Assessment Of Institutional Capacity For Research And Testing Of Plant Medicinal Products In Ghana

A Report Submitted To

The Deputy Director, Traditional Medicines Directorate

Ministry of Health, Accra, Ghana.

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Consultants

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EXECUTIVE SUMMARY

An assessment of institutional capacity for carrying out research on and/or testing of herbal medicines has been carried out using self-administered structured questionnaires and on-site visitation. The survey revealed huge disparities in terms of the location, staff capability and institutional ability to carry out various types of studies.

Out of 21 institutions surveyed, 13 were located in the Greater Accra Region, 5 in the Ashanti Region and one each in the Central,. Eastern and Volta Regions. This creates a potential problem of geographical access to testing centres for practitioners in the northern sector of the country.

Three institutions, the Centre for Scientific Research into Plant Medicine at Mampong-Akwapim, the Noguchi Memorial Institute for Medical Research at Legon, the Faculty of Pharmacy KNUST and the Department of Pharmacology, University of Ghana Medical School have the capacity to carry out studies to ascertain the safety and quality of herbal medicines.

In general, the institutions surveyed have the ability to conduct efficacy studies on plant medicines for certain disease areas although these vary from one institute to the other. However, the ability of each institution to independently carry out research for all disease areas requires strengthening but inter-departmental or institutional collaboration can enhance research output.

The study also revealed that the various institutions visited have peculiar strengths with regard to herbal medicine research and testing. National capacity for herbal medicine research and testing can thus be built by creating multi-disciplinary and inter-departmental teams that would be capable of researching/determining the safety, quality and efficacy of herbal medicines.

A major output of the current consultancy has been the production of a Microsoft Access® database, which gives complete details (staff, equipment, funding, track record, disease areas etc.) of each institution's capacity with regard to research and

testing of herbal medicines. This database, which provides for the addition of new entries should enable accurate details to be kept on institutional capacity for herbal medicine research and testing in Ghana.

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INTRODUCTION

In Ghana, plant medicine is an important component of the health care delivery system. It caters for the health care needs of a large section of the population. Most traditional medical practitioners including spiritual healers use various plant parts as sources of medicines. There are many reasons for the wide patronage of plant medicines in Ghana. These include their affordability, accessibility and cultural harmony compared to allopathic medicine. Currently, there is a proliferation in the number of herbal products on the market with increased sophistication in their packaging and a large number of advertisements in the media. These have contributed to the increased appeal and use of such products even among urban dwellers.

In spite of its wide patronage and immense contribution to health care delivery, herbal medicines have a number of limitations, which make their official acceptance into the national health care delivery system difficult. These concerns are related to their unregulated use (both in frequency and quantity), self-medication, and issues associated with their dosage, efficacy, safety and quality. These and the emergence of charlatan herbal medicine practitioners pushing plant medicine products onto the market have necessitated the regulation of such products.

A Traditional Medicine Law has been enacted in Ghana to address some of the above concerns. This law is designed to regulate the practice of traditional medicine. It is consistent with the policy of WHO on the integration of Traditional or Alternate Medicine into national health care delivery systems (WHO, 1976 and 1978). Under the law, a Traditional Medicine Practice Council (TMPC) is to be established and charged to set the standards for the practice of traditional medicine in Ghana. Thus, a major function of the TMPC is to determine and enforce, in conjunction with recognized association(s) of traditional medicine practitioners, a code of ethics for the practice of traditional medicine.

The Food and Drug Law (1992) mandates the FDB to implement regulatory measures that aim at achieving in Ghana, high standards of safety, efficacy and quality of food and drugs, including herbal medicines. Thus in Ghana, the FDB regulates the

registration, advertisement, manufacture, packaging, preparation, labeling, sale, supply, exportation and importation of all herbal medicines. To this end, the FDB requires evidence of efficacy, safety and quality from FDB-certified institutions before it approves and registers any plant medicine in the country.

A Traditional and Alternative Medicine Directorate (TAMD) has been created within the Ministry of Health with a mandate to oversee reforms that would develop herbal medicine in Ghana. Specifically, the Directorate is to register traditional medical practitioners in the country and identify their training needs. Other functions of the TAMD include establishing procedures and avenues for research into plant medicine and encouraging traditional medical practitioners to test and register their products. This raises the need for adequately resourced research and testing facilities in the country. Although substantial research into plant medicines are undertaken in the country's universities and other research institutes, the research efforts are largely uncoordinated and these institutions have not been used as testing facilities to evaluate the efficacy, safety and quality of plant medicines. Currently, most traditional medicine practitioners who require testing of their products for safety, efficacy and quality have to rely on the Centre for Scientific Research into Plant Medicine in Mampong-Akwapim. This Centre was established in 1975, specifically to conduct and promote scientific research relating to the utilisation of plant medicines in Ghana. However, it is doubtful whether the CSRPM alone has the capability to carry out the wide range of studies required to ascertain the safety, quality and efficacy of herbal medicines. Furthermore, the Centre is located in the Eastern Region of Ghana thus physical accessibility to its service could be difficult to some herbalists.

It is against this background that this survey was undertaken to determine institutions that can research into plant medicine in general, and in particular Centres that do or can assess the efficacy, safety, and quality of plant medicinal products in use in the country.

OBJECTIVES

The specific objectives of the survey were to determine:

a) Institutions that are engaged in plant medicine research and/or testing and their geographical location
b) Personnel strength, experience, qualification(s) and specialization
c) The availability of requisite equipment for testing and the willingness of the institutions to carry out work involving traditional medicine products

METHODS

The survey was carried out in June 2001. A structured questionnaire was developed and pre-tested in consultation with the TAMD (see appendix I for copy).

The consultants visited all relevant research institutions and university departments/faculties with the notable exceptions of the University of Development Studies and the Department of Pharmacognosy, Faculty of Pharmacy, KNUST. Responsible officers in these institutions were interviewed and inventory of all equipment and their state were recorded. Institutions were also requested to indicate additional equipment required to test and/or conduct research into plant medicines.

The team also recorded the staff strength of the institutions, their qualifications and experience in testing plant medicines. In addition, diseases for which institutions have expertise in investigating were also recorded.

RESULTS AND DISCUSSION

Affiliation of Testing Facilities

In all, a total of 21 Institutions were visited. As shown in Figure 1, nearly all the Institutions were found to be in the public sector with only Dr Noamesi's Laboratory, Hohoe being in the private sector. This is perhaps not surprising considering the fact that most producers of herbal medicines operate on a small scale with little or no research and development activities being undertaken. 15 of these potential testing/research sites are in university departments or institutes whilst two (the Ghana Standards Board and the Food and Drugs Board) are statutory regulatory bodies. Two institutes, the Animal Research Institute and the Science and Technology Policy Research Institute are units of the Council for Scientific and Industrial Research whilst the Centre for Scientific Research into Plant Medicine at Mampong-Akwapim, as the name suggests is a national centre set up purposely to conduct scientific in all areas of plant medicine. It is a World Health Organization (WHO) collaborating centre for research into plant medicine. The affiliation of these institutions is depicted in Figure 2.

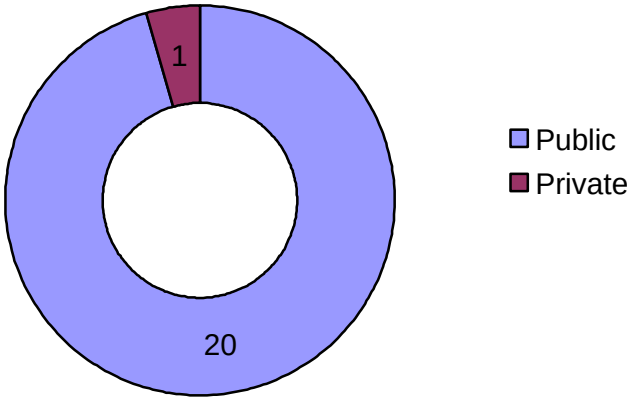

Figure 1 Testing Institutions in Ghana

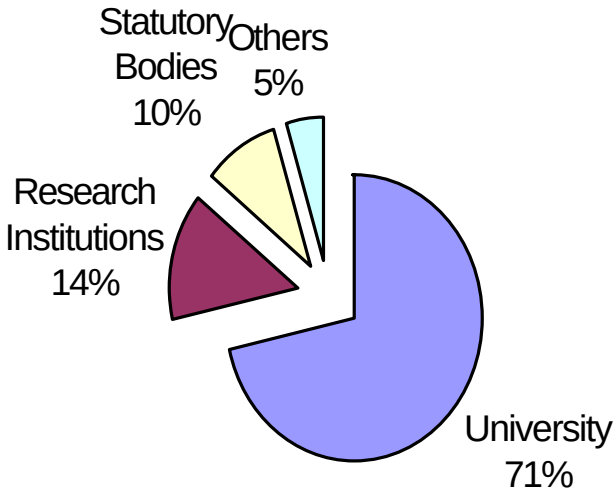

Figure 2 Affiliation of institutions carrying out research on herbal medicines

Regional Distribution of Testing Institutions

The testing institutions visited are all located in the southern and middle sections of the country with the majority being in the Greater Accra Region (Figure 3). The geographical location of these potential sites for testing the safety, efficacy and quality of herbal medicines raises potential problems of physical access for practitioners in the northern sector of the country. A way of improving access and making these services available to practitioners nationwide might be the development of "collection centers" in each district. With proper co-ordination and procedures materials submitted to these centers can then be submitted to the most appropriate research/testing centre regardless of where that centre is located.

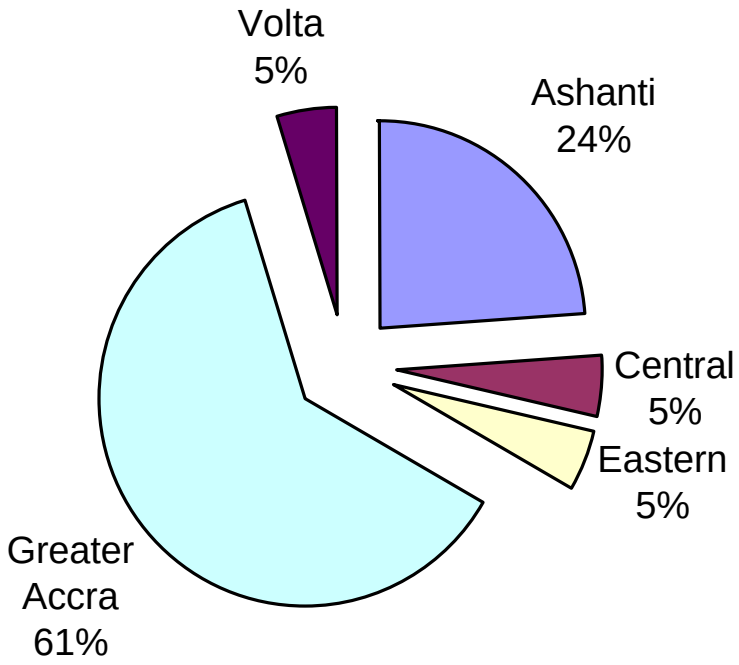

Figure 3 Regional distribution of testing centres

Staffing of Testing Institutions

There are several highly qualified scientists working on herbal medicines. Generally, several researchers who claim to be working on herbal medicines have at least a Masters degree (Figure 4). In addition, there were several others who are currently not

working on herbal medicines but who nevertheless are willing to carry out research into or tests (for safety, quality and efficacy) on herbal medicines (Figure 5). Generally, most of the scientists appear to be working on individual projects which is often based on personal interests. There appeared to be very little co-ordination in the activities of scientists and a national focus on herbal medicine research appeared missing. Most of the institutions surveyed are willing to carry out inter-disciplinary research with other institutions so it should be possible to organize and focus national research and testing on herbal medicines. This task can be spearheaded by the TAMD.

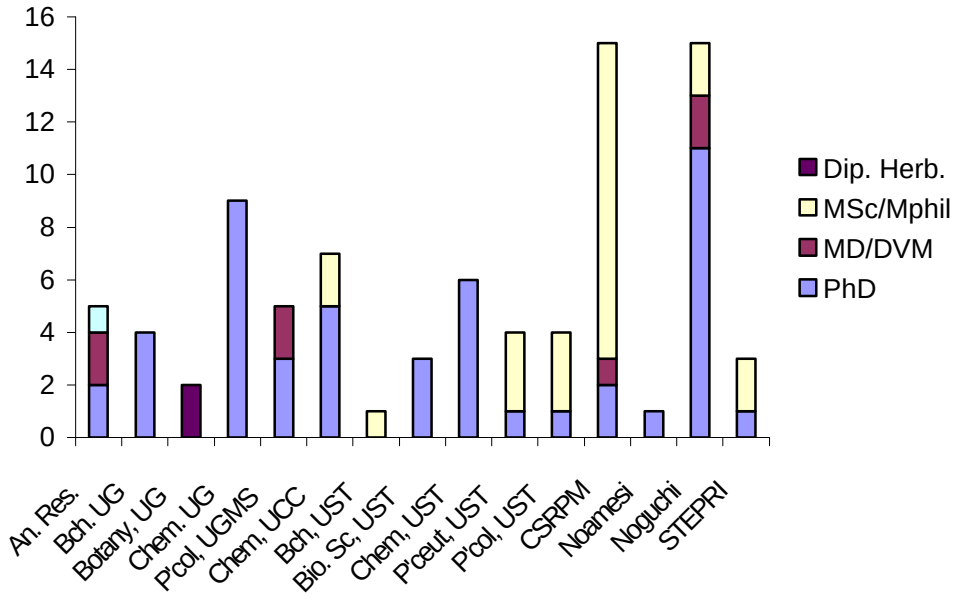

Figure 4: Qualification of staff currently working on herbal medicines

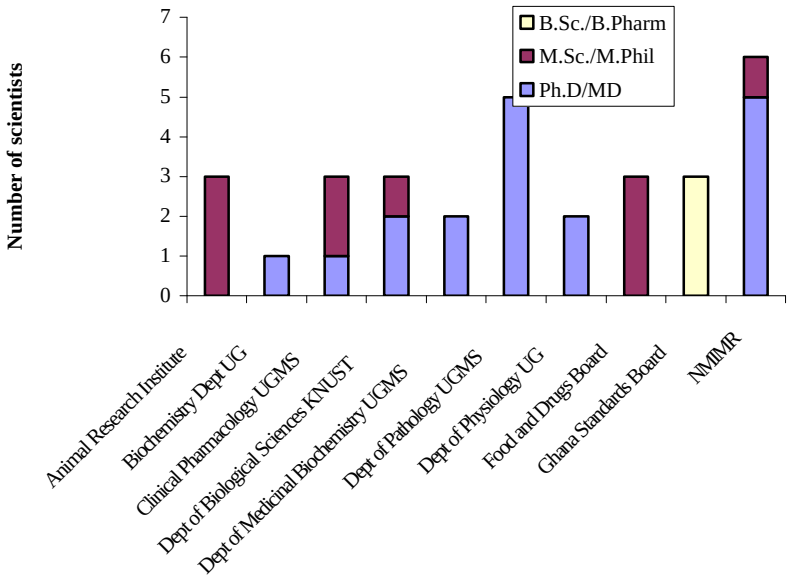

Figure 5 Number and qualification of scientists willing to carry out research on herbal medicines

Scientists working on herbal medicines vary widely in their specialization. There are chemists, pharmacologists, microbiologists, botanists and biochemists all working on herbal medicines (Figure 6). Whilst their research is neither inter-disciplinary nor integrated, the wide range of skills available makes the creation of teams to undertake specific multi-disciplinary research possible.

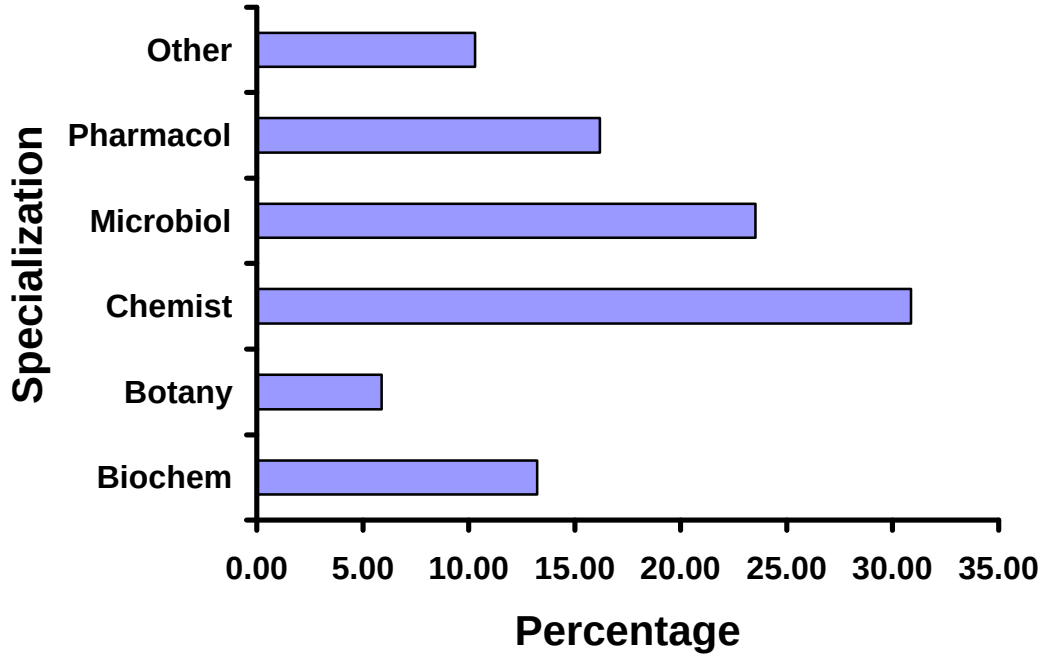

Figure 6 Specialization of Staff with M.Sc./M. Phil degrees or above

Availability of testing equipment

The survey revealed wide disparities in the number, types and functional status of equipment within the various institutions. A detailed inventory was taken of all equipment available as well as of equipment needed by the institutions for traditional medicine research. Full details of these are provided in the ACCESS database but a summary of the types of equipment available in each institution and are presented in the tables below:

ANIMAL RESEARCH INSTITUTIE, CSIR, ACCRA

Available Equipment

Equipment	Functional?
Atomic Absorption Spectrophotometer	Yes
Autoclave	Yes
HPLC	Yes
Incubator	Yes
Spectrophotometer	Yes

Needed Equipment

Coulter Counter

BIOCHEMISTRY DEPARTMENT, KNUST

Available Equipment

Equipment	Functional?
Analytical Balance	Yes
Calorimeter	Not specified
Centrifuge (Table Top)	Not specified
Freezer/Fridge	Not specified
pH Metre	Yes

Needed Equipment

Centrifuges (Refrigerated)

Electrophoretic apparatus

Fraction collector

Spectrophotometer (IR and UV)

Vortex mixer

BIOCHEMISTRY DEPARTMENT, UNIVERSITY OF GHANA

Available Equipment

Equipment	Functional?
Centrifuge (High speed)	Yes
Chromatography (Column & TLC)	Yes
HPLC	No
Incubator	Yes
pH metres	Yes
Rotary evaporator	Yes
Spectrophotometer	Yes

Needed Equipment

Freeze-drier

Spectrophotometer

BOTANY DEPARTMENT, UNIVERSITY OF GHANA

Available Equipment

NONE

Needed Equipment

Computer and accessories

CENTRE FOR SCIENTIFIC RESEARCH INTO PLANT MEDICINE, MAMPONG-AKWAPIM

Available Equipment

Equipment	Functional?
Activity cage	Yes
Autoclave	Yes
BP Machine	No
Calorie counter	No
Centrifuge	Not specified
Counter current extractor	Yes
Flame photometer	No
Freeze dryer	Yes
GC	No
Glucose Analyser	No
Incubator	Yes
IR Spectrophotometer	No
Methysmometer	Yes
Organ bath	Yes
Oven	Yes
Respirometer	Yes
Rotary evaporator	Yes
Tail flick/Hot plate	Yes
UV-Vis Spectrophotometer	No
Water bath	Yes
Weighing balances	Yes

Needed Equipment

Air pump

Anaerobic jar

BP Machine

Colony counter

Densitometer

Gas Chromatograph

HPLC

Laminar flow hood

Microtome

Safety cabinet

Stereomicroscopes

UV-Vis spectrophotometer

CENTRE FOR TROPICAL CLINICAL PHARMACOLOGY AND THERAPEUTICS, UNIVERSITY OF GHANA MEDICAL SCHOOL (UGMS), KORLE-BU

Available Equipment

Equipment	Functional?
HPLC	Yes
Microscopes	Yes
Spectrophotometer	No

Needed Equipment

None specified

CHEMISTRY DEPARTMENT, UNIVERSITY OF GHANA

Available Equipment

Equipment	Functional?
HPLC	Yes
IR Spectrophotometer	Yes
UV Spectrophotometer	Yes

Needed Equipment

Refractometers

NMR

Mass Spectrometers

GLC

DEPARTMENT OF BIOLOGICAL SCIENCES, KNUST

Available Equipment

Equipment	Functional?
Rotary evaporator	Yes
Soxhlet apparatus	Yes
Vacuum pump	Yes

Needed Equipment

Dissecting kits

Embedding oven

Microtomes and accessories

Refrigerator

Staining jars

DEPARTMENT OF CHEMISTRY, UNIVERSITY OF CAPE COAST

Available Equipment

Equipment	Functional?
GC/MS	No
IR Spec	Yes
Rotary Evaporator	Yes
Soxhlet Apparatus	Yes

Needed Equipment

GC/MS

HPLC/MS

NMR

DEPARTMENT OF MEDICAL BIOCHEMISTRY, UGMS

Available Equipment

NONE

Needed Equipment

Extraction Unit

Freeze Drier

Fractionation Unit

Chromatographic Unit

DEPARTMENT OF PATHOLOGY, UGMS

Available Equipment

Equipment	Functional?
Centrifuge	No
Cytospin	Yes
Histocentre	Yes
Shandon Tissue processor	No
Tissue processor	Yes
Water baths	Yes

Needed Equipment

Automatic tissue processor of lager capacity

Automatic tissue stainer

Centrifuge (Centrifuge)

Cytospin

Microscopes

DEPARTMENT OF PHARMACEUTICAL CHEMISTRY, KNUST

Available Equipment

Equipment	Functional?
UV Spectrophotometer	Yes
HPLC	Yes
Flash chromatograph	No
Rotary evaporator	Yes

Needed Equipment

Analytical balances

IR Spectrophotometer

DEPARTMENT OF PHARMACEUTICS, KNUST

Available Equipment

Equipment	Functional?
Electronic balances	Not specified
HPLC	Not specified
UV Spectrophotometer	Not specified

Needed Equipment

None specified

DEPT OF PHARMACOLOGY, KNUST

Available Equipment

Equipment	Functional?
Channel recorder	Yes
Hot plate	Yes
Metabolism cage	Yes
Organ bath	Yes
Rotary evaporator	Yes

Needed Equipment

Anal Thermometer

HPLC

Microplate Reader

UV Spectrophotometer

DEPARTMENT OF PHARMACOLOGY, UGMS

Available Equipment

Equipment	Functional?
Hot Plate	Yes
Physiograph	Yes
Tail Flick	Yes

Needed Equipment

Activity Cage

Freeze drying equipment

Vacuum pump

DEPARTMENT OF PHYSIOLOGY, UGMS

Available Equipment

Equipment	Functional?
Vitalograph	No

Needed Equipment

None specified

DR. NOAMESI LABORATORY, HOHOE

Available Equipment

NONE

Needed Equipment

Spectrophotometer

pH meter

FOOD AND DRUGS BOARD, ACCRA

Available Equipment

Equipment	Functional?
HPLC	No
Rotary Evaporator	Not specified

Needed Equipment

Mass Spectrophotometer

GHANA STANDARDS BOARD, ACCRA

Available Equipment

Equipment	Functional?
GC	Yes
HPLC	Yes

Needed Equipment

None specified

NOGUCH MEMORIAL INSTITUTE FOR MEDICAL RESEARCH, UNNIVERSITY OF GHANA, LEGON

Available Equipment

Equipment	Functional?
Atomic Absorption spectrophotometer	Yes
Centrifuges	Yes
Clean bench	Yes
Electron Microscope	Yes
Fascan	Yes
HPLC	Yes
Microscopes	Yes
Organ bath and transducers	Yes
Spectrophotometer	Yes
Thermocyclers	Yes
UV Vis Spectrophotometer	Yes
Water bath	Yes
Weighing scales	Yes

Needed Equipment

Activity cage

Analgesimeter

Freeze-drier

Metabolic cage

Plethysmometer

Rota-rod

Sphygmomanometer for animal studies

Tail flick/Hot plate

SCIENCE AND TECHNOLOGY RESEARCH POLICY, CSIR, ACCRA

Available Equipment

Equipment	Functional?
Computers	Yes

Needed Equipment

Computers

DISEASE CONDITIONS BEING INVESTIGATED BY INSTITUTIONS

Herbal medicines are currently being investigated or used in the treatment and/or management of several diseases. Some institutions, notably the Centre for Scientific Research into Plant Medicine and the Noguchi Memorial Institute for Medical Research are working in a number of therapeutic areas. The focus of some institutions is highly focused and restricted to narrow specializations for example clinical trials or isolation and characterization of active principles from plants. These latter institutions, which include the Centre for Tropical Clinical Pharmacology & Therapeutics the Departments of Chemistry, clearly do not have the ability to carry out the whole range of tests required to assess the safety, quality and efficacy of herbal medicines. However, their focus and specialization gives them the ability to carry out cutting edge research into plant medicine. This ability also makes it possible for them to carry out some of the tests required to ascertain the safety, quality and efficacy of these products. A summary of the various institutions surveyed and the disease areas they claim to be working is shown below.

Table 1: Institutions and the disease areas they are researching

Disease /Therapeutic Category	I.D. Number of Institution(s)
Abdominal pains	**14**
Abortifacients	**8**
Anaemia	**3, 12, 14, 21**
Anaesthetic	**8**
Analgesic	**3, 6, 10**
Antimicrobial agents	**12, 20**
Anxiety	**9**
Aphrodisiacs	**15**
Arthritis	**21**
Ascaricides	**13**
Asthma	**3, 4, 5, 7, 10, 12, 14, 19, 20, 21**
Bacteria infection	**13**
Barrenness	**14**
Biliary calculus	**21**
Blood coagulation	**13**
Boils	**11**
Cancer	**21**
Cervical cancer	**7**
Coccidiosis	**13**
Contraceptive	**12, 14**
Cough	**21**
Diabetes	**10, 12, 15, 19, 20, 21**

Disease/Therapeutic Category	I.D. Number of Institution(s)
Diarrhoea	**10, 15**
Diuretics	**21**
Dizziness	**3**
Duodenal ulcer	**10**
Dysmennorhea	**21**
Epilepsy	**21**
Filariasis	**12**
General Ailments	**17**
Haematinics	**13**
Haemorrhoids	**7, 21**
Helminthiasis	**8, 13**
HIV/AIDS	**12**
Hypertension	**3, 6, 9, 12, 14, 15, 21**
Immune boosters	**13**
Infertility in women	**21**
Inflammation	**10**
Insect repellents	**14**
Insecticides	**12**
Jaundice	**8, 21**
Laxatives	**9**
Lung function	**4**

Malaria	**3, 5, 6, 9, 12, 15, 16, 20, 21**

Disease/Therapeutic Category	**I.D. Number Institution(s)**
Microbiological evaluations of herbals	**21**
Migraine	**21**
Nausea and stomach pains	**21**
Numbness in extremities	**21**
Osteoarthritis	**21**
Parkinsonism	**21**
Pesticides	**20**
Purgative	**21**
Ringworm	**13**
Schistosomiasis	**12**
Sexual weakness	**3**
Sickle cell	**21**
Skin conditions	**11, 13, 15**
Stomach ulcer	**19**
Typhoid	**21**
Ulcer	**14**
Urinary retention in men	**21**
Wounds	**13**

Key to institutions

Institution	ID Number
Animal Research Institute	**13**
Biochemistry Dept, KNUST	**7**
Biochemistry Dept, UG	**20**
Botany Dept, UG	**17**
Centre for Scientific Research into Plant Medicine	**21**
Chemistry Dept, UG	**19**
Clinical Pharmacology, UGMS	**1**
Dept of Biological Science, KNUST	**8**
Dept of Chemistry, UCC	**15**
Dept of Medical Biochemistry, UGMS	**5**
Dept of Pathology, UGMS	**2**
Dept of Pharmaceutical Chemistry, KNUST	**9**
Dept of Pharmaceutics, KNUST	**11**
Dept of Pharmacology, KNUST	**10**
Dept of Pharmacology, UGMS	**6**
Dept of Physiology, UGMS	**4**
Dr Noamesi Laboratory	**14**
Food and Drugs Board	**3**
Ghana Standards Board	**18**

Noguchi Memorial Institute for Medical Research	**12**
Science and Technology Research Policy, CSIR	**16**

INSTITUTIONAL CAPACITY FOR TESTING AND RESEARCH ON HERBAL MEDICINES: DATABASE OF INSTITUTIONS SURVEYED

One of the main outputs of the current consultancy has been a comprehensive database on institutions carrying out or intending to carry out research into herbal medicines. The database, developed in Microsoft Access® provides complete details on each of the institutions surveyed and is arranged in a way that makes retrieval of the information easy. It also allows for new records to be easily included. Each major field in the database is arranged in both "Table" and "Form" formats and can thus be exported into the appropriate software programmes for further analysis and manipulation. The main fields are:

a. INSTITUTE

This gives the full address, telephone and fax numbers as well as email addresses (where available) of each of the institutions visited. It also provides the name of a contact person in the institution who can provide information on the institution's activities in herbal medicine research.

b. RESEARCH HISTORY

This field has data on the mandate of each institution. Furthermore it has details on whether the institution is currently working on herbal medicines or not. For those working on herbal medicines, details on the number of years of research are indicated. Furthermore, data on the number of decoctions as well as plants being

investigated is also recorded. This field also has a compilation of the disease/therapeutic categories being investigated by the institute

c. STAFF

The staff field provides details on all staff at the institution. It lists the names, qualifications and area of interest of staff currently engaged in herbal medicine research. It also lists the names, qualifications and areas of interest of staff willing to undertake herbal medicine research. The field also covers support staff – their numbers and the training they have received and contains information on the current staff employed in the institution as well as the actual staff numbers (scientists, research assistants and technicians) required by each institution

d. EQUIPMENT AND ANIMALS

This deals with the types of equipment available in each institution, what they are used for and whether they are functioning or not. It also provides details on equipment required by each institution and the function of such equipment in herbal medicine research. It also has an inventory of laboratory animals used by each institution in their research with details on the sources and reliability of supply of these animals.

e. ACADEMIA

The number of research papers published and the future plans of the institute are kept in this field. Also included here is the funding situation (availability of funds) of the institute as well as the ability of the institute to obtain chemical reagents for research.

GENERAL DISCUSSION AND RECOMMENDATIONS

The results obtained from the current consultancy have been presented and discussed above. A comprehensive Microsoft Access® database has also been produced. The implications of the results obtained with respect to the testing of herbal medicines for safety, quality and efficacy are discussed below. It must be pointed out that these recommendations are based on the physical evidence obtained during visit to the various institutes as well as on impressions gathered during interactions with scientists at these same institutes.

SAFETY

Safety assessment of traditional medicine products usually involves undertaking toxicity testing in suitable animal models. This is then followed by clinical trials, which is carried out in four phases, each with an increasing number of patients. Among the institutions visited, there seem to be differences in interpretation of the term "safety assessment of herbal medicines". What constitutes adequate and acceptable toxicity testing appeared to be determined by each institution and different institutes have different standards for safety testing. Furthermore, neither the Food and Drugs Board nor the Traditional and Alternative Medicine Directorate has a definition of what the minimum standards for safety testing of herbal medicines are. It must be pointed out that the area of safety testing for commercially produced herbal medicines is new and fraught with various interpretations and regulations worldwide. The WHO has recently produced a guideline for safety testing of herbal medicines[1] and any national guideline on safety testing in Ghana is likely to be based on this model.

From the results obtained, some institutions, notably the Noguchi Memorial Institute for Medical Research, the Centre for Scientific Research into Plant Medicine, the Department of Pharmacology, Faculty of Pharmacy, KNUST and the Department of Pharmacology, University of Ghana Medical School can carry out complete animal toxicity studies to assess the relative safety of herbal medicines. Institutions like the Department of Pathology, University of Ghana Medical School have expertise in

[1] General guidelines for methodologies on research and evaluation of traditional medicines. WHO Geneva 2000

assessing long-term damage to organs and tissues in man and animals and can be used by the aforementioned institutes for this highly specialized task. The various biochemistry departments could also have huge inputs in relation to safety assessment by carrying out tests (enzyme assays, blood tests) for biochemical markers in animals and humans. They can also carry out acute and chronic toxicity testing either alone or in collaboration with other institutions. A summary of the capabilities of each institution with regard to safety testing is shown below:

In summary it can be said that, with a proper definition of what the minimum standards are, there are several institutions that can carry out adequate safety testing of herbal medicines in Ghana. Whilst some of these institutions are well resourced and staffed and can carry out the whole range of studies required, there are some who can only carry out highly specialized, but nevertheless important, studies with relation to safety. A combination and proper co-ordination of the herbal medicine research activities of these various institutions should provide sufficient national capacity for safety assessment of herbal medicines.

QUALITY

Quality assessment of herbal products involves assessing the identity, content, content-uniformity, stability and related physico-chemical properties of the products. It also involves microbiological analysis of the products to ensure that any microbial load is within accepted limits. Unlike safety testing, there appears to be no confusion with regards to the standards required for quality assessment. However, commercially available herbal products vary from ordinary herbs and roots (powdered or not powdered) to crude decoctions, bitters, tinctures, potions, creams and lotions to isolated and purified extracts. The type of tests carried out will thus vary from product to product.

The institutions that can carry out quality assessment of herbal medicine products include the Centre for Scientific Research into Plant Medicine, the Departments of Chemistry and Biochemistry, the Food and Drugs Board, the Ghana Standards Board and possibly the Department of Pharmacognosy, KNUST (whose response to the survey had not been received at the time of compiling this report). Institutions like the

Noguchi Memorial Institute for Medical Research and the Department of Pharmaceutics, KNUST can carry out detailed microbiological studies on herbal medicines and can be used in quality assessment of herbal medicine.

The results of this study indicated an abundance of talent with respect to chemistry and chemical testing of medicinal plant material. There is adequate capacity in Ghana for quality control and quality assessment of herbal medicines. What is required is proper co-ordination and focus to make these services available and affordable to commercial producers of herbal medicines.

EFFICACY

Assessment of efficacy of traditional medicine is a complex area. Each disease condition requires a different approach to assess the efficacy of products used in its treatment. For some diseases also, there is no easy measure of "cure" and the efficacy of any medicinal products can only be ascertained using surrogate markers. Furthermore, the influence of the "placebo effect" in any perceived efficacy by the users cannot be ruled out. Assessment of efficacy can be carried out *in vitro* and *in vivo.* In the area of malaria chemotherapy for instance, methods exist for analyzing *in vitro*, the efficacy of herbal antimalarials. For some conditions however, *in vitro* testing is not possible as there are no suitable models for efficacy testing. Also *in vitro – in vivo* correlation is not always straightforward and there will always be the need to carry out efficacy testing in suitable animal models and also in humans. Efficacy testing in humans can however only be carried out after safety studies have shown the products to be suitable for use in humans. Efficacy testing in humans will normally take the form of controlled clinical trials.

From the survey conducted, it is doubtful whether any one institution has the capacity or capability to carry out complete efficacy testing of any herbal medicine product. The Centre for Scientific Research into Plant Medicine has been carrying out studies to assess the effectiveness of certain herbal medicines in humans. These studies, however fall short of the gold standard for clinical trials i.e. they are not randomized, multi-centre, placebo controlled and blinded. The Centre for Tropical Clinical Pharmacology and Therapeutics of the University of Ghana Medical School is a

clinical and research Centre located within the Medical Block of the Korle-Bu Teaching Hospital. It can thus be used as a focal point for organizing clinical trials of herbal medicines. However, the Centre will need to be equipped and its staff numbers expanded to include a few medical practitioners to permit such studies to be realistically carried out.

The Noguchi Memorial Institute for Medical Research of the University of Ghana is a huge multi-disciplinary unit with expertise in a wide range of clinical areas. It is therefore an attractive choice for carrying out a large range of pre-clinical efficacy studies of herbal medicines.

Some of the other institutions surveyed e.g. the Departments of Pharmacology at KNUST and UGMS and the Centre for Scientific Research into Plant Medicine also have specialized strengths which can be exploited for pre-clinical assessment of efficacy of herbal medicines.

In summary, it can be said that the area of efficacy testing of herbal medicines requires strengthening in terms of staff and facilities. The various institutions surveyed have limited capabilities which can be co-ordinated and harnessed but overall, there is the need for substantial capacity building in this area. This would also include, among other things, recruiting and training orthodox medical practitioners to carry out clinical trials of herbal medicine products according to international standards.

CONCLUSION

A detailed survey has been made of the capability of Ghanaian institutions to carry out research and testing of herbal medicines. Whilst capacity for assessing the safety and quality of herbal medicines exist (albeit not co-ordinated), there is the need to develop and strengthen capacity for efficacy testing. The development of multi-

disciplinary and inter-departmental teams to work on herbal medicines should provide the needed national capacity for herbal medicine research and testing.

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