REPORT OF A MEETING ON THE OPTIMAL USE OF REGIONAL DRUG QUALITY CONTROL LABORATORIES IN AFRICA

Niamey, 8-12 November 1993
## TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>EXECUTIVE SUMMARY</td>
<td>1</td>
</tr>
<tr>
<td>1. Introduction</td>
<td>3</td>
</tr>
<tr>
<td>1.1 Background</td>
<td>3</td>
</tr>
<tr>
<td>1.2 Participants</td>
<td>3</td>
</tr>
<tr>
<td>1.3 Objectives</td>
<td>3</td>
</tr>
<tr>
<td>1.4 Expected outcome of the meeting</td>
<td>4</td>
</tr>
<tr>
<td>1.5 Preparatory activities undertaken</td>
<td>4</td>
</tr>
<tr>
<td>2. OPENING OF THE MEETING</td>
<td>4</td>
</tr>
<tr>
<td>3. METHODOLOGY OF WORK</td>
<td>5</td>
</tr>
<tr>
<td>4. MAIN TOPICS PRESENTED AND DISCUSSED AT PLENARY</td>
<td>5</td>
</tr>
<tr>
<td>4.1 National drug policies in Africa</td>
<td>5</td>
</tr>
<tr>
<td>4.2 Quality control of drugs in Africa</td>
<td>6</td>
</tr>
<tr>
<td>4.3 Reports on the regional drug quality control laboratories</td>
<td>8</td>
</tr>
<tr>
<td>4.4 The experience of the national drug control laboratory of Tunis</td>
<td>10</td>
</tr>
<tr>
<td>4.5 Place and role of the regional drug quality control laboratory in quality assurance systems</td>
<td>11</td>
</tr>
<tr>
<td>4.6 The assistance of SNIP to African drug quality control laboratories</td>
<td>12</td>
</tr>
<tr>
<td>5. REPORTS OF THE WORKSHOPS</td>
<td>12</td>
</tr>
<tr>
<td>5.1 Identification of the main problems of the regional drug quality control laboratories</td>
<td>13</td>
</tr>
<tr>
<td>5.2 Criteria and list of drugs to be controlled in the laboratories</td>
<td>13</td>
</tr>
<tr>
<td>5.3 Responsibilities and duties of countries</td>
<td>14</td>
</tr>
<tr>
<td>5.4 Responsibilities and duties of regional drug quality control laboratories</td>
<td>14</td>
</tr>
<tr>
<td>5.5 Mechanisms of financing of quality control laboratories</td>
<td>15</td>
</tr>
<tr>
<td>5.6 Organization of information exchanges on the quality of drugs</td>
<td>15</td>
</tr>
<tr>
<td>5.7 Discussion on a draft proposal of an action plan for 1994-1995 and follow-up of the conclusions of the Niamey meeting</td>
<td>16</td>
</tr>
<tr>
<td>6. CONCLUSIONS</td>
<td>17</td>
</tr>
<tr>
<td>7. RECOMMENDATIONS</td>
<td>17</td>
</tr>
</tbody>
</table>
APPENDICES

I. Programme of the meeting ........................................ 19

II. List of participants ............................................. 23

III. Technical document ........................................... 27

1. INTRODUCTION .................................................. 27
2. OBJECTIVES ..................................................... 27
3. EXISTING SITUATION ........................................... 27
   3.1 The regional drug quality control laboratory of Cameroon ........................................ 27
   3.2 Regional drug quality control laboratory of Ghana ...................................................... 29
   3.3 Regional drug quality control laboratory of Niger ....................................................... 30
   3.4 Regional drug quality control laboratory of Zimbabwe .................................................. 32
4. ANALYSIS OF THE FINDINGS .................................. 34
5. CONCLUSIONS ..................................................... 35
6. RECOMMENDATIONS ............................................. 35

Annex 1: Summary of the responses of the four regional
drug quality control laboratories .................................. 37
Annex 2: RDQCL questionnaire ...................................... 41
Annex 3: List of drugs to be regularly controlled ................. 45
Annex 4: Consolidated report on four departments of pharmacy in
drug quality control: Burkina Faso, Côte d’Ivoire, Kenya
and Zambia .......................................................... 47
Annex 5: Consolidated report on four central medical stores in
drug quality control: Benin, Gambia, Malawi and Mozambique 51
List of abbreviations

ADB    African Development Bank
AFRO  Regional Office for Africa
DMP    Drug Management and Policy
DPM    Department of Pharmacy and Medicine
EDV    Essential Drugs and Vaccines
EEC    European Economic Commission
GMP    Good manufacturing practice
GTZ    Gesellschaft für Technische Zusammenarbeit
NGO    Non governmental organization
SGS    Société générale de Surveillance
UNIDO  ed Nations Industrial Development Organization
EXEuctive SUMMARY

A meeting on the optimal use of the regional drug quality control laboratories (RDQCLs) in Africa was the subject of a five day meeting organized by the Action Programme on Essential Drugs (DAP) and EDV/AFRO in Niamey, Niger, 8-12 November 1993.

The meeting was attended by the directors of regional drug quality control laboratories, managers of central medical stores, directors of drug regulatory authorities, experts in quality control and observers from Syndicate of National Pharmaceutical Industries (SNIP), France, the International Federation of Pharmaceutical Manufacturers Association (IFPMA) and Réseau Médicaments et Développement (ReMeD).

The meeting discussed national drug policies in Africa, the quality of drugs in Africa, and the role of a regional drug quality control laboratory in a quality assurance system. It also reviewed the status of the regional drug quality control laboratories with emphasis on problems of functioning and causes of under utilization.

Exchanges made during the presentations set the stage for subsequent workshop discussions on the following themes: main problems of regional laboratories, criteria and list of drugs to be controlled in the laboratories, responsibilities and duties of countries and regional laboratories, mechanisms of financing quality control laboratories and mechanisms of information exchange.

The meeting recognized the importance of a well defined national drug policy and agreed that quality assurance be included as a component when formulating national drug policies for countries in Africa.

It was also clear from the discussions that the regional laboratories were not optimally utilized as anticipated. Major problems that contributed to their under utilization were identified to be:

- absence of a proper administrative framework, legal base and autonomy;
- poor linkage with drug regulatory authorities both in host countries and user countries;
- lack of proper management and technical capability, inadequate human and material resources;
- absence of a communication system on the quality of drugs.

The participants were in agreement that optimum utilization of the laboratories requires a proper administrative framework, statutory power, adequate funds and human and material resources. Financing mechanisms such as diversification of activities, utilization of staff expertise, recycling of fees collected were suggested to promote sustainability of activities of the laboratories.

The meeting also took note of the importance of organizing an information exchange mechanism on the quality of drugs and recommended the publication of a quarterly bulletin on the activities of the laboratories and a brochure about the regional drug quality control laboratories.

Three partners - the governments, regional laboratories, and WHO - and other international agencies were identified to play a major role in promoting the proper utilization of the laboratories and it was recommended that:
a. **Regional laboratories should:**

- prepare a project document and seek financial and technical assistance to strengthen their activities;
- compile and diffuse information about their activities to interested parties and member countries of the region;
- establish a preventive maintenance system for equipment;
- develop self financing mechanisms.

b. **National authorities should:**

- grant legal a basis for drug regulatory authorities;
- establish an administrative framework for drug regulatory authorities;
- make available adequate funds to establish small quality control laboratories;
- promote the sustainability of laboratories by authorizing self financing mechanisms.

c. **WHO and other international agencies should:**

- offer financial and technical assistance to strengthen the regional laboratories;
- support the establishment of small quality control laboratories within Member States;
- advise Member States in developing drug legislation and national drug quality assurance policies.
1. INTRODUCTION

1.1 Background

In response to the emergence of the serious problem of substandard drugs moving in the African markets, the World Health Organization decided to support financially and technically selected national drug control laboratories in Africa to enable them to serve as regional drug quality control laboratories. The main objective of the support was to reinforce the quality assurance systems in the region and to allow those countries without national laboratories to use the nearest regional laboratory. The four regional laboratories created under the support programme were those of Cameroon, Ghana, Niger and Zimbabwe.

In practice, however, the use of the regional laboratories by the host countries and by other countries of the region is very limited.

In order to assess the status of the laboratories and define their precise role, DAP and EDV/AFRO in conjunction with the Ministry of Health of Niger organized a five day meeting in Niamey, 8-12 November 1993.

1.2 Participants

The participants of the meeting were principally directors of the four regional laboratories, the directors of pharmacies from Burkina Faso, Côte d’Ivoire, Kenya and Zambia and the directors of central medical stores from Benin, Gambia, Malawi and Mozambique.

WHO was represented by a participant each from DAP, from DMP and from EDV/AFRO, and one consultant.

There were also observers and quality control specialists from the Syndicate of National Pharmaceutical Industries of France, Réseau Médicaments et Développement, and the Tunis quality control laboratory. Representatives of Zambia, the African Development Bank and the International Federation of Pharmaceutical Manufacturers Associations were invited but were unable to attend the meeting.

1.3 Objectives

1.3.1 Principal objective

The overall objective of the meeting was to assess the status of the four RDQCLs and propose mechanisms for their optimal utilization.

1.3.2 Specific objectives

The specific objectives of the meeting were to:

- identify problems of under utilization of the four regional drug quality control laboratories;
- establish criteria for the selection of a priority list of drugs to be controlled regularly for their quality by countries of the region;
- define the responsibilities and obligations of the host and user countries and the regional laboratories;
- propose mechanisms for the exchange of information on the quality of drugs moving in the African region;
- propose a scheme for financing the cost of controlling the quality of drugs by the RDQCLs through contribution from countries, support from WHO and other agencies or organizations of bilateral and multilateral cooperation.

1.4 Expected outcome of the meeting

The expected outcome of the meeting included:

- a synthesis report on the exact situation of the regional laboratories, problems and abilities;
- a list of criteria for the selection of drugs to be controlled on a priority basis;
- an indicative list of responsibilities of countries and regional drug quality control laboratories;
- a proposal for the mechanism of exchange of information on the quality of drugs;
- a proposed plan of action for 1994-1995 for the follow up of the conclusions of the meeting.

1.5 Preparatory activities undertaken

In order to identify problems pertaining to the quality control of drugs in the African countries, three different sets of questionnaires were prepared by WHO and distributed in June 1993 to the directors of the four RDQCLs and to four directors of pharmacies and four directors of central medical stores of selected countries in the region. In addition, WHO sent a mission to Cameroon and Ghana to assess the status of the RDQCLs in the two countries. The responses to the different questionnaires were compiled separately, analyzed and synthesis reports prepared based on the results of the analysis. A consolidated report on the four RDQCLs was also prepared on the basis of the responses of the regional laboratories and the reports of the mission. The above documents served as reference materials for the meeting.

2. OPENING OF THE MEETING

Mr J.M. Trapsida, the Director of the RDQCL of Niger, made a welcome speech on behalf of the organizing committee. This was followed by the speech of Dr Th. Sodogandji who briefed the participants on the objectives of the meeting, the preparatory activities undertaken for the realization of the meeting and the expected outcome of the meeting. The WHO Representative of Niger also made an opening address stressing the important role that drugs play in the health care delivery system in the African countries.

The meeting was officially opened by the Minister of Health of Niger, who in the course of his address highlighted some of the important achievements of his country especially in making available good quality essential drugs to the population. He stated that ensuring the availability of sufficient quantities of good quality essential drugs to the population of Niger was a major preoccupation of the government. In order to realize this policy the National Office of Pharmaceutical Products and Chemicals was created in 1962 charged with the responsibilities of producing and importing drugs. The government also established in 1980 the National Public Health Laboratory and Expertise (LANSPEX) to regulate the quality of both locally produced and imported drugs and to fight against counterfeit products.
Following the speech of the Minister, the meeting elected the following three officers:

- Professor Moussa Kone of Côte d'Ivoire, President
- Mrs Mariatou Tala Jallow of the Gambia, English Rapporteur, and
- Mr Kokou Afogbe of Benin, French Rapporteur.

Participants then adopted the revised programme.

3. METHODOLOGY OF WORK

The meeting was divided into morning and afternoon sessions consisting of plenary and workshops. The plenary sessions entailed the presentation of a number of background papers followed by discussions.

The participants were divided into two working groups, French and English speaking, to discuss the workshop themes. Each theme was discussed by both working groups separately. The findings were then presented at plenary session for discussion.

On the morning of day one the topics: national drug policies in Africa, quality control of drugs in Africa as well as reports of the directors of the regional laboratories of Niger and Zimbabwe; the experience of Tunis quality control laboratory and the report of the consultant on the four RDQCLs were presented. In the afternoon a round table discussion on the place and role of RDQCL in the quality assurance system took place.

On day 2, reports on the regional laboratories of Cameroon and Ghana were presented and workshops and plenary sessions were conducted on themes 1, 2, 3, and 4.

On day 3, the representative of SNIP made a presentation on the assistance of SNIP to the African countries and this was followed by workshops on themes 5 and 6. The afternoon was devoted to a visit to the quality control laboratory of Niger.

On day 4, the meeting concentrated on the draft proposed action plan for 1994-1995, completion of the synthesis report of the meeting and elaboration of the conclusions and recommendations of the meeting.

The meeting was officially closed by the representative of the Minister of Health on Friday morning, 12 November 1993 after presentation and adoption of the recommendations and the synthesis report.

4. MAIN TOPICS PRESENTED AND DISCUSSED AT PLENARY

This part of the report reflects a summary of the presentation made by each speaker. Each presentation was followed by discussion by members of the plenary. Comments made at plenary have been included in the report.

4.1 National drug policies in Africa (by Mrs M. Helling-Borda, Acting Director of DAP)

The subject was presented by Dr Th. Sodogandji on behalf of Mrs M. Helling Borda who was unable to attend the meeting due to other commitments.
The aim of a national drug policy (NDP) is to develop, within the resources of a country, the potential that drugs have to control common diseases and alleviate suffering. This means to make available, safe, efficacious drugs of good quality at reasonable prices to those who need them. The goal of a NDP is difficult to reach in the developing countries due to economic and political reasons, and also the lack of infrastructure, human resource and managerial capabilities.

A drug policy is a complex combination of health related, cultural, economic and political factors. It covers how drugs are selected, procured, distributed, regulated, and used. It involves a number of government agencies such as the Ministries of Health, of Trade, of Finance, of Planning, of Industry, and the National Bank.

The formulation and enactment of a NDP has a number of health related, economic and national developmental goals. In the developing countries the realization of these goals is limited by the lack of legal framework, human resources, skills, funds and political support.

According to UN classification, out of the 45 countries in Africa, one is classified as developed, 29 less developed, and 15 least developed. Out of these, 22 countries have NDPs and 12 are in the process of developing one. 38 have essential drugs lists. But, even in those countries where NDPs exist, because of economic pressure and crisis, lack of defined relationship between the various structures, unrealistic planning and lack of an action group to implement them, essential drugs programmes have not materialized as expected.

In Africa problems of NDPs are linked to:
- problems of health i.e hygiene, malnutrition, malaria, AIDS, etc;
- problems of health policy and the system of health services, and;
- problems of the concept of drugs (drugs are considered as ordinary commodities).

There is inequity in the distribution of drugs, quality control often does not exist and where it exists, it is inadequate, and the various activities are not coordinated.

In the development of a national drug policy in Africa it is essential to identify the problems first and then set priorities, define the objectives (health, economic, and development goals) and develop strategies. The national drug policy should reflect clearly the concept of quality, the norms of quality, the instruments of measure and the regulation for its implementation. There should be an action group to implement the NDP.

Remark

The plenary accepted the importance of a well defined and realistic national drug policy, in particular, the need for the inclusion of quality assurance as a component in a national drug policy. It emphasized that African countries should be encouraged and assisted to develop realistic NDPs.

4.2 Quality control of drugs in Africa [by Mr A. Rambert (ReMeD)]

ReMeD was mandated by WHO to undertake a survey on the quality of drugs in the African market and to analyze the situation to identify problems, with special emphasis on counterfeit drugs.

The study had two phases. The first phase, which was carried out in November 1992, involved questionnaires covering 90 different issues. The questionnaires were distributed to respondents in 37 African countries, the majority of which were pharmacists (heads of
pharmacies, supply, hospital pharmacies, cooperative pharmacies, etc.). The indicators used in the study included the existence of a regulatory authority, adequate pharmaceutical inspection, local production, importation, distribution and pharmaco-vigilance.

Out of the 37 countries, 25 replied to the questionnaires. Major study findings included the following:

Quality control

18 countries have regulations to ensure the quality of pharmaceuticals. The authorities involved in the regulation of pharmaceuticals are: Ministry of Health in 24 countries, Ministry of Finance in 8, Ministry of Commerce in 12, and Ministry of Industry in six countries. Eight countries indicated that they have national drug quality control laboratories and 10 said they have a system of inspection. The number of technical staff available in the laboratories ranged from one to three pharmacists. Tests performed were mostly physico-chemical and microbiological.

Production

Twenty countries replied that they have local production. Of these, 14 have GMP, 15 have registration procedure and 17 have in-house quality control.

Import

With the exception of one country, where drug imports are a state monopoly, respondents stated that the Ministry of Health, social bodies, para-public bodies, wholesalers, retail pharmacies, etc. are involved in the importation of drugs. In 19 countries a permit is required to import. 24 have drug lists for the public sector and nine have specific registration systems for generics. In 14 countries there is a special commission for the registration of drugs. The WHO Certification Scheme is used in only 11 countries. In 11 countries import for the public sector is done by tender. Statistics on drugs were said to be available in 15 countries of which eight said they were not willing to show them. In a few countries import surveillance is carried out by Bureau Veritas, Société générale de Surveillance (SGS) and others.

Distribution

In 15 countries pharmacies are managed by pharmacists. 11 countries have controls for private pharmacies and 16 have a network of authorized pharmaceutical depots. Illicit pharmaceutical markets exist in 17 countries and the sources of supply have been identified in 15 of them. Pharmacy inspection systems exert effective control on pharmacies in nine countries and on drugs on the markets in four countries.

Counterfeit drugs

Ten countries responded that fake drugs exist in their markets. However, only one of them indicated that it is possible to evaluate their numbers and values.

Remark

The survey showed that quality of drugs is of concern to countries in Africa. Information available is inadequate and lacks precision. Data on the percentage of counterfeit drugs in circulation are not available and this makes it difficult to draw conclusions at this stage of the study. On the other hand, the presence of illicit markets is a serious issue which needs to be addressed.
4.3 Reports on the regional drug quality control laboratories

a. The Regional Drug Quality Control Laboratory of Niger (by Mr J.M. Trapsida, Director of Laboratory)

The National Public Health Laboratory and Expertise of Niger was established in 1980 after the creation of the National Office of Pharmaceutical Products and Chemicals (ONPPC). The latter is an organization responsible for the production, import and distribution of drugs in Niger. The main purpose of the laboratory is to regulate the quality of both locally manufactured and imported drugs. The laboratory has no special creation act but it operates as an autonomous body under ONPPC. The capital and recurrent costs of the laboratory are covered by ONPPC.

The laboratory is managed by a Board consisting of the Director of Pharmacy and Laboratory, the Hydraulic Minister, and the Minister of Agriculture. The Director of the laboratory reports to the Board.

The laboratory has a staff of two pharmacists, nine technicians, and three assistants. Its activities include: control of the quality of drugs produced by ONPPC and imported generic drugs, water and food analysis, pesticide analysis, forensic investigation, training and research, and analysis of narcotic drugs. Between 1991 and 1993, the laboratory tested a total of 2924 samples. Under a sub-regional cooperation, the laboratory tested drugs from Benin, Burkina Faso, Côte d’Ivoire, and Togo and cooperated with Mali and Senegal in training and exchange of information. It also collaborated with UNIDO, GTZ and Canada in research activities especially in the field of pesticide residue. In the past it had received assistance from WHO on organizational aspects.

Problems of the laboratory include: lack of a legal base to operate as an independent organization, shortage of qualified staff and lack of staff training opportunities especially in the use of major analytical equipment.

b. The Regional Drug Quality Control Laboratory of Zimbabwe (by Dr Ian Nyarazai Matondo, Director of Laboratory)

The laboratory was established as a result of the signing of an agreement between WHO and the Ministry of Health and Child Welfare in 1986. The objective was to establish a sub-regional drug quality control laboratory in Harare to serve Zimbabwe and the other countries of the sub-region.

Organizationally the laboratory comes under the Drugs Council Board but is expected to be completely autonomous in three months time. It is legally mandated to operate as a drug quality control laboratory and to issue certificates.

The laboratory has five departments: chemistry, microbiology, training, drug standards, and medical devices. Its clients are the University of Zimbabwe, the Drugs Council, private manufacturers, hospitals, retail outlets, family planning programmes, NGOs, and countries of the region.

The staff of the laboratory consists of 33 professionals of whom seven are specialized and 26 qualified technical staff.

The number of samples analyzed by the laboratory by test types over the last three years (1991, 1992, 1993) was: galenic 144, physico-chemical 2004, and microbiological 356.
The laboratory operates on funds obtained from the government, WHO, the Standards Development Fund, and fees collected by the laboratory for services rendered.

The laboratory collaborates with the Danish National Laboratory, the Swedish National Laboratory and the Medical Testing Laboratory of UK. It is also actively engaged in medical devices testing activities in collaboration with UNFPA.

Main problems include: poor payment by clients, difficulty in procuring spare parts and reagents, and lack of staff training opportunities.

c. The Regional Quality Control Laboratory of Ghana (by Mrs Charlotte Afi Ohene-Manu, Head of Laboratory)

The laboratory was established by the Ministry of Health with the assistance of WHO. It became operational in 1991. It is housed in the complex of Ghana Standards Board, an organization responsible for the standardization of all industrial products in the country. It operates as an organ of the Board.

It has the necessary equipment and facilities to carry out physico-chemical tests on drugs. Tests performed include: hardness, friability, dissolution, uniformity of weight, identification and determination of active ingredients. The number of samples tested in 1991 and 1992 was 45 and 44 respectively. No samples were tested in 1993. The activities of the laboratory have been described in the Essential Drugs Monitor published by DAP. But, the use of the laboratory by countries of the region has not been as expected.

The laboratory charges a flat rate of 50 US$ for tests performed. Capital and running costs of the laboratory are met by Ghana Standards Board. The human resources available include: four specialized staff, three qualified technicians, and one administrative staff.

d. The Regional Quality Control Laboratory of Cameroon (by Dr Abol Bollo Epee)

The laboratory was created in 1989 with financial and technical assistance from WHO and Ciba-Geigy, a Swiss pharmaceutical firm. It is organized as a division of the Office of National Pharmaceutics of Cameroon (ONAPHARM), which is a state owned pharmaceutical importing and distributing agency for the public sector. It operates under the legal framework of ONAPHARM.

It became operational in 1990 with four staff (1 pharmacist and three technicians). In 1991 and 1992, the laboratory tested a total of 71 samples. No test was carried out in 1993. In addition, the laboratory tested the quality of 174 condom samples obtained from local sources and neighbouring countries. It also developed reporting forms, price tariff, and analysis request forms.

The laboratory has no proper administrative framework, legal base or budget to operate. Because of financial problems faced since March 1993, the three technicians have been transferred to the Ministry of Health. Shortage of chemicals, reagents, reference standards and spare parts also pose problems.

e. Report on the four regional quality control laboratories (by Mr Eshetu Wondemagenegneth, WHO Temporary Adviser)

A survey was carried out in 1993 by WHO to collect information on the current operation of the four laboratories and to analyze the information and identify problems of
functioning and causes of under utilization. The methodology of work involved questionnaires and field visits.

Questionnaires covering 19 different elements were prepared by WHO and sent to the directors of the four laboratories in June 1993. A field visit was made by the consultant to Cameroon and Ghana to assess the laboratories. Indicators used included: the ministry responsible, legal status, creation act, budget, source of funds, human resources, number of drug samples analyzed, origin of samples, average cost of test, etc. Review of the responses from the four laboratories and the reports of the consultant revealed the following:

1. Only the laboratory in Zimbabwe has a legal basis to operate as a drug quality control laboratory and to issue certificates. It has a proper administrative framework and linkage with the drug regulatory authority in the country.

2. All the laboratories are under utilized as regional laboratories.

3. The laboratories in Niger and Zimbabwe operate mainly as national laboratories (service as a regional laboratory is less than 1%).

4. The laboratories in Cameroon and Ghana are under utilized both as regional and national laboratories.

5. With the exception of the laboratory in Zimbabwe the rest have no legal provision to use fees collected for self financing purpose.

6. There is lack of funds to cover capital and recurrent costs of the laboratory in Cameroon.

7. There is a shortage of trained personnel and facilities to run the laboratories in Cameroon and Ghana.

8. There is a lack of awareness and commitment on the part of countries of the region to use the services of the laboratories.

Conclusions

The participants concluded that in order to promote optimum utilization, the laboratories should be reorganized under a proper administrative framework, given a legal basis and autonomy to operate independently. An adequate budget, qualified staff, and facilities should be made available and a proper management system established. Communication systems should be created between laboratories and between laboratories and user countries.

4.4 The experience of the national drug control laboratory of Tunis (by Abderrazak Saddem, Pharmacy Inspector, Head of the Chemical Section)

The laboratory was created in 1979 without a legal basis under a project of cooperation between Tunis and Japan. It attained legal status in August 1990 by Law no.90-79. The operational organogram was implemented in December 1990.

It has technical and administrative sections. The technical section has the following divisions: Physico-chemical, Microbiological, Biopharmacy and Pharmacokinetics, Animal Experimentation, Pharmacognosy, Para-pharmaceuticals and Accessories.
The laboratory controls the quality of drugs, hygienic products, cosmetics, and other products related to drugs.

The laboratory is technically linked to other organizations such as the Direction de la Pharmacie et du Médicament (DPM), Pharmaceutical Inspection, Center of Pharmacovigilance, Ministry of Economy, Ministry of Health and the Central Pharmacy of Tunisia.

The system of quality assurance involves the laboratory. DPM, Pharmacy Inspection, Center for Pharmacovigilance, pharmaceutical industries and Central Pharmacy of Tunisia.

The laboratory is legally permitted to apply a self-financing scheme by collecting fees and by using part of registration taxes. In 1993, the laboratory tested a total of 1634 samples.

Essential activities in Tunis are divided into the control of conformity of pharmaceutical specialties submitted for registration, control of commercially available drugs through post marketing surveillance, and the role of the national drug control laboratory in the system of quality assurance.

**Remark**

The meeting acknowledged that proper linkage between organizations and cooperation and coordination of activities are essential elements for optimum utilization of regional laboratories.

4.5 **Place and role of the regional drug quality control laboratory in quality assurance system (round table discussion)**

After an extensive exchange of views the round table discussion on the place and role of the regional drug quality control laboratory concluded that:

a. Drugs are indispensable for the health of people and need to be of good quality. The concept of quality is the conformity to accepted norms or standards i.e. compliance with all the provisions of registration, compliance with official standards, homogeneity of a product within a batch, etc.

b. Quality control measures include registration, inspection, post marketing surveillance and quality testing.

c. A quality control laboratory is an instrument to verify, check and realize whether a drug conforms to certain specifications.

d. The responsibility of a quality control laboratory should be limited only to the results of the analysis it produces. It cannot be the judge to make the final decision on the quality of a drug.

e. The decision to accept or reject a drug should be the responsibility of the Ministry of Health or any other drug regulatory authority which has a legal mandate to take action.

f. The running of a drug quality control laboratory needs human resources as well as equipment, reagents, reference standards, etc. Therefore, mechanisms of financing must be designed.
g. Legislation gives authority to carry out functions and duties. It is therefore required in quality assurance including laboratory activities.

4.6 The assistance of SNIP to African drug quality control laboratories (by Mr M. Pesez, Expert, SNIP)

SNIP has been giving assistance to francophone countries in Africa for 10 years to develop quality control laboratories. Its assistance covered:

- training of technical personnel,
- supply of equipment, consumables, reagents, chemicals, standards, etc.
- technical assistance,
- development of analytical procedures,
- improvement of the storage conditions for drugs.

In the field of training, 27 pharmacists from 17 francophone African countries were offered short-term on-the-job training in pharmaceutical industries in France. SNIP has also developed and distributed analytical monographs for selected essential drugs to serve as teaching materials and to be used for screening purposes but not for administrative decisions.

SNIP believes that the quality assurance of drugs can be fulfilled in Africa by establishing a drug quality control laboratory in each country. Analytical monographs should be simple and inexpensive i.e. limited to identification and determination of active ingredients. To control all imported drugs, donations and counterfeit drugs is not possible. Development of laboratories should go step by step.

From experience, even if money is available, it is not easy to create laboratories due to lack of trained human resources, equipment maintenance problems, and long delays in procuring spare parts and accessories.

Despite the problems, SNIP will continue its assistance to African countries in the area of drug quality control and this will be announced officially at the World Health Assembly in May 1994.

Remark

The participants appreciated the assistance of SNIP and commented that the monograph developed by SNIP is good and can serve to perform basic tests. However, it is not validated and has no limits and therefore cannot be used for litigation.

5. REPORTS OF THE WORKSHOPS

The workshops discussed the following themes:

* Identification of the main problems faced by the regional drug quality control laboratories
* Criteria and lists of drugs to be controlled in the laboratories
* Responsibilities and duties of countries
* Responsibilities and duties of RDQCLs
* Mechanisms of financing the quality control laboratories
* Organization of information exchanges on the quality of drugs
* Discussion of a draft proposal of an action plan for 1994-1995 and follow-up of the conclusions of the Niamey meeting.
Introductions to each theme were made by the resource person designated. Each theme was then discussed by the two working groups independently and the findings of each group presented at a plenary for discussion. This section contains reports which were prepared after each plenary and reflects the common views of the groups.

5.1 Workshop 1: Identification of the main problems of the regional drug quality control laboratories

The workshop identified the following to be major problems of the regional drug quality control laboratories in Africa:

1. Absence of a proper administrative framework, legal basis and autonomy.
2. Poor linkage between the RDQCLs and the drug regulatory authorities (DRA) in both the host and the user countries.
3. Lack of a national drug policy and comprehensive national drug law which will mandate adequate inspection of drugs within the countries and therefore promote the utilization of RDQCLs.
4. Lack of proper management, technical capability, human resources, training opportunities for personnel, equipment and materials, reference standards, standard methods, etc.
5. Inadequate financial resources.
6. Absence of communication between laboratories and weak communication between laboratories and clients.
7. Absence of a system to monitor and evaluate the activities of the laboratories.
8. Inadequate funds within countries of the region to pay for the analysis of drugs.
9. Poor logistics for the despatch and receipt of samples.
10. Absence of properly functioning drug inspection services within countries.
11. Inadequate definition of the role and functions of RDQCLs i.e. whether their role is to serve as reference laboratories and centers of excellence or as laboratories for routine analysis of drugs for Member States.
12. Inability to diversify activities and self-finance by using money generated.

5.2 Workshop 2: Criteria and list of drugs to be controlled in the laboratories

The following criteria were developed for the selection of drugs to be regularly controlled by the laboratories:

1. Drugs submitted for registration.
2. All drugs submitted for tender (during buying and receiving).
3. All drugs imported (during buying, receiving and in the course of use).
4. Drugs with high turnover both in financial terms and in quantities (high consumption drugs).
(5) Drugs known to be unstable.

(6) Drugs with high toxicity risk.

(7) Drugs which are available in stock in large quantities and nearing expiry date.

(8) Drugs about which there are complaints.

(9) Drugs, dosage-forms and formulations which show resistance.

(10) Intravenous solutions.

(11) Drugs from unknown suppliers.

The participants remarked that the criteria suggested cannot be exhaustive and that the regulatory authorities should have the freedom to send drugs for testing whenever there is a specific problem.

5.3 **Workshop 3: Responsibilities and duties of countries**

The participants agreed on the following country obligations and responsibilities:

(1) Develop a well-defined drug regulatory authority which demands analytical control of drugs.

(2) Make available adequate human, material and financial resources.

(3) Provide sufficient budget for the drugs to be analyzed.

(4) Organize a pharmacy inspection system with all the necessary means for its proper functioning.

5.4 **Workshop 4: Responsibilities and duties of regional drug quality control laboratories**

The workshop suggested that the laboratories should:

(1) Clearly define their role, objective, and mode of operation.

(2) Have an adequate number of qualified personnel of high integrity and skill.

(3) Have an efficient management system.

(4) Promote their activities by disseminating information.

(5) Have a reasonable costing mechanism for their services.

(6) Develop a programme of training in collaboration with other laboratories.

(7) Establish mechanisms for the maintenance of equipment by collaborating with field institutions.

(8) Convince the authorities to remove the various taxes on laboratory spare parts and accessories.
5.5 Workshop 5: Mechanisms of financing of quality control laboratories

The workshop suggested the following financing mechanisms:

1. Government allocation in the form of budget.

2. Support from other institutions, such as WHO, EEC, ADB, etc.

3. Diversification of activities: control of water, preservatives, pesticides, veterinary products, cosmetics, etc.

4. Training activities for technicians of other institutions (local and external).

5. Use of staff expertise in consultancy and research contracts, and designing of bilateral projects for funding.

6. Use of part of the registration taxes collected.

7. Use of fees levied and collected for analysis of samples.

8. Other possible sources of financing are: taxes paid by agencies that import large quantities of drugs and money seized by court from counterfeit drugs.

5.6 Workshop 6: Organization of information exchanges on the quality of drugs

1. Rationale:

The exchange of information is essential because it improves knowledge and skills. It will enable the laboratories to know more about each other and will create closer linkages and mutual confidence.

2. Type of information:

The type of information to be exchanged could be:

a. related to laboratories:

name, complete address—P.O. Box, telephone, fax, telex, analytical capability, analysis carried out, comment on formulation requested for analysis, method of analysis, types of tests performed, cost of analysis, perspectives of the laboratory, method of despatch of samples for analysis, etc.

b. related to regulatory authorities:

information reflecting the precise job description of departments of pharmacies, pharmacy inspectorate, national and regional quality control laboratories, negative list of manufacturers and suppliers, etc.

3. Circuits of information:

a. Information on the quality of drugs emanating from the regional drug quality control laboratories or WHO could arrive in the department of pharmacy and laboratory in each country and could be circulated to professionals.

b. Technical information concerning protocols of analysis could go to laboratories.
(4) **Support to information:**

Two types of information support mechanisms could be used:

a. Emergency information: by using fax, telex and telephone.

b. Publication of bulletins every three months in the form of abstracts (2 to 4 pages) and a brochure on the four RDQCLs in French and English. The focal point for French could be Niger and Zimbabwe for English.

(5) **Sources of information:**

National and/or regional quality control laboratories should collect information.

(6) **Cost of publication:**

WHO should cover the cost of publication and circulation of information.

5.7 **Workshop 7: Discussion on a draft proposed action plan for 1994-1995 and follow-up of the conclusions of the Niamey meeting**

During the period 1994-1995 the main effort will be to reinforce the existing regional drug quality control laboratories in particular those lacking a legal framework and proper administrative structure. DAP and EDV/AFRO will define the precise activities to be undertaken and implementation will be monitored and evaluated jointly. The main activities for the period will be to:

1. Strengthen the regional laboratories by supplementing the equipment, supporting maintenance and repair, training, providing reference documents and consumables (reagents, chemicals, standards).

2. Assist countries wishing to establish national drug quality control laboratories.

3. Arrange financial assistance for analysis of drugs in a priority list from countries of the region.

4. Assist Member States in establishing legal base for their laboratories.

5. Strengthen the drug regulatory authorities of Member States.


7. Assist the laboratories financially and technically to publish and circulate reports on their activities and information brochures.

8. Assist laboratories in improving their management and technical capabilities.

9. Organize study visits between laboratories.
6. CONCLUSIONS

At the end of the meeting the participants identified the following as main causes for the under utilization of the four regional drug quality control laboratories.

(1) The laboratories received WHO technical and financial assistance without clear definition of their role. No feasibility studies were conducted and user countries were not consulted.

(2) Absence of a proper administrative framework, legal basis and autonomy for the laboratories. Lack of legal provision to allow them to diversify activities, collect and use funds generated through services rendered.

(3) No functional linkage between the laboratories and the drug regulatory authorities of both the host countries and the user countries.

(4) Lack of national drug policy and comprehensive drug law within the countries which will allow adequate inspection of drugs and therefore promote optimum utilization of the regional drug quality control laboratories (non-functionality of inspection systems in Member States has a negative effect on the utilization of the laboratories).

(5) Deficiency in terms of management, technical capability, human resources, training, equipment, reference materials, reference standards, guidelines and procedures, etc.

(6) Inadequate financial resources and mechanisms to sustain the operation of the laboratories.

(7) Nonexistence of a clearly defined national essential drugs programme with adequate budget and proper management system.

(8) Lack of funds to cover the cost of analysis, absence of information to Member States on the competence of the laboratories, cost of analysis, and procedures for sample submission, problems of logistics for despatching of samples and receiving of results.

(9) Absence of communication system between laboratories and between laboratories and clients.

7. RECOMMENDATIONS

The workshop identified three partners to play a role in promoting optimum utilization of the regional drug quality control laboratories and made the following recommendations.

(1) The regional drug quality control laboratories should:

a. prepare project documents and seek financial and technical assistance to strengthen the functioning of the laboratories;

b. compile information about their activities including an annual report and diffuse this to interested parties and Member States of the region;

c. establish a preventive maintenance system for equipment;

d. prepare bulletin on urgent issues such as counterfeit drugs; copies of the bulletin to be sent to countries of the region; Niger to prepare the French version for the francophone and Zimbabwe the English version for the anglophone countries.
e. develop self-financing mechanisms such as setting price tariffs, use of part of drug registration fees, government subsidy, diversification of activities, and grants from the international and donor agencies.

(2) National authorities:

Governments and concerned ministries should:

a. grant a legal basis for drug regulatory authorities (inspection, registration and quality control laboratory);

b. establish an administrative framework which will permit proper functioning of the drug regulatory authorities (inspection, registration and quality control laboratory);

c. give financial support, by making funds available through allocation of specific budget, authorizing self-financing, allocating part of the drug registration fees and penalties and reallocation of money allocated to surveillance companies such as SGS, Veritas, to promote the credibility of the laboratories;

d. make funds available to establish a small quality control laboratory in each country or to strengthen existing national drug quality control laboratories to promote self-reliance.

(3) WHO in collaboration with other international agencies should:

a. strengthen regional drug quality control laboratories through training of personnel, provision of equipment, books and documentation, reagents, chemicals, fellowships, arranging seminars, workshops, etc.;

b. support laboratories by arranging external quality control or audit system;

c. advise Member States in developing drug legislation;

d. allocate special budget to finance part of the cost of analysis of a list of priority drugs on behalf of Member States;

e. offer technical and financial assistance to governments in developing national quality assurance policies, establishing national drug quality control laboratories and staff training.
APPENDIX I

Programme of the meeting

Sunday, 7 November 1993

Arrival of participants

Monday, 8 November 1993

09:00  Official opening
       Speech by DAP
       Speech by WR
       Speech by MOH

09:30  Election of officers
       Adoption of the objectives and programme

10:00  National drug policies in Africa
       (Dr T. Sodogandji, DAP)

10:30  Coffee break

10:45  Quality of drugs in Africa: a survey carried out by ReMeD

11:30  Reports of the directors of regional quality control laboratories:
       * Cameroon
       * Ghana
       * Niger
       * Zimbabwe

12:30  Lunch

14:00  (Continued)

14:30  Reports of the consultant on the four regional quality control laboratories

15:30  General discussion

16:00  Coffee break

16:30  Round table: Place and role of RDQCL in the quality assurance system (DAP, DMP, EDV, SNIP, RDQCL Zimbabwe, DPH Ivory Coast, Central Medical Stores, Benin)

18:00  End of the day’s session
Tuesday, 9 November 1993

08:00  Report of 8 November

08:30  Working group No.1: Identification of the main problems of the regional drug quality control laboratories
       (Introduction by M. Eshetu Wondemagegnehu)

09:30  Plenary session

10:00  Coffee break

10:15  Working group No.2: Criteria and lists of drugs to be controlled in the laboratories
       (Introduction by Mr Eshetu Wondemagegnehu)

11:30  Plenary session

12:30  Lunch

14:30  Working group No.3: Responsibilities and duties of the countries (legislation, registration, inspection, sampling, delivery, payment, utilization of results, etc.)
       (Introduction by Dr T. Sodogandji)

15:30  Plenary session

16:00  Working group No.4: Responsibilities and duties of RDQCL (organization, management, human resources, training, cost and price of analyses, recurrent costs, etc.)
       (Introduction by Mr Eshetu Wondemagegnehu)

17:00  Coffee break

17:30  Plenary session

18:00  Reception

Wednesday, 10 November 1993

08:00  Report of 9 November

08:30  Working group No.5: Mechanisms of financing of quality control laboratories
       (Introduction: Mr Eshetu Wondemagegnehu and Dr A. Saddem, Director of Quality Control Laboratory of Tunisia)

10:00  Plenary session

10:30  Coffee break

10:45  Working group No.6: Organization of information exchanges on the quality of drugs
       (Introduction by Mr Rambert, ReMeD)
12:00     Plenary session
12:30     Lunch
15:00     Visit to the Quality Control Laboratory of Niger

Thursday, 11 November 1993

08:00     Report of 10 November
08:30     Working group No.7: Discussion of a draft proposal of an action plan for
          1994-95 and follow-up of the conclusions of the Niamey meeting
          (Introduction by Dr T. Sodogandji)
10:30     Coffee break
11:00     (Continued)
11:30     Plenary session
12:30     Lunch
14:30     Plenary session
15:00     Completion of a synthesis report of the meeting
          Elaboration of recommendations
17:00     Coffee break

Friday, 12 November 1993

09:00     Presentation and adoption of recommendations and synthesis report
10:30     Coffee break
11:00     Closure of the meeting
          Presentation of synthesis report and recommendations
          Speech by DAP
          Speech by MOH
APPENDIX II

List of participants

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Consultant, DAP
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Scientist (STP), DAP

Mr Eshetu WONDEMAGEGNEHU
Consultant, DAP

* Could not attend the meeting
APPENDIX III

Technical document

CONSOLIDATED REPORT ON THE FOUR REGIONAL DRUG QUALITY CONTROL LABORATORIES IN AFRICA

1. INTRODUCTION

The consultant visited Cameroon and Ghana from 4 - 11 September 1993 to assess the conditions of the regional drug control laboratories in the two countries. In addition, WHO prepared a questionnaire entitled "RDQCL QUESTIONNAIRE" and sent copies to the regional drug quality control laboratories in Cameroon, Ghana, Niger, and Zimbabwe. The consolidated report is based on the responses of the four laboratories and the field visit. A summary of the responses to the questionnaire and a sample of the questionnaire are attached as Annex 1 and 2 respectively.

2. OBJECTIVES

The specific objectives of the field visits and the questionnaire were:

a. To collect information on the current operation of the four regional drug quality control laboratories.

b. To analyze the information obtained and identify problems in functioning.

c. To find the causes of under utilization.

d. To write a consolidated report on the four laboratories mentioning the problems in functioning, the causes of under utilization and the experiences in regulation, organization, analysis and prices.

3. EXISTING SITUATION

3.1 The regional drug quality control laboratory of CAMEROON

The national drug quality control laboratory of Cameroon was established in 1989 with the assistance of WHO and Ciba Geigy, a Swiss pharmaceutical company. The laboratory is organized as a division of the Office of National Pharmaceutics of Cameroon (ONAPHARM) which is a state owned pharmaceutical importing and distributing agency for the public sector.

As stated in the project document of the laboratory, its functions are:

- to control the quality of drugs purchased by ONAPHARM,
- to control the quality of drugs submitted for registration,
- to control the quality of drugs distributed by other suppliers, private wholesalers or charitable organizations.
The laboratory has no special creation act. It functions under the legal framework of ONAPHARM, Decree No. 85/1126 of 8 August 1985. The Decree empowers ONAPHARM to control the quality of medicines imported or manufactured locally.

The Ministry of Health of Cameroon is the responsible supervisory authority for both the laboratory and ONAPHARM.

The Ministry has also recently created a pharmacy department within its structure to function as a national drug regulatory authority. The activities of the Department include: drug registration, inspection, and pharmacy administration i.e. development of regulations and guidelines. The Pharmacy Department and the RDQCL have no structural or functional linkage.

The laboratory is housed in one of the buildings of ONAPHARM and has most of the basic equipment and facilities needed for physico-chemical testing of drug samples. It started functioning in 1990 with 4 staff, consisting of one pharmacist, who is the head of the laboratory, and three technicians.

In the past three years, the laboratory tested a total of 82 drug samples submitted mainly by private importers and non-governmental organizations. The number of samples tested per year was: 30 in 1991, 52 in 1992 and 0 in 1993. The laboratory also tested about 174 condom samples from 1990 to 1993.

Tests carried out were all limited to physico-chemical methods such as description of product, average weight/volume, weight variation, net content, friability, hardness test, refractive index, disintegration test, identification test and assay of active substances. The minimum and maximum delays for one analysis were two and seven days respectively.

The average cost of a test by formulation is estimated to be:

<table>
<thead>
<tr>
<th>Formulation</th>
<th>Cost (CFA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capsule</td>
<td>60,000</td>
</tr>
<tr>
<td>Tablet</td>
<td>50,000</td>
</tr>
<tr>
<td>Syrup</td>
<td>50,000</td>
</tr>
<tr>
<td>Injectable vial</td>
<td>50,000</td>
</tr>
</tbody>
</table>

(Before devaluation)

CFA 60,000 (US$ 204)
CFA 50,000 (US$ 178)
CFA 50,000 (US$ 178)
CFA 50,000 (US$ 178)

The laboratory has developed analysis result reporting form, price tariff and analysis request form. But, laboratory instructions and guidelines for sample submission and acceptance, standard method of analysis, care of instruments, etc. have not been developed.

The laboratory has no budget of its own. Up to March 1993, ONAPHARM covered the running costs of the laboratory. But, as of March 1993, ONAPHARM has stopped financing the laboratory due to financial problems. As a result, the three technicians who were working in the laboratory have been transferred to the Ministry of Health.
Weakness

The laboratory is not functioning due to:

- lack of a legal base and a proper administrative framework,
- lack of linkage with the drug regulatory organization,
- shortage of qualified human resources,
- non availability of budget, shortage of chemicals, reagents, reference standards, spare parts, books, etc.

3.2 Regional drug quality control laboratory of GHANA

The WHO/GSB Sub Regional Drug Quality Control Laboratory of Ghana, as it is called, was established as a result of an agreement reached between WHO and the Government of Ghana in 1986 to assist the quality control laboratories of Ghana Standards Board (GSB), in particular the quality control of drugs.

The laboratory is housed in the complex of GSB and functions as an organ of Ghana Standards Board. There is no special act passed by the Government to define the duties, functions, responsibilities and authorities of the laboratory.

The laboratory operates under the legal framework of the Board, Ghana Standards Board, on the other hand, is responsible for the development of standards and specifications for the country and is supervised by the Ministry of Industry and Trade.

The laboratory started implementing its activities in 1991. The capital and running costs for the laboratory are met by GSB. The budgets for the past three years were:

<table>
<thead>
<tr>
<th>Year</th>
<th>Budget</th>
</tr>
</thead>
<tbody>
<tr>
<td>1993</td>
<td>US$ 25,714</td>
</tr>
<tr>
<td>1992</td>
<td>US$ 22,000</td>
</tr>
<tr>
<td>1991</td>
<td>US$ 22,875</td>
</tr>
</tbody>
</table>

The human resources available includes:

- Specialized staff (pharmacists and biochemists) 4
- Qualified technicians 3
- Administrative staff 1

The laboratory is reasonably equipped to control the quality of drugs by means of physico-chemical analysis. Tests carried out include: hardness, friability, dissolution, uniformity of weight, identification test and determination of active ingredients.

In 1991 and 1992, the laboratory tested a total of 89 drug samples submitted by the Pharmacy Board of Ghana, the Central Medical Stores of Ghana and the WHO Office in Ghana. The laboratory has not tested drug samples in 1993. The break down for the three years is:

<table>
<thead>
<tr>
<th>Year</th>
<th>No. of samples tested</th>
</tr>
</thead>
<tbody>
<tr>
<td>1991</td>
<td>45</td>
</tr>
<tr>
<td>1992</td>
<td>44</td>
</tr>
<tr>
<td>1993</td>
<td>0</td>
</tr>
</tbody>
</table>
The number of samples analyzed by type of test was:

Physico-chemical  
Microbiological  
Others

<table>
<thead>
<tr>
<th>Type</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physico-chemical</td>
<td>89</td>
</tr>
<tr>
<td>Microbiological</td>
<td>28</td>
</tr>
<tr>
<td>Others</td>
<td>3</td>
</tr>
</tbody>
</table>

In the past three years, the laboratory tested three samples submitted by two African countries, namely Liberia and Sierra Leone. It has also collaborated in an inter-laboratory trial tests for condoms initiated by American Programme for Appropriate Technology and has been involved in the training of quality control personnel for local industries.

The average cost of a test by formulation is Cedis 25,000 or US$ 50 for all types of formulations. The tests carried out were limited to physico-chemical and microbiological methods.

The minimum and maximum time required to analyze one drug sample ranges from 1 to 14 days.

Weakness

The laboratory is under utilized and is not functioning as a regional laboratory. Problems of functioning and causes for under utilization are:

- lack of a legal base authorizing the laboratory to carry out quality control tests and issue certificates,
- lack of a proper administrative framework,
- lack of linkage with the Pharmacy Board of Ghana and the Ministry of Health, and
- competition with the drug quality control laboratory of the Pharmacy Board of Ghana.

3.3 Regional drug quality control laboratory of Niger

The National Public Health Laboratory and Expertise of Niger functions under the National Office of Pharmaceutical Products and Chemicals (ONPPC). It was created after the formation of ONPPC and has no special creation act. It started operating in 1981.

ONPPC, on the other hand, is a public sector drug importing and producing agency under the Ministry of Health. The Ministry of Health is, therefore, the final authority to supervise both the laboratory and ONPPC.

The capital and running costs of the laboratory are covered by ONPPC. The budgets during the last three years were:

<table>
<thead>
<tr>
<th>Year</th>
<th>Amount in US$</th>
</tr>
</thead>
<tbody>
<tr>
<td>1993</td>
<td>192,857</td>
</tr>
<tr>
<td>1992</td>
<td>175,000</td>
</tr>
<tr>
<td>1991</td>
<td>172,837</td>
</tr>
</tbody>
</table>

30
The laboratory has a staff of 14, consisting:

- Specialized staff: 2
- Qualified technical staff: 9
- Others: 3

Between 1991 and 1993 (September), the laboratory tested a total of 2924 samples i.e. 621 (1993 Sept.), 1092 (1992) and 1211 (1991). The number of samples analyzed by category was:

- Galenic: 53
- Physico-chemical: 2924
- Microbiological: 987

Samples were obtained from ONPPC (imported and locally manufactured drugs), police and Red Cross. The types of tests performed included: physico-chemical, sterility and pyrogen tests.

Under a sub-regional cooperation, the laboratory tested drug samples from Togo, Burkina Faso and Benin. The number of samples tested and the cost of analysis were:

<table>
<thead>
<tr>
<th>Country</th>
<th>Year</th>
<th>Samples</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Togo</td>
<td>1992</td>
<td>8</td>
<td>46,800 CFA</td>
</tr>
<tr>
<td></td>
<td>1991</td>
<td>2</td>
<td>Free</td>
</tr>
<tr>
<td>Burkina Faso</td>
<td>1991</td>
<td>5</td>
<td>23,400 CFA</td>
</tr>
<tr>
<td>Benin</td>
<td>1993</td>
<td>4</td>
<td>26,370 CFA</td>
</tr>
</tbody>
</table>

The laboratory collaborates with Mali and Senegal in the exchange of information. In Europe, it collaborates with France, Germany and Austria in quality assurance training programmes.

The average cost of a test by formulation is:

- Tablet/capsule: 4,500 CFA
- Syrup: 3,500 CFA
- Injectable vial: 18,000 CFA
- Solution for perfusion: 27,000 CFA

The minimum and the maximum delays for one analysis are:

- Sachet and syrup: 2 to 4 days
- Solid: 14 days

The laboratory is also engaged in other activities such as water and food analysis, pesticide analysis, forensic investigation, training of technicians and in research programmes.

Weakness

The laboratory is under utilized as a regional laboratory.

Main problems are:

- lack of a legal base and a proper administrative framework,
- lack of linkage with the drug regulatory authority.
- lack of training in the operation of major laboratory instruments and lack of maintenance facilities for equipment.

3.4 **Regional drug quality control laboratory of ZIMBABWE**

The Zimbabwe Regional Drug Quality Control Laboratory is a joint project between WHO and the Ministry of Health of Zimbabwe. It was established as a result of the signing of a Technical Agreement on January 1, 1986 to establish a sub regional III Quality Control Laboratory in Harare to serve Zimbabwe and the other countries in sub-region III.

Organizationaly, the laboratory comes under the administrative structure of the Drug Quality Assurance Board (DQAB) of Zimbabwe which is a legal body established by the Drugs Control and Allied Substances Act to ensure and promote the provision of adequate, suitable drug control laboratory facilities in Zimbabwe in order to ensure the quality, safety, and efficacy of drugs (human and veterinary), cosmetics, chemicals, foods, medical devices and related substances; to provide training facilities in drug analysis and related fields.

The purposes of the laboratory include, among others, the following:

1. To test drugs and allied substances for various purposes.
2. To serve as a Regional Training Center for drug analysis.
3. To develop a database and furnish drug regulatory information for the subregion.
4. To carry out accelerated stability studies as requested by clients and other joint projects.

The Ministry of Health of Zimbabwe has the overall supervisory authority over both the Board and the Regional Drug Quality Control Laboratory.

The budgets of the laboratory for the last three years were:

<table>
<thead>
<tr>
<th>Year</th>
<th>Amount (US$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1993</td>
<td>50,000</td>
</tr>
<tr>
<td>1992</td>
<td>40,000</td>
</tr>
<tr>
<td>1991</td>
<td>20,000</td>
</tr>
</tbody>
</table>

The sources of funds were: WHO, the Standards Development Fund (SDF) and funds generated by the laboratory.

The human resources of the laboratory consists of:

<table>
<thead>
<tr>
<th>Category</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specialized staff</td>
<td>7</td>
</tr>
<tr>
<td>Qualified technical staff</td>
<td>19</td>
</tr>
<tr>
<td>Administrative staff</td>
<td>9</td>
</tr>
<tr>
<td>Others</td>
<td>2</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>37</td>
</tr>
</tbody>
</table>

The laboratory is equipped to carry out physico-chemical and microbiological tests, such as uniformity of weight, fill volume, disintegration, dissolution, uniformity of content, identification, impurities and related substances identification, refractive index, relative density, viscosity and assay of active ingredients and microbial contamination, sterility tests and microbiological assay.
During the past three years the laboratory tested a total of 2348 drug samples and the breakdown is:

<table>
<thead>
<tr>
<th>Year</th>
<th>Samples tested</th>
</tr>
</thead>
<tbody>
<tr>
<td>1993 (August)</td>
<td>437</td>
</tr>
<tr>
<td>1992</td>
<td>1216</td>
</tr>
<tr>
<td>1991</td>
<td>695</td>
</tr>
</tbody>
</table>

The number of samples analyzed by test types was:

- Galenic: 144
- Physico-chemical: 2004
- Microbiological: 356

The samples for analysis came from the University of Zimbabwe, private drug manufacturers, hospitals, WHO, UNICEF, and countries of the region.

Under a sub-regional cooperation, the laboratory accepted and analyzed drug samples from countries in Africa. The following are some of the countries which sent samples for analysis:

<table>
<thead>
<tr>
<th>Countries</th>
<th>Year</th>
<th>Samples</th>
<th>Cost in US$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Namibia</td>
<td>1993</td>
<td>5</td>
<td>199.00</td>
</tr>
<tr>
<td>Namibia</td>
<td>1992</td>
<td>5</td>
<td>186.60</td>
</tr>
<tr>
<td>Botswana</td>
<td>1993</td>
<td>2</td>
<td>182.10</td>
</tr>
<tr>
<td>Botswana</td>
<td>1992</td>
<td>1</td>
<td>109.25</td>
</tr>
<tr>
<td>Zambia</td>
<td>1993</td>
<td>1</td>
<td>267.00</td>
</tr>
<tr>
<td>Zambia</td>
<td>1992</td>
<td>2</td>
<td>203.00</td>
</tr>
</tbody>
</table>

Other countries which cooperated with the laboratory but for which data have not been submitted by Zimbabwe are Mozambique, Seychelles and Mauritius.

The Regional laboratory collaborates with Medicines Testing Laboratory in UK in the training of ZRDCQL staff, the Danish National Laboratory in analytical results validation, and with the Swedish National Laboratory in chemical reference standards. It also collaborates with the FDA of the States of America. The laboratory is actively engaged in planned testing of steroids, condoms, syringes and needles.

The average cost of a test by formulation is:

<table>
<thead>
<tr>
<th>Formulation</th>
<th>Cost in US$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tablet/capsule</td>
<td>50.0</td>
</tr>
<tr>
<td>Syrup</td>
<td>43.3</td>
</tr>
<tr>
<td>Injectable, vial</td>
<td>43.3</td>
</tr>
<tr>
<td>Solution for perfusion</td>
<td>82.4</td>
</tr>
<tr>
<td>Suppository</td>
<td>43.4</td>
</tr>
<tr>
<td>External solutions</td>
<td>82.4</td>
</tr>
</tbody>
</table>

The minimum and maximum delays for one analysis are:

- Chemistry: 3 to 7 days
- Microbiology: 13 to 42 days
Weakness

It is under utilized as a regional laboratory.

Major problems of the laboratory are reported to be: poor payment by clients, difficulty to procure spare parts, backup services and reagents.

4. ANALYSIS OF THE FINDINGS

The regional drug quality control laboratory in Zimbabwe tested, on the average, 939 drug samples per year during the last three years, while that of Niger analyzed 1043 drug samples annually. Comparison of these figures to the number of specialized staff working in the laboratories, which is seven and two respectively, gives the number of samples tested annually by one analyst as 134 for Zimbabwe and 521 for Niger. Calculation in terms of the staff working in the laboratories will give the number of samples tested annually by each staff as 25 and 75 respectively. The figures for Cameroon and Ghana are 27.3 and 7.4 samples per analyst, per year, or 6.8 and 4.2 per year/ per staff respectively.

The above findings show that the laboratories in Niger and Zimbabwe have less problems in functioning as national laboratories and are better utilized than the laboratories in Cameroon and Ghana.

Some of the factors which may have contributed to the optimal use of the laboratory in Zimbabwe could be that:

a. It operates as an organ of the Drug Quality Assurance Board of Zimbabwe.

b. It is legally authorized to carry out drug quality control tests and issue certificates.

c. It has relatively adequate number of trained human resources and support staff.

d. It has adequate budget and it is permitted to use the funds generated from the testing of drugs to expand and improve its services.

e. It has the necessary equipment and facilities to carry out diverse physico-chemical and microbiological tests.

f. It has better sub-regional cooperation as well as better collaboration with other countries in Africa and Europe.

The laboratory of Niger is not organized under the administrative framework of the national drug regulatory authority of Niger and has less staff than Zimbabwe. But, it has tested more samples than Zimbabwe. This may be due to one of the following reasons:

(1) That drugs produced and imported by ONPPC are routinely tested before they are placed on the market.

(2) The cost of analysis is low.

(3) The delay time for analysis of drug samples is short.

Comparison of the average costs of a test by formulation of the laboratories in Cameroon, Ghana, Niger and Zimbabwe shows that the price schedules developed by Zimbabwe and Niger are more reasonable than those of Cameroon and Ghana. The price tariffs of Zimbabwe acknowledges the
disparity in effort between the examination of different formulations. The average cost of a test in Ghana is US$ 50.- irrespective of the type of formulation. The average cost of a test in Cameroon, on the other hand, is much higher than in Ghana, Niger and Zimbabwe. The cost of analysis in Niger is much lower and reasonable than the costs of analysis in the three countries. In general, the costs of analysis differ very much between the countries and need to be standardized and made comparable to the services rendered.

The laboratories in Cameroon and Ghana tested very few drug samples in 1991 and 1992. Both laboratories have not carried out analysis in 1993. The reasons for their under utilization could be:

1. Lack of collaboration with the drug regulatory authorities/ lack of proper administrative framework for the laboratories to function effectively.

2. Absence of legislation which gives power to control the quality of drugs and issue certificates.

3. The presence of a competing drug quality control laboratory specially in the case of Ghana.

4. Lack of adequate budget, qualified staff and shortage of laboratory facilities such as chemicals, glassware, etc. in case of Cameroon.

Comparison of the delay time for one analysis indicates that Zimbabwe takes much longer time to perform microbiological tests than the other laboratories.

5. CONCLUSIONS

The four laboratories are not functioning as regional laboratories. The laboratory in Ghana is not adequately used as a national laboratory and the one in Cameroon is not functioning at all.

6. RECOMMENDATIONS

A drug quality control laboratory plays a complementary role with other sections of a drug control administration in assuring the safety, efficacy and quality of medicines. A modest laboratory working within a proper administrative framework in collaboration with other sections of a drug control administration can be more effective than a big laboratory working without such administrative support and collaboration. Such a laboratory can contribute effectively by:

a. Examining the quality of samples of drugs prior to granting registration certificates.

b. Evaluating written test methods and specifications of product application.

c. Testing samples in connection with the procurement of drugs.

d. Acting as a quality control laboratory for small scale pharmaceutical manufacturers.

e. Serving as a regional drug quality control laboratory for other countries, etc.

To promote optimum utilization of the regional drug quality control laboratories the following are recommended:

a. A strong national drug control administration should be established by statute in countries where it does not exist.
Laboratories which have no linkage with drug regulatory authorities should be reorganized as sections of the drug control administration and should be made to operate in collaboration with other sections of the administration.

The laboratories should be given a legal basis and a proper administrative framework to control the quality of drugs and to issue certificates.

The drugs to be tested and the type of tests to be applied should be defined.

A sampling scheme which will ensure optimum use of laboratory resources should be outlined.

Adequate number of qualified human resources and auxiliary staff should be assigned.

Adequate budget and essential laboratory facilities including, equipment, chemicals, glassware, books, etc., should be made available.

The cost of analysis should be commensurate with the services rendered and a system of subsidizing the cost of analysis should be looked into.

The delay time for analysis should be shortened so that countries will be encouraged to send samples for testing.
Annex 1

Summary of responses of the four regional drug quality control laboratories
### SUMMARY OF THE RESPONSES OF THE FOUR REGIONAL DRUG QUALITY CONTROL LABORATORIES

<table>
<thead>
<tr>
<th>Questionnaire</th>
<th>Cameroon</th>
<th>Ghana</th>
<th>Niger</th>
<th>Zimbabwe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Creation Act</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>Yes</td>
</tr>
<tr>
<td>Date of implementation of activities</td>
<td>1990</td>
<td>1991</td>
<td>1981</td>
<td>1990</td>
</tr>
<tr>
<td>Ministry responsible</td>
<td>MOH</td>
<td>Ministry of Trade and Industry</td>
<td>MOH</td>
<td>MOH</td>
</tr>
<tr>
<td>Legal status</td>
<td>Public service</td>
<td>Public service</td>
<td>Public service</td>
<td>Public service</td>
</tr>
<tr>
<td>Budget in US$:</td>
<td>NA</td>
<td>25,714</td>
<td>192,857</td>
<td>500,000</td>
</tr>
<tr>
<td></td>
<td>1992 NA</td>
<td>20,000</td>
<td>175,000</td>
<td>400,000</td>
</tr>
<tr>
<td></td>
<td>1991 NA</td>
<td>22,875</td>
<td>172,000</td>
<td>200,000</td>
</tr>
<tr>
<td>Sources of funds</td>
<td>ONAPHARM</td>
<td>Government</td>
<td>ONNPC</td>
<td>WHO, SDF, and funds of the laboratory</td>
</tr>
<tr>
<td>Human resources:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>* Specialized staff</td>
<td>1</td>
<td>4</td>
<td>2</td>
<td>7</td>
</tr>
<tr>
<td>* Qualified technicians</td>
<td>0</td>
<td>3</td>
<td>9</td>
<td>19</td>
</tr>
<tr>
<td>* Administrative staff</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>9</td>
</tr>
<tr>
<td>* Others</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>No. of drug samples analyzed:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1993</td>
<td>0</td>
<td>0</td>
<td>621</td>
<td>437</td>
</tr>
<tr>
<td>1992</td>
<td>52</td>
<td>44</td>
<td>1092</td>
<td>1216</td>
</tr>
<tr>
<td>1991</td>
<td>30</td>
<td>45</td>
<td>1211</td>
<td>695</td>
</tr>
<tr>
<td>No. of samples analyzed by type of tests:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>* Galenic</td>
<td>0</td>
<td>0</td>
<td>53</td>
<td>144</td>
</tr>
<tr>
<td>* Physico-chemical</td>
<td>82</td>
<td>89</td>
<td>1924</td>
<td>2004</td>
</tr>
<tr>
<td>* Microbiological</td>
<td>0</td>
<td>28</td>
<td>737</td>
<td>356</td>
</tr>
<tr>
<td>* Others</td>
<td>0</td>
<td>3</td>
<td></td>
<td>0</td>
</tr>
</tbody>
</table>
### SUMMARY OF THE RESPONSES OF THE FOUR REGIONAL DRUG QUALITY CONTROL LABORATORIES

(Continued)

<table>
<thead>
<tr>
<th>Questionnaire</th>
<th>Cameroon</th>
<th>Ghana</th>
<th>Niger</th>
<th>Zimbabwe</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Origin of samples</strong></td>
<td>* ONAPHARM</td>
<td>* Pharmacy Board</td>
<td>* ONPPC</td>
<td>* University of Zimbabwe</td>
</tr>
<tr>
<td></td>
<td>* Private importers</td>
<td>* Central Medical Stores</td>
<td>* Police</td>
<td>* Private manufacturers</td>
</tr>
<tr>
<td></td>
<td>* NGOs</td>
<td>* WHO, Accra</td>
<td>* Red Cross</td>
<td>* Hospitals</td>
</tr>
<tr>
<td></td>
<td>* Others</td>
<td></td>
<td></td>
<td>* Other countries</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* WHO, UNICEF</td>
</tr>
<tr>
<td><strong>Average cost of a test:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>* Tablet</td>
<td>CFA</td>
<td>US$</td>
<td>CFA</td>
<td>US$</td>
</tr>
<tr>
<td></td>
<td>60,000</td>
<td>204</td>
<td>4,500</td>
<td>16</td>
</tr>
<tr>
<td>* Capsule</td>
<td>50,000</td>
<td>178</td>
<td>4,500</td>
<td>16</td>
</tr>
<tr>
<td>* Syrup</td>
<td>50,000</td>
<td>178</td>
<td>3,500</td>
<td>12</td>
</tr>
<tr>
<td>* Injectable vial</td>
<td>50,000</td>
<td>178</td>
<td>18,000</td>
<td>64</td>
</tr>
<tr>
<td>* Solution for perfusion</td>
<td>50,000</td>
<td>178</td>
<td>27,000</td>
<td>96</td>
</tr>
<tr>
<td>* Suppository</td>
<td>50,000</td>
<td>178</td>
<td></td>
<td></td>
</tr>
<tr>
<td>* External solution</td>
<td>50,000</td>
<td>178</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Minimum and maximum delays</strong></td>
<td>2-7 days</td>
<td>1-14 days</td>
<td>2-14 days</td>
<td>Chemistry 3-7 days</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Microbiology 14-42 days</td>
</tr>
<tr>
<td><strong>Priority criteria for selecting</strong></td>
<td>* Source of origin</td>
<td>* Essential drugs</td>
<td>* Essential drugs</td>
<td>Essential drugs</td>
</tr>
<tr>
<td>drugs for quality control testing</td>
<td>* Generic products</td>
<td>* Drugs used for disease eradication programme</td>
<td>* Degradable essential drugs</td>
<td></td>
</tr>
<tr>
<td></td>
<td>* High consumption drugs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>* Form of drug</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>* Drugs used for local diseases</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Sub-regional cooperation</strong></td>
<td>NA</td>
<td>Liberia</td>
<td>University of Dakar, Lome</td>
<td>* Namibia</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sierra Leone</td>
<td></td>
<td>* Botswana</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Mozambique</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Seychelles</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Mauritius</td>
</tr>
<tr>
<td><strong>Collaboration</strong></td>
<td>Belgium</td>
<td>Condom testing with USA</td>
<td>WHO, University of Dakar, GTZ/Germany, Canada, IDA</td>
<td>* Medicines Testing Laboratory, UK</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>WHO, University of Dakar, GTZ/Germany, Canada, IDA</td>
<td>* Swedish National Laboratory, Sweden</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Danish National Laboratory</td>
</tr>
<tr>
<td>Questionnaire</td>
<td>Cameroon</td>
<td>Ghana</td>
<td>Niger</td>
<td>Zimbabwe</td>
</tr>
<tr>
<td>---------------------------------------------------</td>
<td>----------</td>
<td>----------------</td>
<td>--------------------</td>
<td>-------------------------------</td>
</tr>
</tbody>
</table>
| List of active substances in accordance with the criteria above | * Antimalarials  
* Antiparasites  
* Anti-infectives  
* Analgesics  
* Antipyretics  
* Antihypertensives | * Antibiotics  
* Antibacterials  
* Antimalarials  
* Anthelminitics  
* Analgesics  
* Oral rehydration  
* Anti-inflammatory agents | * See Annex 3 | * Tetracycline  
* Gentamycin  
* Rifampicin  
* Acetaminophen  
* Phenacetin  
* Paracetamol  
* Phenylbutazone |
| Other laboratory activities:                      | No       | No             | Yes                | No                           |
| * Water and food analysis                         | No       | Yes            | Yes                | No                           |
| * Pesticides                                      | No       | Yes            | Yes                | No                           |
| * Training                                        | No       | Yes            | Yes                | Yes                          |
| * Others                                          | Condoms testing | Condoms testing | Yes                | Condoms, syringes, needles |
| General comments                                  | * Laboratory should be autonomous  
* Organization and effectiveness of pharmacy inspection  
* Registration of drugs  
* Training of personnel  
* Budget  
* Harmonization of legislation | NA       | * Maintenance  
* Lack of training in analytical instruments  
* Collaboration with laboratories in other countries | * Poor payment by clients  
* Difficulty to procure spare parts, back-up services and reagents  
* Good cooperation with countries of the region |
Annex 2
RDQCL questionnaire

1. Laboratory name .................................................................
   Address: ...........................................................................
   Telephone: .........................................................................
   Fax: ................................................................................

2. Creation act ........................................................................
   dated: .................................................................................
   (Please attach a copy of the act)

3. Date of implementation of the activities ................................

4. Ministry responsible ..............................................................

5. Legal status ...........................................................................
   * public service: ..................................................................
   * autonomous agency: ..........................................................
   * others (please specify): .....................................................

6. Budget for
   * 1993: ..............................................................................
   * 1992: ..............................................................................
   * 1991: ..............................................................................

7. Sources of funds ......................................................................
   ..........................................................................................
   ..........................................................................................

8. Human resources 30 June 1993
   * specialized staff (pharmacist, engineer, etc.):
     ....................................................................................
   * qualified technical staff for laboratory activities:
     ....................................................................................
   * administrative staff:
     ....................................................................................

41
9. Number of drug samples analyzed in

* 1993: .........................................................
* 1992: .........................................................
* 1991: .........................................................

10. Number of samples analyzed by type of tests

* galenic: .........................................................
* physicochemical: .............................................
* microbiological: .............................................
* pharmacological: ............................................
* others: .........................................................

11. Origin of the samples

* Department of Pharmacy: ......................................
* referred to for expertises: ....................................
* others (please specify): ....................................

12. Sub-regional cooperation

List of countries asking for analyses. Please specify the number of analyses by country, cost and mode of payment:

<table>
<thead>
<tr>
<th>Country</th>
<th>Number of samples</th>
<th>Cost in US$</th>
<th>Mode of payment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1993:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1992:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1991:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1993:</td>
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<td>1991:</td>
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<td>1993:</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>1992:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1991:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

13. Collaboration with other laboratories (with detail on the type of collaboration)

* in Africa, country: ........................................
* in Europe, country: ......................................
* others: ......................................................
14. Average cost of a test by pharmaceutical formulation, in local currency and in US$:
   * tablet, capsule:
   * syrup:
   * injectable vial:
   * solution for perfusion:
   * suppository:
   * solution for external use:

15. Minimum and maximum delays for one analysis according to the pharmaceutical formulation:

16. In your view, which should be the priority criteria for selecting drugs for quality control testing?

17. List the actives substances/products in accordance with the criteria selected above, under 16:

18. Do you have other laboratory activities?
   * water and food analysis:
   * pesticides analysis:
   * training:
   * others:

19. General comments (major problems with quality assurance, positive experiences, etc.)
Annex 3

List of drugs to be regularly controlled

1. Acetylsalicylic acid tablet
2. Ascorbic acid tablet
3. Folic acid tablet
4. Aminophylline
5. Amodiaquine
6. Amoxicilline
7. Ampicillin
8. Atropine
9. Benzathine Benzypenicilline
10. Benzylpenicilline
11. Chloramphenicol
12. Chloroquine
13. Chlorpromazine
14. Cloxacillin
15. Co-trimoxazole
16. Dexamethasone
17. Diazepam
18. Epinephrine
19. Ergometrine
20. Erythromycin
21. Furosemide
22. Gentamicin
23. Haloperidol
24. Hydrocortisone
25. Hydroxocobalamin
26. Hydroxyzine
27. Indomethacin
28. Ketamine
29. Levodopa
30. Lidocaine
31. Mebendazole
32. Methyl dopa
33. Metronidazole
34. Oxytetracycline
35. Paracetamol
36. Phenobarbital
37. Phenoxy methyl penicilline
38. Phytomenadione
39. Praziquantel
40. Prednizolone
41. Procaine Benzylpenicilline
42. Promethazine
43. Propanolol
44. Pyranthel
45. Pyridoxine
46. Ferruos salts
47. Quinine salts
48. Oral rehydration salts
49. Glucose solutions
50. Ringer solution
51. Saline solutions
52. Streptomycin
53. Thiamine
54. Tetracycline
55. Thiopental
56. Tinidazole
Annex 4

Consolidated report on four departments of pharmacy in drug quality control: Burkina Faso, Côte d'Ivoire, Kenya and Zambia

1. INTRODUCTION

WHO prepared a questionnaire entitled "Questionnaire No.2 (Director of Pharmacy)" and distributed to the directors of pharmacies in four countries, namely, Burkina Faso, Côte d'Ivoire, Kenya and Zambia to collect information relevant to the quality control of drugs. The report is based on the information supplied by the four directors of pharmacies. A summary of the responses of the four directors of pharmacies is at the end of this annex.

2. OBJECTIVE OF THE STUDY

The specific objective of the questionnaire was to assess the application of quality control tests to drugs imported into the respective countries.

3. SUMMARY OF THE RESPONSES

3.1 Drug registration

In all the countries, the number of drugs available on the market is more than the number of drugs registered. In Kenya and Zambia the number of drugs available on the market is not known but in Burkina Faso and Côte d'Ivoire it is estimated to be 1991 and 4200 respectively.

The number of registered drugs is: 1931 in Burkina Faso; 1982 in Côte d'Ivoire; 4000 in Kenya and 700 in Zambia. In all the countries, there are taxes for registration and import of drugs. In Kenya and Zambia, taxes are collected by the government treasury and the Pharmacy Board. In Burkina Faso and Côte d'Ivoire taxes are collected by the government.

3.2 Quality control

Information obtained from the directors of pharmacies showed that drugs imported into the respective countries are not routinely tested for their quality. For example, in Burkina Faso a total of four samplings were made between 1991 and 1993, while Kenya and Côte d'Ivoire made a total of 112 and 184 samplings during the same period. When compared to the number of drugs registered, the percentage of samplings made by the two directors of pharmacies, per year is 1.8% and 0.5% of the registered drugs respectively.

In the selection of samples for testing, priority is given to drugs: offered for tender, purchased from new suppliers, having bioavailability problem, kept under poor storage conditions, and drugs known to have toxicity problems. Samples are also sent for testing in connection with drug registration and post marketing surveillance. In most cases, sampling is done by pharmacy inspectors. But, in Burkina Faso and Zambia, police and customs officers are also involved in the sampling process.

In Burkina Faso and Côte d'Ivoire, analysis was done locally and in foreign countries, while Kenya and Zambia did their testing locally. Samples are sent by car to local quality control laboratories and by plane and train to laboratories outside the countries. In certain
cases, the cost of despatch of sample is much higher than the cost of analysis. In Burkina Faso, for example, the cost of despatch of sample to Niger was 700 000 FCFA (US$ 245).

The cost of analysis by formulation in Burkina Faso is:

Tablet ........................................ 15 000 FCFA (US$ 52.5)
Injectable vial ............................... 20 000 FCFA (US$ 70.0)

In Côte d'Ivoire the cost of analysis is:

Tablet ........................................ 20 000 FCFA (US$ 70.0)
Syrup .......................................... 35 000 FCFA (US$ 122.5)
Injectable vial ............................... 30 000 FCFA (US$ 105.0)
Solution for perfusion ..................... 30 000 FCFA (US$ 105.0)

The funds for analysis were obtained from government and industries in Kenya and Côte d'Ivoire. In Burkina Faso wholesalers and suppliers covered the cost of analysis.

4. COMMON PROBLEMS

The directors of pharmacies indicated the following problems:

- absence of laboratory facilities to perform basic tests,
- difficulty in interpreting WHO type certificates,
- lack of model certificate for tenders,
- lack of funds and adequate equipment,
- lack of systematic control over drugs,
- difficulty in controlling generic products,
- non availability of information about regional drug control laboratories,
- lack of foreign exchange to equip the laboratories.

5. MAJOR FINDINGS

- registration is not effective and there are illicit markets in all the countries,
- quality control test is not carried out adequately on products available on the market,
- there is no clearly set criteria for selecting samples for quality control,
- in some countries, the cost of despatch of samples is very high when compared to the cost of analysis.

Remark:

There is weak regulatory and analytical control over drugs. The systems available in the countries cannot ensure the safety, efficacy and quality of drugs.
<table>
<thead>
<tr>
<th>QUESTION</th>
<th>Burkina Faso</th>
<th>Côte d'Ivoire</th>
<th>Kenya</th>
<th>Zambia</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 No. of registered drugs</td>
<td>1991</td>
<td>1992</td>
<td>4000</td>
<td>700</td>
</tr>
<tr>
<td>2 No. of commercialized drugs</td>
<td>1991</td>
<td>About 4200</td>
<td>Not known</td>
<td>NA</td>
</tr>
<tr>
<td>3 No. of samplings made by analysis</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>* 1993</td>
<td>1</td>
<td>8</td>
<td>32</td>
<td>NA</td>
</tr>
<tr>
<td>* 1992</td>
<td>1</td>
<td>19</td>
<td>38</td>
<td>NA</td>
</tr>
<tr>
<td>* 1991</td>
<td>2</td>
<td>85</td>
<td>114</td>
<td>NA</td>
</tr>
<tr>
<td>4 Selecting criteria for samplings</td>
<td>* drug offered for open tender</td>
<td>* source (origin)</td>
<td>* registered drugs and,</td>
<td></td>
</tr>
<tr>
<td>* support to MEDIFA</td>
<td>* storage condition</td>
<td>* drugs with bioavailability problem</td>
<td></td>
<td></td>
</tr>
<tr>
<td>pharmaceutical production ind.</td>
<td>* change of formulation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>* problem of toxicity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 WHO is in charge of sampling</td>
<td>Pharmacy inspectors in presence of police</td>
<td>Pharmacy Insp.</td>
<td>Pharmacy inspectors and the Director of NDQCL</td>
<td>Pharmacy inspectors, police inspectors, customs officers.</td>
</tr>
<tr>
<td>6 Place of analysis</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>* in the country</td>
<td>NSRI</td>
<td>National Public Health Lab.</td>
<td>DARU, NDQCL</td>
<td>Food and Drug Control</td>
</tr>
<tr>
<td>* in foreign country</td>
<td>ONPFC, Nimay, Bieff Lab, Italy</td>
<td>France</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7 Mode of despatch of samples</td>
<td>Car, air</td>
<td>Air</td>
<td>Car</td>
<td>Car</td>
</tr>
<tr>
<td>8 Average cost of despatch</td>
<td>1000 FCFA (US$ 3.5) local</td>
<td>10 000 FCFA (US$ 35)</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>* 70 000 FCFA (US$ 245)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9 Average cost of analysis by formulation:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>* Tablet</td>
<td>150 000 FCFA (US$ 52.5)</td>
<td>20 000 FCFA (US$ 70.0)</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>* Syrup</td>
<td>NA</td>
<td>35 000 FCFA (US$ 122.5)</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>* Injectable vial</td>
<td>20 000 FCFA (US$ 70.0)</td>
<td>30 000 FCFA (US$ 105.0)</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>* Solution for perfusion</td>
<td>NA</td>
<td>30 000 FCFA (US$ 105.0)</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>10 Cost of analysis made in:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>* 1991</td>
<td>None</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>* 1992</td>
<td>None</td>
<td>NA</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>* 1993</td>
<td>120 000 FCFA (US$ 420)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11 Sources of funds</td>
<td>Wholesalers and industries</td>
<td>Government and laboratories</td>
<td>Government</td>
<td>NA</td>
</tr>
<tr>
<td>12 Do drug importation taxes exist?</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>14 Criteria for the selection of drugs for regular control</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>* generic products for tender</td>
<td>* essential drugs,</td>
<td>* drugs with bioavailability problem,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>* drugs for public consumption,</td>
<td>* drug of high consumption,</td>
<td>* deterioration problem,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>* drugs used in high incidence</td>
<td>* galenic form,</td>
<td>* generic anti-infectives, and</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>* irregular bioavailability,</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>* thermostable products.</td>
<td></td>
</tr>
</tbody>
</table>
### SUMMARY OF THE RESPONSES OF THE FOUR DIRECTORS OF PHARMACIES TO THE WHO QUESTIONNAIRE

(Continued)

<table>
<thead>
<tr>
<th>QUESTION</th>
<th>Burkina Faso</th>
<th>Côte d'Ivoire</th>
<th>Kenya</th>
<th>Zambia</th>
</tr>
</thead>
</table>

NA = not available
Annex 5

Consolidated report on four central medical stores in drug quality control: Benin, Gambia, Malawi and Mozambique

1. INTRODUCTION

A questionnaire entitled, "Central Medical Stores Questionnaire" was prepared and copies were sent to the central medical stores of Benin, Gambia, Malawi and Mozambique. The questionnaire consisted of 10 questions and its objective was to collect information on procurement and quality control of drugs by the four central medical stores. The central medical stores of Benin, Gambia and Malawi responded to the questionnaire while Mozambique sent a general report on the pharmaceutical situation of the country. The consolidated report is based on the responses of the three central medical stores. A summary of the responses is attached to this annex.

2. OBJECTIVE OF THE STUDY

The objective of the study was to assess if the four central medical stores have a reliable quality control system to assure the quality of the drugs they procure.

3. SUMMARY OF THE RESPONSES

The central medical store (CMS) of Gambia is the oldest (1950) of the four central medical stores. The CMS of Benin, Malawi and Mozambique were established in 1991, 1984 and 1977 respectively.

All the stores operate as public organization under the MOH with a certain degree of autonomy. Drug procurement is based on a budget which is allocated by the government annually. The drug budgets for the four stores ranged from US$ 337 500 for Benin to US$ 9 million for Malawi.

Information obtained on drugs purchased by the four CMS in 1993 was inadequate. However, all reported that they have purchased drugs in 1993 and most of the drugs bought were generics. None of them knew if the drugs purchased by them were registered with the drug regulatory authorities in their respective countries.

In general, drugs procured by the stores are not tested for their quality. The Central Medical Stores of Benin which had a budget of US$ 8 500 for quality control sent only seven samples for testing in 1992. No quality control testing was done in 1993. The remaining central medical stores reported that they have no budget for quality control. All the stores depend on the services of foreign laboratories.

Although there are no clearly set criteria for selection of samples for laboratory testing, it is reported that drugs with high consumption rate and in large stock are sent for testing.
4. **MAJOR FINDINGS**

* Procurement of drugs by the stores is not limited to drugs registered by the drug regulatory authorities in the respective countries. There is no linkage between drug regulatory authorities and the central medical stores.

* The quality of the drugs procured is not tested both at the time of buying and receiving.

* There are no quality control laboratories within the countries.

* Criteria for the selection of samples are not well established.

5. **REMARK**

Procurement practice is poor and there is no quality assurance system to guarantee the quality of drugs.
<table>
<thead>
<tr>
<th>QUESTION</th>
<th>Benin</th>
<th>Gambia</th>
<th>Malawi</th>
<th>Mozambique</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Creation date</td>
<td>1991</td>
<td>1950</td>
<td>1984</td>
<td>1977</td>
</tr>
<tr>
<td>2 Status</td>
<td>Autonomous</td>
<td>Public (semi-autonomous)</td>
<td>Public (semi-autonomous)</td>
<td>Semi-autonomous</td>
</tr>
<tr>
<td>3 Budget:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>* 1993 US$ 335 000</td>
<td></td>
<td>US$ 7.3 million</td>
<td>US$ 9.76</td>
<td>NA</td>
</tr>
<tr>
<td>* 1992 US$ 340 000</td>
<td></td>
<td>US$ 6.5 million</td>
<td>US$ 9.00</td>
<td>NA</td>
</tr>
<tr>
<td>* 1991 NA</td>
<td></td>
<td>NA</td>
<td>US$ 8.26</td>
<td>NA</td>
</tr>
<tr>
<td>4 No. of drugs bought in 1993:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Branded, registered</td>
<td>NA, NA</td>
<td>NA</td>
<td>15, NA</td>
<td>NA, NA</td>
</tr>
<tr>
<td>Generic, registered</td>
<td>80, NA</td>
<td>NA</td>
<td>190, NA</td>
<td>NA, NA</td>
</tr>
<tr>
<td>Others, registered</td>
<td>25, NA</td>
<td>NA</td>
<td>Plenty, NA</td>
<td>NA, NA</td>
</tr>
<tr>
<td>5 Have QC budget</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>NA</td>
</tr>
<tr>
<td>6 Amount of QC budget</td>
<td>US$ 8 500</td>
<td>None</td>
<td>None</td>
<td>NA</td>
</tr>
<tr>
<td>7 Drugs tested past + 2 years</td>
<td>7 (1992)</td>
<td>NA</td>
<td>1</td>
<td>NA</td>
</tr>
<tr>
<td>Frequency of test</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8 Places of analysis:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>* in country</td>
<td>France</td>
<td>Ghana</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>* in region</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>* elsewhere</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9 Criteria for sample selection</td>
<td>* high consumption</td>
<td>* high consumption</td>
<td>* excess expired stock</td>
<td>NA</td>
</tr>
<tr>
<td>10 Average cost/formulation</td>
<td>US$ 50 - 15 000 FCPA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

NA = not available