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FRAMEWORK ON BIOPROSPECTING

Framework on Bioprospecting and Effective Commercialization of Traditional Knowledge

A. Background

This draft framework is a product of a meeting that was held in Mauritius from 10-12th September, 2007. The meeting was officially opened by Dr Patrice Cure who represented the Minister of Foreign Affairs, International Trade and Cooperation. He noted that his country felt especially honoured to host the two meetings. He was grateful that Mauritius was playing its role in the generation of draft frameworks that would be useful to the continent. A welcome address was delivered by Professor I. Fagonee, the Vice-Chancellor of the University of Mauritius, who stressed the importance of such a meeting in view of the growing importance of natural plant products in the well-being on communities.

Dr M.H.K. Timamy, representing the Commissioner for Human Resources, Science and Technology, conveyed greetings from the Commissioner. He observed that the Commissioner has expended considerable effort in advancing the cause of science and technology in Africa, and the meetings in Mauritius were a reflection of her desire to see effective arrangements being put in place to promote growth and prosperity in Africa. He stated that Her Excellency was aware that traditional knowledge and the useful biotic heritage in our midst was not being properly cared for, but hoped that the discussions would produce outcomes that enhance commercialization and protection of our genetic heritage. He concluded by wishing the participants a fruitful meeting.

B. Objective of the meeting

The objective of the meeting was to discuss a paper entitled: *Bioprospecting and Commercialization of Indigenous Knowledge*, with a view to generating a draft framework from discussions and cross-fertilization of ideas. The idea stemmed from the concern that Africa does not have a bioprospecting framework to guide Member States beneficially exploit the rich biotic resources in their midst. Over the years, Member States have been relying on international instruments and conventions (many of which have been ratified but not domesticated) when seeking to exploit her biotic heritage.

However, there is need to institutionalize arrangements that would ensure equitable sharing of benefits, conditional access to biodiversity resources based on leads from traditional knowledge, effective material transfer agreements, and robust capacity-building. The meeting succeeded in generating a draft framework outlined below.

At least 30 experts from Africa attended the meeting. The list of participants is attached.

C. Introduction

Over the last few years, advances made on the utilization of indigenous medical knowledge for production of therapies has raised important concerns about the readiness of many African countries to exploit commercialization opportunities that would enhance local drug production capabilities. At the international level, cases of biopiracy continue to deny benefit flows to Africa. Issues of contention regarding access to biological resources, sharing of benefits, and securing of consent are still dominating the debate many years after the Convention of Biological Diversity was adopted. Vital genetic resources are facing risks of disappearing as harvestors of raw materials rush to make quick short-term gains. The question that arises is whether the formulation of a Bioprospecting Framework, replete with projects, can facilitate the creation of institutions and other capacities to broaden the base of health security among Member States.

Successes scored on the bioprospecting front have raised the potential of traditional health systems being accommodated by, and institutionalized within, modern functional arrangements. And Africa's productive possibilities would be greatly enlarged if Member States are facilitated to harness the biological riches within their midst.

D. Principles

- 1.1. Sovereign rights of States over their national resources;
- 1.2. Interdependence of all biodiversity components including humans;
- 1.3. Rights of indigenous and local communities;
- 1.4. Distribution of benefits should be fair and equitable;
- 1.5. Prior informed consent (PIC) is a sine qua non;
- 1.6. Gender equality;
- 1.7. Respect for community culture, biodiversity, and traditional knowledge;

- 1.8. Inclusiveness;
- 1.9. Public participation in decision-making
- 1.10. Institutional transparency and accountability,
- 1.11. Effective leadership
- 1.12. Broad-based ownership of decisions.

E. The Strategy for bioprospecting

Africa has become acutely sensitized to the exploitative dangers surrounding the biological wealth in her midst. The use of medicinal biodiversity over time has been at the very core of traditional health systems. In more recent times, efforts to harness this knowledge have assumed critical dimensions given the numerous cases of biopiracy many Member States have experienced. Not only have losses been huge, but benefits to Africa have been few and far between. It is in this connection that Member States need to be guided by a bioprospecting strategy with a view to ensuring effective utilization of Africa's bioresources. The following suggestions have been advanced:

1. Formation of a Multidisciplinary Committee of stakeholders including NGOs to take the lead in the management of bioprospection matters with a networked database and adoption of measures to curb biopiracy.
2. Creation of a centralized control system on the issuance of permits, licences or certificates
3. Need to sensitize the local people (especially at the grass roots level) on the importance and value of biotic resources is essential.
4. A networked database to enable the appropriate authorities to know the status of various genetic resources and the enquiries that have been made on them needs to be developed.
5. The development of a centralized website providing information on the medicinal and other economic value of Africa's genetic resources to assist Member States in making informed decisions on bioprospecting

6. Coordinated controls between Member States should be devised thus making it impossible for bioprospectors to move from Member State to Member State even when they have been rejected in one or committed an illegal act in that State.

7. Genetic resources know no political boundaries, and hence the need for long, medium and short term planning is required. Each country should plan for the following:

- the formulation of policies;
- the enactment of appropriate legislation that is harmonized throughout the Continent;
- the implementation of the laws and the monitoring of the implementation;
- contracts that are clear and uniform across borders;
- the education/enhanced awareness of communities and citizens at all levels especially the grassroots level
- prioritization of bioprospecting issues.

F. National Policy framework for management of bioprospecting

For the most part, Africa has relied on international instruments and conventions to manage bioprospecting activities through ratification of such devices. A policy framework will provide the necessary controls with stringent penalties for contraventions of the law to deter offenders. Member States need to undertake the following:

- ratify CBD and all other relevant treaties on bioprospecting;
- carry out gap analysis
- develop a national bioprospecting framework
- enact legislation on bioprospecting
- harmonize national legislation for eco-regional collaboration on bioprospecting
- build national inventory of biological resources and associated traditional knowledge, innovations, technologies and practices
- invest in ethnobotanical and Geographical Information System (GIS) databases

- effect judicious management of bioresources
- promote and facilitate capacity-building
- promote education and awareness
- develop a national Bioprospecting Strategic Action Plan (NBSAP)
- share knowledge between States on best practices on bioprospecting.
- ensure domestication the CBD.
- sensitize the leadership on bioprospecting issues and the need to take immediate interventions.
- formulate national policies and enact legislation to regulate access to their genetic resources;
- encourage research, sharing of knowledge and the exchange of ideas, information and expertise from Member States and other countries that have advanced in bioprospection;
- ensure that laws are enacted to provide for the protection of intellectual property rights.
- ensure that where new drugs are introduced into their countries clinical trials should be conducted on those drugs, in their respective countries to confirm their safety and efficacy before they are administered or put on the market;
- exercise caution when preparing databases to ensure that the information is only accessible on permission. Databases should be protected.
- ensure that they identify institutional watchdogs to safeguard their interest and further ensure that they are not disadvantaged by international organizations that are funded by big pharmaceutical companies on the exploitation of genetic resources in their respective countries;
- ensure they upgrade the infrastructure and capacities of their enforcement agencies for purposes of enforcing their laws to prevent and curtail the illegal exploitation of genetic resources (biopiracy). The law should provide for a definition of “biopiracy” which definition should be adopted by all Member States.

- There should be mechanisms in place to ensure that approvals for the exportation of genetic resources are acceptable to all relevant appropriate bodies responsible for biodiversity control;
- There should be intercontinental networking and Member States should share experiences;
- ensure a fair return is made on Africa's contribution to the global market in the form of not only health but also on economic aspects. Member States should also enact legislation which regulates trade in biological resources. Governments should look at plants as commercial entities;
- ensure that bioprospectors negotiate with their respective Governments and the concerned communities before bioprospectors exploit their genetic diversities. (It is cardinal that Governments be privy to bioprospecting undertakings in their respective countries);
- require bioprospectors to import technology and equipment for the processing of genetic resources, to develop local expertise and process the genetic resources in their Member States;
- develop their own bioprospecting agreements;
- enact laws that require the sharing of benefits arising from access to genetic resources and should ensure that where bioprospective agreements are concluded they culminate in the sharing of benefits;
- promote value addition on their genetic resources;
- develop national herbaria and encourage the use of electronic voucher specimens (plant images collected by way of digital camera);
- provide for the training or capacity building of taxonomists, lawyers (with emphasis on IPR), biotechnologists, phytochemists, pharmacologists, skilled negotiators (including lawyers), computer experts (database protection);
- Member States should provide effective control of their biodiversity at national, grassroot and regional levels;
- formulate policies and enact legislation on traditional knowledge;

- encourage Public-Private-Partnerships (PPP) on both the conservation and exploitation of genetic resources;
- enable information about biotic resources to be diffused down to the grassroots, preferably in local languages
- ensure that controls on access to genetic resources are provided both in legislation and administratively;
- provide for the centralized issuance of permits, licences or certificates
- facilitate the education of their people countrywide, especially at the grassroot level, on the importance of genetic resources and their value (monetary);
- facilitate the development of a networked database enabling the appropriate authorities to know the status of various genetic resources and the enquiries that have been made on them;
- introduce and harmonize controls on bioprospecting at national levels

G. International cooperation and relevant models on bioprospecting

Africa can benefit from experiences drawn from other countries that have advanced regimes on bioprospecting. Upfront payments as well as long-term payments (royalties) have not always been made by bioprospectors. There is a tendency among bioprospectors not to implement provisions on capacity-building, transfer of technology and other programmes intended to benefit local communities.

As a matter of fact, bioprospecting initiatives often contain a large international component since the search activity and R&D work rely on expertise not usually available in Africa. Certain capacities need to be built, and appropriate technology transfer mechanisms need to be devised to ensure development of requisite technological capabilities. Member States should thus formulate regulatory mechanisms replete with relevant conditions and incentives.

International partnerships will facilitate endogenous capacity-building and conservation. These will entail evaluating existing capacity and capabilities,

assessing the contribution of current arrangements impinging on bioprospecting, strengthening long-term cooperative arrangements, and improvement of technical cooperation.

H. Conditions and incentives for bioprospecting

Member States should formulate conditions and incentives with a view to promoting the equitable flow of benefits to various stakeholders. At the present time, there is lack of capacity to plan, implement and monitor bioprospecting matters. In particular, Member States should ensure the following:

- build capacity in skills for negotiation in order to conclude robust bioprospecting agreements;
- ensure that bioprospectors provide a fair return on Africa's biotic resources
- ensure that bioprospectors make upfront payments as well as long-term payments for flora and fauna.
- institutionalize a rigorous system of obtaining prior informed consent

I. Bioprospecting management: scientific and technological capacities

Responsibility for issuing permission to conduct bioprospecting activities should be managed by a singular national agency. Regulation by a single body is vital to prevent biopiracy and unscrupulous exploitation of national biotic resources. Member States should therefore establish an appropriate institutional arrangement for this purpose.

This institution should handle all matters pertaining to training, capacity-building, transfer of technology and development of requisite skills, and maintenance of a database. It should deal with:

- general commercial contracts
- biological material transfer agreements
- environmental permits
- intellectual property licenses
- software shrink wrap licenses

- option agreements
- real estate leases
- letters of intent

It would also be vital for the national agency to deal with the following:

- actual identities of the parties
- resources to be collected and researched on
- local facilities for R&D
- ownership over resources
- compensation and benefits provided in exchange for access
- technology transfer
- restrictions on third party transfer
- measures to promote conservation
- data reporting
- intellectual property and ownership
- exclusivity and confidentiality
- conflict resolution procedure

J. Conclusion

Africa does not have a bioprospecting framework to guide Member States towards developing respective national frameworks. It is vital that governments develop such a mechanism. Such a device will go a long way in ensuring beneficial utilization and commercialization of biotic resources in the continent. It will also guard against cases of biopiracy which are responsible for major losses. Member States have relied in some cases on international instruments and conventions to guide them on bioprospecting. The lack of an effective bioprospecting framework that institutionalizes relevant activities and processes has hindered sustainable progress. This effort attempts to offer guidelines to developing national bioprospecting frameworks by Member States.