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ESSENTIAL DRUGS IN THE WHO AFRICAN REGION: SITUATION AND TREND ANALYSIS

Report of the Regional Director

EXECUTIVE SUMMARY

1. WHO's mission in the area of essential drugs is to help reduce morbidity and mortality due to common illnesses by collaborating with the countries of the African Region to develop and implement national drug policies and programmes that will ensure equitable access to and rational use of essential drugs of proven quality.

2. Drugs are important because they help to save lives and to promote trust and participation in health services. Although they are costly, significant improvements in their supply and use are possible with proper management and planning within the context of national drug policies.

3. Changes in the economic, sociopolitical and demographic environment, globalization of trade including in pharmaceuticals, increasing poverty, currency fluctuations, the problem of emerging and re-emerging diseases, disease resistance to existing drugs, and irrational drug use are all putting an extra burden on already overstretched drug budgets.

4. In the light of the above, there is a need for a renewed commitment to the development and implementation of national drug policies that will ensure an effective increase in access to essential drugs of proven quality.

5. This document gives an overview of the pharmaceutical situation in the African Region with particular focus on ongoing efforts, the challenges to be met and the future perspectives within the context of the Intensified Essential Drugs Programme for the African Region.

6. The Regional Committee is invited to review this document and provide further guidance for the implementation of country and regional programmes in this important domain.

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INTRODUCTION

1. In 1975, WHO Member States in resolution WHA28.66 requested the Director-General to institute measures by which the Organization could provide greater assistance to Member States in, *inter alia*, the formulation and implementation of national drug policies (NDPs). WHO then proposed the Essential Drugs concept which involves the careful selection and procurement of a limited number of affordable essential drugs of proven quality, taking into account the health needs of the country. In 1977, WHO published the first Model Essential Drugs List (EDL). In 1978, at the Alma-Ata Conference on Primary Health Care (PHC), "access to essential drugs" was included in the eight elements of PHC. In 1981, the Director-General established the Action Programme on Essential Drugs in accordance with resolution WHA32.41.

2. Concerned with the problem of inequitable access to essential drugs, health ministers took measures aimed at improving access to essential drugs. The Bamako Initiative was thus launched in 1987, and a resolution on the local production of essential drugs was adopted in 1988 (AFR/RC38/R19). In spite of the above measures, WHO still estimates that over 50% of the population of the African Region do not have regular access to essential drugs.

3. The present document analyses the pharmaceutical situation and trends in the Region and proposes a framework for action. The overall view is that the successful reform of health systems and services depends on access to drugs in health facilities, and that improvements in health care delivery systems lead to better management and use of drugs.

GLOBAL AND REGIONAL PHARMACEUTICAL ENVIRONMENT

4. Changes in the economic, sociopolitical and demographic environment at global, regional and country levels continue to influence the pharmaceutical sector in the Region. Globalization of trade and the conclusion of the World Trade Organization's conventions such as the Trade-Related Aspects of Intellectual Property (TRIPS) may curtail the supply of cheap drugs that were in the past produced in countries not applying strict pharmaceutical patent protection. There is a need to assess and monitor further the impact of these agreements on the implementation of NDPs and the availability of essential drugs.

5. The fall in the prices of primary commodities, coupled with currency fluctuations in a Region heavily dependent on imported drugs and grappling with persisting poverty, have affected drug supply. In response to the 1994 devaluation of the CFA Franc, the 14 affected countries have adopted drug supply strategies based on the systematic use of generic essential drugs.

6. Economic reforms (including structural adjustment programmes) and sectoral reform programmes have reduced health sector funding, thus affecting drug availability. Most countries spend between 30% and 60% of their health budgets on drugs (World Bank Report 1993/1994), which represents on average US $8 out of a total US $36 per capita earmarked for health. Public funding covers only 33.4% of total health expenditure in most countries of the Region. The rest is borne by patients. Governments have divested themselves of drug production and are shifting from the provision of services to policy definition and monitoring. Market-oriented reforms are forcing the countries to consider appropriate public/private sector mixes in drug supply systems. Operators in the private sector (profit and non-profit) have stepped up their role in drug supply and distribution. However, operators in the profit-oriented private sector are mainly urban based.

7. Emerging diseases such as AIDS, re-emerging diseases like tuberculosis, diseases of old age and resistance to existing antibiotics and antimalarials are putting an extra burden on already overstretched drug budgets. The implementation of pharmaceutical sector reforms like drug revolving funds introduced by Governments is hampered by the fact that, as reported by UNDP, 23% to 84% of the population of the Region live below the income poverty line of US $1 per day. These health sector reforms and private sector initiatives may marginalize the poor and compromise public health objectives.

SITUATION ANALYSIS

Formulation and implementation of national drug policies

8. The formulation and implementation of comprehensive NDPs are necessary for attaining equity of access to essential drugs within the context of national health policies. The major components of NDPs are legislation and regulation, quality assurance, drug supply, rational drug use, economic strategies and human resources development. In 1993, the African Region adapted the 1988 WHO guidelines for formulating NDPs. These guidelines have been used by 33 Member States of the Region in the formulation of their NDPs (Figure 1).

9. In order to assess the impact of NDPs on regular access to essential drugs, WHO interviewed national experts whose estimates indicated that in 1987, 28 countries had a drug access rate of less than 50%. In 1997, this number of countries dropped to 20. Over the same period, the number of countries with a drug access rate of 50%-80% rose from 10 in 1987 to 23 in 1997 (Table 1). Greater effort has to be made to ensure that the implementation of NDPs brings about effective improvement in access to essential drugs in Member States.

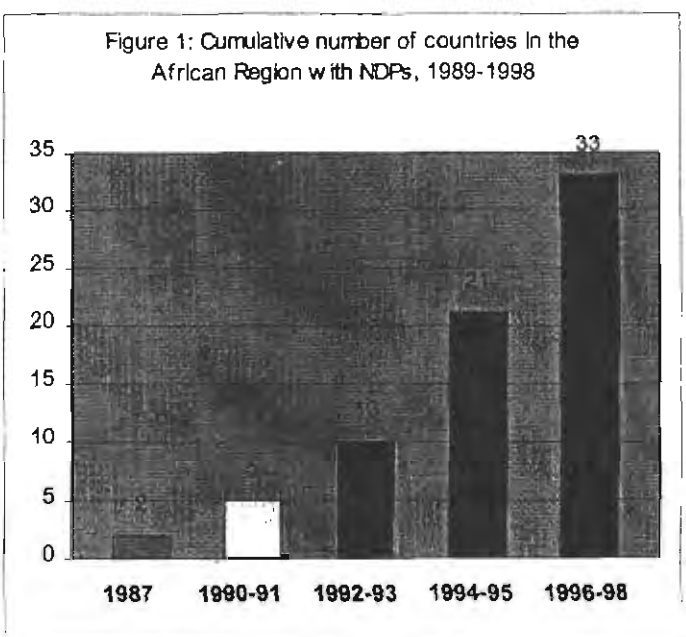


Table 1: Population with regular access to essential drugs: coverage achieved by countries, 1987/1997

COVERAGE	>50%		50-80%		80-95%		Over 95%
	No. of countries	Pop. studied (%)	No. of countries	Pop. studied (%)	No. of countries	Pop. studied (%)	
1987(n=40)	28 (70%)	71%	10 (25%)	23%	2 (5%)	5%	0
1997(n=46)	20 (43%)	48%	23 (50%)	47%	3 (7%)	5%	0

Legislation and regulations

10. The implementation of NDPs through pharmaceutical master plans calls for the review and enactment of appropriate legislation and regulations. Some Member States such as Comoros, Malawi, Namibia, Niger, South Africa, Swaziland and Tanzania have reviewed or are in the process of reviewing their legislation in order to implement NDPs. Such legislation can best be implemented by independent drug regulatory authorities responsible for the registration of drugs, the control of manufacturing standards, the import and export of drugs, inspection and quality assurance. *A survey of 17 English-speaking Member States carried out in November 1998 revealed that 12 of them (71%) had updated their legislation and regulations, while only 7 (41%) have some form of post-marketing surveillance (Table 2).*

11. The African Drug Regulatory Authorities Network (AFDRAN) was established in 1997. Over 40 nationals have been trained in various aspects of drug regulation, in particular drug inspection, analysis, registration, and pharmacovigilance.

Table 2: Drug regulation and quality assurance in the African Region

Countries	Updated legislation	Functional drug regulatory authority	Drug registration	WHO certification scheme	National quality control laboratory	PMS* (basic)
n=17	12 (71%)	16 (94%)	14 (82%)	11 (65%)	16 (94%)	7 (41%)

*PMS: Post-marketing Surveillance

Drug quality assurance

12. Drug quality assurance is the whole series of arrangements made to ensure that drugs meet established quality standards for their intended use. In 1975, the World Health Assembly adopted the WHO Certification Scheme. The certificate in this scheme which is issued by the regulatory authority of an exporting country states that: (i) the drug is registered and approved for sale in the exporting country or

where it is not it states the reasons therefor (ii) the manufacturer's facilities are inspected regularly and they comply with GMP (Good Manufacturing Practices) standards and meet quality control requirements.

13. By 1994, 39 (85%) countries had subscribed to the scheme, but an assessment conducted in that same year revealed that the scheme was not being used. Although the scheme depends on the effectiveness of the regulatory authority in the exporting country, it nevertheless allows countries with limited quality assurance facilities to import drugs with some degree of quality assurance and to avoid importing substandard and counterfeit drugs.

14. Because many countries of the Region have no national quality control facilities, WHO provided, in 1985, US $778 000 to reinforce the capacity of four national laboratories in Cameroon, Ghana, Niger and Zimbabwe to enable them to cater for the quality control needs of the other countries of the Region. An assessment carried out in 1993 showed that the laboratories were underutilized. In 1994, quality control experts who met in Brazzaville recommended that information on the laboratories be widely disseminated and that financial support for drug analysis be provided. These recommendations have resulted in the analysis of over 3900 drug samples. The analysis revealed that some Chloroquine tablets had 10% of the declared quantity of active ingredient, and that freeze dried plasma contained hepatitis B. An information brochure on the laboratories was published and a second edition is under preparation.

15. New global trade arrangements and deregulation in the area of drugs are affecting the pharmaceutical market worldwide, leading, *inter alia,* to a proliferation of pharmaceutical products which may increase counterfeiting. There is a need for greater cooperation and collaboration among Governments and organizations to combat the further spread of counterfeit drugs.

Drug supply

16. The main objective of a national drug policy is to ensure the availability of efficacious, good quality drugs at affordable cost. Such an objective can be achieved through an efficient drug supply system comprising three elements: production, procurement, and storage and distribution. An appropriate mix of private-public sector roles can improve the performance of a supply system. A multi-country comparative study of drug supply systems is being conducted to provide the countries with information on the advantages and disadvantages of different supply systems.

17. The WHO regional meeting on local drug production held in Cape Verde in September 1998 recommended the facilitation of information exchange, regional and intercountry arrangements, assistance to Member States in improving GMP and inspection services and the putting in place of tools to regulate production.

18. World drug production increased from US$70 billion in 1975 to US$ 290 billion in 1996, with Africa accounting for less than 1% of this production. The 200 local manufacturers in 33 Member States of the Region meet 10% of the Region's drug needs. *The question therefore is not whether Africa can produce, but what can be done to improve the existing regulatory environment and quality assurance mechanisms, in order to produce better in terms of quality and quantity to satisfy a larger portion of the Region's drug needs.*

19. *What role should governments play in local drug production?* There is little evidence of governments' efficiency in the direct production of essential drugs. Governments have to play the key role of creating an enabling and stable economic and political environment, laying down effective regulations, and instituting tax and duty incentives to encourage production.

20. **Procurement**: Given the limited technical capacity of traditional central medical stores owned and managed by the States, there is an urgent need to set up autonomous drug supply agencies to achieve the efficiency associated with private enterprises while respecting public health objectives. The AFRO Essential Drugs Price Indicator is published to provide managers of drug supply agencies with information about drug suppliers and prices. This publication will be updated every two years. An Association of Central Medical Stores (ACAME) has been set up by five West African Member States with support from WHO and other partners. This association has enabled these countries to carry out the bulk purchasing of essential drugs,

thus saving between 7% and 27% on the cost of four drugs. Other Member States of the Region should be encouraged to institute the bulk purchasing of drugs.

21. Since many countries still depend on drug donations, WHO, in collaboration with other partners, has produced Guidelines for Drug Donations. Countries are encouraged to use these guidelines and to adapt them to their specific situations. Zimbabwe and Uganda have already produced their own guidelines.

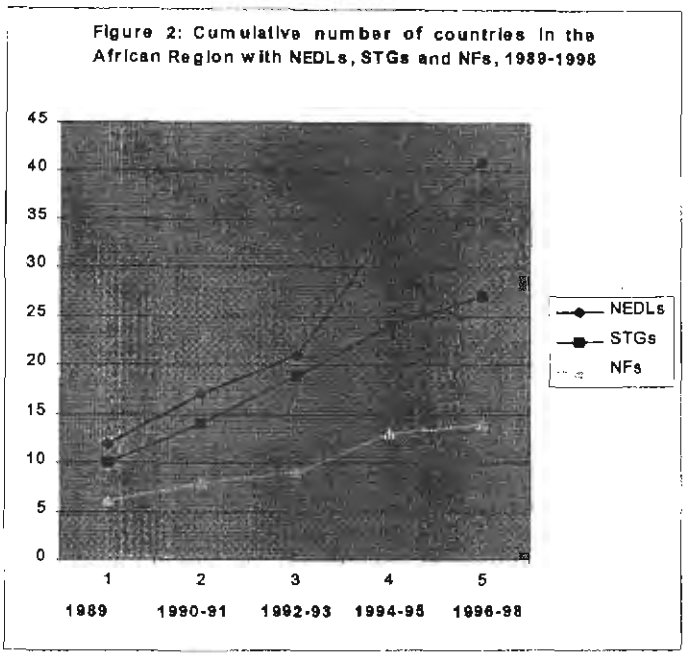
22. **Distribution and storage:** An efficient drug distribution mechanism is essential in a drug supply system. Various public and private sector initiatives in the distribution channel, for example, contracting out transport and transit operations, may significantly improve efficiency. Unfortunately, private sector operators are concentrated in urban areas in a bid to make maximum profits whereas the majority of the population are in rural areas. It is therefore necessary to provide incentives to encourage the private sector to operate in less lucrative rural markets in order to promote equity. These include higher retail margins in remote areas and tax reductions for the provision of services in specified areas. Also, distribution margins should not make the sale of expensive drugs more rewarding.

Rational drug use

23. After the 1985 Nairobi Conference on Rational Drug Use, the World Health Assembly passed, in 1986, a resolution on the revised drug strategy. The establishment of the International Network on the Rational Use of Drugs (INRUD) in 1989 led to the organization of six courses on the promotion of rational drug use. The courses were attended by 298 participants principally from the African Region. Various studies confirm the widespread nature of irrational drug use which encompasses, *inter alia,* over prescribing and overuse of injections and antibiotics.

24. A National Essential Drug List (NEDL) is one of the fundamental tools of the Essential Drug Concept. Its use in drug procurement and prescribing, together with Standard Treatment Guidelines (STGs) and National Formularies (NFs), contributes to rational drug use. Over the past 15 years, 27 Member States (59%) have developed STGs while 14 of them (30%) have developed NFs (Figure 2).

25. The provision of objective drug information also contributes to rational drug use. Kenya, Nigeria, South Africa, Tanzania and Zimbabwe are consolidating their national drug information centres for this purpose. Raising the awareness of the other countries in the African Region to the need for objective drug information should be accorded priority.



Traditional medicines

26. About 80% of the population in developing countries use plant-based traditional medicines. In 1989, resolution WHA42.43 urged Member States to carry out inventories and assessments of medicinal plants used by traditional practitioners and by the population. Resolution AFR/RC28/R3 invited Member States and WHO to take appropriate steps to ensure the use of traditional medicines. The regional meeting on local drug production held in Cape Verde in September 1998 recommended that Member States should include traditional medicines of proven efficacy and safety in their national essential drug lists, encourage local industry to invest in the cultivation of medicinal plants, and improve quality assurance mechanisms for plant-based preparations.

27. Various locally manufactured plant-based preparations have been registered in Cameroon, the Democratic Republic of the Congo, Ghana, Guinea, Madagascar, Mali, Niger and Senegal for use in conditions such as chronic infectious diarrhoea, liver disorders, amoebic dysentery, constipation, cough, eczema, ulcers and malaria. In 1997, Madagascar registered an antidiabetic preparation ("Madeglucyl").

CHALLENGES AND FRAMEWORK FOR ACTION

Economic strategies for drugs

28. Public-sector economic strategies have gradually changed in the past decade from a predominantly state-funded approach to a mix of private-public funding, reflecting shifts in economic policies in countries from central planning to market-driven strategies. Some countries in this Region are still dependent on donors.

29. All the countries in the African Region have introduced some form of cost sharing such as the Bamako Initiative or drug revolving funds. However, the funds collected have not been sufficient to replace all the drugs and many schemes have become bankrupt. Nevertheless, there are some exceptions worth emulating. For example, in Senegal, funds mobilized by districts for general health expenditure more than doubled between 1992 (CFAF 1 billion) and 1995 (CFAF 2.2 billion). In Mauritania, cost recovery in 1995 generated one and a half times the amount allocated by the State for drug procurement.

Operational research

30. Operational research for strategic adjustments in the implementation of NDPs is essential. Areas of research include: economic aspects of drug supply; socio-cultural aspects of drug use, including self medication, and knowledge, attitudes and practices of drug users; injection practices; drug prescribing and dispensing at various levels; traditional medicine; and indicators for monitoring the implementation of NDPs. Priority should be given to the establishment of a relationship between the formulation and implementation of NDPs and the effective increase of access to essential drugs. Strengthening the countries' capacity to conduct research in these areas through the training of researchers and the development of standard research protocols is also a priority. Protocols on injection practices and on drug utilization in communities and health facilities have already been developed.

Human resources

31. Human resources are in short supply in the public pharmaceutical sector in the African Region. Yet the implementation of NDPs requires adequate and appropriately trained staff. Health workers in the Region are from different training backgrounds. Some of them are not initiated into the essential drug concept. It is therefore essential to re-train them in their working environment. Priority should be given to strengthening management and appropriate technical skills so that staff are prepared to assume their roles within the decentralized health care delivery system.

32. Capacity-building through the review of curricula for training health workers, the organization of study tours, seminars and meetings, the production and dissemination of publications and the organization of various courses particularly on drug management are some of the efforts being made by WHO in collaboration with Member States to address the issue of human resources development. There is a need to address the problem of inadequacy of trained staff and brain drain from the public to the private sector due to conditions of remuneration.

Technical cooperation

33. Technical cooperation among countries helps them to make the best use of limited resources. Examples of cooperation are the sharing of experiences on NDP formulation and implementation and the common use of results of multi-country studies in the assessment of the impact of NDPs. Other areas of cooperation include exchange of information through publications and alert notices; use of regional quality control laboratories and WHO collaborating centres; inspection of pharmaceutical plants; bulk purchasing of essential drugs; training of staff; and harmonization of drug registration requirements.

Monitoring and evaluation

34. Monitoring and evaluation are essential components of NDP implementation. WHO published 129 indicators in 1994 (WHO/DAP/94/.12). A reduced number of core indicators were adopted after review by Regional meetings held in November 1998 and May 1999. Some countries, namely the Central African Republic, Chad, Niger, South Africa and Zimbabwe, have used or are in the process of using them to monitor and evaluate their NDPs.

FUTURE PERSPECTIVES AND THE ROLE OF WHO

35. Governments need to shift gradually from their traditional roles in the pharmaceutical sector such as the distribution of drugs free of charge in order to increasingly focus their attention on areas and issues like drug regulation and quality assurance; drug registration, inspection and quality control; information gathering and dissemination; solidarity and equity mechanism building; and quality assurance.

36. In order to assist Member States in addressing these issues, the WHO Regional Office for Africa is intensifying the activities of its Essential Drugs Programme through the Intensified Essential Drugs Programme for the African Region (AFRO IEDP) which is a five-year initiative that seeks to build on ongoing activities in the Region and comprises five major components:

Component 1: Capacity-building in drug regulation and quality assurance.

Component 2: Information exchange to improve policy implementation and cost control.

Component 3: Improving drug supply systems for health care.

Component 4: Improving the rational use of drugs by prescribers, dispensers and the public.

Component 5: Building institutional capacity in Africa in order to strengthen management capacity so as to meet the technical challenges of the AFRO IEDP and provide more effective assistance to Member States.

37. The Intensified Essential Drugs Programme has objectives, activities and expected outputs at both regional and country levels. The Regional Office intends to implement it over a five-year period in collaboration with EDM/HQ (Essential Drugs and Other Medicines at headquarters) and other interested partners. The Regional Office will report to a Programme Advisory Committee (PAC) comprising donor agencies and governments of Member States participating in the programme. The role of the Committee is to advise the Regional Director on the management of the programme.

38. The estimated cost of implementing this programme is US $16.2 million. The Regional Office, in collaboration with EDM/HQ, has already started implementing some aspects of the programme using regular budget funds: bulk purchasing by four West African Member States; publication of the first edition of the AFRO Essential Drugs Price Indicator and the AFRO Pharmaceuticals Newsletter; and establishment of the African Drug Regulatory Authorities Network (AFDRAN). A comparative analysis of drug supply systems is also being conducted.

39. The support and commitment of all Member States of the Region are necessary to enable the Regional Office to raise funds for the implementation of the proposed programme.

CONCLUSION

40. This report gives an overview of the situation of a continent whose pharmaceutical sector requires attention. The sector is evolving from one controlled by individual governments to one which is more open to private sector initiatives as long as such initiatives are seen to improve efficiency without undermining public health objectives. Challenges facing health workers and health authorities in the Region are decreasing or stagnating health budgets, lack of alternative drug procurement strategies, the problem of the roles of the State and the private sector in local drug production and distribution, effects of world trade liberalization, lack of effective regulation of the pharmaceutical sector, irrational drug use, the problem of decentralization of health care delivery systems and the overall issue of regular access to essential drugs.

41. Responses to these challenges are included in the various components of the programme and in activities to be carried out at country level in collaboration with Member States and at regional level within the context of the Intensified Essential Drugs Programme. Challenges not covered by the programme will be addressed as they arise.