Gender, Biodiversity and Local Knowledge Systems (LinKS) to Strengthen Agricultural and Rural Development (GCP/RAF/338/NOR)

Benefits and Risks of Sharing Local Knowledge

Summary Report

from a meeting held at the MS Training Centre for Development Cooperation (TCDC)

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Gender, Biodiversity and Local Knowledge Systems To Strengthen Agricultural and Rural Development in Southern Africa
FAO PROJECT #GCP/RAF/338/NOR

VETAID TZ
Afya ya Mifugo - Afya kwa Watu
Healthy Animals - Healthy People

Organised by the FAO LinKS project and Vetaid Tz

Table of Contents

Chairperson's introduction

It was my great pleasure and honour to be invited to chair this very important meeting. The report that follows outlines the theme, discussions and recommendations of this meeting, along with copies of the keynote papers presented.

It seems to me that we started out with the idea of determining a path through the very complicated mire of legalese surrounding intellectual property rights, patents and royalties to discover that what communities really want, in exchange for sharing their knowledge, is improved services. I think that the papers and subsequent participant dialogue amply demonstrates this point. We trust that all researchers will take heed of this meeting and be guided by its output.

Let us hope that the way forward from this informed and articulate gathering will result in a maximising of the benefits and a minimising of the risks that local communities face when sharing knowledge. Research workers must bear their responsibility in ensuring that communities do benefit from their research. The code of practice developed by this meeting provides clear guidelines as to how to achieve this ideal.

As Chairperson, I have the duty and pleasure of thanking the FAO LinKS Project for making this meeting possible. We witnessed a synthesis of the FAO LinKS Project Team's technical excellence and the informed views of experienced field practitioners to create a potent mix for addressing key areas of concern in advancing the development process. Models of good practice is what we seek for setting our workplans and agendas on a positive course. I believe that the output from this meeting has provided just that – a model for good practice. Respecting local knowledge and adopting an approach that empowers communities to benefit and improve their livelihoods from the sharing of that knowledge must be taken seriously to heart. A challenge and responsibility for all of us that care.

Dr Chris Daborn
Vetaid Tz

About the LinKS project

The LinKS project is a regional FAO effort looking at the linkages between gender, biodiversity and local knowledge. The main objective is to promote increased food security through focusing on local knowledge systems, gender roles and biodiversity conservation. LinKS operates in three countries, namely Zimbabwe, Mozambique and Tanzania. In Tanzania, the project is hosted by Tanzania Food and Nutrition Centre (TFNC). The project is supporting efforts to bring individuals and institutions together to share experiences, and to strengthen and deepen the collaboration with national and international partners and projects. For more information, please contact:

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About Vetaid Tz

Vetaid Tz is a registered NGO that works, in partnership with the Ministry of Agriculture and local organisations, to improve livestock food security and reduce poverty. By active promotion of animal health, production and marketing, Vetaid Tz seeks to enhance the well being of pastoralist communities and the livestock that they depend on for their survival.

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1 Background

There have been a number of efforts to document traditional use of medicinal plants for animal health care, in Tanzania as in other countries in the region. In doing this, however, a dilemma arises. On the one hand, documentation and sharing are necessary steps towards a wider application of the knowledge base. It is widely recognised that locally developed plant-based animal health care practices, handed down through the generations, represents a highly valuable resource. On the other hand, there are well-founded concerns that documenting and sharing of knowledge may leave the door open for commercial exploitation by outsiders ("biopiracy", "bioprospecting"), giving little or no benefits back to the communities from which the material originated.

This meeting addressed two main issues. First, what are the potential benefits and risks of sharing such knowledge? In other words, how can sharing of knowledge be encouraged without putting local communities at risk of losing access and control over the resources they have developed? Presentations were given on intellectual property rights and the implications for a country like Tanzania, and how communities' rights and interests can be protected and promoted. At the beginning of the day, participants expressed their interest to know more about the legal implications of sharing local knowledge, and it is hoped that the meeting helped to demystify the issues and increase the understanding of the various concepts of Intellectual Property Rights.

Secondly, what are the responsibilities of researchers and development agents who record and document local knowledge? The meeting attempted to develop a draft set of simple, basic guidelines for anyone involved in documenting and sharing of local knowledge. Sharing of knowledge on the use of medicinal plants is part of the broader issue of sharing results and benefits of any intervention to document local knowledge. Medicinal plants is a case where sharing of local knowledge has potentially large economic implications for the communities. In other – perhaps most – cases of sharing local knowledge, the issue may not be about money, but about the responsibility of the researcher or development worker towards the communities. How should a researcher or development agent approach the communities so as to make sure that the intervention keeps the local community in control over their own resources? The draft guidelines are given in Chapter 6.

2 Use of Medicinal Plants Among Maasai Pastoralists: Findings of the

Some Potential Benefits and Risks of Sharing Local Knowledge
(Adapted from groupwork discussions)

Benefits

1. Economic gain (access to markets, job creation, improved livelihoods)
2. Improvements of, and added value to, local knowledge practices
3. Feedback that can assist communities in solving problems they are facing
4. Guidance to communities on strengths and weaknesses of their own practices
5. Empowerment of communities
6. Raised community awareness of practices from elsewhere that can assist them
7. Promotion of community conservation of biodiversity

Risks

1. Overexploitation of biological resources
2. Failure to get feedback from researchers and development workers
3. Loss of control over their own local knowledge
4. Loss or devaluation of the communities' cultural values
5. Loss of popularity, monopoly, power, and/or mysticism of traditional leaders/practitioners
6. Biopiracy, exploitation of biological resources and local knowledge without receiving any benefits in return

Ethnoveterinary Knowledge (EVK) Project in Simanjiro District
Dr M. Minja, Animal Diseases Research Institute, Dar es Salaam

Dr Minja presented a case study on documentation of local knowledge among Maasai pastoralists in Northern Tanzania. The case study provided the main background for further discussions during the meeting on benefits and risks of sharing local knowledge and the associated legal implications.

The study was undertaken as a collaborative effort between Vetaid Tz and the Ministry of Agriculture and Co-operatives, and co-ordinated by ADRI (Animal Diseases Research Institute). Research partners included TPRI (Tropical Pesticides Research Institute), SAHLC (Simanjiro Animal Health Learning Centre), and local NGOs (Inyuat E Moipo and Ilaramatac Lorkonerei).

After finalising the documentation of knowledge on ethnoveterinary practices in Simanjiro, Vetaid now aims at integrating the information in their programme on community based veterinary services. Vetaid's approach has been to do the project work parallel to provision of animal health services in the community. This has proven to be a successful approach, as it helps with the facilitation and increases the information gathered.

Ethnoveterinary knowledge is widely practised in the study area. Simanjiro pastoralists have since time immemorial resorted to nature in the search of substances required to prevent and cure diseases in both man and animal. The current situation is that delivery of animal health services is hampered by weak infrastructure, lack of funds, unavailability of modern practices, and the fact that Ethnoveterinary Knowledge (EVK) provides cheap and efficacious curative local material.

The aim of the project, launched in 1997, was to

- provide information on alternative treatments for common animal ailments through documenting traditional veterinary practices and disease coping strategies,
- support continued use of effective practices,
- produce educational materials on EVK for extension staff and tertiary education, and to
- support ADRI's development of EVK in Tanzania, especially pharmacology of medicinal plants.

A total of twenty villages distributed widely throughout the district were selected for information gathering. Information was collected by the use of PRA[1] methods. The study used enumerators conversant in both Kimaasai and Kiswahili and undertook three visits to each village: the first to collect basic information, the second to carry out focused group interviews with key informants, and the third to conduct group interviews in each village on socio-economic aspects of ethnoveterinary practices.

The study has resulted in an inventory of 96 plants used for a total of 81 different pathological conditions. The team compiled a consolidated list of livestock diseases in local terms and their scientific equivalence. Further, diseases have been ranked in order of importance based on their lethality and confidence of treatment by traditional methods. Finally, the socio-economic aspects of ethnoveterinary practices were scrutinised in order to understand the system of knowledge transfer and roles played by various social groups.

[1] Participatory Rural Appraisal

The project has provided a good base for further development of community based animal healthcare services that could incorporate the ethnoveterinary knowledge gained. Key recommendations are:

- To validate the efficacy of promising plants and treatments that were identified during the project, including an examination of any potential harmful (e.g. cancer-inducing) side effects of the local ethnoveterinary practices.
- To integrate the confidently used EVK treatments into community based healthcare extension services as another option available to pastoralists in Simanjiro District, and
- To start similar community based EVK projects in other parts of Tanzania.

Discussion

Dr Mbwembo from the Institute of Traditional Medicine (ITM) in Dar es Salaam raised the issue of looking at veterinary medicine together with human medicine. Dr Minja responed that although the study had not considered medicinal plants for human use *per se*, the team had made observations on such use of medicinal plants in the communities they visited.

Dr Daborn of Vetaid called for enhanced collaboration between the areas of human and veterinary medicine. He emphasised that the study represented a model for how different government departments could work together, and hoped it would encourage further collaboration among a wider group of government institutions.

Quoting from a booklet from the study, Ms Gogadi from Tanzania Women Lawyers' Association (TAWLA) pointed out that a statement saying "All Intellectual Property Rights belong to the Communities (…)" merely gives a copyright protection. A copyright protection only covers the expression of the knowledge and not the knowledge itself.

Ms Chinyemba from the LinKS project in Zimbabwe asked if any gender differences could be seen on the use of medicinal plants. Dr Minja responded that the general trend observed that the women are the main bearers of ethnoveterinary knowledge.

3 Use of medicinal plants for animal treatment and gender roles in different animal production systems in Tanzania *Prof. A. Maeda-Machang'u, and Mr D. Mwaseba, Sokoine University of Agriculture, Morogoro*

Prof. Maeda-Machang'u and Mr Mwaseba presented a summary of their work on local knowledge in the livestock sector in Tanzania. The team has since 1995 documented local knowledge, skills, practices and beliefs pertaining to animal husbandry and health care in the country, paying particular attention to gender roles. The studies have been conducted in six different areas (Morogoro/Tanga, Mbeya, Iringa, Mara, Mwanza, and Kilimanjaro), reflecting the large differences in livestock production systems in the country.

One of the objectives has been to develop a practical approach to merging local and scientific knowledge on animal health care. Despite modern veterinary services, traditional and local methods for tackling health problems and diseases of livestock were still widely practised in the studied production systems. Modern drugs are, however, sought and used where possible. The pastoralist communities, being more attached to their animals than other livestock

keepers, had acquired health care skills and knowledge on medicinal plants against bacterial, viral, protozoan and fungal diseases.

Women were in most cases found to be the custodians of the records of good quality animals and their origin, and their progeny helped in selecting the best animals for breeding. Women were also skilled in managing illnesses of animals. However, women's participation in the livestock sector was limited by several factors, which contributed directly to food insecurity. Women had no right to own land in many traditions and cultures, and because of that they had no collateral for loans or credit. Similarly, ownership of livestock was vested in the heads of the household, the majority of whom were men.

Prof. Maeda-Machang'u pointed to the need for more research on the impacts of changes taking place within the households in the study areas, and how these changes are affecting the food security situation. The team presented a proposal for a study on the use of medicinal plants in a dynamic pastoral production system. There is a wealth of local knowledge on medicinal plants for use in animal and human health care. However, current changes in the pastoral societies (such as more restricted mobility, diversification of livelihood activities, changes in social structures, migration to urban areas) are accompanied by losses of ecosystem knowledge. The objectives of the study would be to determine the opportunities for and the threats to the use of medicinal plants under these circumstances.

Discussion

Mr Salehe of the Cross Border Biodiversity project in Arusha raised a concern about research fatigue among the communities, as they had seen especially in areas close to cities. The tendency is to pay for the researchers' salaries and DSA, but not for the collection of data. Prof. Maeda said the team had experienced this during their work, but said communities normally volunteered their information once the purpose of the research was explained to them.

There was also a concern that medicinal plants may be overused and that some plants may come under threat of extinction. Mr Lawrence Shongon of Inyuat E Moipo stressed that there is a need for conservation measures for many plants, as herbal medicine are popular in markets all over the East African region. Dr Minja emphasised the need for looking into both *ex situ* and *in situ* conservation measures.

National Coordinator for the LinKS project in Tanzania, Mrs Missano, called for a discussion on why the communities should give out their information in a situation where researchers often do not give feedback after finishing their work. Prof. Maeda-Machang'u echoed the concern. The team had used local contact persons to get a clearer idea on how the research would fit into farmers' own systems, in turn making it more likely that the communities would approve the study to be undertaken.

Dr Massawe of Selian Agricultural Research Institute (SARI) in Arusha said that one of the problems with efforts to improve animal health care in the communities was the lack of coordination among development agencies, resulting in conflicting messages being sent out. One group would advocate for the use of farmers' own knowledge, while another promoted modern drugs.

4 Intellectual property rights and strategies for protecting local communities' interests and rights *John Kabare, Kenya Industrial Property Office (KIPO), Nairobi*

Mr Kabare's presentation focused on challenges, constraints and perspectives for intellectual property rights and medicinal plants in Africa.

Herbal medicine has a high importance worldwide. Mr Kabare referred to estimates that 80% of the African population depends solely on traditional medicine for treatment of various ailments. There is a significant international trade in medicinal plants, including material originating from East Africa. In the US, an estimated 79% of all drugs have a natural products origin, and 25% of them are derived from plants.

Intellectual Property Rights (IPR) are closely linked to issues of ownership. In the past, ownership of medicinal plants in Africa was not an issue, as herbal practitioners could criss-cross their communal lands at liberty in search of the relevant plants. Today, the availability is decreasing due shrinking forests, decimation of shrubs and tree species, increasing population pressure and other factors. As a result, practitioners have to travel long distances in search of material.

Mr Kabare outlined and discussed the four main types of IPR regimes:

1. *Industrial Property:* Patents, Industrial designs, Utility Models, Technovations, Trade Marks, Service Marks, Geographical Indications, Layout Designs (topographies).
2. *Copyrights:* Literary works, musical works, art, computer programs, compilation of data
3. *Plant Breeders Rights*
4. *Trade Secrets* (undisclosed information)

The use of patent protection is common for medicinal plant products. A large number of protected patents in developed countries (USA and Europe) are based on plant material originating from the tropics. One of the most controversial sources is the Neem tree, widespread in the tropics and utilized traditionally from time immemorial.

Mr Kabare raised concern on the issue of biopiracy, as demonstrated by patenting of Neem tree products. This is a worrisome trend, as it makes a mockery of the advantages of IPRs, pitching groups against one another and promoting unethical and unfair competition in the race to produce new and effective drugs worldwide. Biopiracy is a moral question. Rice Tec's US patent on basmati rice involves 22 basmati varieties from Pakistan and India, countries which have grown them from time immemorial. The varieties got into the hands of the American prospectors through the US gene bank, where they had been deposited for safe keeping by India and Pakistan!

He noted that the greatest weakness of classical IPR protection is their limitations in addressing issues close to the hearts of developing countries, which include indigenous/traditional knowledge, access to genetic resources and Farmers' Rights. The debate on these issues is likely to take long before solutions are found. Mr Kabare said there is a need for a new property regime that local communities can have access to and come under. Efforts to discuss these issues by the Crucible Groups are encouraging, particularly if they can result in tangible policy options for countries such as those in Africa to utilise in their development of required laws.

He was of the opinion that intellectual property could be a powerful tool in the promotion of income for sharing with local communities and investment in research and development, apart from its importance in the promotion of technology transfer. To benefit Africa, collaborative efforts with the private sector must take into account ownership of traditional knowledge upon which the investigation is based, and be able to apportion adequate compensation to the local communities for accessing their knowledge and material.

For the future development, Mr Kabare pointed to the needs for:

- Cultivation of herbal medicine by practitioners for the sole purpose of yielding medicinal components. This would save time spent in searching for the plants. The developed material may also qualify for protection under existing IPR systems such as a patent or plant variety regime.
- Incorporation of modern biotechnology methods in the research
- Addressing issues on community rights in light of the provisions in the Convention of Biological Diversity
- Addressing questions of ownership by striking a balance between national sovereignty and private ownership
- Sustainable utilisation and conservation of the resources

5 Research, Policy and Legal Context in Tanzania *Dr J. Kasonta, Tanzania Commission for Science and Technology (COSTECH) and Dr P.J. Kabudi, Faculty of Law, University of Dar es Salaam*

Dr Kasonta and Dr Kabudi provided background on the research, policy and legal context in Tanzania.

Tanzanian policy and research

Dr Kasonta gave an overview of current biotechnology research in Tanzania. In response to little availability of updated information in the field, COSTECH conducted an in-depth survey in 1998 to collect and systematise information about institutions involved with biotechnology research and development in the country.[2] From the survey, main constraints to biotechnology research in Tanzania has been identified as a lack of a biotechnology policy, lack of funding and manpower, lack of relation between the research areas and the needs of the country, and a lack of awareness among stakeholders of the potential of biotechnology for socio-economic development in the country.

Dr Kasonta emphasised the important linkages between biotechnology, biodiversity and agriculture. For example, the Convention on Biological Diversity (CBD) recognises the role of indigenous and traditional knowledge in biodiversity conservation (Article 17), but does not specifically provide for the modalities of sharing benefits arising from such knowledge or the kind of property rights that holders of such knowledge can get. In his presentation, Dr Kasonta recommended an awareness-raising workshop to expose policy and decision makers to the benefits and hazards of biotechnology for economic development in the country. The workshop should aim to:

[2] The survey results are presented in the full paper on page 33.

1. Increase their understanding and appreciation on the role of biotechnology for socio-economic development,
2. Broaden the understanding of policy issues associated with agreements such as the Trade Related Intellectual Property Rights (TRIPS), CBD and other related agreements, and
3. Stimulate awareness and public debate on biotechnology policies in relation to questions of Intellectual Property Rights, patenting life forms and trade in germplasm.

The legal context

Dr Kabudi's presentation focused on legal aspects and ownership issues. He stressed that one main problem regarding intellectual property rights and medicinal plants arises when applying a western property regime, where the individual is in the centre, to African communities, where communal ownership is the norm.

He mentioned three pieces of legislation that are relevant in a discussion of intellectual property protection in Tanzania: (1) Trade and Servicemarks Act, 1986; (2) Patents Act, 1987; and (3) Copyright and Neighbouring Rights Act, 1999. The most relevant, and which formed the basis for his talk, was the Patents Act, 1987. The Act is further supplemented by the Patents Regulations, 1994.

Dr Kabudi outlined how the three criteria for patenting (novelty, inventive step and industrial applicability) would apply to medicinal plants. To be patentable, a mere discovery is not enough, an invention must be a manner of manufacture. However, an invention of a way of extracting an active element within a plant or development of a new use for a natural organism may be eligible for patent protection.

The criteria of novelty is compared to the so-called "prior art base", defined under the Patents Act as, "Everything made available to the public anywhere in the world by means of written (…) [or] oral disclosure, use, exhibition or other non-written means (…)" before the patent application is made. This means, for example, that when accounts of the uses of medicinal plants by indigenous people are published, it becomes public knowledge and therefore part of prior art base. However, in cases where the disclosure is made for a certain allowed purpose, and within a certain period prior to filing of an application, the information will not be considered as having become public knowledge.

Dr Kabudi discussed other means of legal protection with less rigorous requirements than the patent system. Two options are trade marks and utility models. Utility models are known as weaker patents, as they may be granted even on basis of a modification of existing material. Thus, the questions of novelty and prior art base do not arise. A trademark may offer some protection of rights to medicinal plants and traditional medicine knowledge, but are limited in that they are basically there to protect the public and sellers, and to serve as a marketing and advertising device.

The Convention for Biodiversity provides new opportunities for intellectual property rights protection to medicinal plants and knowledge. For example, article 10 (c) calls on parties to,"protect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements".

Dr Kabudi also mentioned the avenue of developing a *sui generis*[3] system under article 27.3b of the Trade-Related Intellectual Property Systems (TRIPS) Agreement. The article allows members to exclude plants and animals from patenting, other than micro-organisms and biological and microbial processes, if another (*sui generis*) form of intellectual property system is established.

In conclusion, he stated that intellectual property rights regimes available in Tanzania serves to protect the rights of commercial breeders and biotechnology companies, but are inadequate for the protection of medicinal plants and for the protection of traditional knowledge of local communities. This is because it is usually considered not "new" (lacks novelty) and its attendant components. Moreover, in many instances it is held in the "public domain"; in other words, it is commonly held and shared by the community and therefore part of the prior art base.

Discussion

Ms Gogadi (TAWLA) commented that although the Patents Act and its regulations are in place, applicants might be forced to seek assistance of outside patent attorneys to prepare their applications. This is because Tanzania does not have people who are trained in the sciences and the law, qualified in drafting claims, and the specifications to a standard required by the patent office. Moreover, we do not as yet have patent examiners. All senior officers in the patent office are pure lawyers. This means that applicants are faced also with the only choice of applying through another system like the Patent Cooperation Treaty, where they then designate Tanzania as one of the countries where they want their patent protected. She doubted whether community knowledge could be patentable. The knowledge could potentially be monopolised as a trade secret, but this would be difficult to protect and against the nature of local knowledge.

Professor Nkunya of the University of Dar es Salaam raised the issue of patenting fees and noted that patents often do not give immediate benefits. Mr Kabare elaborated that fees of patenting include (1) filing fee, (2) examination fee, (3) certificate fee, and (4) from the beginning of the 2nd year a maintenance fee, increasing over time up to the 20-year duration. He further said that a large percentage of patents are not utilised for a long time, and may even have expired before they can be used.

Ms. Chinyemba of the LinKS project in Zimbabwe called for an indigenous/grassroot level system applicable to African societies. Other participants echoed this and recommended exploring existing systems that has been designed and implemented (though with a varying degree of success) as partnerships between private companies and local communities.

6 Draft guidelines for documentation of local knowledge to maximise benefits and minimise risks to local communities

The participants developed three separate sets of guidelines (see Annex 1), which are synthesised below. One group of participants looked at the role of policymakers; another

[3] *Sui generis* is Latin for "of its own kind", meaning in this context, an intellectual property right designed specifically for the protection of biological resources and materials.

discussed the role of researchers, and the third looked at documentation from the local communities' point of view. The synthesised guidelines below also include issues raised in the plenary discussion. They have also benefited from a set of guidelines for qualitative research developed for the LinKS project. It should be pointed out that these are draft guidelines, intended for further discussion and testing.

Before the work starts

1. *Review potential benefits and risks of the intervention to the community*. Does it address an existing problem? Is there a demand for this kind of work? What are the potential social, economic and environmental implications of the work? How will it impact on various groups in the community (men, women, youth, and elders), and the relations between them?

2. *Consult with communities to gain their confidence and approval of the work.* The researcher should consult with various groups of the community to inform them about the intentions of the work and get their viewpoint and advice on the work. The researcher should obtain a prior informed consent and approval from the communities (Contract, Memorandum of Understanding, Up-Front Agreement) that clearly states:
   - The goals of the research and the relevance to the communities' situation
   - What they intend to do, how, by whom, how long the work will go on and when
   - How the information will be used, including how IPR issues will be handled, how benefits will be shared and how the communities themselves will benefit.
   - A realistic and concrete list of how the work will benefit the communities, to be followed up during feedback seminars

3. *Use appropriate tools and approaches*. The researcher should use tools and approaches that involve various groups of community members. A variety of data collection methods should be used to respond to the research questions (triangulation), and an interdisciplinary approach should be used to understand the socio-economic context. Sampling strategies to be used should be appropriate for the study purpose and the research questions to be answered.

4. *Involve central and local regulatory bodies*. The research should involve the central regulatory body in the country and follow laws at international, national and community level. The researcher should respect local/traditional decision-making structures and laws.

During implementation

5. *Keep a flexible research approach and design*. The research set up should be flexible, so as to allow for changes after feedback from the local community and other stakeholders.

6. *Involve communities as research partners.* The researcher should maximise communities' involvement through design, implementation and finalisation of the work.

7. *Give useful feedback to communities during implementation.* This could be in a

"passive" form, with information updates of the work, or a more active form as technology transfer, capacity building, technical advice or other interventions. The form and contents of the feedback could be agreed in earlier consultations, and feedback should be an integrated part of the setup and design. Further, the feedback should be in a medium of communication that can be understood, given in reasonable time, as well as provide new knowledge and a recognition of the value of local knowledge. Examples are:

- Community workshops/village seminars
- Study/discussion groups
- Simple manuals
- Final version of the research document for the village library
- Posters and leaflets
- Role plays
- Theatre
- Songs
- Documentary films

<u>After finalising the work</u>

8. *Final feedback/consultation meeting with the communities.* Upon completion of the work, the researcher should hold a final consultation meeting with the communities. The meeting should follow the earlier set up guidelines and review the extent to which the promises made have been fulfilled and whether the objectives have been met.

9. *Provide final agreed outputs within reasonable time and lay out strategies for follow up.* The researcher should provide the agreed outputs to the communities within a reasonable time frame after completion of the work, and give realistic advice on the anticipated follow up. He or she should also make available the raw data material to the communities and inform on where and with whom the data material is shared. If the material is going to be used for other purposes than those earlier agreed upon, it is the researcher's responsibility to get the communities' approval for this change in use.

7 Annexes

Groupwork discussion and guidelines

Group 1: What guidelines would you suggest to maximise benefits to communities of sharing local knowledge while minimising risks?

1. Researchers should provide the community with a clear description of their research objectives and obtain prior informed consent.
2. Gain confidence / support of community, e.g. through using participatory practices (PRA etc.)
3. Develop a Memorandum of Understanding with the community, specifying what is to be done, how, by whom, how long, and when
4. Incorporate community participation and maximise utilisation of community assistance in the research activity
5. Ideally involve community in selection/refinement of the research objective, in order to instil community ownership
6. Set up a contract for any Intellectual Property Rights and how benefits are to be shared. Examples could be "Up Front Agreement", "Milestone", "Royalties"
7. Sharing of results and feedback
8. Build in technology transfer/capacity building/resources to leave with community.
9. Inventory and regeneration of limited natural resources
10. Make use of central regulatory body i.e. research council/central board - for issuance or research permits or advice on correct procedure.
11. The work must comply with existing International, National and community laws.

Group 2. Prepare a code of conduct for Researchers to assure that communities benefit from the research activity.

1. The research should be demand driven and oriented towards existing problems
2. Involve local communities as research partners
3. Observe transparency on research objectives and what communities will benefit
4. Develop a "Memorandum of Understanding" with the communities, based on local/indigenous ways of doing things
5. Support local facilitators for sustainable development, train local facilitators
6. Develop long-term relationships with local communities
7. Continuous sharing of useful information even after completion of research, give feedback through e.g. Village seminars, Leaflets, Study/discussion groups, and to give final version of the document to the village
8. The research should have a multidisciplinary approach
9. Researchers should be aware of the social implications, "push-and-pull" processes within the villages, that the research may lead to

Group 3. Prepare a set of guidelines on the approach researchers should use to give back information and useful applications to a community.

The researchers should: (1) Have a conviction and moral obligation to give us the feedback; (2) Have common guidelines about how their work will benefit us; and (3) Get us to approve the research project so that it helps us to solve our problems.

What do we want from them? (a) Knowledge and information; (b) Applicable advice to solve our problems.

1. *What is useful feedback?* (a) Should be in a medium of communication that we can understand; (b) Should be given back in reasonable time; and (c) Should provide new knowledge and / or recognize the value of our Local Knowledge.
2. *Some ideas for feedback:* (a) Community Workshops; (b) Communication materials, e.g. Posters, Simple manuals, Role plays, Theatre, Songs, documentary films etc.

Researchers should not make unrealistic promises and during feedback they should have a checklist of their promises to countercheck their achievements.

Findings of the Ethnoveterinary Knowledge (EVK) Project in Simanjiro District

By Dr. M.M.J. Minja
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Abstract. Between 1997 and 2000 Vetaid, in collaboration with the Ministry of Agriculture and Co-operatives, conducted a systematic study of ethnoveterinary practices by the Masai of Simanjiro District in Northern Tanzania. The aim was to provide information on alternative treatments for common animal ailments. This was done through documentation of ethnoveterinary practices in the area. An inventory of medicinal plant resources has been documented as to the species, availability, parts used and their therapeutic usage. In the future, steps will be taken to determine species to be cultivated to meet the demand. A consolidated list of livestock diseases in local terms and their scientific equivalence has been compiled.

1. Introduction

The delivery of animal services among the nomadic and transhumant Masai of the Simanjiro District of North Eastern Tanzania has not been an easy task due to weak infrastructure and the semi arid environment characteristic of the area (Ann Muir 1994). In the face of this reality, the Simanjiro pastoralists have since time immemorial resorted to nature in the search of substances required to wade off diseases in both man and beast. Although scientific inquiry has only recently influenced indigenous thought, and that but slightly, it is now generally accepted that pastoral societies have detailed knowledge, gained through experience, of animal health and production (Sollod and Stem 1991). Moreover, natural explanations, rather than supernatural or religious ones, are given for most disease processes.

A vast amount of information has been accrued by an Ethnoveterinary Knowledge (EVK) Project. The project has been implemented by Vetaid in collaboration with the Ministry of Agriculture and Co-operatives, and was co-ordinated by the Animal Disease Research Institute. Other, co-opted institutions included the Tropical Pesticides Research Institute (TPRI), the Veterinary Investigation Centre (VIC) in Arusha, the Simanjiro Animal Health Learning Centre (SAHLC), and two local NGOs in Simanjiro, Inyuat E Moipo and Ilaramatac Lorkonerei. The accrued information indicates that Simanjiro pastoralists rely on a vast array of plants for the treatment and control of animal diseases (Minja 1998, Minja 1999).

2. Main Objectives of the Project

1. To elicit and document traditional veterinary practices and disease coping strategies in Simanjiro
2. To support continued use of those practices which appear to be effective by communicating them to government extension workers and NGOs
3. To produce educational materials on EVK for extension staff and tertiary education
4. To support ADRI's development of EVK in Tanzania, especially pharmacology of medicinal plants

3. Information collection

The Simanjiro District was split up into 6 blocks grouping areas of similar agriculture, vegetation, and geographical location. A total of twenty villages distributed widely throughout the district were selected for information gathering (See Appendix 1). Information was collected by the use of PRA methods. This involved three separate visits to each village. The first visit was done to carry out mapping, raise awareness of EVK amongst communities, and to identify those who would be involved in later interviews. The following visit dealt with semi-structured interviews of key informants, and the purpose of the third visit was to carry out a socio-economic survey.

In the first visit, two enumerators conversant in both Kimaasai and Kiswahili visited each village in order to:

- Describe the project objectives,
- Carry out a mapping of the villages to indicate important land marks and sites in relation to EVK,
- Develop a list of diseases affecting livestock in the area,
- Rank the diseases in order of importance and confidence of treatment through the use of local techniques (see Appendices 2 and 3),
- Collect voucher specimens of plants used in the treatment of animals for botanical identification, and
- Identify key informants (known experts on EVK) who would later be involved in validation interviews.

During the second visit, the enumerators carried out focused group interviews with key informants from each village. For the third visit, the enumerators conducted group interviews in each village on socio-economic aspects of ethnoveterinary practice. Meanwhile, students of the Simanjiro Animal Health Learning Centre conducted one-on-one interviews with their parents/grand parents during the vacations.

4. Results

An inventory of medicinal plant resources has been documented as to the species, availability, parts used and their therapeutic usage. A total of 96 plants were reported from six research blocks of the Simanjiro District. These plants were identified at the Tanzania National Herbarium, situated at the Tropical Pesticides Research Institute in Arusha. A consolidated list of livestock diseases in local terms and their scientific equivalence has been compiled. The pastoralists described a total of 81 diseases (pathological conditions). The diseases were ranked in order of importance, i.e. depending on lethality and confidence of treatment by traditional methods. Finally, the socio-economic aspects of ethnoveterinary practice were scrutinised with a view to understanding the system of knowledge transfer and roles played by various social groups.

Publicity and publications

- Participation at Nane-Nane Agricultural shows in 1998 and 1999 at Arusha
- Preparation of EVK information booklet, calendar & pamphlets
- Feedback workshops carried out in January 2000 in the three units of Simanjiro where the EVK research work was conducted involving twenty key informants from each unit (See Appendix 4).
- Round up workshop at the Simanjiro district headquarters

Paper publications

- EVK Final Report

5. Recommendations for future work and sustainability

Awareness regarding the importance of ethnoveterinary knowledge has increased during the period of the project, to which the project has made a significant input. The EVK project has provided a good base for developing further community based animal healthcare services that could incorporate the ethnoveterinary knowledge gained.

Key areas that could be followed up are:

- Validation of the efficacy of promising plants and treatments that were identified during the project
- Integrating the confidently used EVK treatments into community based healthcare extension services, as another option available to pastoralists in Simanjiro District
- Start similar community based EVK projects in other parts of Tanzania

6. Validation work

Future work on validation should concentrate on treatments for endo/ectoparasites and wounds as well as work on immunomodulators. Validation methods could include some of the cheaper and simpler methods such as in vitro and in vivo tests, toxicity studies and observation of short term clinical trials. Monitoring of field use of these plants and treatments could also be carried out. It would also be important to look at safe and effective dosage levels, as well as determining the efficacy of the tested plants.

7. References

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Appendix 1: Area of Operation

Simanjiro District was divided into three main units, with each unit consisting of two blocks according to geographical location and economic activities. Each unit consisted of seven villages.

- Unit I consisted of: Terrat, Loswaki, Sukuro, Loiborsoit, Emboreet, Loibosiret and Narakauwo villages.
- Unit II consisted of: Komolo, Oljoro 5, Oiborkishu, Olbili, Shambarai sokoni and Naisinyai villages. The seventh village Lemkuna could not be visited because at the time there was an outbreak of cholera.
- Unit III consisted of: Ruvu Remit, Ngage, Loiborsoit (M), Londerkes, Orkesumet, Naberera and Namalulu villages.

Appendix 2: Overall district disease ranking indicating a total of 18 diseases which are confidently treatable by ethnoveterinary practices for the whole of Simanjiro District.

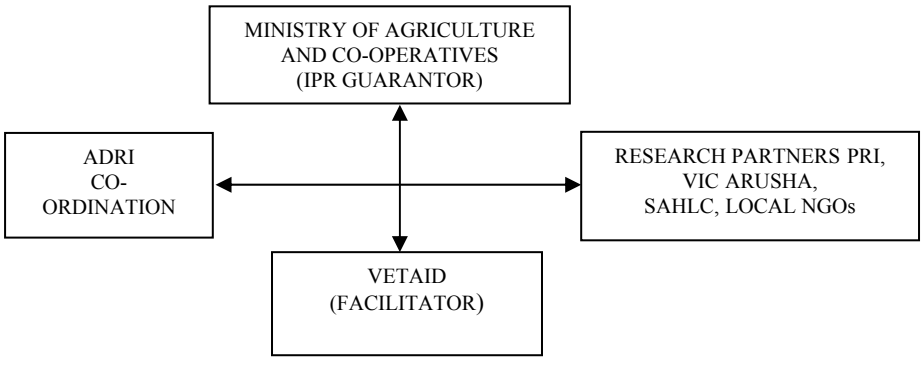
1. Alairahrash *Overgrowth of hooves resulting from eating a plant called alairahirah (Crotalaria polysperma Schwein)*
2. Alakirkir *(Shivering) - Any infection that causes fever in the animals*
3. Emanyita *(Intestine) – Intestinal obstruction/torsion – volvulus*
4. Embukori *(Retention of the lochia) – foul smelling vaginal discharge / pyometra following abortion or parturition*
5. Emodoki *(Blindness) – Blindness*
6. Emoilaa *Insect poisoning*
7. Engeeya nayengi *Cancer*
8. Engibooto emudong *(Retained placenta) – Retained placenta*
9. Esurai *(sharp pain which occurs during the rainy season) – Sudden collapse of calves or kids*
10. Ilchuta *(Leech) – Leech infesation*
11. Iloisusu *(Fleas) – Flea infestation*
12. Imaheri *(Ticks) – Ticks problem*
13. Nunuk *(curled in) – Ephemeral fever*
14. Olodoentolit *(Red bone marrow) (The disease is believed to be associated with a red star from the East) – Nutritional deficiency*
15. Olodokulak *(Red urine) – Babesiosis*
16. Oloirobi *(Fever-)/ORKULUK (nasal discharge) - FMD*
17. Orkirenyata *(Tenesmus – Straining during defaecation) – Scours*
18. Orkurto *(Worm) – Worm infestaion*

Appendix 3: Overall district ranking, indicating 21 diseases regarded as important in Simanjiro i.e.

causing highest livestock mortality or morbidity.

1. Alariri Skin infection
2. Emburuo (Smoke) – Blackquarter
3. Emoilaa (Insect - hard shelled beetle /caterpillar) – Insect /caterpillar poisoning
4. Emonywa Anaplasmosis
5. Emukuji (Mange)
6. Enaipoki (A small insect which can produce a humming sound, very disturbing to animals as a result of the vibrations of the wings)- Refers to swellings on the skin of the animals akin to the ones caused by tick bite.
7. Endorobo Trypanosomiasis
8. Engirowaj/Empurasi Anthrax
9. Engorotik Diarrhoea
10. Ingaati (MCF)
11. Irmaheri Tick infestation
12. Lipis (lungs problem) – Condition associated with ECF and CBPP
13. Olodokulak Babesiosis (Red water)
14. Oloirirwa looldian Rabies
15. Oltikana (ECF)
16. Oltipilikwa Plant poisoning
17. Orkibiroto - (Aborted foetus/premature newborn) –Manifestation of prevalence of a number of diseases leading to abortion
18. Orkipieyi (CBPP/CCPP)
19. Orkirenyata (Tenesmus - Straining during defaecation) - Scours
20. Orkiyapore (plant name) /ENDOTIHOI (erosion of the skin from the dorsal aspect) – Photosensitisation due to plant poisoning
21. Ormilo (Heart water/cerebral ECF)

Appendix 4: Research organisational structure



Intellectual Property Rights and Strategies for Protecting the Local Communities Interests and Ownership Rights

By John N. Kabare
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1. Introduction

The world today has come to realise the importance of herbal medicine. Be it from the sophisticated point of view, where in the West high powered laboratories refine active molecules from plant extracts, formulate and market them, or from the point of view of a traditional herbalist with a concoction of roots, leaves and bark from a variety of plants.

The usefulness of herbal medicine has finally attained global attention. In fact, it is big business from West to East and South. China is a country where the tradition of herbal medicine is engraved in the culture. It is estimated that 79% of all USA drugs have origin from natural products, 25% of them derived from plants. Annual income from natural product based drugs in the USA runs into billions of shillings, mostly to pharmaceutical companies who also own patents on the drugs. Their use is broad, covering areas as antimicrobials, immuno suppressives, cholesterol lowering drugs and anti cancer drugs. Herbal practice in Africa commands even greater popularity. It is estimated that 80% of the population in Africa depends solely on traditional medicine for disease treatment.

What is the role of intellectual property in the exploitation of medicinal plants for clinical purposes? Taking into account that IPR has become a critical element in global trade, industrial development and technology transfer, and since issues relating to ownership is central to the concept of intellectual property, this paper discusses challenges and opportunities posed in the utilisation of medicinal plants and the trade in their products as it affects Africa.

2. Ownership, availability and access to medicinal plants and their products

IPR and medicinal plant varieties

Availability and access to medicinal plants in Africa is fast becoming a serious limitation to herbal practitioners. Shrinking forests, decimation of riverine shrubs and trees and high population growth has put pressure on once fallow land, converting it for agricultural production. The result is reduced medicinal material, and at worst, threat of extinction for many medicinal plants and trees.

In the past, ownership of medicinal plants in Africa has not been an issue, as herbal practitioners could criss-cross their communal lands at liberty in search of the relevant plants. Today, individual traditional healers walk long distances in search of material. Whereas plant variety laws are well established in developing countries, these are largely for agricultural and ornamental purposes. Both the UPOV system for plant varieties and the patent system can be exploited today to determine ownership of a plant variety.

Plant breeding for herbal plants is not common. Today, the challenge for herbal medicine practitioners is the need to cultivate plants with the sole purpose of yielding the medicinal components required. This is not an intangible project. In view of the modern biotechnological methodologies now readily available, it should be possible to move the genes responsible for active medicinal products from one plant to another for ease of production of the required product. While this may sound futuristic, it is interesting to note that agricultural plants such as maize are being manipulated to produce high lysine content varieties and resistant varieties to drought and insect pests. Cotton varieties with resistance to insect pests and disease have been available for several years. Currently, some useful medicines such as insulin are being

expressed and synthesised commercially from sources other than animal. Plant genomics is a rapidly developing science and has attracted the attention of large companies such as Monsanto, Novartis, Aventis to invent huge sums of money into the unravelling of the plant genome with the view to isolate useful genes.

Modern biotechnological techniques, such as Marker Assisted Selection (MAS) and gene transfer techniques, are responsible for these breakthroughs. Possibilities that new plant varieties could be created to exude target medicinal products are therefore not far fetched. Unfortunately, most of Africa lags way behind in molecular biology and biotechnology application, and it thus not feasible immediately to expect novel medicinal plants that can qualify for classical Patent Protection or Plant Breeders Rights.

Nevertheless, Africa should wake up to this reality and put in place policies to support biotechnology and quickly embark on programs to benefit from their rich medicinal plant genomes. In the meantime, ownership of medicinal plants in Africa will continue to depend on communal or private ownership of wooded land mass. As intellectual property rights regimes practised today do not address issues of community rights, solutions to who owns medicinal plants on the continent must be addressed in light of the provisions contained in the Convention of Biological Diversity. Most notable are sections dealing with access to genetic resources and the view taken that genetic resources are under the sovereign rights of countries. Access laws and regulations are yet to be developed and widely applied in Africa. Africa should also move quickly to put IP laws in place for indigenous and local knowledge, as well as *sui generis* regimes for the protection of plant varieties, as provided for in the Trade Related Aspects of Intellectual Property (TRIPS).

IPR and Medicinal Plant Products

A different scenario exists with regard to IPR protection and ownership of medicinal plant products. The use of patent protection for products and processes is common, particularly in developed countries where technology for screening, purification and analysis is advanced. Records available for the last 5 years from the USA Patent and Trade Mark Office, the European Patent Office and the Japanese Patent Office for compositions which contain active compounds or material derived from plants attest to this.

Number of Patents Granted

Year	**USA**	**Europe**	**Japan**
1995	128	27	242
1996	127	38	145
1997	155	42	132
1998	174	59	18
1999	180	60	--
Total	**764**	**226**	**537**

Patent applications involving medicinal plant products received by patent offices in Africa are much fewer. This is shown by data from Kenya, where in the last five years only a total of 12 applications have been received through the national channel, whereas 16 applications have come through the African Regional Industrial Property Organization (ARIPO) and 2 Patent Co-operation Treaty (PCT) applications have reached national stage.

What is interesting is that a large number of protected patents in developed countries (USA and Europe) are based on plant material originating from the tropics. One of the most controversial sources is the Neem tree *(Azadirachta indica),* widespread in the tropics and utilised traditionally from time immemorial, a source of drug and chemical extracts for numerous applications. The on-going legal case in Europe on an EPO granted Patent for a Neem oil formulation controlling fungi on plants, exemplifies the dilemma caused by patenting of medicinal plant products based on indigenous knowledge of communities in the tropics. The opponents to the patent, the Green Group, Research Foundation for Science, Technology and Natural Resource Policy (New Delhi) and the International Federation of organic Agriculture Movements (Germany), have submitted evidence to the EPO showing that the fungicidal

effects of the Neem tree oil extracts have been known for centuries in India.

Other trees frequently researched are those with products active against malaria, stomach infections, worms, chest infections, rheumatism, childbirth, and sexually transmitted diseases, amongst others. Many such trees and shrubs are under threat due to overharvesting, where there is a need for urgent attention to reverse the trend.

The issue of biopiracy, as shown by the patenting of the Neem tree products, is a worrisome trend. It makes a mockery of the advantages of IPRs, pitching groups against one another and promoting unethical and unfair competition in the race to produce new and effective drugs world-wide. Developing countries, such as countries in Africa, are disadvantaged in this competition due to lack of sophistication in their research. The fact that biopiracy exists is not disputable. It gives a bad name to IPR. Biopiracy is a practice where someone (company, institutions, individual etc.) appropriates biological resources without the prior informed consent of the local people/competent authority of a state without authority and proceeds to obtain IPR on it or uses it for their own gain without sharing benefits with the owner of the knowledge.

In developing countries, and particularly in Africa, biopiracy happens when someone under the pretext of research, in an unorthodox manner and without the knowledge of the local counterpart, collects material and repatriates it clandestinely for their own advantage. In other cases, research results are "stolen" for patenting abroad without the participation of the local scientist in the patent. Or it could be a "tourist" who lures a local community to collect material in exchange for a few pennies.

Examples are numerous. In Kenya there is much talk of the impending depletion of the tree *Prunus Africa*na, which has already been wiped out in countries such as Cameroon and Madagascar and is threatened in Uganda and Tanzania. What is happening in Kenya regarding *Prunus africana* is biopiracy. The maasai in Maasai Mara where collection is going on do not know that their trees are being depleted to serve some prostate interests in Europe!

Biopiracy is a moral question. One example is the current "patent wars" on basmati rice. Rice Tec's US patent involves the protection of 22 basmati varieties from Pakistan and India, countries which have grown them from time immemorial. The varieties got into the hands of the US prospectors through the US gene bank, where they had been deposited for safe keeping by India and Pakistan!

There is a need for laws against biopiracy internationally. These should be simple, straightforward and easily applicable, to tackle with speed such distressful occurrences as the current patent claims on the Neem and Basmati products by the West. Patenting of medicinal plant products when carried out correctly and procedurally is advantageous for the development of pharmaceutical industry, as can be seen by income gained by the USA, Europe, China, Japan, amongst others, from herbal based drugs. Encouraging for developing countries is the example of India, whose drug companies such as the Himalaya Drug Company have succeeded in exporting abroad numerous formulations based on extracts from medicinal plants. China stands out as a country whose medical advances are firmly rooted in natural products. They now export their products and operate popular clinics world-wide. Thus, it is abundantly clear that there is gain to be made in embracing the patent system as a medium for greater trade in herbal pharmaceuticals, with high revenue earnings through commercialisation.

Income can be earned through, for example, licensing, partnerships and shares arising from the commercialisation of patents. Furthermore, patenting of medicinal plant products is in support of the CBD, where it can be an important tool for assessing the value of a genetic resource, an important element in the issue of equitable sharing. IP is a powerful tool in the promotion of technology transfer and in the generation of income for sharing with local communities and investment in research and development, apart from its importance in the promotion of technology transfer.

In Africa, screening of medicinal plants for clinical activity is slowly picking up. Several countries now have well established laboratories that routinely professionally investigate medicinal activity in plant

material for various clinical purposes. The OAU made an early start when it in 1985, through its Scientific Technical and Research Commission (STRC), came up with the African Pharmacopoeia describing 100 medicinal plants from Africa and their products. This was followed by a publication in 1986 on detailed general methods of analysis of active products.

Local capabilities are critical if Africa is to harness its enormous medicinal potential from natural products. A number of institutions are well on the way to pioneering high calibre research leading to drug preparations from herbal plants and other natural products. Nigeria's National Institute for Pharmaceutical Research and Development and the International Centre for Ethnomedicine and Drug Development are involved in the development of phytomedicines and the standardization of herbal medicine. The Kenya Medical Research Institute has potential herbal based drugs in the pipeline, effective against, among others, high blood pressure, diabetes, and asthma. Similar work is to be found in Tanzania's Institute of Traditional Medicine (ITM) of the Muhimbili University College of Health Sciences, and TRAMEDEA of the University of Cape Town Department of Pharmacology. Several other countries in Africa have similar institutions active in ethnomedicine, including Cameroon, Madagascar and Uganda.

To promote faster development of expertise in ethnobiology, there is need for greater collaboration with the private sector. Commercialisation of pharmaceuticals is an expensive process, requiring high financial input. A good example is the collaboration of Bioresources Development with Shaman Pharmaceuticals Inc. of the USA in the investigation of novel plants derived compounds and extracts for the treatment of malaria, leshraniaus and trypanosomiasis. However, to benefit Africa, such collaboration must take into account the ownership of traditional knowledge upon which the investigation is based, and be able to apportion adequate compensation to the local communities for accessing their knowledge and material. The trend in many African countries is to put in place regulations for access to genetic resources and once this is done, prospectors will be required to adhere to national protocols and laws.

Once purified and characterised, it is possible to patent the medicinal plant products and the processes developed for their isolation, formulation, stabilisation etc. Owners of patents stand to increase their incomes many times over by being able to commercialise and export high value herbal products rather than their raw materials.

It is recognised that characterisation of a compound to the high level required for patenting is not easily attainable. For this reason, some countries such as Kenya are in the process of revising their industrial property law to allow protection of weaker patents as utility models.

Use of Trade Marks

In addition to the refinement of herbal products for patenting, trade marks are a powerful mode of promotion of one's commodities. A good number of herbal practitioners in Africa have trade names, although they may not be aware that the names under which they practice are indeed trade names.

There is a need for education for traditional healers and herbal practitioners on modalities of use of IPRs for promotion of their trade. Most IP offices in Africa register trade marks and issue patent and should indeed promote educational programmes for their national and from linkages with groups such as herbal practitioners.

Intellectual Property Regimes

1. Industrial Property
- Patents
- Industrial designs
- Utility Models
- Technovations
- Trade Marks
- Service Marks
- Geographical indications
- Layout Designs (topographies) (of semiconductor integrated circuits)

2. Copyright
- Literary works, musical works, Art, computer programs, compilation of data.

3. Plant Breeders Rights
4. Trade Secrets (undisclosed information)

Intellectual Property Rights Covered by the TRIPS Agreement

- Copyright and related rights
- Trade marks
- Geographical Indications
- Industrial designs
- Undisclosed information (Trade Secrets)
- Patents
- Layout designs (topographies) of integrated circuits

Criteria for Patenting

- Patent

1. Novelty - Must be new
2. Inventive step
3. Industrial application

- Utility Model and Technovation

1. New/modification
2. Industrial application

Intellectual Property Systems in Africa

Most African countries have some intellectual property systems that are operational and based on the Paris Convention, (Industrial Property), and Bern (Copyright). Only two African countries have acceded to UPOV (The International Convention for the Protection of New Varieties of Plants): South Africa and Kenya. Zimbabwe has recently made attempts to accede to UPOV 1978. Nevertheless, a number of countries do have some forms of Plant Breeders Rights.

In spite of the fact that intellectual Property systems are established in Africa, very little use is made of them by nationals. Most applications to IPR offices are those received from countries outside Africa. There is need for concerted effort to educate the public in Africa about the advantages of IPR protection. With the globalisation of trade and liberalisation of economies, it just doesn't make any sense for African countries to remain outside the IPR system, now adopted by the rest of the world. Besides, most countries in Africa have signed the TRIPS Agreement, which makes it mandatory for them to institute national IPR systems compliant with the TRIPS requirements. Even with the best chance that the TRIPS can be revised, there will still be need for countries to adhere to internationally harmonised minimum standards of IP protection.

Most African countries which are members of WIPO are also members of WTO, and are signatory to the TRIPS Agreement. There are however areas of contention and concern in the TRIPS agreement which have in the last few years captured the attention of African or developing countries. In particular Article 27.3b of the TRIPS, which makes provision for the patentability of plants and animals, has received extensive discussion and was one of the areas to be discussed in the aborted Seattle WTO meeting of November 1999. Most African countries prefer not to patent life forms, as a matter of ethics. In terms of medicinal plants, it would indeed be an issue of concern to protect by patent even if they have been engineered, in view of the strong measures normally instituted for patent protection.

The greatest limitations of all classical IPR protection are their limitations in addressing issues close to the hearts of developing countries, which include indigenous/traditional knowledge, access to genetic resources and Farmers' Rights. The debate on these issues is likely to take long before solutions are found. Efforts to discuss these issues in fora like that provided by the Crucible Groups are encouraging, particularly if they can result into tangible policy options for countries such as those in Africa to utilise in their development of required laws.

Another often expressed area of concern is that patenting results in high costs for pharmaceutical companies, and thus may have a negative impact in Africa regarding access to essential medicines, such as those for the treatment of AIDS and Malaria. One active NGO is the Medecins Sans Frontieres (MSF) (Doctors without Borders), whose current intensive advocacy is highly critical of patenting regimes. It will be very interesting to watch the developments of organisations such as these, as it is similar emotive sentiments by stakeholders who brought down WTO in Seattle.

Conclusions

It is clear that the challenges, constraints and perspectives brought about by intellectual property regimes are indicative of a system which is evolving and that one by one issues of concern or contention will in time have solutions as groups, governments and international organizations continue to discuss and revisit the role and place of intellectual property in matters of everybody's life.

Some Legal Aspects on Intellectual Property Rights in Relation to Medicinal Plants in Tanzania

Talking Notes
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1. Introductory Remarks

Intellectual property rights in relationship to medicinal plants found in the developing countries like Tanzania are riddled with a lot of controversy. Thus, it is a complex issue attracting a lot of questions, few of which can be satisfactorily answered.

Medicinal plants form part of the indigenous cultural and intellectual property of different communities. This has two components: indigenous knowledge and indigenous resources:

(a) Indigenous knowledge includes nutritional knowledge, medicinal knowledge, agricultural knowledge, environmental knowledge and spiritual knowledge
(b) Indigenous resources include human genetic materials and species of plants and animals. These contribute a lot to the biotechnology industry (drugs and pharmaceutical products).

2. Limitations of Applying Classical Intellectual Property Regimes

International conventions and national laws in Tanzania use the classical approach in tackling intellectual property rights issues. These are much influenced by capitalist development and attendant individualism. This is opposed to the socio-economic setting of rural African communities, where things such as plants are considered to be a common property. Problems arise when applying a classical intellectual property rights framework to African communities that are still premised in communal ownership of medicinal plants and that ownership being perpetual, as opposed to the state law where individual ownership is recognised and protected.

3. What is Intellectual Property

Generally, intellectual property refers to the current system of laws which provide exclusive moral and economic rights in:

- Artistic and literary works by virtues of the copyright system;
- Inventions by virtue of the patents system
- Trademarks identifying the origin of the goods and services under the trademark system;
- Registered designs for an article's appearance by virtue of the industrial designs system; and;
- Certain developed species and varieties of plant breeder's' rights system.

The classical or traditional approach on intellectual property is based on the notion that:
(a) Innovation is the product of the creative, intellectual and applied concepts of individuals;
(b) Specific economic rights are granted to inventive persons as a reward for sharing their contributions; and
(c) It stimulates inventive activities.

2. The Tanzanian Legal Framework Relevant to Medicinal Plants

The following pieces of legislation are relevant in a discussion of intellectual property protection in Tanzania:

(1) Trade and Servicemarks Act, 1986
(2) Patents Act, 1987
(3) Copyright and Neighbouring Rights Act, 1999

The most relevant, and which is going to form a basis of the discussion of this talk is the Patents Act, 1987. The Act is further supplemented by the Patents Regulations, 1994.

(a) What is a patent

In the classical approach, a patent is essentially a right to protect inventions. The patentee is granted the exclusive right, during the term of the patent, to exploit and to authorise another person to exploit the invention.

(b) Meeting criteria for protection

The following are the criteria to be fulfilled for an invention to be accorded protection. These are:
(i) It needs to be new or novel compared to prior art base:
(ii) It must involve an inventive step; and
(iii) Capable of industrial application.

Section 8 of the Patent Act, 1987 requires that an invention is patentable if it is new, involves an inventive step and it is industrially applicable. The Act gives a narrow definition of an "invention", as stated under section 7 (1):

"For the purposes of this Act 'invention' means a solution to a specific problem in the field of technology and may relate to a product or process".

Other items that are regarded as inventions elsewhere have been specifically excluded under the Act. Section 7 (2) lists the excluded items as follows:
(a) discoveries, and scientific and mathematical theories;
(b) plant or animal varieties or essentially biological processes for the production of plants or animals, other than microbiological and the products of such processes;
(c) schemes, rules or methods for doing business, performing purely mental acts or playing games;
(d) methods for the treatment of the human and animal body by surgery or therapy, as well as diagnostic methods; but shall not apply to products for use in any of those methods; and
(e) mere presentation of information.

It should, however, be noted that under section 10 of the Patent Act, 1987 it is possible to apply to be granted a patent in respect of an invention the exploitation of which is prohibited by law. There is also a provision on temporary exclusion from patentability of certain kinds of products, or processes for the manufacture of such products. This general exclusion may be for a period not exceeding 10 years.

(a) Ownership of a Patent

Section 14 (1) provides that the rights to a patent rest with the inventor, i.e. the person who made an invention or under section 14(2) of joint inventors. According to section 14 (4)(a) an owner of a patent can transfer or assign her or his right. However, that right is not automatic. One has to lodge an application for patent. Under section 18 (1) application for a grant of a patent is to be made to the Registrar of Patents. The application must contain:

- a request for a grant of a patent
- the description of the invention.

The information must disclose the invention in a manner that is sufficiently clear and complete for the invention to be evaluated and carried out. The application can be made by the inventor or joint inventors or through an agent (section 18(2)).

2. Patenting Medicinal Plants – Limitations of the Law

It is imperative to note that to be patentable, an invention must be a manner of manufacture. A good idea or mere discovery is thus not patentable. The discovery of existing, naturally occurring substance cannot be patented unless an invention is found in some new method of using the material, or some new adaptation of it to serve a new purpose. Invention of a way of extracting an active element within a plant or development of a new use for a natural organism may be eligible for patent protection.

Another element required is novelty. This is when it is compared with prior art base. Prior art is defined under section 9 (2) (a) of the Patents Act to be:

"Everything made available to the public anywhere in the world by means of written disclosure (including drawings and other illustrations) or by oral disclosure, use, exhibition or other non-written means shall be considered prior art provided that such making available occurred before the date of the filling of the application, of priority date, validly claimed in respect thereof."

This brings complexity to patent traditional uses of medicinal plants and knowledge held by different communities in Tanzania and which is available and owned in common. This is partly because such knowledge is available in the prior art base. The problem is further compounded by publishing accounts of the uses of medicinal plants by indigenous people by ethnobotanists and ethnopharmacologists. Once that is done then it becomes public knowledge and therefore part of prior art base. However, in cases where the disclosure is made for a certain allowed purpose, and within a certain period prior to filing of an application, the information will not be considered as having become public knowledge.

3. Other Legal Options

There are other means of legal protection with less rigorous requirements than the patent system. These include, *inter alia*, trade marks and utility models.

Utility models are known as weaker patents. This may be granted even where what has been done is a modification of what exists. The question of novelty and therefore the question of prior art base does not arise.

A trademark may also offer protection of rights to medicinal plants and traditional medicine knowledge. A trademark is a sign used to indicate the trade origin or source of goods or services. A sign includes any letter, word, name, signature, numeral, device, brand, heading, label, ticket, and aspect of packaging, shape, colour, sound or section. However, trademarks as means of protecting medicinal plants and knowledge is limited by the fact that trademarks are basically there to:

- Protect the public – preventing mistake, deception and confusion with regard to origin;
- Protect sellers – good will;
- Indicate origin;
- Guarantee equality; and
- Serve as marketing and advertising device.

The Convention for Biodiversity provides new opportunities for intellectual property rights protection to medicinal plants and knowledge. For example, article 10 (c) calls on parties to:

"protect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements".

There is also the avenue of developing a *sui generis* system under article 27.3b of the Trade-Related Intellectual Property Systems (TRIPS) Agreement. The article provides that:

"Members may also exclude from patentability – plants and animals other than micro-organisms, and essentially biological and microbial processes. However, members shall provide for the protection of plant varieties either by patents or by effective *sui generis* system or by any combination thereof".

2. Concluding Remarks

Intellectual property rights regime available in Tanzania serves to protect the rights of commercial breeders and biotechnology companies, but are inadequate for the protection of medicinal plants and for the protection of traditional knowledge of local communities. This is because such knowledge is usually considered not "new", i.e. that it lacks novelty and its attendant components. Moreover, in many instances it is held in the "public domain", which is commonly held and shared by the community and therefore part of the prior art base.

Biotechnology Research and Development Policy Needs for Tanzania

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Abstract. Biotechnology research and development activities are increasingly being carried out in Tanzania. Biotechnology techniques such as microbial fermentation, plant tissue culture, diagnostic kits in animal diseases surveillance and DNA-based molecular markers in plants as well as animals are being applied at various levels in a number of institutional laboratories with the agricultural sector being most active. In spite of the increasing level of biotechnology application in agricultural research and development, and the potential risks to human and the environment associated with it, Tanzania does not yet have a regulatory mechanism for its safe application. Also, those efforts lack public policy support because most of those activities do not get adequate funds from the government. This may be due to the fact that the research and development activities do not reflect the needs of the country as well as the currently available human and technical capabilities. Policy guidance will, therefore, provide the basis for research strategies that will ensure maximum utilisation of available resources, including identification of the real needs and potentials of the country and requirements for capacity building.

1.0 Introduction

After realising that only scanty information was available on the actual status of biotechnology research and development activities in Tanzania[1], the Commission for Science and Technology (COSTECH) conducted a survey aimed at collecting more in-depth information[2]. Since then, more data and information have been collected and constantly updated[3]. Table 1 presents the type of institutions and their activities, Table 2 provides the sources of funds, Table 3 summarises the products and Table 4 deals with the institutional linkages.

A number of institutions are found actively engaged in biotechnology or biotechnology related research and development activities. The most active institutions include the Mikocheni Agricultural Research Institute (MARI), the Applied Microbiology Unit (AMU) at the University of Dar es Salaam, the Animal Disease Research Institute (ADRI) as well as the Department of Animal Science and Production in collaboration with the Department of Physiology, Biochemistry, Pharmacology and Toxicology at the Sokoine University of Agriculture (SUA).

Apart from capacity building, noteworthy results have been recorded in the following areas[3,4]:

(a) **Agricultural Biotechnology**

(i) the application of tissue culture techniques for micropropagation of various crops eg. banana, coconut, cashew, pineapple, roots and tubers;
(ii) development of specific DNA probes for diagnosis of diseases in various crops eg. coconuts and sweet potatoes;
(iii) development of the first preliminary genetic map of coconut using DNA markers;
(iv) the application of monoclonal antibody technique and polymerize chain reaction as means of rapid diagnosis of Contagious Bovine Pleuro-Pneumonia (CBPP), Food and Mouth Disease (FMD) and Rinderpest in cloven hoofed animals;
(v) characterization of various Tanzania Shorthorned Zebu (TSZ) cattle ecotypes using molecular makers; and
(vi) rapid mushroom identification using DNA techniques and the cultivation of edible local and wild mushrooms on agro-wastes.

(a) **Environmental/Industrial Biotechnology**

(i) treatment of agro-industrial wastes and affluents to reduce environmental pollutants through using aerobic systems to produce biogas and enzymes derived from micro-organisms (eg. fungi) for detoxification;
(ii) understanding of and, if possible, improvement of traditional biotechnology practices eg. in food fermentation (cassava) and the extraction as well as purification of enzymes, proteins and other substances of commercial value for industrial application.

(a) **Pharmaceutical/Medical Biotechnology**

Research activities have so far focused on obtaining bioactive substances from locally available plants, such as marine soft corals, which may be of pharmaceutical use e.g. for antimalarial treatment.

Research and Development activities at MARI are funded by the German Technical Co-operation (GTZ) at USD 10,000 per year until November 2000, and the European Union at ECU 137,000 for 3½ years (October 1997 – March 2001). The Department for International Development (DFID) provided USD 5000 from February 1998 up to February 2000.

At ADRI, diagnostic kits as well as consumables for laboratory use are provided by the International Atomic Energy Agency (IAEA), but financial resources provided by the Government of Tanzania (GoT) for field work were inadequate.

The Chemistry Department of the University of Dar es Salaam received funds from the International Foundation for Science (IFS) on a project titled "A search for biologically active and other natural products from Tanzanian medical plants and marine soft corals" up to 1996. On the other hand, the Institute for Traditional Medicine (ITM) of the Muhimbili University College of Health Sciences received funds from NORAD/COSTECH to work on "Development of antidiabetic drugs from indigenous plants" in 1994.

Major constrains so far have been in the following aspects[2,3]:

(a) Research areas are not yet focused to reflect national priority,
(b) Most institutions have no adequate manpower conversant in biotechnology related subjects e.g. molecular biology, genetics, microbiology and biophysics including techniques such as rDNA, tissue culture, PCR etc.,
(c) Biosafety guidelines and regulatory structures are not yet in place,
(d) Inadequate allocation of funds from the GoT,
(e) Biotechnology policy is not yet in place, and
(f) Most policy and decision makers as well as other relevant stakeholders are not yet aware of the potential of biotechnology for socio-economic development of the country.

Therefore, since 1999 Sida/SAREC has provided funds for research and capacity building at MARI, AMU and COSTECH in the framework of a project titled 'The East African Programme and Research Network for Biotechnology, Biosafety and Biotechnology Policy Development', with the acronym BIO-EARN for agricultural biotechnology, environmental/industrial biotechnology, biosafety and biopolicy[3]. The institutions involved are MARI (agricultural biotechnology), AMU (environmental/industrial biotechnology) and COSTECH (biosafety and biopolicy), which is also the National Focal Point.

2.0 Importance of Having a Biotechnology Policy

Currently, Tanzania has no specific policy on biotechnology despite its increasing application[2,3,4,5,6]. Much as the 1996 National Science and Technology Policy for Tanzania recognized the importance of biotechnology application, it is silent on strategies of developing biotechnology policy guidelines as well as organizational and institutional frameworks for research and development. Critical factors in the formulation of a biotechnology policy and its implementation strategies include priority setting, institutional framework, biosafety guidelines, intellectual property rights, financing, technology transfer and public awareness[2,3,4,5,6].

Many countries in Africa, Tanzania included, are today faced with severe reductions in funding for agricultural research. Given that biotechnology is often more expensive than conventional research, it should then be focused on solving priority national problems. Biotechnology research and development programmes must, therefore, conform to national research policies balanced by technical realities and needs. In the absence of a biotechnology research and development policy, tools for biotechnology cannot be effectively harnessed to increase production or processing because no realistic priority setting would have been done[7]. For Tanzania, it means that appropriate policies, which mount efforts to identify key national priorities for biotechnology, have to be developed. These should bear in mind the needs of the resource poor, who are about 90% of the population, live in rural areas and depend mainly on agriculture for their livelihood. Such an approach should take into consideration national development policies in other areas, private sector interests, market possibilities, and technology diffusion mechanisms and linkages[8]. Therefore, diverse stakeholders should be involved in the formulation of national biotechnology policies and strategic plans for its implementation.

In formulating biotechnology policies, another aspect to be considered is that of Intellectual Property Regimes. Tanzania is a contracting party to the Convention on Biological Diversity (CBD). According to Article 8 (g) of the CBD, 'each contracting party shall as far as possible and appropriate establish or maintain means to regulate, manage or control the risks related with the use and release of Living Modified Organisms (LMOS) resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health'.

The CBD does not only seek to promote conservation of biodiversity and the sustainable use of its component, it emphasises on a fair and equitable sharing of benefits arising from the use of the resources, including appropriate access to genetic resources and transfer of relevant technologies (Article 19). The CBD, however, recognises different potentially conflicting rights: It recognises the need to ensure equitable allocation of ownership rights and access to biotechnology, but emphasise that such rights should support the objectives of the convention and not run counter thereto. The Convention also recognises the role of indigenous and traditional knowledge in biodiversity conservation (Article 17) but does not specifically provide for the modalities of sharing benefits arising from such knowledge or the kind of property rights hat holders of such knowledge can get.

The Biotechnology policy framework should therefore recognise informal or indigenous innovations through developing a system of community registers for local innovations related to the use of genetic resources.[9] This would not only revitalise traditional knowledge, skills and techniques as well as protect local rights of tenure over biotechnology raw material, it will also protect the same from exploitation by commercial users through proof of prior use[9].

3.0 The Way Forward for Tanzania

During the First BIO-EARN Biosafety Training Workshop in Entebbe (November 29 – December 3, 1999), a proposal to form a brainstorming task force on the way forward for Tanzania with regard to formulation of biotechnology safety guidelines and policy framework was presented, discussed and

accepted[10]. The task-force (comprising of 11 members) held its first meeting on 13 –14 April 2000 in Arusha[11].

The task-force, apart from proposing a 27 man strong Interim National Biosafety Committee, proposed holding an awareness workshops on "The state-of-the-art in biotechnology and the way forward in Tanzania" for scientists/researchers, technical staff and other relevant stakeholder as well as on "Policy options for biotechnology research and development in Tanzania" to mainly include policy and decision makers.

In the latter workshop, four papers will be presented:

(a) Overview on the potentials and risks of biotechnology;
(b) Overview of international agreements related to biotechnology;
(c) Policy and regulatory framework for biotechnology; and
(d) Concepts for the formulation of national biosafety guidelines.

The general objective of the latter proposed workshop is to expose both policy and decision makers to the benefits and hazards of biotechnology for economic development of the country. Specific objectives are:

(i) To increase their understanding and appreciation on the role of biotechnology for socio-economic development and induce their catalytic function in formulation and implementation of appropriate biotechnology policies and strategies;
(ii) To broaden their understanding of policy issues associated with such agreements like the Trade Related Intellectual Property Rights (TRIPS), Convention on Biological Diversity (CBD) and other related agreements; and
(iii) To stimulate awareness and public debate on biotechnology policies in relation to questions of Intellectual Property Rights (IPR), patenting of life forms and trade in germplasm.

Efforts are currently underway to seek funding from the United Nations Environment Programme (UNEP). However, it is utmost important that the Government starts to allocate adequate funds to support biotechnology research and development in the country. The private sector engagement in biotechnology is also encouraged because it is the focal organ for biotechnology development in most developed countries[8]. Meanwhile, assistance through collaboration with international organisations should be promoted, especially to provide information on available technologies, their use and application as well as the use of electronic information tools and databases. In January 2000, the President of the United Republic of Tanzania signed the Instrument of Accession for Tanzania to become a member of the International Centre for Genetic Engineering and Biotechnology (ICGEB). The Centre conducts research, training and collaborative research programmes as well as providing scientific services on genetic engineering and biotechnology.

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Table 1: Activities and Actors

Type of Institution	Actors	Specific activities	Coverage
RESEARCH AND DEVELOPMENT	(a) Mikocheni Agricultural Research Institute DSM (MARI)	Developing specific DNA probes for diagnosis of diseases Constructing genetic maps by using RAPD and ISTR techniques Tissue culture Genome fingerprinting	- Coconut palms - Sweet potatoes - Cashewnut - Coconut palms - Banana, coconut, anamas - Coconut, cashewnut, banana, ananas
	(b) Kizimbani Agricultural Research and Training Center, Zanzibar (KARTC)	Field testing of varieties obtained through tissue culture from IITA laboratories. Tissue culture	- Cassava - Cassava and sweet potatoes
	(c) Animal Diseases Research Institute, DSM (ADRI)	Sero-diagnosis of CBPP, FMD and Rinderpest	- Cattle (including all other cloven hoofed animals)
	(c) Horticulture Research Institute, Tengeru Arusha (RI-Horti)	Tissue culture	- Horticultural crops, especially banana and sweet potato
	(e) Ukiriguru Agricultural Research Institute, Mwanza.	Tissue culture Field testing of varieties obtained through tissue culture from IITA and CIP	- Cassava, yams and sweet potato
	(f) Sugarcane Research Institute, Kibaha	Tissue culture Field testing of varieties obtained through tissue culture from IITA and CIP	- Cassava - Cassava and sweet potato
	(g) Hombolo Agricultural Research Institute, Dodoma	Field testing of varieties received from IITA through tissue culture	Cassava
	(h) Naliendele Agricultural Research Institute, Mtwara	Field testing of varieties received from IITA through tissue culture	Cassava
	(i) Maruku Agricultural Research Institute, Kagera	Field testing of varieties received from Kawanda Research Station, Uganda through tissue culture	Banana
UNIVERSITIES	(a) Faculty of Pharmacy (MUCHS)	Tissue culture	Indigenous medicinal plants
	(b) Sokoine University of Agriculture (SUA)	Biotechnology laboratory	Technique in plants and livestock
	(c) Applied Microbiology Unit (AMU) UDSM	Biotechnology laboratory	Anaerobic fermentation Waste water treatment Food microbiology Biomethanation
PRIVATE	(a) Commercial – TANADE	Tissue culture	Food and cash crops Ornamental trees
	(b) NGO – KCDP	Tissue culture Farm level testing of banana varieties received from INIBAP through tissue culture	Banana

Table 2: Source of Funding

Institution	Funding Institution	Type of Investment
MARI	GTZ, EU, DFID, Sida/SAREC	- Equipment, Chemicals and Reagents - Staff capacity building
ADRI	IAEA EU	- Equipment, Chemicals and Reagents - Staff capacity building
AMU	Sida/SAREC	Capacity building
TANADE	Private	Equipment, Chemicals and Reagents
MUCHS, SUA	GoT	Station Upkeep
KARTC	SARRNET (USAID) IFAD	Equipment, Chemicals and Reagents
Horti-RI	CIP, GTZ and SARRNET	Equipment, Chemicals and Reagents
ARI-MARUKU	THE NETHERLANDS	Capacity building
ARIs – Ukiriguru Naliendele Hombolo Kibaha	SARRNET, CIP	- Capacity building - Equipment, Chemicals and Reagents
KCDP	BELGIUM	Equipment, Chemicals and Reagents

Table 3: Products of Biotechnology

Institution	Products
MARI	Techniques developed and in application: DNA probes, PCR primers (for phytoplasma detection)
	Embryo culture techniques (coconut)
	Preliminary coconut linkage map
ADRI	Disease surveillance
	Disease diagnostic tools
	Training of field staff
TANADE	Capacity up to 150,000 seedlings/month for sale, however underutilized
AMU, SUA, MUCHS	Capacity building (Students) Cultivation of local and wild edible mushrooms (AMU) Preliminary fingerprints of local cattle ecotypes (SUA)
KARTC & ARIs	Staff capacity building
	Increased germ plasma collection of cassava, yam, banana and sweet potato
KCDP	Availability of a wide range of banana varieties