced medicines are mostly generic and satisfy only a small proportion of national requirements.

11. Review of some of the pharmaceutical industries in the Republic of South Africa indicated that local producers were invariably scaling down on the range of products to achieve better economies of scale since they cannot compete with cheap imports.[12] Some of the factors affecting local production include restrictions from intellectual property rights and patent requirements, wide fluctuations in cost per unit, and inefficient purchase of raw materials.

---

[9] Botswana, Chad, Republic of Congo, Equatorial Guinea, Gambia, Guinea, Mauritania, Sao Tome and Principe.
[10] WHO, Level I pharmaceutical sector assessment, Brazzaville, World Health Organization, Regional Office for Africa, 2003 (unpublished).
[11] http://www.mbendi.co.za/indy/chem/phrm (accessed on 5 January.2005).
[12] Kaplan W, Laing R, Local production of pharmaceuticals: Industrial policy and access to medicines, Washington DC, World Bank, 2005.

12. In Kenya, where there is a good industrial base, about 90% of medicines have to be imported. Manufacturers have been experiencing difficulties which have resulted in restructuring and staff retrenchment. The majority of local manufacturers in this country suffer from underutilization of their facilities mainly due to lack of government protection against competing imports and consumer preference for imported medicines.

13. In Ghana, only half of the total pharmaceutical industrial capacity is operational for the entire year. Generally, overhead costs in these facilities are low, but high interest rates, taxes and mark-ups raise the prices of the medicines. Recent government policy, however, is to support local producers by waiving import duties and taxes on most raw materials and imposing restrictions on importation of some finished products.

14. In Algeria, which has a relatively good industrial base, medicines are largely imported. Recently the government decided to stop importation of finished pharmaceutical products. Although government policy supports national production of medicines, the sector experienced a negative growth in 2002 due to increased imports and local competition.

15. The fifty-fourth session of the Regional Committee for Africa underscored that HIV/AIDS is one of the leading causes of morbidity and mortality in the Region. The high cost of medicines is one of the challenges in providing care and treatment for people living with HIV/AIDS, hence the importance of promoting local production to ensure sustained supply.[13] Although the price of ARVs currently available on the market has fallen with the introduction of generic medicines, their price is still unaffordable for many people in the Region. Besides, inefficient procurement and management of ARVs coupled with weak health systems exacerbate lack of access to ARVs.

16. Analysis of the situation in the Region indicates that even countries with a relatively good industrial base, positive economic performance and sizeable markets are experiencing difficulties with competition. In the context of the constantly-changing socioeconomic environment, globalization of trade and patents, double disease burden and increasing health-care costs and medicine prices, public demand for essential medicines remains largely unmet in the Region. Countries that are embarking on local production of medicines, including antiretrovirals, should therefore carefully examine these issues and make appropriate decisions before setting up new medicine production facilities.

ISSUES, CHALLENGES AND PERSPECTIVES

Issues

17. The health-care budget in many African countries is inadequate, and as much as 30% of it is spent on pharmaceuticals. High medicine prices coupled with inadequate financing restrict poor people from accessing medicines. Some governments assume that locally-produced medicines are cheaper and improve affordability; hence policies that promote local production are put in place.

18. The intention of countries to produce medicines locally can be viewed from an industrial as well as a health policy perspective. These two perspectives are inseparable and should be maintained in order to meet public health objectives. Considering current global trade, international economics of the pharmaceutical industry and the assumed real need of national

[13] Resolution AFR/RC54/R5, Improving access to care and treatment for HIV/AIDS in the African Region: The 3 by 5 Initiative and beyond. In: *Fifty-fourth session of the WHO Regional Committee for Africa, Brazzaville, Republic of Congo, 30 August – 3 September 2004, Final Report,* Brazzaville, World Health Organization, Regional Office for Africa, 2004 (AFR/RC54/19), pp. 14 –17.

governments to maintain industrial and public health policies, the debate continues on whether local production of medicines in developing countries is feasible.[14]

19. The African Union recognizes that policies to support industrial development and competitiveness are imperative. It advocates for industrial development which emphasizes strong regional cooperation and using the private sector as a driving force for industrialization, research promotion, harmonization of standards, investment promotion and protection from drug dumping.[15]

20. International trade agreements, including trade-related aspects of intellectual property rights (TRIPS), affect medicine prices. TRIPS introduced global minimum standards for protecting nearly all intellectual property, including pharmaceuticals, with provisions for compulsory licensing and parallel importation (TRIPS safeguards). Compulsory licensing enables a competent government authority to license the use of an invention to a third party or government agency without the consent of the patent-holder. Parallel importation promotes competition for a patented product by allowing importation of equivalent patented products marketed at lower prices in other countries.[16]

21. In an effort to clarify whether or not the TRIPS Agreement prevents governments from taking measures to protect public health, the World Trade Organization (WTO) Ministerial Conference in November 2001 adopted the Doha Declaration which recognizes the right of countries to take measures to protect public health and promote access to medicines.[17]

22. Most countries in the Region lack or have insufficient manufacturing capacity to make full use of the TRIPS safeguards. The August 2003 decision adopted by WTO members is a temporary waiver of limitations observed in the Doha Declaration on export of pharmaceutical products produced under compulsory licence. This decision allows WTO Member countries to import generic medicines from a foreign producer. In addition, countries need to be cautious of including any TRIPS-plus provisions in trade agreements since these require patent protection beyond TRIPS requirements and impede effective use of TRIPS safeguards.

Challenges

23. As from 2005, production of generic versions of new patented medicines will depend on several factors. The first is whether governments are willing to make effective use of TRIPS safeguards, including the extension of the transition period for least-developed countries so they need not enforce pharmaceutical patents until 2016. The second is whether generic manufacturers will be persuaded of the economic feasibility of producing patented medicines under compulsory licence. The third factor is whether there will be increased cooperation between generic producers and research-based industries. The last factor might be linked to the first in that patent-holders are likely to be more willing to enter into voluntary licensing agreements when the bargaining position of generic manufacturers has been strengthened by government willingness to use TRIPS safeguards.

24. Experience from Kenya and South Africa indicate that patent-holders of antiretrovirals can agree to issue voluntary licences to local producers. However, in many African countries, implementation of compulsory licensing still remains a challenge as they lack or have insufficient

[14] Kaplan W, Laing R, Local production of pharmaceuticals: Industrial policy and access to medicines, Washington DC, World Bank, 2005.
[15] ECA, Assessing regional integration in Africa, Addis Ababa, Economic Commission for Africa, 2004.
[16] WHO, Policy perspective on medicines, Geneva, World Health Organization, March 2001, issue No. 3.
[17] WHO, Policy perspective on medicines, Geneva, World Health Organization, March 2001, issue No. 3.

pharmaceutical manufacturing capacity, administrative infrastructure and tools for implementation of TRIPS safeguards.

25. Efficient local production of affordable and quality essential medicines can be achieved through development and implementation of appropriate strategies as well as concerted efforts of governments, WHO and all development partners to properly address the challenges. Other challenges include slow industrial development and technology transfer; lack of conducive political and socioeconomic environment in some countries for technology transfer; limited human and financial resources; underdeveloped infrastructure coupled with high costs of electricity, water and transport; inefficient procurement of pharmaceutical raw materials; small market size and underutilization of existing medicine production facilities; poor performance or absence of effective medicine regulatory systems; weak enforcement of medicine policies and legislation; lack of consumer preference for locally produced medicines.

Perspectives

26. From a public health policy perspective, uninterrupted supply of essential medicines is the backbone of health systems which presently are dependent on the goodwill of overseas suppliers and pharmaceutical manufacturers in industrialized countries. However, long-term solutions, including development of economically-viable local production capacity in the Region, should be fostered. It is necessary to establish a pharmaceutical regulatory facility at regional level to take care of, among others, quality control issues and building dialogue on related matters among countries.

27. Implementation of TRIPS safeguards and local production of competitive generic medicines play important roles in reducing prices. Developing countries with domestic manufacturing capacity on a viable scale should promote production of safe, efficacious and high quality medicines. Where local production is not possible, the options of parallel importation and compulsory licensing for generic equivalents could be employed.[18]

28. Economic appraisals of alternative options should be explored, including continued importation from developing countries; importation of generic essential medicines from least developed countries; and regional, subregional or national production. Governments should make appropriate decisions on alternative options based on cost-benefit analysis, equity and sustainability criteria. Equally important are assessing the existing production facilities and developing mechanisms to maximize use of idle facilities and improve their efficiency.

29. Local pharmaceutical production at subregional and regional levels should be promoted to ensure sustainability through:

(a) Encouraging south-south collaboration;

(b) Identifying centre(s) of excellence for subregional or regional production;

(c) Fostering public and private partnerships;

(d) Undertaking feasibility studies with a focus on quality and accessibility.

30. It would not be feasible to expect all countries in the Region to establish production facilities to furnish medicines for their domestic markets. Local production of assured quality, when economically feasible and where it follows Good Manufacturing Practices, can result in lower

[18] Velasquez G, Constraints and challenges in drug access in economically less developed countries, Geneva, World Health Organization, 2004 (unpublished paper).

medicine prices. Manufacturers of generic medicines in Brazil, India and Thailand have offered their help to low- and middle-income countries to produce antiretrovirals locally through South-to-South collaboration and technology transfer.[19] Some countries[20] have started producing generic antiretrovirals, whereas Ethiopia, Gabon, Mozambique, Namibia, Tanzania, Uganda and Zambia plan to start manufacturing soon.

31. Appropriate government policies should encourage intraregional trade and production of competitive products at national, subregional or regional level through existing economic communities such as the Economic Community of West African States, Southern African Development Community, and Common Market of Eastern and Southern Africa. Regional economic communities should draw up strategic plans for all aspects of industrial cooperation as redefined, with time-bound goals for output, resource allocation and creation of necessary institutions.[21] It is encouraging to note that the East African Community has agreed to negotiate with licensed antiretroviral manufacturers for local production.[22] Similarly, the New Partnership for Africa's Development should offer opportunities to build productive capacities, expand intercountry collaboration and promote intraregional pharmaceutical trade.

32. Generally, medicine and vaccine production is best left to the private sector. Governments should move away from owning or directly managing pharmaceutical industries and instead move towards effective regulation of medicine production. The government can promote the quality of locally-produced medicines and thereby improve industrial capacity by strengthening the official regulatory agency and arranging for training in Good Manufacturing Practice.[23]

ROLES AND RESPONSIBILITIES

33. Governments have the responsibility to:

(a) Create an enabling policy and economic and regulatory environments for technology transfer, and facilitate the development of local production capacity for essential medicines;

(b) Use regional economic integration to improve local production and encourage countries to join regional economic communities;

(c) Enhance collaboration among the various ministries (health, trade, industry, finance), patent offices, private sector and other development partners;

(d) Undertake economic appraisals of alternative options to ensure sustained supply of essential medicines;

(e) Enhance pharmaceutical research and development, especially using locally-available medicinal plants and other raw materials, in order to generate data on safety, efficacy and quality needed for large-scale production;

(f) Build national medicines regulatory capacity to enable implementation of Good Manufacturing Practice and TRIPS safeguards such as compulsory licensing.

Formatted: Bullets and Numbering

Formatted: Bullets and Numbering

[19] Velasquez G, Constraints and challenges in drug access in economically less developed countries, Geneva, World Health Organization, 2004 (unpublished paper).
[20] Such as Benin, Kenya, South Africa, Zimbabwe.
[21] ECA, Assessing regional integration in Africa, Addis Ababa, Economic Commission for Africa, 2004.
[22] http://www.aegis.com (accessed 16 November 2004).
[23] WHO, How to develop and implement a national drug policy, second edition, Geneva, World Health Organization, 2001.

34. It is the responsibility of the World Health Organization to support countries to:

(a) Build medicine regulatory capacities and implement Good Manufacturing Practice;

(b) Implement national medicine policies, patent laws and regulations; play an advocacy role; and monitor the impact of globalization on access to medicines.

Formatted: Bullets and Numbering

35. Development partners also have various roles. It is envisioned that they would:

(a) Mobilize resources to support the development of local production of essential medicines;

(b) Identify countries with potential for success in local production and advise them on making informed decisions on the development of an economically-viable pharmaceutical industry;

(c) Assist countries to effectively implement TRIPS safeguards.

Formatted: Bullets and Numbering

CONCLUSION

36. Local pharmaceutical industries capable of producing quality affordable medicines contribute to ensuring a sustainable supply of essential medicines. Learning from the experiences of some countries, governments in the Region should explore cost-effective alternative options prior to making decisions to invest in local production of essential medicines.

37. Governments should promote public-private partnerships as well as regional collaboration in local production and enhance their regulatory role in order to improve quality in local economically-viable production facilities.

38. In collaboration with WHO and development partners, governments should build national and regional private sector production capacities, effectively implement TRIPS safeguards and enhance technology transfer.

39. The Regional Committee is requested to review and adopt the orientations contained in this document.