PhytoTrade Africa

The Southern African Natural Products Trade Association

Bio-Prospecting Guidelines






Bioprospecting Guidelines

Guidelines for PhytoTrade members on Bio-prospecting

1. Introduction: Bio-prospecting – what is it all about?

Bio-prospecting is the systematic research, collection and utilisation of biological and genetic resources for commercial benefit. It has a long history, but has recently attracted a lot of commercial interest. In the past 10-15 years there has been an increasing global demand for biologically active plant materials and other genetic resources that could be exploited for the development of marketable products, for sale primarily in the rich consumer markets of the industrialised countries. This market demand has driven a world-wide search for biological and genetic resources that might be potentially exploitable biological and chemical ingredients. Part and parcel the hunt for exploitable genetic resources has been systematic surveying of unexplored flora and fauna and screening of large numbers of samples from a cross-section of biological and genetic resources. But in developing countries most of the steps required to develop and market commercial products have taken place in the laboratories of companies based in industrialised countries.

2. Global bio-prospecting industries – some characteristics

Bio-prospecting provides materials, knowledge and other inputs to a number of global industries, including:

- Pharmaceutical industries;
- Agricultural and seed industries;
- Horticultural industries;
- Phyto-medical (herbal medicines) industries;
- Personal care and cosmetic industries;
- Food and beverage supplement (or neutraceutical) industries.

These industries often overlap to the extent that several of them may fall under one large company. While all of these industries depend on bio-diversity as a source for new commercial products, their use of genetic resources may vary, and several differences exist in:

- technological capability and market know-how
- levels of investment required to develop and test products until they are ready for the market;
- lead times involved in product identification and development;
- levels of risk and potential financial return.

On one hand, the pharmaceutical industry promises the largest returns on bio-prospecting investments. Potentially huge pay-offs materialise in situations where particular genetic resources are found to contain biologically active chemical compounds that can be used for new formulas against major human diseases. But on the other hand, drug development requires cutting edge technological capability, sophisticated market know-how, and enormous financial resources to sustain long lead times in product development (often 10 years or more). So it is often natural product industries (such as the herbal medicines, personal care, and food supplement industries) that offer greater chances for successful product development and more immediate financial gains.

3. Changing international policies and laws

As bio-prospecting has become a global commercial activity, new international agreements have changed the global policy, legal and regulatory setting in which bio-prospecting operates. Of particular relevance are two recent international agreements — the global UN **Convention on Biological Diversity** (CBD,1993), the FAO-sponsored **UN International Treaty on Plant Genetic Resources** for Food and Agriculture (ITPGRFA, 2001), and the WTO-sponsored agreement on **Trade-Related Intellectual Property Systems** (TRIPS, 1996). These agreements are focused on the environment and global trade, and aim to introduce legal mechanisms for the protection of bio-diversity.

The CBD focuses on national sovereignty over genetic resources within national borders. Previous international environmental law considered biological resources as common heritage and allowed free access. The CBD now entrusts States with the responsibility of regulating access to national genetic resources, to provide incentives for the conservation and sustainable use of bio-diversity, on the basis of arrangements ensuring equitable benefit–sharing from the use of genetic resources among providers and recipients. The CBD also recognises role that local communities play in the conservation of biodiversity. In order to enable local communities to continue to play this role, the CBD requires each Party (national member State) "subject to their national legislation, to respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity, and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices, and encourage the equitable sharing of the benefits arising from the utilisation of such knowledge, innovations and practices".

ITPGRFA addresses issues left unresolved by the CBD, particularly "traditional" farmers' rights with formal-sector plant breeders and how to regulate access and use of biodiversity maintained within international gene banks. The purpose of the TRIPS agreement is to help create an international **intellectual property** (IP) mechanism that underpins international trade by ensuring effective and consistent legal protection of IP rights. PhytoTrade member countries have been given until 2006 to comply with these requirements.

4. National policy and legal contexts in PhytoTrade membership countries

The changing international scene has brought about changes in national laws and policies. Of relevance to bio-prospecting laws and policies that relate to **access and benefit-sharing** (ABS); intellectual property (IP) rights, natural resource management, environmental conservation, sustainable harvesting practices, protection of rare and endangered plant and animal wildlife, prevention and control of plant pests and diseases, biological research and the export of plant materials and other genetic resources.

All five PhytoTrade countries are Parties to the CBD and are obliged to introduce new legislation, that reflects the main CBD principles. In response to these international obligations, each of these countries has started to put in place new laws and policies. Four PhytoTrade countries – Botswana, Namibia, Zambia and Zimbabwe – have been developing ABS policies and legislation that uses stakeholder committees to co-ordinate consultation processes. Drafts of ABS policies and legislation have been made but it is difficult to know how soon these will be approved and enacted by Parliament.

Malawi has followed a different path. Instead of pursuing ABS legislation, it opted to put a general ABS provision in national environmental framework legislation (Environmental Management Act of 1996) and established a government-level Genetic Resources and Biotechnology Committee to regulate the collection and exportation of genetic resources for research purposes. Subsequently, it issued specific ABS 'Procedures and Guidelines' (2000), including the prescribed use of standardised Material Transfer Agreements (MTAs), designed to apply to all cases where genetic resources are to be collected for non-commercial use. But in practice, there is little awareness of the role of these committees and new regulations.

All five PhytoTrade countries are Members of the WTO and Parties to TRIPS – and have embarked on processes to update IP rights regimes to comply with TRIPS requirements. None of legislative processes has been completed yet, nor have any decisions been about complying with TRIPS.

All PhytoTrade countries have instituted policy reforms for bio-prospecting. For instance, the forestry and wildlife sectors now have more decentralised approaches to natural resource management that integrate with benefit-sharing principles and mechanisms. In compliance with these amended or updated laws and policies, bio-prospecting partnerships permits or certificates that may include:

- phyto-sanitary permit/ certificate required for plant export
- seed certificate required for seed exports
- plant collection permit, license or concession
- research permit
- export permit

5. Bio-prospecting in PhytoTrade member countries

Southern Africa's rich biological and genetic resources have attracted considerable interest among bio-prospectors in the North. International bio-prospecting companies have made approaches to institutions in PhytoTrade countries to access to local biological resources. But because legislation is not yet in place, it has been quite easy for international bio-prospectors to develop partnerships directly with individual institutions in the region. A number of bio-prospecting partnerships have been made between overseas and local research institutions, mainly in South Africa. There have been some successes in developing new products, and as a result there has been increased interest from international bio-prospectors in Southern Africa.

There is also an 'informal market' of undercover bio-prospecting transactions in the region, which continues to provide bio-prospectors and intermediaries with 'back-door' access to bio-diversity. This results in the loss of precious genetic resources and associated benefits. Various factors come together in driving a good deal of bio-prospecting activity underground:

- continuing local mistrust of foreign bio-prospecting interests;
- lack of local organisational capacity, clear national institutional channels and co-ordinated national programmes for bio-prospecting;
- little local awareness of bio-prospecting opportunities or experience with bio-prospecting partnerships;
- weak or no enforcement of existing regulations;
- individual need and greed among locals with access to valuable bio-diversity;
- the resulting inability to actively and transparently engage with foreign bio-prospecting partners.

6. The purpose of having a PhytoTrade policy on bio-prospecting

Bio-prospecting activities are happening throughout the region and PhytoTrade members may be at the receiving end of partnership approaches from various international bio-prospectors. The potential benefits of a properly informed and structured bio-prospecting programme outweigh the risks, and therefore approaches from bio-prospectors cannot be ignored. The purpose of this policy is to guide you as PhytoTrade's members in how to go about dealing with bio-prospecting partners. This is in situations where you need to respond to partnership approaches and when you are actively pursuing a bio-prospecting strategy.

A strategy of early proactive engagement with potential bio-prospecting partners may have advantages because it:

- engages serious bio-prospectors and increases understanding of the relevant issues;
- maximises the share of benefits to PhytoTrade members by setting the terms of trade from the beginning rather than trying to influence them later;
- convinces prospective investors that PhytoTrade members are serious about bio-prospecting and a PhytoTrade presents a useful institutional conduit to conduct business of mutual interest;
- pre-empts or deters potential bio-pirates by removing incentives for bio-prospectors to seek 'informal' or illegal channels to gain access to genetic resources;
- discourages bio-prospectors from turning to other easier-to-deal-with countries in pursuit of commercially exploitable biological resources;
- facilitates early identification of plants to investigate as potential crops for agricultural diversification;
- speeds up delivery of benefits to the poor rural families with whom PhytoTrade works;

◆ relies on established and internationally enforceable laws – as well as on ABS regulations where they exist (e.g. Malawi);
◆ starts building up a body of ABS experiences from which lessons can be learnt for future bio-prospecting deals.

7. Developing Bioprospecting contracts

The most frequently used tool for defining and agreeing on formal legally binding relationships among bio-prospecting partners are **bio-prospecting contracts (BPCs)**. Bio-prospecting partnerships and contracts come in all shapes and sizes, reflecting the mass of genetic resources and knowledge as well as the diversity of rights and responsibilities of access and control over genetic resources. Given this, it is hard to generalise about what works and what doesn't. There can be no one-size-fits-all solution to setting up effective and equitable partnerships and water-tight contractual agreements. The most successful arrangements are often those tailored to the specific circumstances of individual cases. But it is possible to provide advice on the steps that should be followed to enter into partnerships and contractual arrangements. Whether PhytoTrade members are responding to incoming requests from international bio-prospectors or proactively looking for suitable institutional partners to exploit bio-prospecting opportunities, these guidelines are intended to serve as checklist for setting up and formalising bio-prospecting partnerships.

7.1 Identifying the right partners

It is difficult to provide hard and fast rules on the kinds of institutions to approach or respond favourably to. The choice of partners depends on the type of genetic resources and associated traditional knowledge that is being considered as well as possible commercial uses. In cases where PhytoTrade members are being approached by international bio-prospectors, we should:

◆ Ascertain whether the approaching party is an intermediary for an international bio-prospecting organisation and if so, on whose behalf the intermediary is making the approach;
◆ Collect as much information as possible from the approaching party about the nature, business activities and interests, and track record of its business;
◆ If approached by an intermediary, establish direct contact with the bio-prospector to obtain more information about the nature and characteristics of their organisations, business interest and activities, and track record**;**
◆ Consult with the PhytoTrade Office and its market information data and information base to access any available information about the bio-prospector/ intermediary;
◆ Consult as widely as possible – and ask the PhytoTrade Office to assist in this task to obtain independent opinions about the approaching party and their bio-prospecting partners;
◆ Check whether the interests of the approaching party match our interests and capabilities;
◆ Verify that the organisation has a solid track record and reputation;
◆ Investigate the degree to which the capabilities and know-how of the bio-prospector/ intermediary is complementary to the PhytoTrade members' capabilities and know-how.

If the approaching party has mutual interests and enjoys a solid track record and good reputation, you may want to pursue the proposed partnership further. If you have doubts then it may be better to reject the proposal or refer the approaching party to someone else. If it is difficult to find enough independent information about the approaching party, then care should be taken not to make any firm commitments until independent verification is possible. If the approaching party does not have any significant track record because they are new in the business, then it is probably better not to make a decision until you can establish the capabilities and seriousness of the venture. Where PhytoTrade members proactively search for bio-prospecting partners to help them commercialise some of their local genetic resources, similar considerations apply. However, members can decide on the best organisation to approach on the basis of market research, past PhytoTrade experience, and PhytoTrade's information resources.

7.2 Choosing appropriate institutional partnership structures

There are three types of actors involved in biodiversity prospecting agreements:

a) the party with jurisdiction over the sources of biological material – usually a government agency, but this would also include local communities, private landowners, and others;
b) a collector who obtains the materials;
b) a transferee typically plans to commercialise products of the material.

A typical flow of material and associated knowledge is from the source via the collector to the transferee. A typical flow of benefits goes in the reverse direction – from the transferee via the collector to the source. Some PhytoTrade members will be collectors and the rural communities with which they work will be providers. Commercial PhytoTrade members may act as collectors or commercial developers. Many different partnership structures have evolved and have been grouped into two categories: 'hub-and-spoke' structures and 'consortiums'.

In **consortium structures**, a number of parties, including public, private and/or civil society entities, join together under one contract. **Intellectual property rights (IPRs)** associated with their joint bio-prospecting venture may be held in common, all parties may have rights to use new technologies being developed, and benefits may be pooled at consortium level and shared among the parties. Alternatively, each party may separately retain the rights to the intellectual property being created, with cross-licensing of the rights among parties.

There is a difference between a full consortium and a partial consortium. In a full consortium, all parties – providers, collectors, and commercial product developers and marketers – agree to common terms in a single document. In practice, most consortia are partial consortia where some parties agree to obligations amongst each other. For instance, several providers such as a national regulatory agency, a local community, and a conservation trust fund may enter into an agreement to provide materials to a single collector (such as a national university), without having a direct relationship with commercial developers. The source parties ('providers consortium') may agree to give approval for a collection activity to proceed, and to share commonly in any benefits that may result. Similarly, 'collectors consortia' and '**research & development (R&D)** consortia' may be formed. An example of a collectors consortium is a national museum, a national university and a foreign botanical garden together signing an agreement with the government in the source country. An example of a R&D consortium is an international company, a national research institute, and a university concluding an agreement with a particular collector to develop and commercialise products.

'Hub-and-spokes' arrangements involve more than one contract (the spokes) with one entity common to each of the contracts (the hub). An example is a provider (e.g. an agency of a biodiversity source country) contracting with a collector (e.g. a non-profit research organisation) and the collector signing a separate agreement with a for-profit R&D corporation. Each of the contracts must be carefully reviewed to ensure that it is consistent with the other contracts. Some advantages and disadvantages are:

Consortium approach – advantages:

◆ Such an approach may combine the advantages of public and private entities in satisfying environmental, economic, equity and ethical goals.

◆ In some situations, source communities and countries may favour a one-contract consortium approach because the process can provide education, empowerment, and more direct bargaining power over commercial terms.

Consortium approach – disadvantages:

◆ One-contract consortia tend to be relatively complex institutional arrangements. Setting up such consortia, therefore, may require complex and lengthy negotiations. Once finalised, such multi-

lateral agreements may be difficult to adjust and re-negotiate, in case retro-active changes in partners or terms need to be made.

Hub-and-spokes approach – advantages:

- Bilateral agreements are easier to negotiate and change than a consortium approach.
- From the point of view of a commercial researcher, this approach avoids culturally and politically sensitive negotiations with local communities and agencies. Such negotiations require a different set of skills than many business people from industrialised countries are familiar with. In turn, public opposition to bio-technology companies may be less if the hub organisation is locally known and trusted, and the industrial corporation remains in the background rather than in a direct contractual relationship with the source country.
- If there is one widely respected lead organisation who can serve as the hub, the hub-and-spokes arrangement brings flexibility and other benefits - and such an arrangement may be feasible in situations where a pure consortium approach might not work.

Hub-and-spokes approach – disadvantages:

- The hub institution must carry the burden of negotiation and co-ordination between the contracts.
- There may not be any contractual relationship between providers and downstream recipients, so that providers cannot enforce their rights if downstream material transfers are made without restrictions. This problem may be addressed by way of setting up triangular contractual relationships. But even in the absence of formal triangular relationships, the various spoke parties may nonetheless have rights in the other agreement spokes, even though they are not parties, under the legal principle of third-party beneficiary. This principle provides third parties with contractual rights to intercede and make a claim against the contracting parties to enforce the third parties' rights, provided that the agreements give third-party beneficiaries express rights.

8. Negotiating bio-prospecting agreements

8.1 Some considerations about negotiations

Bio-prospecting partnership agreements require negotiations between partners that have an interest in entering into a legally binding arrangement under which the parties will each assume obligations in return for some compensation or benefit. Negotiations will normally commence after one party demonstrates its interest in accessing or providing resources or in acquiring them from another party. In cases where an international bio-prospector or an intermediary approaches a PhytoTrade member, negotiations may begin when the member has verified that reputation of the bio-prospector is sound. Where a PhytoTrade member is proactively looking for an R&D partner, for instance, to help screen and investigate genetic resources with a view to commercial product development and marketing, negotiations may begin as soon as a promising partner institution has been identified.

Article 15 of the CBD states that access to genetic resource be granted by source countries on **'mutually agreed terms' (MAT**). The negotiation process is fundamental to reaching MAT. Since MAT outcomes depend on the interests and characteristics of the negotiation partners and on other factors, it is difficult to define what constitutes MAT. To some, MAT is deemed to have been demonstrated where **prior informed consent (PIC)** has been obtained from the government of the source country as well as from the local communities from whose biological resources are to be collected or whose traditional knowledge is to be used in commercial R&D efforts. But it is often necessary or desirable to have the contractual arrangements reviewed by independent third parties in order to ensure equitable benefit-sharing arrangements. Another way of 'defining' MAT is in terms of win-win negotiations that are necessary for agreements to be supported by all parties. From this perspective, MAT may refer to those terms that provide sufficient benefit and incentive to the parties to ensure their continued compliance with their responsibilities during the lifetime of an agreement.

Generally, knowing what the other party wants is key to achieving a good agreement. For instance, the value of given genetic resources to users and providers may be quite different. It is important to consider all involved parties' views of resource value when negotiating. Industrial R&D partners, for instance, can be expected to look for reliability, quality control and clear access to resources, in line with national and international law. Knowledge of the existing market for resources and acceptable forms of doing business in the natural-product market place are essential. Members will be able use PhytoTrade's database and experience for information and advice.

8.2 Preparing for negotiations

Prior to any negotiations, it is important for PhytoTrade members to do their homework. This includes:

i) Identify the 'subject matter': What resources and/or knowledge are being sought/offered and what are the intended uses?

ii) Gather information on the value of the resources and knowledge in question: To begin with, PhytoTrade's own data and information base should be consulted. Other sources of information may be sought, as necessary, with the assistance of PhytoTrade.

iii) Decide who to negotiate with: Identify parties with whom to negotiate and their capacity to make decisions. It is important to negotiate with parties that have the legal right to enter into a contract. Contracts are only legally binding upon the parties to the agreement and can only be enforced by the parties. Be careful to negotiate with those parties that are in a position to compensate providers for any losses, including lost profits.

iv) Identify all stakeholders, including national authorities, who have rights to be involved in negotiations.

v) Identify other parties whose opposition or support may affect the possibility of implementing any negotiated agreement.

vi) Identify negotiation objectives and develop a negotiating strategy.

vii) Establish a negotiation team – It will be necessary to:

- identify the human resources and negotiating skills needed;
- define team leadership and internal decision-making processes;
- identify decision support that is required (e.g. access to information);
- establish means to avoid conflict within the team during negotiations;
- agree on internal lines of communication;
- establish lines of communication with other stakeholders or negotiators;
- ensure that all relevant decisions and agreements are recorded in writing;
- ensure that adequate legal and technical support is available.

8.3 Establishing rules for negotiation

Whether an initial partnership approach comes from a PhytoTrade member or another institution, in most cases the parties will begin to get to know each other by exchanging information. Before negotiations begin, the parties may find it useful to establish clear guidelines for the negotiation process. This may include:

- prepare timetables for meetings;
- propose dates for the termination of the negotiations;
- arrange for the confidentiality of meeting reports and other information exchanged – these may be specified in a letter of intent, with parties committing to negotiate in good faith;
- agree not to enter into negotiations with other parties;
- agree on modalities, including language and location, of negotiations;
- set up procedures for preparing draft contracts;

- decide who will carry out the negotiations (parties themselves or legal advisors);
- agree on how to present offers and counteroffers – and during what time scales;
- agree on whether always to negotiate face-to-face;
- agree on when to bring in those responsible for final decisions, in order to resolve issues which intermediaries cannot decide;
- establish the authority of each party's negotiators to have the right to make commitments;
- ensure that legal advisors are representing the positions of their clients;
- keep negotiations simple and avoid technical jargon that some stakeholders may not understand.

8.4 Obtaining legal advice

Members will be able to draw on the resources and advice of PhytoTrade, but it may be necessary to bring in outside specialists for advice on legal or commercial matters ensuring that:

- advisors are trustworthy;
- they tell you want you need to know to make informed decisions;
- the right kinds of advisors are involved – they should fit the negotiation objectives;
- there is sufficient expertise available on aspects of commercial and contractual law;
- the advisors have access to relevant information about the legal and regulatory environment of the countries in which the resources are to be used;
- local legal advisors are involved, even in cases where free legal advice is available from major law firms in developed countries – so that local law and practices are duly taken into account and national capacity is enhanced.

8.5 The role of mediating institutions

Mediating institutions can have an important role in making sure that the interests of source countries, national NGOs and local communities are secured. While members can rely on PhytoTrade to promote biodiversity prospecting partnerships and assist in ensuring fair negotiation of agreements, additional negotiating services may be needed. PhytoTrade's resources and skills can be used to help mobilise such services. While the role of honest brokers can be essential, it is worth being cautious about:

- incompetent or unscrupulous intermediaries.
- intermediaries may be limited in national ABS legislation in PhytoTrade membership countries.
- There is a risk that intermediaries may hide institutional weaknesses that stop providers from securing their rights and an equitable share in benefits.

8.6 Benefit-sharing

Benefit-sharing aspects are key to bio-prospecting agreements. Generally, there has been a trend towards more creative benefit-sharing, involving more varied types of benefits. However, what may be seen as fair benefit-sharing differs substantially across industry sectors, product areas, and individual R&D programmes. Successful arrangements are often those tailored to specific circumstances of individual cases. While benefit-sharing experience varies, we can highlight current 'best practices' within industrial sectors (**Annex A**).

Whatever the particular industry and commercial partner, PhytoTrade members may want consider the following points when considering benefit sharing:

- Negotiations about ABS are commercial negotiations, requiring commercial and legal know-how.
- The potential commercial value of genetic resources and traditional knowledge may be exhausted in a first contract between partners– for instance, where a patent over an active compound is obtained under the first agreement.
- Benefits may be non-monetary as well as monetary and may include benefits derived from the existence of resources and rights of free access and use.
- It is important to look at the agreement as a whole in order to fairly share the benefits.
- There must be a balance between guaranteed payments and potential future income (such as

royalties) to prevent unfulfilled expectations. It is important to secure some benefits as early as possible in the R&D process.

- Keep in mind possibilities that may exist to: promote the development of national or local capacity; negotiate and monitor compliance; identify value of resources and locally add value to resources.
- Identify opportunities to get national industry involved in the manufacture or distribution of products and the R&D process.
- Appreciate the value of training at home or abroad.
- There may be a need to protect confidential information, as when the source of an active compound must be kept secret in order to maintain an edge over potential competitors.
- It is important to be able to trace the use of resources, such as through access to laboratory notes, in order to determine the origin of genetic resources used in developing a product. The greater the trust between bio-prospecting partners the less need for tracing resources and their use.
- Ensure that all payments and non-monetary benefits are viewed as compensation, not gifts.
- Bio-prospecting agreements should include a clear conflict resolution procedure.

8.7 Enforcing contracts and ensuring equity

In most countries, there are several basic requirements for contracts to be binding. These include: offer and acceptance, compensation and confidentiality.

8.8 Contract offer and acceptance

Agreements normally come about when one party makes an offer and the other party accepts the offer. If a counter-offer is made, the roles between the two parties are reversed. The law of the country where an agreement is made determines whether a contract has been concluded. Most contracts specify the country under whose legal regime the contract falls.

8.9 Compensation and benefit-sharing

Regarding compensation, a promise to grant access to resources will not normally be enforceable, unless the party seeking access has agreed to provide compensation. It is in the interest of all parties to ensure that compensation (benefit-sharing) is fair. The principle of fairness in benefit-sharing is central in the CBD and reflected in national access laws. Where national ABS legislation and regulations are in place, fair benefit-sharing will be required by law and is likely to be a national mechanism set up to ensure equitable compensation. Where national ABS legislation or regulations are not in place, as is the case in all PhytoTrade countries but Malawi, it will be up to the parties to ensure fair benefit-sharing. Even if ABS legislation is in place, there is no guarantee that a contract would be overturned if it does not conform to best practice (**Annexes A and B**).

8.10 Confidentiality

Issues of confidentiality arise when:

- the contract itself and its provisions;
- material, intellectual property, traditional knowledge, and other information;
- in research and development results.

It is usual to demand and maintain confidentiality at these levels. Contracts and their provisions are often kept confidential in order not to bias subsequent negotiations with other partners. Information shared under agreements that providers oblige recipients to keep confidential may include trade secrets, traditional knowledge, methods for doing business and commercial practices. This excludes information in the public domain that has been received without restriction from a third party. Disputes may arise over whether traditional knowledge that is known amongst local communities is considered to exist within in the public domain. Using a loose definition of 'public domain' to justify the use of traditional knowledge not knowingly shared for commercial purposes is questionable. Not even publication of information about traditional knowledge should be presumed to remove rights to control its use and to impose limitations on further distribution.

Keeping research and development results confidential may serve different purposes. For instance, it may keep information away from competitors before final products have been developed. Or it may protect information for which patents or other commercial intellectual property protection may be sought. Possible fears by recipients that some provider institutions and especially local communities may not be capable of ensuring confidentiality of commercially sensitive information should not be used as an excuse to deprive providers and local communities of access to relevant information regarding ongoing R&D activities. But every effort should be made by local provider and collector institutions to maintain confidentiality.

8.11 Dispute resolution

Many agreements now provide for arbitration of disputes to avoid legal proceedings. Often, the more independent dispute resolution processes are, the more likely it is that disputes can be fairly resolved. When putting together dispute resolution mechanisms, care should be taken to include expertise in law and practice of both source and recipient countries, including customary laws and practices of relevant local communities. It may be useful to include provisions in partnership agreements that costs of arbitration be borne by the recipient and that arbitration proceedings be held in the source country. As for the choice of the applicable rules for arbitration, parties should place arbitration under the laws of a foreign country with a legal system that offers better prospects for enforcing arbitration rules, obtaining relief for damages, or recovering lost benefits. If the bio-prospecting agreement is executed according to the laws of the recipient country, then consideration should be given using the same legal system for purposes of arbitration.

8.12 Control mechanisms

In order to ensure that partnership contracts are executed on the agreed provisions, it is important to monitor the parties' compliance with the agreed use of resources, benefit-sharing, and protection of information. Various measures are available to monitor compliance with contractual obligations:

- confidentiality arrangements;
- audit of royalty reports;
- control of the application for, and protection of, IPRs;
- access to internal documents recording R&D activities;
- reports of advances in scientific research and R&D activities in general.

Most BPAs now require the user to report R&D activities. The provider should retain the right to require modification or withholding of publications and IPR applications, if such steps would go against the terms of the agreement, infringe on the provider's rights, or fail to give adequate recognition to providers' resources and knowledge. On the other hand, it would not be in the interest of providers to create unnecessary obligations that may unduly delay publication, IPR applications or product development.

It is important that providers can identify the use of their resources and pinpoint rights to royalties and other benefits. In science industries, it is common practice to require access to the licensee's laboratory notes. When it comes to ensuring royalty payments, contracts should oblige users to maintain records for at least three years from the date of the payment, with a right for the provider to audit these documents at least once a year. While such measures may be important in allowing providers to monitor recipients' compliance with contractual obligations, it is sometimes more important to invest in building long-term working relationships with partner organisations. A high degree of mutual trust among partners in each others' commitment to contractual obligations will minimise risks of breach of contract and encourage partners to keep to agreements.

9. Formulating bio-prospecting contracts (BPCs)

There is now a significant pool of negotiated **bio-prospecting agreements** (BPAs) from which to learn lessons for how set up effective and equitable contractual arrangements. Historically, BPAs have evolved from other types of agreements, including commercial contracts, intellectual property licenses, material transfer agreements, environmental permits, real estate/ land leases, option agreements, and letters of intent.

BPAs involve the transfer of biological materials, so they may be considered to be examples of MTAs. However, BPAs are more complex than most MTAs. Firstly, biological materials may be treated as property, intellectual property, or traditional knowledge and different approaches are needed to protect rights to these different forms of property. Secondly, the rights of providers over genetic materials go beyond property rights and include issues such as sovereign rights of national governments, prior informed consent by national governments and local communities, access to land resources, 'fair and equitable' benefit-sharing, natural resource conservation, and environmental permitting.

Bio-prospecting agreements come in a variety of different shapes and sizes. For instance, biological resources may be transferred to non-commercial or non-profit organisations for different purposes that might lead to commercial applications, even though commercial use is not the motive for such transfers. Transfer of biological resources to commercial organisations, on the other hand, presents different contractual issues and hence requires different contractual arrangements. This makes it difficult to make a 'model contract' for the range of contractual arrangements necessary to govern and regulate the variety of different forms of bio-prospecting partnerships. But it is possible to identify and characterise contractual features common to most bio-prospecting agreements.

9.1 Elements of BPCs: introduction and definitions

The purpose of the 'introduction and definitions' section of a BPC is to:

- Outline the goal and objectives of the BPA;
- Identify and define the parties to the agreement and their authorised representatives;
- Identify the material to be transferred as tangible property or intellectual property

(i) Purpose and objectives of the bio-prospecting agreement (BPA)

Possible purposes of the transfer of genetic resources includes:

- scientific research on the taxonomy of plant materials;
- scientific research on their chemical or biochemical properties of plant materials;
- the screening of plant extracts for biologically active chemical components/ compounds (possibly on the basis of hints derived from traditional knowledge and uses of plant components) that might lend themselves for commercial applications;
- development of plant material, R&D inventions or traditional knowledge into commercial products.

In the event that disputes arise an amendments become necessary, this is likely to be the starting point for the contractual parties to revise the old agreement.

(ii) Parties to the agreement

a) **Provider** - institution or individual of the source country providing or authorising collection of material. Provider's authorised representative; e.g. chief executive of providing institution, project manager, or other liaison person. In cases involving consortia, or partial provider consortia, there may be several providers and accordingly several authorised representatives.

b) **Recipient** - institution receiving the material

Recipient's authorised representative - chief executive, project manager, or other liaison person. In cases involving consortia, or partial recipient consortia, there may be several recipients.

c) **Third parties** - any parties who are neither providers nor recipients such as

- The government authority of the source country;
- Local communities of the source country that are consenting to collections of material found on land in regular use. Such land may be communal land legally owned, under lease, or historically occupied by communities, or otherwise vital to the livelihood of the communities;
- Third parties affected by the agreement.

Some of these third parties, particularly those whose prior informed consent (PIC) is required (such as the government authority or particular local communities) may co-sign the agreement through authorised representatives. Other affected third parties may be mentioned in the contract. Other third parties that are not listed in the agreement cannot claim any rights or be held liable for any responsibilities, although they may play a role in dispute settlement processes and procedures.

(iii) Materials, R&D inventions and traditional knowledge being transferred

Biological materials covered under a BPA may be tangible property and/or intellectual property. The physical embodiment of substances such as biological organisms can be owned as "tangible property'. Examples include live plant material (leaves, bark, seeds, etc) as well as plant extracts. Inventions by an innovator or a group of innovators, involving components of, uses of, or processes involving biological material, can be owned by the innovator(s) as 'intellectual property'. Examples include inventions that can be patented, are eligible for plant variety (plant breeders rights) protection, or can be protected as trade secrets. Intellectual property may have a physical embodiment as well, as with improved hybrid seed.

Two types of materials are recognised by these agreements, biological organisms and derivatives. The latter are substances derived from biological organisms by relatively simple manipulations. Examples include, but are not limited to, uncharacterised chemical or biochemical extracts and heterogeneous cell cultures derived from tissue explants. Note that transferred biological organisms such as soil microbes or parasites are considered material and are covered by these agreements. Ownership of material as tangible property is defined under 'terms and conditions of the agreement'.

Inventions should be carefully defined to include the widest possible set of discoveries available from biological organisms or their components. Examples of inventions include, but are not limited to:

- new chemicals such as molecules, genes, genetic sequences, chemical derivatives
- hybrid or transgenic organisms and parental lines;
- homogeneous and stable cultured cells or cell lines from tissue explants or microbial samples;
- organisms, chemical extracts or biochemical extracts derived from organisms which are discovered to possess medicinal, diagnostic, agricultural, or other useful properties;
- useful chemical or biochemical processes utilising organisms or chemical extracts;
- products based on specific molecular formulations such as those from a gas chromatograph trace.

Inventions need not be patentable, or eligible for other forms of formal intellectual property protection. Any useful application of transferred material discovered by the recipient places the recipient under contractual obligation to the provider and/or local communities regarding the use and disposition of the invention or discovery. Inventions such as tangible or intellectual property are owned by their creators. Inventions thus may be recipient's or provider's inventions. Inventions jointly created by provider and recipient are their shared intellectual and tangible property.

Traditional knowledge involving material may be regarded by consenting local communities as their inventions. Although there no legal basis for assigning IPRs to traditional knowledge in any of the PhytoTrade countries, the BPC can address this issue by recognising that local communities may regard their traditional knowledge as inventions. All parties are assumed to co-operate in recognising this knowledge as the intellectual property of these communities. When benefit-sharing (ABS) legislation has entered into force, traditional knowledge will become legally recognised as the intellectual property of local communities.

(iv) Terms and conditions

This is the core part of any BPC, spelling out terms and conditions governing the transfer of material, as tangible or intellectual property. The general purpose of these terms and conditions is to:

- define the rights and responsibilities of recipient, provider and third parties in current and future research, development and commercial activities concerning the material transferred;
- spell out the benefits that the provider receives in the event of discoveries leading to commercial applications, from the recipient in compensation for making the material available.

(v) Description of material and inventions

This provides for a detailed description of:

- all material and inventions to be transferred;
- ownership of material, including derivatives, as tangible and intellectual property;
- a list of material to be kept confidential.

This description may be presented under a separate attachment to the BPC, especially if the description is lengthy. Locations from which material is taken may also be listed. Material that cannot be described, such as microbes or parasites is still covered by the BPC. A special case to be aware of is the creation of a self-replicating invention such as a transgenic plant in which a foreign gene is inserted into a plant originally transferred as material. In this case, the transgenic plant becomes the intellectual property of the inventor while the physical embodiment of this invention would become the tangible property of the recipient.

(vi) Use of transferred material or inventions

This specifies the use for the transferred material and inventions by the recipients, also indicating whether the recipients are entitled to exclusive use. Material transferred to commercial partners is normally transferred for their exclusive use as an incentive for costly R&D by guaranteeing exclusive ownership of inventions developed by the recipient. Material transferred to a non-profit organisation is normally understood to be for its non-exclusive use. In cases where taxonomic inventory is planned, parties are required to leave copies of voucher specimens with collaborating institutions from the source countries (eg national herbaria). If genetic resource samples are transferred as extracts, it is reasonable to ship coded extracts, especially when transferring for industrial research. Offers to re-supply samples can be made upon a statement interest in the samples and offers to break the code can be made upon an expression of interest in further R&D collaboration on the basis of fair and equitable benefit-sharing. The description of the research to be performed and compensation for transferred material can be made a separate attachment to the BPC especially if it is lengthy.

(vii) Compensation for transferred material and/or inventions

This section specifies types and levels of compensation by the recipient to the provider in exchange for the material transferred. Compensation may consist of monetary benefits and/or non-monetary benefits. Monetary benefits may include:

- up-front payments - e.g. fees or charges for plant samples or extracts received or compensation for administrative costs incurred;
- milestone payments - when particular stages are successfully reached in the R&D process;
- royalty payments - as a percentage of annual net income or profits from products that have been successfully commercialised.

Annex B lists the kinds monetary compensation used by the pharmaceutical industry. Up-front payments for plant samples or extracts tend to be higher in the pharmaceutical industry than in other industries. Parties may agree to focus requests for extension of exclusivity on those of the of transferred plants materials or extracts that are of continuing scientific or commercial interest.

When working with non-profit or non-commercial research institutes, it is reasonable to request a percentage (eg 50%) of all net income from R&D. Other options include obtaining free research services or access to scientific information from recipients. There has been a trend toward more diversified compensation packages involving various monetary and non-monetary benefits. Non-monetary benefits may include research capacity-building, training, transfer of know-how, technology and equipment, scientific validation of traditional medicinal uses of plant extracts (toward low-cost phyto-medicines more readily accessible to local populations), and other in-kind contributions such as for tropical disease research or local community-level development projects. **Annex A** summarises current best practices in benefit-sharing for different bio-prospecting industries. Where the products to be developed are known at the outset, parties may agree on types and levels of monetary and non-monetary compensation. Where research is to be conducted with a view to possible but uncertain discoveries that could have commercial applications, the BPC should include a provision for benefit-sharing and arrangements to be agreed in the future.

(viii) Confidentiality

Confidentiality is dealt with in the contract in order to:

- keep material, inventions and information secret if this is requested in writing by the Parties, if it is of commercial interest;
- treat the contents of the BPA as confidential.

In the first provision, it may be to the advantage of provider or local communities to keep transferred material, inventions or related information confidential, in order to maintain greater control over them or to retain a marketing advantage. In the second provision, it is critical that Parties keep specific details of their negotiations confidential, in order not to bias future negotiations or to compromise sensitive information shared by collaborating organisations.

(ix) Transfers of material or inventions to third parties

Transfers of material or inventions to third parties are normally allowed under BPAs. For instance, taxonomic voucher specimens may be loaned for research purposes, or a commercial partner may choose to sub-contract specific R&D tasks. Transfers to third parties by non-profit recipients can be made without prior informed consent (PIC) of the provider, but the provider (and local communities) must be notified. Commercial recipients should be required to check with the provider before making transfers to third parties, in view of the exclusivity that is guaranteed by the contract.

BPCs with commercial partners should include provisions:

- to allow transfer material or inventions by the recipient to third parties upon written permission by the provider (including local communities), for specified purposes such as further research;
- for the recipient to notify the provider in writing of any such transfers to third party recipients;
- for the recipient to keep records of all such transfers;
- for the terms and conditions of the BPA to apply equally to all third party recipients;
- for the recipient to be responsible for ensuring compliance by third parties.

BPCs should stipulate that any such transfer to a third party be accompanied by a letter defining terms and conditions of the transfer and a notice stamped on each transferred sample to the effect that the material is received under a material transfer agreement, that its use is restricted, and that material, inventions and related information be kept confidential.

(x) Period of time during which the recipient may keep the transferred material

This specifies the period of time during which the recipient may keep the transferred material. It is usual that all remaining material should be returned or destroyed at the expense of the recipient, or that the provider may request such return or destruction at the end of the specified time period. Typical periods for transfers to commercial partners being granted exclusive rights are between 3

months and 2 years. Commercial firms willing to pay more for samples should be entitled to longer exclusivity periods. Time limits and exclusivity periods may be extended if promising biologically active compounds or components are discovered that call for further researcher and testing. Another provision may be added that failure of the recipient to provide compensation may be grounds for termination of the BPA and return of all material.

(xi) Intellectual property protection and commercialisation of material

Where there is scope for the recipient to seek intellectual property rights for inventions created by the recipient through R&D using material or inventions received from the provider, such rights and their protection are governed by relevant provisions in BPCs. Recipients are not allowed to patent unmodified transferred material or inventions if the purpose of the BPA is to conduct basic research, or commercial R&D and a provision to this effect may be included in the BPC. Inventions developed solely by the recipient are the property of the recipient and may be patented or otherwise protected and licensed for commercial development. However, the provider should be notified in writing of these inventions, since successful commercial development and marketing of products should give rise to benefits to be shared with the provider. In cases where the provider shares in the invention, the recipient must seek written permission for intellectual property protection or commercial licensing of these joint inventions. A similar provision holds for provider's inventions or traditional knowledge considered to be intellectual property of local communities. BPCs should include provisions reflecting these points. The terms of intellectual property protection and commercialisation of material or inventions may be summarised in a separate attachment. This includes guidelines for obtaining intellectual property protection on inventions, and for commercialising or licensing this intellectual property.

(xii) Warranties and indemnities

Warranties and indemnities are standard in most BPCs. Warranties may cover the right to enter into an agreement, the right to provide resources for use, and the right to use the resources provided for a particular purpose. The following two types of warranties are often included in BPCs:

- that providers promise that material or inventions were transferred legally
- that provider and recipient have obtained PIC from named local communities, recognise the local communities' traditional knowledge as the communities' own inventions, and keep this knowledge and all related information confidential if requested.

Indemnities provide contracting parties with protection against any claim or action for loss or damages, including loss of life, arising from any act or omission on the part of the other party. For instance, an action may be brought against the provider for the damage caused by the release of genetically modified organisms, or for the side effects of a drug, especially if the provider received benefits from these activities. Seeking an indemnity against such claims is a means of transferring any potential liability from the provider to the user in such cases. Therefore, BPCs should include a provision explicitly indemnifying providers against such claims by waiving any liability on the part of the provider for any damages resulting from use or misuse of material or inventions by the recipient.

(xiii) Legality of transfer of material or invention

Providers promise that material or inventions were transferred legally. They can be held liable for a breach of this promise. The legality of transfer constitutes a warranty by the provider whose breach may lead to loss of rights for the provider. BPCs will normally include a provision certifying that sufficient permission has been obtained from the government of the source country for the export of material or inventions to the recipient. Copies of relevant documentation proving 'sufficient permission' being granted by the source government will be attached to the BPC.

(xiv) Prior informed consent (PIC) of relevant local communities

If local communities are parties to a BPA, it is the responsibility of both providers and recipients to ensure that the rights of these local communities are upheld by including corresponding provisions in the BPC and having authorised representatives of the communities, as well as of providers and recipients, sign the BPC. If national ABS legislation is in place, then access to relevant traditional knowledge of the named local communities is regulated and the traditional knowledge is protected as the communities' intellectual property under this legislation. If national ABS legislation is not in place, then traditional knowledge should be treated as an invention by local communities in the BPA. In both situations, the BPA should explicitly extend to local communities the right to require both providers and recipients to keep this knowledge confidential. Under commercial intellectual property law, the only option to protect the confidentiality of such traditional knowledge is to treat it as a trade secret. Both providers and recipients promise that they have secured PIC for the transfer of resources or knowledge and can be held liable for a breach of this promise. PIC and benefit-sharing with local communities can be reflected in BPCs by means of provisions such as:

- Consenting local communities agree to transfer material derived from land in regular use by communities, or traditional knowledge regarded as the intellectual property of communities, to provider and recipient for the agreed purposes specified in the BPA. Material which is known to be rare or endangered may not be collected.
- Both provider and recipient certify that they have explicitly obtained PIC from named consenting local communities to transfer material or traditional knowledge. Both provider and recipient agree that traditional knowledge regarded as the intellectual property of communities will, for the purposes of the BPA, be treated as inventions of the communities. Parties will treat traditional knowledge as a trade secret and keep this information confidential if requested to.
- Parties shall negotiate compensation for consenting local communities, according to terms and conditions of their involvement. Failure of Parties to comply with these terms and conditions may be grounds for termination of this BPA.

Processes and procedures to obtain PIC from local communities in an appropriate fashion will vary from country to country, depending on national and local traditional authority structures, land tenure patterns, indigenous peoples rights issues and community-based natural resource management processes. The terms and conditions of consenting local community involvement may be presented in a separate attachment. This will include a PIC Agreement with the relevant signatures and a description of how PIC of the local communities was obtained. For purposes of returning benefits to local communities, the use of trust funds may be preferable to direct monetary payments to particular community members. Trust funds provide a means for benefiting relevant local communities, in recognition of the ownership of traditional knowledge or of material collected from land in regular use by communities. Various different communities in different locations may all be custodians of the same traditional knowledge or material and hence trust funds should attempt to make sure that local communities benefit from its use. It is crucial to devise a transparent mechanism for managing trust funds and disbursing payments.

(xv) Communication channels and modifications to agreement

BPCs may include provisions to the effect that:

- written communications between parties shall occur via authorised representatives in the BPCs;
- modifications to the BPAs must be approved in writing by all parties;
- consenting local communities must give PIC to modifications.

(xvi) Duration of contract, dispute resolution mechanism and severability of terms

Transfers of material or inventions will continue for a specified time, after which parties are required to negotiate a new agreement or to renew the current one. However, all other obligations between the

parties remain in effect, such as the delivery of compensation, or rules governing future commercialisation of inventions. Dispute resolution mechanisms are built into most BPCs to avoid costly litigation in cases where disputes between parties cannot be resolved by negotiation. A BPC may stipulate that any dispute be arbitrated by a mutually acceptable non-party attorney. Dispute resolution mechanisms specify the rights of providers, consenting local communities and others if recipients or providers are in violation of BPAs. Typically, providers or communities may request the return of all material or inventions/ traditional knowledge provided by providers or local communities. The terms and conditions of BPAs are stipulated to be severable. This means that if any provision is invalid by a court of law, the remaining provisions remain in effect.

(xvii) Choice of legal system under which the BPA is interpreted and enforced

In international BPCs, it is up to the parties to choose the legal system under which the BPCs will be interpreted and enforced. It is normally best to choose the country or city of the recipient's institution, if the recipient is located in an industrialised country with well-developed contract law and intellectual property legislation and an effective judiciary.

(xvii) Signatures

BPCs are signed by the authorised representative of each party to the agreement. This may include one or more providers, recipients, consenting local communities and government authority.

(xviii) Attachments

If there are any attachments to the BPC, they can be put at the end. These could include:

Attachment A - Description of material and inventions
Attachment B - Description of research to be performed and of compensation
Attachment C - Standard form letter agreement for transfer of material to third-parties
Attachment D - Guidelines for obtaining intellectual property protection on inventions
Attachment E - PIC Agreement with local communities and how it was obtained.

10 Sample BPCs

10.1 Sample material transfer agreement (MTA) used by PhytoTrade

This BPC (**Annex D**) governs the transfer of fruit samples to a research institute for research services to be rendered. The sample contract's purpose is to secure the provider's property rights to material and know-how. The purpose of the agreement is defined up-front and includes a description of the material to be transferred: "samples of Namibian *Moringa ovalifolia* and associated knowledge". The 'terms and conditions' section address the following issues:

- transfer to third parties;
- warranties;
- duration of the agreement;
- intellectual property protection and commercialisation;
- confidentiality.

10.2 Sample Material Transfer Agreement

This BPC governs the transfer of genetic materials and intellectual property to a non-commercial organisation for research and non-profit purposes, under a non-exclusive license (**Annex B**). It covers:

- a description of the material;
- the use of the material;
- intellectual property rights to research results that are anticipated to emerge from the research - all proprietary and intellectual property rights remain with the provider;
- transfer to third parties (third party material transfer for commercial purposes is not allowed);
- Confidentiality;

- Publication of research results – recipient will inform provider of research results and not release results without permission of provider; provider has the right to vet research results and publications prior to dissemination by recipient; provider will be duly acknowledged in any publications prepared by the recipient, and will receive copies of any publications;
- Duration/ termination of agreement and return of unused material; provider owns results achieved under MTA, but recipient has a first option to pursue the commercialisation of results under a (follow-up) license agreement to be effected within stipulated period during/after MTA;
- Indemnities – the recipient indemnifies the provider for any risks, claims, demands or actions airing from the recipient's acceptance use and disposal of the materials;
- Choice of national legal system.

10.3 Government of Malawi Material Transfer Agreement for non-profit Collectors

This material transfer agreement (MTA) will be mandatory for non-profit collectors in Malawi, under the country's New Procedures and Guidelines for Regulating Access to and Collection of Genetic Resources (**Annex C**). The agreement lists the parties and their representatives, describes the material, and presents definitions for a number of terms, such as 'material', 'progeny', 'derivatives', 'modifications', 'commercial purposes', and 'non-profit organisations'. In the agreements 'terms and conditions' section, the following issues and aspects are addressed:

- Distribution of ownership rights to the material and modifications between provider and recipient;
- Purpose for which the material is to be used;
- Compensation – benefit-sharing arrangements;
- Requests from third parties for the material and transfer of material to such parties;
- Transfer of recipients' modifications (inventions) to third parties;
- Prior written consent of the provider for modifications to be provided for commercial purposes – but recipients are allowed to grant commercial licenses for their own modifications;
- Recipient may file for patents, but must inform the provider;
- Commercial licenses between provider and recipient (provider will negotiate in good faith, but does not have any obligation to grant a commercial license; the parties will use best-practice arrangements for benefit-sharing);
- Provider extends no warranties;
- Recipient assumes all liability for damages from use of material;
- Research publications allowed, recipient scientist acknowledges source of material;
- Recipient agrees to compliance with all applicable regulations;
- Termination of agreement, return/destruction of all remaining material, and provisions remaining in force after termination;
- Severability of terms and conditions;
- Dispute resolution;
- National law under which the agreement is to be executable;
- Collectors must be institutions, not individuals;
- Recipient shares with provider results of work.

10.4 Sample Research and Development Agreement

This sample BPC (**Annex D**) is used by NPI to establish collaborative framework agreements for research and commercial product development with partner organisations involved in scientific research and development of new medicinal materials from botanical sources. The BPC also describes the nature and capabilities of NPI and the partner organisation and establishes:

- Who will make final decisions on whether to go for commercial development of any product;
- Collaboration on an exclusive basis;
- Responsibility for final decisions about implementing any specific research programme - and is contingent on agreed work programmes and budgets;
- Responsibility for technical aspects of research programmes;

- Expected contributions by partner organisation for which NPI will provide assistance to the partner on the basis of reasonable commercial contract terms;
- Any sub-contracting by the partner organisation with third parties are required on an exclusive basis, and the terms of the contract is to be confidentially disclosed to NPI to confirm exclusivity;
- Intellectual property being generated as a result of the development work to be discussed;
- Initial steps - negotiating separate project contracts for R&D on particular identified products;
- Confidentiality aspects;
- Duration of contract;
- Choice of law – specifying the country whose law is to govern the contract.

10.5 Sample commercial agreement

This sample BPC (**Annex H**) is used by Natural Products International (NPI) to establish framework agreements with partners involved in the development and manufacture of botanical medicines, for the appraisal and development of botanical products as licensed phytopharmaceuticals or dietary supplements for markets outside the partner's country. Aside from the purpose of the agreement, the 'Preliminary' section also describes the nature and capabilities of NPI and the partner organisation. The 'terms and conditions' section of the BPC establishes:

- Collaboration of the partners on an exclusive basis;
- Responsibility for decisions on whether to embark on full commercial development of any product;
- NPI is responsible for technical direction and supervision of the collaborative programme;
- The partner's responsibilities are also itemised;
- NPI will pay for all services and supplies, on the basis of 'reasonable commercial contract terms' for the services provided to NPI in the development of the product;
- NPI undertakes to pay an initial 'mobilisation payment' as well as royalties on net sales or license fees for a period of 15 years, for each product entering commercial production as a dietary supplement or licensed phytopharmaceutical;
- Third parties - the above payment schedule to remain binding;
- Intellectual property generated as a result of the development work – will be owned by NPI;
- Confidentiality;
- Duration of contract;
- Choice of law – contractual arrangements to be governed by English law.

Key references

"Biodiversity and Traditional Knowledge – Equitable Partnerships in Practice", Sarah A Laird (ed), *People and Plants Conservation Series, Earthscan*, 2002; in particular Section IV (chapters 8-10): *"Commercial use of biodiversity and traditional knowledge"*.

Kerry ten Kate & Sarah A Laird, *"The Commercial Use of Biodiversity – Access to Genetic Resources and Benefit-Sharing"*, Earthscan, 1999.

John Mugabe *et al.*, *"Access to Genetic Resources – Strategies for Sharing Benefits"*, ACTS Press, 1997; in particular, Chapter 14: Daniel M Putterman, "*Model transfer agreements for equitable biodiversity prospecting"*.

Annex A: Best practices in benefit-sharing - by type of industry

Pharmaceuticals

◆ This sector has a longer history, more experience and more interest in establishing benefit-sharing arrangements than any other sector. Reasons include the relatively high research budgets and profit margins as well as the extensive collecting activities and high-throughput screening programmes to date in this sector.

◆ Unlike 10 years ago, pharmaceuticals nowadays pay royalties on net sales of commercial products. Milestone payments at key stages in the product development process and initial fees for samples or grants to cover research are also common.

◆ Over the past 10 years, monetary benefits have been increasingly accompanied by 'packages' of non-monetary benefits. The latter may include: involvement of source-country scientists in collaborative research; technology transfer; the supply of literature; laboratory equipment; chemicals necessary for plant chemistry research and screening; training and capacity building; and/or in-kind benefits such as medical assistance and development projects for the benefit of local communities.

◆ Many commercial companies are increasingly open to collaborations at a higher level in the discovery and development process, as the capacity of source countries to engage in value-added research has grown over the past decade.

Botanical medicines, food supplements, personal care and cosmetic products

◆ Except for large cosmetic companies, these industries do not depend on large numbers of samples for use in high-throughput screening programmes. Information leading to the targeted development of new products tends to be gleaned from literature, databases, trade shows, and intermediaries.

◆ In these industries, benefit-sharing has developed primarily in the context of the supply of raw materials for the manufacture of products. In some cases, companies have established partnerships involving transfer of technology to and capacity-building in source countries. However, genetic resource access is often de-linked from benefit-sharing in that the genetic resource may be treated as a commodity and/or traditional knowledge is acquired from literature and databases.

◆ Demand for access to new species is increasing in these industries. So is the scientific and technological capacity for more efficient and affordable research and testing. For both reasons, the interest in closer relationships with source countries and communities is likely to rise. This makes it increasingly possible to design benefit-sharing packages that link both raw material supply and commercial research and product development to local capacity-building and institutional strengthening.

◆ Where source countries act as mere raw material suppliers, benefits are limited. By way of raising the level at which source country institutions and companies participate in the value added chain it is possible to locally capture a greater share of overall benefits.

◆ A strategy of increasing the local value added also provides a basis for source-country groups can develop domestic markets for processed products, which are generally less unstable than international botanical medicine markets.

◆ While few botanical medicine products are patented, in recent years increasing attention has been placed on two other forms of intellectual property – geographic indications and trademarks - that can be used as tools both to market natural products more effectively by distinguishing them from competitors and to help holders of traditional knowledge to benefit more equitably than they have in the past from the commercial use of their knowledge.

Seed

◆ It is common for seed companies to obtain genetic resources for free (or for a nominal handling fee), although licensing agreements are common for access to elite germplasm. Many actors are involved in the chain from initial access to genetic resources, via pre-breeding and commercial development, to the sale of final products to the farmer or consumer.

◆ As a result of the gradual privatisation of the global seed industry, more seed is patented and sold under license, and formal written agreements are increasingly entered into toward the end of the chain. However, benefits are usually not passed back along the chain to each contributor.

◆ Reciprocal access to genetic resources is viewed among agricultural researchers as the major benefit shared through the current informal system of exchange. The sharing of more indirect benefits such as research results, access to technology and capacity-building takes place predominantly in the public sector. Such benefit-sharing is often not linked to access to specific germplasm, but flow between institutions involved in collaborative crop research that involves access to germplasm.

Crop protection

◆ Crop-protection products are often developed by departments or subsidiaries of companies that are involved in pharmaceuticals. Where links with a pharmaceutical company exist, crop-protection companies are more likely to be familiar with current practice in benefit-sharing, and to include aspects of benefit-sharing in their agreements with suppliers of genetic resources.

◆ On the other hand, the crop protection industry also has some similarities with the seed industry in that basic research is often conducted in the public sector, from which genetic resources are passed, often for free, to industry.

◆ As well, most crop protection companies have synthesis programmes developing new products on the basis of model

compounds derived from templates originally discovered in natural products. Product discovery and development of this kind does not require access to new genetic resources. Crop protection companies tend to see little rationale for sharing the benefits from such commercial products – unlike pharmaceutical companies where royalty arrangements generally guarantee some (however modest) level of benefit-sharing for derivatives of genetic resources, even for wholly synthesised analogues.

Biotechnology applications other than in health care and agriculture

◆ Biotechnology companies often obtain free samples that were collected by university researchers. Licensing agreements for access to value-added genetic resources and biotechnology innovations are normally seen as a part of the bargaining process, so as to maintain access to quality samples and enjoy the advantages of collaboration with high-calibre scientists and to remain competitive in future – rather than as 'benefit-sharing'.

◆ Genetic resources may have passed through many hands before reaching commercial companies, and benefit-sharing with source countries is relatively rare. Where it does take place, it is usually confined to cases where the companies collect genetic resources themselves or establish arrangements with intermediary institutions overseas.

◆ Rather than initiating benefit-sharing arrangements of their own, biotechnology companies often follow the lead of intermediary organisations such as culture collections, which are increasingly supplying materials under material transfer agreements (MTAs).

◆ Existing benefit-sharing agreements typically involve technology transfer and training, as well as commitments to pay royalties. Information sharing and capacity building often arise informally as part of business relationships.

Horticulture

◆ Benefit-sharing has not played much if any role in commercial ornamental horticulture development, although some commercial arrangements do involve royalties and payment of fees, and various in-kind benefits may be shared. In-kind benefits may include reciprocal access to plant material, acknowledgement of the names of providers of genetic resources in the downstream marketing of bred cultivars, supply of equipment, and training.

◆ Horticulture companies that breed new ornamental varieties tend to conduct most of the research in-house, unlike the joint research programmes that are common in the pharmaceutical and seed industries.

Annex B: Forms of monetary benefit-sharing in the pharmaceutical industry

The following are indicative figures for different forms of monetary benefit-sharing, based on a range of cases. While actual amounts vary enormously across the pharmaceutical sector, these figures based on available data reflect typical ranges.

Fees for samples ($US)

- 25 – 200 $/kg dry weight plant sample
- 100 – 200 $/25g plant solvent extract
- 20 – 140 $ microbial cultures
- 60 – 100 $ fungal samples

Advance payments

This involves supporting the implementation of an agreed and well-defined work plan and covering operational costs. It is defined on a case basis.

Milestone payments ($US) (an example from one case)

- First patent filing: $5,000
- Initiation of phase I clinical study: $10,000
- Initiation of phase III clinical study: $25,000
- Filing of National Drug Authority (NDA) or equivalent: $50,000

Royalties (on net sales)

Raw material: 0.5 – 2 percent

- Raw material (e.g. dried plants, soil samples) and basic extracts (organic or aqueous): 0.5 – 2 percent.

producers who invest in building the reputation of a product over time (e.g. by maintaining high standard of product quality while allowing flexibility for product innovation and improvement, in the context of a given tradition).

Geographical indications

Geographic indications are defined under Article 22.1 of the TRIPS agreement as 'indications which identify a good as originating in the territory of a WTO (World Trade Organisation) member, or a region of locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographic origin'. Based on an underlying philosophy of the distinctiveness of local and regional products, geographical indications enhance the power of local producers to sell their distinctive products in a global marketplace, often at a premium. As a type of intellectual property that is linked to territory, they enable the relevant social and industrial groups to distinguish their products, not by company or brand, but by linking them to their origin in a particular territory and the natural and cultural characteristic of that territory relevant to the distinct character of the product. Aside from the locality or region where a product was produced, four criteria have been used to determine whether a product meets the standards for carrying a geographical indication:

- Variety or species (of plant or animal);
- Yield;
- Production methods;
- Processing methods.

Geographic indications have significant potential as tools for the protection of traditional knowledge and management of species, because they:

- Are based on collective traditions and a collective decision-making process;
- Protect and reward traditions while allowing evolution;
- Emphasise the relationships between culture, land, resources and the environment;
- Are not freely transferable and are not subject to unconditional control by a private owner;
- Can be maintained as long as the collective tradition is maintained.

Trademarks

Article 15 of TRIPS provides that 'any sign or any combination of signs, capable of distinguishing the goods or services of one undertaking from those of other undertakings shall be capable of constituting a trademark'. Trademarks serve as marketing tools that highlight a producer's claim to authentic or distinctive products or services. Particularly relevant for genetic resource based products are two specific types of trademarks – collective marks and certification marks. Collective marks are trademarks or service marks used by the members of a cooperative, an association, or another collective group. Certification marks are defined as trademarks 'used in connection with the products or services of one or more persons other than the owner of the mark to certify regional or other origin, material, mode of manufacture, quality, accuracy, or other characteristics of such goods or services'. Trademarks have been used by some indigenous and local communities. Two examples are: agricultural products made by native American Indians, certified as such by the Intertribal Agricultural Council; and Inuit soapstone carvings, certified by the Canadian Department of Indian and Northern Affairs.

Annex C: Sample Material Transfer Agreement used by PhytoTrade

Parties:

PhytoTrade: Gus Le Breton
Chief Executive
PO Box BE 398, Belvedere, Harare, Zimbabwe

Recipient: Institute of Food Research

Purpose: To provide Recipient with samples of Namibian Moringa ovalifolia and associated know-how, hereinafter collectively referred to as the Material.

Terms and conditions: The Material is released to the Recipient under the following conditions:

1. The Material and associated know-how shall only be used for *(purpose that theMaterial may be used)*

2. The Recipient shall not transfer the Material, in whole or in part, to a third party without the express written consent of PhytoTrade. Any third party requesting a sample shall be referred to PhytoTrade.

3. The Material shall remain the property of PhytoTrade and shall not be used for commercials or profit-making purposes without an appropriate license or other permission from PhytoTrade.

4. The Recipient shall keep PhytoTrade informed of the results obtained through its use of the Material, shall provide PhytoTrade with any manuscript that describes the work with the Material prior to submission for publication, and will acknowledge PhytoTrade's contribution to the work reported.

5. The Recipient shall not in any way state or imply that this Agreement or the results of this Agreement is an endorsement of its organisational units, employees, products or services.

6. The Recipient shall comply with all laws, regulations and/or guidelines applying

to the use of the Material, and shall assume sole responsibility for any claims or liabilities which may arise as a result of the Recipient's use of the Material. It is the responsibility of the Recipient to obtain any required permits for the Material before the Material is shipped.

7. PhytoTrade gives no warranties or guarantees, expressed or implied, for the Material, including merchantability or fitness for a particular purpose.

8. Upon completion of the activities performed by the Recipient using the Material, the Material shall be returned, destroyed or otherwise disposed of as instructed by PhytoTrade.

9. The Recipient shall meet with PhytoTrade representatives to determine inventorship of an invention should arise from the work with the Material.

10. The Recipient shall not disclose Material marked 'Confidential' or 'Proprietary' to any third party without written permission from PhytoTrade.

11. Material shall be excluded from the confidentiality requirements of this Agreement if: (1) the Recipient had possession of the Material prior to disclosure; (2) the Material is generally available to the public at the time of disclosure; (3) the information becomes generally available to the public through no fault of the Recipient after disclosure; or (4) after disclosure, the Recipient receives the Material from a third party who does not impose a confidentiality obligation upon the Recipient.

12. If the parties hereto decide, at some future date, to engage in a co-operative research initiative using the Material, a formal Co-operative Research and Development Agreement, or other research agreement, must be negotiated and entered into between the parties. Such an Agreement shall supersede this Material Transfer Agreement.

13. This Material Transfer Agreement shall be construed in accordance with the laws of the United Kingdom.

This Material Transfer Agreement shall become effective upon date of final signature and shall continue in effect for a period of …….. years.

Accepted for PhytoTrade: Gus Le Breton, Chief Executive Officer, _____ _____
SIGNED DATE

Accepted for the Recipient::_____ _____ _____ _____
NAME TITLE SIGNED DATE

Annex D: Sample Material Transfer Agreement for non-exclusive license for research and other non-profit purposes

This Agreement is made this 00th day of month, year, BETWEEN:

1. <The Supplier> ("X") and

2. The Recipient:- Natural Products International plc, Cornbury Park, Huntington, Cambridgeshire CB7 3EH ("NPI")

WHEREAS:

A. "X" has materials, patents, data, know-how, etc, as described in Schedule 1

(hereinafter the "Materials"; and

B. The Recipient (NPI) wishes to receive the Materials for the purposes of

research only and commercialisation of results from the Materials; and

C. "X" wishes to make the Materials available to the Transferee.

IN CONSIDERATION OF THE MUTUAL UNDERTAKING SET OUT BELOW IT IS NOW THEREFORE HEREBY AGREED AS FOLLWS:

1. The biological materials and any accompanying know-how and data (hereinafter "Materials") to be provided to the Recipient by "X" are described in the attached Schedule 1.

2. "X" shall provide the Materials, patents, data, know-how, etc, and permission to use the same exclusively for scientific research and experimental use only by the Recipient. The Materials will not be used for in vivo testing or treatment in human subjects or for any purpose other than those expressly permitted by this Agreement. Use, storage and disposal of the Materials and progeny and derivatives will be in compliance with all applicable national and local laws and regulations. The Materials are to be used with caution and prudence in any experimental work, since all of the characteristics are not known.

3. The Materials, including any progeny thereof, are the property of "X". The Recipient anticipates that it may generate certain results useful for diagnostic, prognostic or therapeutic applications. All such results and intellectual property rights therein shall be the exclusive property of "X", subject to the rights of the Recipient to publish as limited in this Agreement.

4. The Recipient shall not sell or otherwise transfer the Materials to a third party for any purpose. This Agreement and the resulting transfer of the Materials by "X" to the Recipient constitute a non-exclusive license to use the Materials solely for research or other not-for-profit purposes. The Recipient shall not use the Materials for any products or processes for profit-making or commercial purposes.

5a. This Agreement is not assignable by the Recipient.

b. The Recipient shall receive the Materials, patents, data, know-how, etc, in confidence and agrees not to disclose to any others not employed by the Recipient any matter arising from this Agreement or work with the Materials without <The Supplier's> prior written consent. These obligations shall survive the termination of this Agreement.

6. The Recipient shall promptly disclose to "X" in writing any results obtained from the use of the Materials. The Recipient agrees not to disclose results obtained in the Recipient studies involving the Materials, either orally or by submission of a manuscript, without first providing such manuscript to "X" or describing each proposed disclosure with "X" and receiving prior consent from "X" for any such disclosure. The purpose of this restriction is to prevent disclosure of proprietary information or to protect patent rights which may be jeopardised by the submission or release of such results. In all oral presentations or written publications concerning research involving the Materials, the Recipient will acknowledge "X"'s contribution to the results described in said disclosure and will identify "X" as the source of the Materials, unless otherwise requested by "X" or agreed upon by the parties. The Recipient agrees to provide "X" with a copy of any publication which contained experimental results obtained from use of the Materials.

7. The Recipient will at the option of "X" return to "X" or dispose of all unused Materials, patents, data, know-how, etc, progeny and derivatives, if this Agreement is terminated or whenever investigation for which it has been supplied discontinues or is terminated. "X" is entitled to terminate this Agreement on 30 days notice, such termination not to be unreasonably effected. Any results and data generated from the Materials Transfer Agreement will be owned by "X" and any commercialisation of such results and data will be effected by NPI under a License Agreement by mutual agreement of the parties listed in the Agreement, such consent not to be unreasonably withheld.

8. It is understood that any and all proprietary and intellectual property rights of whatever nature, including but not limited to patent rights in and to the Material, patents, data, know-how, etc, and in all results of the Research and in all new uses shall be and remain the exclusive property of "X".

9. It is the intention of the Agreement that the parties will enter into a License Agreement to commercialise the results of the Agreement on fair and reasonable terms, such licenses to be effected over the course of the Agreement or within 90 days of its termination.

10. The Materials provided are experimental in nature and are provided without any warranties, express or implied, including without limitation, warranties of merchantability and fitness for a particular use. "X" makes no representation and provides no warranty that the use of the material will not infringe any patent or other intellectual property or other right.

11. The Recipient shall bear all risk associated with any use (direct or indirect), storage or disposal of the Materials and their progeny and derivatives. To the extent allowable under applicable laws, the Recipient agrees to indemnify, defend and hold harmless "X" and its officers, directors, employees, representatives and agents against all fines, penalties, damages, expenses (including without limitation legal expenses), claims, demands, suits or other actions arising from the Recipient's acceptance, use (direct or indirect) and disposal of the Materials and their progeny or derivatives.

12. The Agreement shall be governed by and construed according to the laws of England. The parties warrant and represent that they have the right to enter into this Agreement and that they are under no contractual obligations inconsistent with the terms of this Agreement.

IN WITNESS WHEREOF the parties hereto have caused this Agreement to be executed by duly authorised representatives, effective as of the last day indicated below.

<Name> Investigator ……

on behalf of

"X"……

Print name and title

Address ……

Date ……..

Duly authorised for Natural Products International

……

Print name and title

Address ……

Date ……..

Annex E: Material Transfer Agreement for Non-profit Collectors prescribed by the Government of Malawi

Material transfer agreement issued by permit-issuing organisations in the case of non-profit institution collecting in scientific fields with possible commercial applications, such as natural products chemistry. Transfer to third parties is allowed, but the Recipient is required to sign contractual agreements with each third party that preserves the original Provider's rights and in either case with the written consent of the original Provider. Patenting of research results is allowed, however if commercial uses are envisioned, the Recipient is required to obtain written consent from the original Provider, and to negotiate a benefit sharing agreement to capture monetary benefits. The Recipient must notify the Provider of all patents filed and granted.

Definitions

1. PROVIDER: Organisation providing the ORIGINAL MATERIAL

Authorised Official:……

Official Stamp: ……..

PROVIDER SCIENTIST (if different from PROVIDER'S Authorised Official):

……

Organisation:……

Address:……

2. RECIPIENT: Organisation receiving the ORIGINAL MATERIAL:

Authorised Official:…….

Organisation:……

Address:……

3. ORIGINAL MATERIAL: The description of the material being transferred:

……

4. MATERIAL: ORIGINAL MATERIAL, PROGENY, and UNMODIFIED DERIVATIVES. The MATERIAL shall not include: (a) MODIFICATIONS, or (B) other substances created by the RECIPIENT through the use of the MATERIAL which are not MODIFICATIONS, PROGENY, or UNMODIFIED DERIVATIVES. The definition of MATERIAL includes all intangible components including knowledge pertaining to traditional or indigenous uses of the ORIGINAL MATERIAL, except where said knowledge has entered the public domain through publication in recognised scholarly journals.

5. PROGENY: Unmodified descendant from the MATERIAL, such as

virus from virus, cell from cell, or organism from organism including any natural recombinants.

6. UNMODIFIED DERIVATIVES: Substances created by the RECIPIENT

which constitute an unmodified functional sub-unit or product expressed by the ORIGINAL MATERIAL. Some examples include: sub-clones of unmodified cell lines, purified or fractionated subsets of the ORIGINAL MATERIAL, proteins expressed by DNA/RNA supplied by the PROVIDER, or monoclonal antibodies secreted by a hybridoma cell line.

7. MODIFICATIONS: Substances created by the RECIPIENT which contain/ incorporate the MATERIAL. For purposes of this Agreement, the definition of "incorporate" includes, but is not limited to, any processes involving uses of, constituents of, or molecular constituents of MATERIAL. Examples include, but are not limited to, chemical derivatives of, analogues developed from, or products chemically modelled after MATERIAL.

8. COMMERCIAL PURPOSES: The sale, license, or other transfer of the MATERIAL or MODIFICATIONS to a for-profit organisation. COMMERCIAL PURPOSES shall also include uses of the MATERIAL or MODIFICATIONS by any organisation, including RECIPIENT, to perform contract research, to screen compound libraries, to produce or manufacture products for general sale, or to conduct research activities that result in any sale, lease, license, or transfer of the MATERIAL or MODIFICATIONS to a for-profit organisation. However, industrially sponsored academic research shall not be considered a use of the MATERIAL or MODIFICATIONS for COMMERCIAL PURPOSES per se, unless any of the above conditions of this definition are met.

9. NON-PROFIT ORGANISATION(S): A university or other institution of higher education or an organisation exempt from taxation. As used herein, the term also includes Government agencies and departments.

Terms and Conditions of this Agreement

In response to the RECIPIENT'S request for the named ORIGINAL MATERIAL, the PROVIDER asks that the RECIPIENT and the RECIPIENT SCIENTIST agree to the following before the RECIPIENT receives the ORIGINAL MATERIAL:

1. The PROVIDER retains ownership of the MATERIAL, including any MATERIAL contained or incorporated in MODIFICATIONS.

2. The RECIPIENT retains ownership of: (a) MODIFICATIONS (except for ownership rights to the MATERIAL included therein as in 1), and (b) those substances created through the use of MATERIAL or MODIFICATIONS, but which are not PROGENY, UNMODIFIED DERIVATIVES or MODIFICATIONS (i.e. do not contain the ORIGINAL MATERIAL, PROGENY, UNMODIFIED DERIVATIVES). If either 2(a) or 2(b) results from the collaborative efforts of the PROVIDER and the RECIPIENT, joint ownership may be negotiated.

3. The RECIPIENT and the RECIPIENT SCIENTIST agree that the MATERIAL: (a) is to be used solely for teaching and academic research purposes; (b) will not be used in human subjects, in clinical trials, or for diagnostic purposes involving human subjects without the written consent of the PROVIDER; (c) is to be used only at the RECIPIENT organisation and only in the RECIPIENT SCIENTIST's laboratory under the direction of the RECIPIENT SCIENTIST or others working under his/her direct supervision; and (d) will not be transferred to anyone else within the RECIPIENT organisation without the prior written consent of the PROVIDER.

4. RECIPIENT agrees to compensate PROVIDER for transfer of ORIGINAL MATERIAL, as described herein (examples include monetary compensation, access to scientific information, technology transfer, or provision of research services):

……

5. The RECIPIENT and the RECIPIENT SCIENTIST agree to refer to the PROVIDER any request for the MATERIAL from anyone other than those persons working under the RECIPIENT SCIENTIST's direct supervision. To the extent supplies are available, the PROVIDER or the PROVIDER SCIENTIST agrees to make the MATERIAL available, under a separate agreement having terms consistent with the terms of this Agreement, to other scientists (at least those at NON-PROFIT ORGANISATIONS) who wish to replicate the RECIPIENT SCIENTIST's research, provided that such other scientists reimburse the PROVIDER for any costs relating to the preparation and distribution of the MATERIAL.

6. (a) The RECIPIENT and/or the RECIPIENT SCIENTIST shall have the right, without restriction, to distribute substances created by the RECIPIENT through the use of the ORIGINAL MATERIAL only if those substances are not PROGENY, UNMODIFIED DERIVATIVES, or MODIFICATIONS.

(b) Under a separate agreement having terms as protective of the

PROVIDER's rights as this Agreement , the RECIPIENT may distribute MODIFICATIONS to NON-PROFIT ORGANISATION(S) for research and teaching purposes only.

(c) Without written consent from the PROVIDER, the RECIPIENT

and/or the RECIPIENT SCIENTIST may NOT provide MODIFICATIONS for COMMERCIAL PURPOSES. It is recognised by the RECIPIENT that such COMMERCIAL PURPOSES may require a commercial license from the PROVIDER and the PROVIDER has no obligation to grant a commercial license to its ownership interest in the MATERIAL incorporated in the MODIFICATIONS. Nothing in this paragraph, however, shall prevent the RECIPIENT from granting commercial licenses under the RECIPIENT's intellectual property rights claiming such MODIFICATIONS, or methods of their manufacture or their use.

7. The RECIPIENT acknowledges that the MATERIAL is or may be the subject of a patent application. Except as provided in this Agreement, no express or implied licenses or other rights are provided to the RECIPIENT under any patents, patent applications, trade secrets or other proprietary rights of the PROVIDER, including any altered forms of the MATERIAL made by the PROVIDER. In particular, no express or implied licenses or other rights are provided to use the MATERIAL, MODIFICATIONS, or any related patents of the PROVIDER for COMMERCIAL PURPOSES.

8. The RECIPIENT is free to file patent application(s) claiming inventions made by the RECIPIENT through the use of the MATERIAL but agrees to notify the PROVIDER upon filing a patent application claiming MODIFICATIONS or method(s) of manufacture or use(s) of the MATERIAL.

9. If the RECIPIENT desires to use or license the MATERIAL or MODIFICATIONS for COMMERCIAL PURPOSES, the RECIPIENT agrees, in advance of such use, to negotiate in good faith with the PROVIDER to establish the terms of a commercial license. It is understood by the RECIPIENT that the PROVIDER shall have no obligation to grant such a license to the RECIPIENT, and may grant exclusive or non-exclusive commercial licenses to others, or sell or assign all or part of the rights in the MATERIAL to any third party(ies), subject to any pre-existing rights held by others and obligations to the PROVIDER's Government. The PROVIDER and the RECIPIENT shall share any benefits basing on either the Benefit-

Sharing Formula, or Regulations or Laws of the Malawi Government if so existent and applicable. In absence of the above, the PROVIDER and RECIPIENT shall enter into legally binding negotiations on best-practice method of sharing benefits.

10. Any MATERIAL delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. The PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.

11. Except to the extent prohibited by law, the RECIPIENT assumes all liability for damages which may arise from its use, storage or disposal of the MATERIAL. The PROVIDER will not be liable to the RECIPIENT for any loss, claim or demand made by the RECIPIENT, or made against the RECIPIENT by any other party, due to or arising from the use of the MATERIAL by the RECIPIENT, except to the extent permitted by law when caused by the gross negligence or wilful misconduct of the PROVIDER.

12. The Agreement shall not be interpreted to prevent or delay publication of research findings resulting from the use of the MATERIAL or the MODIFICATIONS. The RECIPIENT SCIENTIST agrees to provide appropriate acknowledgement of the source of the MATERIAL in all publications.

8. The RECIPIENT agrees to use the MATERIAL in compliance with all applicable statutes and regulations, such as, for example, those relating to research involving the use of animals or recombinant DNA.

9. The Agreement will terminate on the earliest of the following dates: (a) when the MATERIAL becomes generally available from third parties, for example, through reagent catalogues or public depositories or (b) on completion of the RECIPIENT's current research with the MATERIAL, or (c) on thirty (30) days written notice by either party to the other, or (d) on the date specified herein: …….., provided that:

(i) if termination should occur under 14(a), the RECIPIENT shall be

bound to the PROVIDER by the least restrictive terms applicable to the MATERIAL obtained from the then-available resources; and if termination should occur under 14(b) or 14(d) above, the

RECIPIENT will discontinue its use of the MATERIAL and will, upon direction of the PROVIDER, return or destroy any remaining MATERIAL. The RECIPIENT, at its discretion, will also either destroy the MODIFICATIONS or remain bound by the terms of this Agreement as they apply to MODIFICATIONS; and

(iii) in the event the PROVIDER terminates this Agreement under 14(c) other than for breach of this Agreement or for cause such as an imminent health risk or patent infringement, the PROVIDER will defer the effective date of termination for a period of up to one year, upon request from the RECIPIENT, to permit completion of research in progress. Upon the effective date of termination, or if requested, the deferred effective date of termination, RECIPIENT will discontinue its use of the MATERIAL and will, upon direction of the PROVIDER, return or destroy any remaining MATERIAL. The RECIPIENT, at its discretion, will also either destroy the MODIFICATIONS or remain bound by the terms of this Agreement as they apply to MODIFICATIONS.

Paragraphs 7, 10 and 11 shall survive termination.

8. (a) The Terms and Conditions of this Agreement are severable.

(b) Any dispute between the parties regarding interpretation of this Agreement which cannot be resolved by negotiation shall be arbitrated according to the provisions of this Agreement by a mutually acceptable non-party attorney.

(c) This Agreement and the Parties' rights and duties outlined herein shall be

interpreted under the laws of (enter city, county or department, state and country) ……, without reference to conflicts of law provisions.

9. Individual Collectors shall not be permitted unless by application filed by the collector's institution.

10. The RECIPIENT shall send to the PROVIDER the progress and final report of the work that the biological MATERIAL has been provided for.

11. The RECIPIENT violating this Agreement shall be punished according to the relevant Malawi laws.

Certification

This Material Transfer Agreement is effective when signed by all parties and when signed by the Chair of the Genetic Resources Contracts Review Committee of the Government of Malawi. The Authorised Officials executing this Agreement certify that they are the legal representatives of their respective organisations, authorised to sign on behalf of their respective organisations for the purpose of binding said organisations to the terms of this Agreement, for the transfer specified above.

PROVIDER SCIENTIST

Name:……

Title:……

Address:……

Signature:……

Date:……

PROVIDER ORGANISATION CERTIFICATION

Certification: I hereby certify that I am legally entitled to represent the named PROVIDER organisation (may be the PROVIDER SCIENTIST if authorised by the PROVIDER organisation):

Authorised Official:……..

Title:……

Address:……

Signature:……

Date:……

RECIPIENT ORGANISATION CERTIFICATION

Certification: I hereby certify that I am legally entitled to represent the named RECIPIENT organisation (may be the RECIPIENT SCIENTIST if authorised by the RECIPIENT organisation):

Authorised Official:……

Title:……

Address:……

Date:……

CERTIFICATION BY THE GENETIC RESOURCES CONTRACTS REVIEW COMMITTEE OF THE GOVERNMENT OF MALAWI

Chairman of the Genetic Resources Contracts Review Committee:

Title:……

Organisation:……

Address:……

Signature:……

Date:……

Annex F: Sample Research and Development Agreement

This Agreement is signed this th day of <month, Year>.

Parties

(a) The XXXX ("X") of "<address>

(b) Natural Products International plc whose registered office is situated at Cornbury Park, Huntington, Cambridgeshire, CB7 3EH, England ("NPI")

Preliminary

(a) "X" is an institution based in <country> involved in the scientific research and development of new medicinal materials from botanical sources which has the capability to collaborate with NPI in research and development.

(b) NPI is in the business of devising, researching and developing medicinal herbal formulations intended to be sold as licensed phytopharmaceuticals and as dietary supplements.

(c) NPI and "X" wish to establish a collaborative framework under which they can identify, research and appraise the potential for developing commercial products based on medicinal plants and preparations on a project-by-project basis.

(d) "X" has or can obtain the necessary formal Government permissions to enter into research agreements for the scientific investigation and appraisal of medicinal plants and preparations with NPI.

(e) NPI has access to funding necessary to finance the research and development of these products through the application of TQP™ (Total Quality Profiling™).

Now it is agreed as follows:

1. Agreement for the collaborative research and development of new medicinal preparations from botanical materials

(a) NPI and "X" will work together in the research and development of new medicinal preparations from botanical materials. At the end of the research and development phase, NPI will be responsible for determining whether to continue to full commercial development of any product;

(b) For each specific product research and development programme agreed, NPI and "X" will work together on an exclusive basis;

(c) NPI and "X" will both propose potential projects for specific research programmes. NPI will be responsible for the final decision on whether to implement any specific programme.

(d) Prior to implementation of any research programme, a detailed work programme and a detailed working budget covering all costs will be prepared and agreed.

(e) For any specific project agreed, NPI will have overall responsibility for the technical guidance of the research programme including:

i. The investigation through the application of TQP™ of the variability of the chemical profile of extracts of the target plant parts (as a result of genetic, environmental and management variables) leading to the development of a product specification linked to a precise raw material production protocol;

ii. The determination of whatever other analyses are required to be undertaken on the raw material, semi-processed product and final formulated product;

iii. The provision, if necessary, of the PHYTOTRACK™ software system for provision of traceability and audit capability;

iv. The formulation and technical direction and supervision of field programmes covering trials necessary for the programme;

v. The specification and technical direction and supervision of the investigation of product formulation options, and the specification of the final product formulation, and the design and specification of product stability programmes;

vi. The identification, where necessary of clinical trials collaborators, and the design and implementation of any clinical trials programmes;

(f) "X" will collaborate with NPI to provide and develop:

i. legitimate and secure access for the development of all crops and preparation for overseas markets, including the rights to make use of any and all clinical trial results and analytical data that exist, where necessary through relevant licenses from the Government of <country> (and its Agencies) to do so;

ii. access to existing raw material production sites and producers;

iii. the capability to identify, and develop other sites as agreed by NPI;

iv. the capability to manage field production and field trial sites and to impose production and post-harvest handling protocols and to deliver raw material and processed product to meet pre-determined and agreed specifications;

v. the capability to implement and manage extraction and other processing operations according to pre-determined and agreed protocols;

vi. local analytical services (investigating and securing services through sub-contract with third party suppliers where necessary and agreed) as required;

(g) Where "X" secures the services of collaborators on a contractual basis for any specific product programme, "X" will do so on the basis of an exclusive contract with the collaborator for the specific product, and will disclose the terms of contract to NPI under confidentiality to confirm exclusivity;

(h) NPI will pay for all services and supplies listed under Para 1(e) above;

(i) NPI will assist "X" on the basis of reasonable commercial contract terms for the services "X" will provide to NPI in the development of these products under Para 1(f)iii to Para 1(f)vi inclusive above. These terms to be not out of line with terms that "X" could expect to negotiate with other clients in the <country>.

(j) NPI and "X" will discuss the Intellectual Property generated as a result of the development work and the application of TQP™ to the products in subsequent agreements.

2. Initial Developments

NPI and "X" propose to begin work under this Agreement through defining and negotiating separate project contracts for:

(a) the research and development of products with <Y> activity;

(b) the research and development of products with <Z> activity with a range of potential applications;

Other potential product research projects will be proposed for consideration.

For all proposed screening of products for research and development, "X" will provide NPI with copies of relevant scientific information for review by ONP's Research Committee. For each product or programme that NPI agrees to develop a joint research and development programme with "X", NPI will make an initial commitment payment of <amount>.

3. Confidentiality

"X" shall keep strictly confidential all information concerning ONP's business and affairs and ensure that all of its personnel observe similar obligations. NPI shall keep strictly confidential all information concerning "X"'s business and affairs and ensure that all of its personnel observe similar obligations.

4. Duration

This Agreement shall be for an initial period of <number> years from the date of signing, unless terminated by mutual agreement.

5. Choice of Law

This Memorandum is intended to create legally binding obligations governed by <country> law. The parties submit to the non-exclusive jurisdiction of the <country> courts.

Signed by …….

Duly authorised on behalf of **Natural Products International plc**

Signed by …….

Duly authorised on behalf of **"X"**

Annex G: Sample Commercial Agreement

This Agreement is signed this th day of <month, year>.

Parties

(a) XXXX (“”X””) of <address><country>

(b) Natural Products International plc whose registered office is situated at Cornbury Park, Huntington, Cambridgeshire, CB7 3EH, England (“NPI”)

Preliminary

(a) “X” is a company based in <country> involved in the application of scientific research to the manufacturing and marketing of botanical medicines which has the capability on a commercial basis to provide a comprehensive range of services in relation to the development and manufacture of botanical medicines.

(b) NPI is in the business of devising, researching and developing medicinal herbal formulations intended to be sold as licensed phytopharamceuticals and as dietary supplements.

(c) The Agreement is for the collaborative appraisal and development of botanical products as licensed phytopharmaceuticals and/or dietary supplements for markets outside the <country>. “X” will work exclusively with NPI on the development of any specific product for these markets while this Agreement remains in force. Where “X” secures services from collaborators under contract, the contracts will bind the collaborators to work exclusively with “X” on these products, and “X” will provide proof of this exclusivity to NPI.

(d) The application of ONP’s proprietary Total Quality Profiling™ (TQP™) technology can enable the development of licensed phytopharmaceuticals and dietary supplements meeting the regulatory requirements of the international markets.

(e) “X” has the necessary formal Government permissions to work on the component plants and extracts of these products from the Government of <country> and can secure the necessary formal permissions for NPI to collaborate with “X” in the scientific and commercial appraisal and development of these crops and products.

(f) “X” has established or can establish access to managed production areas of these crops where it can impose production protocols; and has the capability to access production of formulated product for commercial supply meeting the regulatory requirements of <country>, and work with producers of formulated product to enable the provision of documented samples.

(g) NPI has access to funding necessary to finance the development of these products through the application of TQP™.

Now it is agreed as follows:

1. Agreement for the collaborative appraisal and development of botanical Drugs

(a) NPI and “X” will work together in the appraisal and development of selected botanical drugs on an exclusive basis. At the end of the Appraisal phase, NPI will be responsible for determining whether to continue to full commercial development of the products;

(b) NPI will be responsible for the technical direction and supervision of the programme including:

i. The investigation through the application of TQP™ of the variability of the chemical profile of extracts of the target plant parts (as a result of genetic, environmental and management variables) leading to the development of a product specification linked to a precise raw material production protocol;

ii. The determination of whatever other analyses are required to ne undertaken on the raw material, semi-processed product and final formulated product;

iii. The provision of the PHYTOTRACK™ software system for the provision of traceability and audit capability;

iv. The formulation and technical direction and supervision of field programmes covering trials necessary for the appraisal programme, and future commercial production;

v. The specification and technical direction and supervision of the investigation of product formulation options, and the specification of the final product formulation, and the design and specification of product stability programmes;

vi. The identification of clinical trials collaborators, and the design and implementation of the clinical trials programmes;

(c) “X” will be responsible for:

i. Providing legitimate and secure access for the development of the necessary crops and products for overseas markets, including the rights to make use of all clinical trial results and analytical data, through relevant licenses from the Government of <country> (and its Agencies) to do so, including the extension of the licenses to match the terms laid out in (f) below if necessary prior to including a product under this Agreement;

ii. Providing access to existing raw material production sites and producers currently used by producers of the existing products;

iii. Providing the capability to identify, and develop other sites as reuqired by NPI;

iv. Providing the capability to manage field production and field trial sites and to impose production and post-harvest handling protocols and to deliver raw material and processed product to meet pre-determined and agreed specifications;

v. Providing the capability to implement and manage extraction and other processing operations according to pre-determined and agreed protocols;

vi. Providing local analytical services (investigating and securing services through sub-contract with third party suppliers where necessary and agreed) as required;

(a) NPI will pay for all services and supplies listed under Para 1(c) above.

(b) NPI will pay "X" on the basis of reasonable commercial contract terms for the services "X" will provide to NPI in the development of these products under Para 1(c)iii to Para 1(c)vi inclusive above. These terms to be not out of line with terms that "X" could expect to negotiate with other clients in the <country>.

(c) In addition, NPI will make the following payments to "X" linked to the continuing development and successful achievement of agreed development milestones for each product:

i. A mobilisation payment of <amount> on signing this Agreement

ii. For each product that enters commercial production as a dietary supplement, a x% royalty on net sales or license fees received for a period of 15 years

iii. For each product that enters commercial production as a licensed phytopharmaceutical, a x% royalty on net sales or license fees received for a period of 15 years or for the period of any patent protection secured.

(a) The payment schedule specified in Para 1(f) above will remain binding in the situation where NPI licenses any product to a third party.

(b) NPI will own the Intellectual Property generated as a result of the development work and the application of TQP™ to the products.

2. Confidentiality

"X" shall keep strictly confidential all information concerning ONP's business and affairs and ensure that all of its personnel observe similar obligations. NPI shall keep strictly confidential all information concerning "X""s business and affairs and ensure that all of its personnel observe similar obligations.

3. Duration

This Agreement shall be binding separately for each product from the date it is included under this Agreement until either the product royalty periods specified in Para 1(f) ii and iii have been completed, or it is mutually agreed to terminate the development programme for a product.

4. Choice of Law

The Memorandum is intended to create legally binding obligations governed by English law. The parties submit to the non-exclusive jurisdiction of the English courts.

Signed by …….

Duly authorised on behalf of **Natural Products International plc**

Signed by …….

Duly authorised on behalf of **"X"**

PhytoTrade Africa represents small-scale producers in the natural products sector in Botswana, Malawi, Namibia, Zambia and Zimbabwe. PhytoTrade's objective is to develop a reliable, efficient and enduring natural products industry in southern Africa, based on natural resources that are accessible to rural producers. Our over-arching goal is to develop a long-term supplementary income source for poor rural people in the region, so enabling them to improve their livelihoods from the sustainable exploitation of natural products.

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