WHERE BIODIVERSITY, TRADITIONAL KNOWLEDGE, HEALTH AND LIVELIHOODS MEET:

INSTITUTIONAL PILLARS FOR THE PRODUCTIVE INCLUSION OF LOCAL COMMUNITIES (BRAZIL CASE STUDY)

Working Paper

Working Paper number 81 April, 2011

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The International Policy Centre for Inclusive Growth is jointly supported by the Poverty Practice, Bureau for Development Policy, UNDP and the Government of Brazil.

Working Papers are available online at www.ipc-undp.org and subscriptions can be requested by email to ipc@ipc-undp.org

Print ISSN: 1812-108X

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Radhika Lal and Waldemiro Francisco Sorte Junior**

1 INTRODUCTION

Brazil recently launched a cross-ministerial programme—the Plano Nacional de Promoção das Cadeias de Produtos da Sociobiodiversidade (PNPSB)—to facilitate the 'sustainable' development of environmentally and socially sustainable productive chains for socio-biodiversity products. The programme framework for the PNPSB incorporates a strong focus on fostering productive inclusion (*inclusão produtiva*) which broadly entails creating conditions for the poor (extractivists, traditional communities and family farmers in this instance) to improve their productive capacities and strengthen their insertion in productive activities. In particular, it centres on how the institutional pillars of a productive-inclusion approach can be reinforced so as to enhance the benefits that such communities can receive from their integration into natural-resource-based production chains and the delivery of services (e.g. phytotherapies and phytocosmetics). With the view to identifying key channels of impact the paper also draws on the experiences of two earlier productive inclusion programmes: i.e. the Food Acquisition Programme (*Programa de Aquisição de Alimentos*, PAA) and the National Program for Production and Use of Biodiesel (*Programa Brasileiro de Produção e Uso de Biodiesel*, PNPB). It seeks to identify 'development functions' best performed by public institutions and explores the concept of a 'regulated market' framework that is characteristic of these types of productive inclusion programmes.

The move by various countries to 'modernize' their traditional medicinal systems and/or to leapfrog to the development of bio-drugs and biomedicine is found to raise a question about possible *productive* roles for traditional communities in these processes. The question is

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* This is the third in the series of IPC-IG Working Papers on productive inclusion initiatives in Brazil. The first two focused on food procurement from smallholder farmers and their integration in the biodiesel value chain: see Chmielewska and Souza (2010) and Zapta et al. (2010), respectively. Comments and inputs received from Clovis Zapata, Darana Souza, Donald Sawyer, Jaqueline Evangelista, Katia Marzall, Katia Torres, Leisa Perch and Savita Mullapudi Narasimhan on an earlier draft and/or particular sections of this paper are acknowledged with many thanks. Particular thanks are due to Yanmei Lin for information on China's approach to the integration of traditional medicine and relevant guidelines; to Darana Souza for explaining the innovativeness, as well as the intricacies and impacts, of Brazil's PAA programme and the issues of family farmers; and to Clovis Zapata for his engagement on production chains. Any errors that remain are those of the authors.

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not simply one of benefit-sharing and facilitating 'prior informed content' as far as the use of genetic resources is concerned. It is also a question of whether traditional knowledge and medicine can contribute to the delivery of primary health services particularly in under-served areas. A related question is whether practitioners of traditional medicine and modern allopathic medicine can partner in the processes related to drug discovery.

The paper considers these questions with regard to medicinal plants with a view to exploring opportunities for productive inclusion of traditional communities. It highlights the importance of bottom-up approaches to policy development in this area. It also explores whether the 'proof of concept' for the productive role of traditional practitioners pointed to by some community networks can be used to help such local communities/farmers move up the production and service value chain by enhancing public awareness about the range of potential activities that local communities can be involved in.

The paper is organised as follows: Section 2 provides a brief background of the economic and social context of rural development issues in Brazil. Section 3 explores Brazil's productive inclusion approach and draws implications for the design of natural-resource-based production chains and the delivery of services (e.g. phytotherapies and phytocosmetics). Section 4 of the paper provides a survey of issues at the intersection of biodiversity, traditional medicine, drug discovery and health care. It discusses Brazil's National Programme on Medicinal Plants and Herbal Medicines (Programa Nacional de Plantas Medicinais e Fitoterápicos, PNPMF), and alludes to the experiences of countries such as India and China so as to place the discussion about Brazil's approach within a broader cross-country context. In light of Brazil's multi-stakeholder approach to productive inclusion, the paper explores the roles of community-based networks and applied public research institutions which can serve to stimulate social and technological innovation and help to address structural asymmetries in the relation between the private sector and local communities. Section 5 focuses on access and benefit-sharing issues. Section 6 concludes the paper by drawing institutional lessons and highlighting issues for policy discussion.

2 BACKGROUND: RURAL INEQUITY ISSUES FOR BRAZIL

Brazil is a highly urbanised society with only 15 percent of its population residing in rural areas (IBGE, 2010). Systematic studies of the distinctions between rural and urban poverty are hard to find, but analysis points to significantly high levels of rural poverty, which has a territorial dimension: more than 70 per cent of the rural population in the North and Northeast is poor, while less than 45 per cent of the rural population is poor in the other three regions (South, Southeast and Centre West), although there are also significant disparities within the various states.[1] In the Northeast, poverty levels amongst landless people and family farmers[2] are relatively higher largely because of adverse climatic conditions, a natural resource base characteristic of a semi-arid region, inequalities in land tenure arrangements (also the case in the country's central regions) and relatively poor access to infrastructure in various places. The region has also witnessed the decline of the old production regime of cotton, livestock and agriculture based livelihoods that prevailed in the area. This fell into crisis around 1990 and there has been no suitable replacement, at least for poor family farmers and sharecroppers. This has apparently resulted in a limited market engagement on the part of significant numbers of family farmers.

Family farmers form the bulk of the rural population and account for 75 per cent of the rural labour force. Their abilities to eke out a living from agricultural activities vary, depending in part on the ecological, social and economic conditions in the different regions. This sector produces 87 per cent of the corn, 70 per cent of the beans, 59 per cent of the pork, 58 per cent of the milk and 50 per cent of the poultry consumed nationally (IBGE, 2009) on just 30 per cent of the cultivated land. Significant numbers of family farmers, however, (such as in the Northeast) are largely subsistence farmers who cultivate extremely small plots of land and also partly rely, on social transfers to supplement their incomes, and on the market for the purchase food.[3]

Poverty levels are also significant for Brazil's indigenous peoples, who comprise about 0.43 per cent of the population (between 700,000 and 750,000 people, according to the IBGE 2000 census).[4] Significant progress has been made as regards indigenous peoples' rights, and their integration into policy processes and development activities, but overall their economic and social circumstances remain challenging in many places. According to a recent study by the Instituto Socioambiental (2010), about 98 per cent of indigenous lands in Brazil are in the region known as the Brazilian Legal Amazon, where 60 per cent of the country's indigenous population lives. The others live in the Northeast, Southeast and Centre-South regions, often crowded into small areas that account for less than 2 per cent of the total area of indigenous lands. In the Amazon, the proportion of protected areas has risen significantly (from 8.5 per cent in 1990 to 44 per cent in 2010, of which 21.7 per cent are indigenous lands and 22.2 per cent are nature reserves and sustainable-use reserves). But the situation is often severe in other regions. In Mato Grosso do Sul, for example, there are conflicts over logging, land use, demarcation of traditional lands and reserve areas. Besides land use, other contentious issues in some areas include the design and implementation of major development projects such as hydroelectric dams and natural-resource extraction activities that directly or indirectly affect the lives of indigenous peoples. According to IBGE (cited in UN, 2009), 15.5 per cent of the Brazilian population lives in extreme poverty, but among indigenous people the figure is 38 per cent. Nearly half (42 per cent) of the Brazilian Amazonian population lives on less than half of the Brazilian minimum wage. This is the case for more than 10 million people (see Celentano et al., 2010). Sustainable livelihood opportunities—particularly those than can realize benefits through conservation activities—are thus a priority for the region.

There is also a high prevalence of malnutrition and various tropical diseases in the Amazon, which will likely increase because of the predicted rise in global temperatures, all other things being equal. In Brazil, 99.8 per cent of malaria transmission is in the Amazon (UNICEF, 2009). Given the use of herbal plants and traditional medicine to treat many of the diseases—almost as the first response because of local availability and low cost—and the growing resistance to many allopathic remedies, it is critical to work with the local communities to study the effectiveness of the most commonly used remedies, assess toxicity risks and knowledge of preparations, and work towards feasible standardisation. For example, Farnsworth (1994) and others point out that the main drugs developed for malaria and used to date (artemisinin and drugs derived from quina alkaloids) were discovered and/or inspired by traditional knowledge and ethno-medical data.[5]

Before looking further at the issues that lie at the intersection of biodiversity conservation, healthcare and value-adding livelihood opportunities for local and indigenous communities, the paper explores the Brazilian framework for productive inclusion with a view to drawing lessons for this emerging area of policy intervention.

3 BRAZIL'S APPROACH TO PRODUCTIVE INCLUSION

In Brazil as elsewhere, while emphasis is placed on rural non-agricultural employment, its potential to serve as a pathway out of poverty depends upon a household's economic profile and location. On average, richer households are more likely to specialise in rural non-agricultural employment (RNAE) than poorer households, and RNAE opportunities increase with closeness to urban environments and the size of cities in a given region (Jonasson and Helfand, 2008).[6] This means that for some of the poorest regions that are further from substantial urban centres and have large concentrations of poor people, (organically evolving) RNAE activities are unlikely to be significant in providing a pathway out of poverty.

Unsurprisingly, therefore, attention has been paid to territorial development strategies[7] and livelihood diversification programmes geared to family farmers, as well as social policies and cash-transfer programmes that can provide a floor/safety net for the rural poor. Productive inclusion (*inclusão produtiva*) is a cross-cutting thread that runs across these areas While there appears to be no standard definition, based on usage, it can be taken to mean capacity building activities to enhance access to formal employment and/or improving the quality of productive work and activity that the poor are inserted into through self employment, individual, collective self-employment (associative or cooperative), family farming etc.

It has social assistance, production chain and territorial dimensions. It incorporates policies aimed at strengthening family farming while providing food to the vulnerable, and includes a focus on complementary policies to strengthen the productive inclusion of social assistance beneficiaries as well as equity-enhancing agrarian development and/or territorial development policies. It incorporates development functions that are to be performed by public entities, particularly in contexts where a regulated market or institutional framework is established but also includes a strong multi-stakeholder and partnership orientation.

As regards productive inclusion under the umbrella of social assistance, the International Labour Organisation (2006) refers to Brazil's Ministry of Social Development and the Fight against Hunger (MDS, 2006) to make the following point: according to the arguments underlying current government policies (such as the Bolsa Família programme and, more generally, the various activities included in the Zero Hunger programme), the link between social protection and productive insertion is repeatedly stressed as necessary and "indispensable for the construction of economic and social relations which are able to foster the survival and improvement of the quality of life of citizens excluded from the formal labour market."

The framework policy document, Brazil's 1997 Organic Law on Social Assistance (*Lei Orgânica de Assistência Social*, LOAS), makes provision for promoting social inclusion into formal labour markets (Article 2) and projects to combat poverty, including by means of investments in economic and social groups and providing financial and technical support to enable them to build up their productive capacities (Article 25).[8] Conceptual approaches and policy instruments to operationalise the various objectives of the LOAS are continuously being developed in Brazil's single social-assistance system (Sistema Único de Assistência Social, SUAS), which is coordinated by MDS,[9] as well as in other thematic/sector ministries that work in the area of social and productive inclusion.[10] In the MDS/SUAS, more conventional policies to help beneficiaries "prepare for the [formal] job market" through training and apprenticeships are being complemented by initiatives that help low-income families in economic relationships and structures outside formal wage labour, such as independent

producers or those working in family/self-managed enterprises and cooperative production units. The programmes are both urban and rural, and range from microfinance and training support to promoting inclusion in production chains. MDS also houses a Secretariat for the articulation of productive inclusion policies and programmes (Secretaria de Articulação para Inclusão Produtiva, SAIP). It contributes to the development of various social development activities, promotes partnerships with the business sector and social partners, and coordinates various cross-ministerial programmes involving MDS and other parts of the Federal Government. The objective is to ensure that interventions are integrated and, thus, produce more effective and sustainable results for programme beneficiaries.

As regards programmes to foster productive inclusion, which are run by the sectoral ministries, the approach is somewhat different. The focus is less on ensuring insertion in labour markets and productive engagement *per se*, and more on exploring how production chains can be made more inclusive or how productive activities for the poor could be improved in sectoral and territorial strategies. The policy instruments also vary, and much more attention is being paid to technical assistance and productive financial support.

"Family farmers" have been subject to considerable attention in rural programmes. Brazil is unusual in having a separate Ministry for Agrarian Development (*Ministério do Desenvolvimento Agrário,* MDA) which is separate from the Ministry of Agriculture, Livestock and Food Supply (*Ministério da Agricultura*, *Pecuária e Abastecimento*, MAPA).[11] MDA has a National Secretariat for Family Farming (*Secretaria Nacional de Agricultura Familiar*). The ministry coordinates cross-sectoral programmes to address family farmers' lack of access to credit, such as the National Programme to Strengthen Family Farming (*Programa Nacional de Fortalecimento da Agricultura Familiar*, PRONAF) and the provision of technical training. In recent years, moreover, it has implemented programmes on access to land, insurance, support to small agro-industries and rural education. It has also introduced initiatives for family farmers to mitigate the risks of involvement in the market as a result of price volatility, being forced to sell at relatively lower prices because of limited bargaining power and/or lack of storage and transport facilities and so on, using tools such as public procurement at guaranteed prices.

Brazil also has a very strong focus on territorial strategies ('desenvolvimento territorial'). The different productive inclusion programmes are not implemented as stand-alone pillars but can be selected by local authorities from a 'menu of options' based on the needs of the particular region or territory. This is particularly the case with regard to areas targeted for special attention through the Territories of Citizenship strategies (*O Territórios da Cidadania,* launched in 2008). The Territories of Citizenship strategies aim to promote economic and social development through the 'universal basic citizenship' programmes and sustainable territorial development strategies.[12]

In principle, the productive inclusion approach allows for and promotes ***differing and potentially changing mixes*** of local development/territorial strategies, social assistance and productive chains/sectoral activities (i.e., vertical and horizontal policies) to ensure sustainable poverty reduction. Research is required to assess the ways in which the different vertical programmes and horizontal territorial strategies are actually being combined to facilitate a dynamic focus on *development pathways* for the different regions.

Two previous productive inclusion programmes are of particular interest: the Food Acquisition Programme (*Programa de Aquisição de Alimentos*, PAA, launched in 2003) and the

National Programme for the Production and Use of Biodiesel (*Programa Brasileiro de Produção e Uso de Biodiesel*, PNPB, launched in 2004).[13]

The PAA is a joint programme involving MDS, state and local governments, civil society organizations of family farmers and network entities. Its twin objectives are to "guarantee access to food in the proper quantity, quality and regularity according to the needs of the population living in food and nutritional insecurity, as well as to promote social inclusion in rural areas by strengthening family agriculture" (MDS website).[14]

Apart from its main aim of increasing biodiesel production in Brazil, PNPB has aimed to encourage diversification of feedstocks and foster the social inclusion of family farmers in the national biodiesel value chain by providing incentive to purchase from them.[15] Unlike the previous national policy on the supply of ethanol from sugarcane (*Proálcool)*, the PNPB makes provision for integrating family farmers by instituting a "social seal" (S*elo Social)* certification that serves as a requirement for suppliers to bid at biodiesel auctions.

Since the new PNPSB programme for socio-biodiversity draws on some of the design elements of earlier productive inclusion programmes such as the PAA and the PNPB, it may be worthwhile to briefly assess the lessons from those programmes as far as productive inclusion is concerned. Firstly, the programmes indicate how important it is that the poor have publically "regulated" market involvement. Even the poorest family farmers need to engage with the market in order to acquire cash to meet basic needs. For the most part, however, poor farmers face high transaction costs and risks, which result in their receiving less than optimal prices and benefits. This is also the case as regards integration in private-sector-driven production chains. Brazil has long had programmes to improve access to finance and training. By themselves, however, these also posed risks for poor farmers: how to repay loans if prices fell or if output was less than expected, for example. The new generation of productive inclusion programmes, which use forms of public procurement, work to mitigate production and financial risks. In principle, therefore, they are likely to be of more interest and could yield more demonstrable benefits, especially as regards guaranteed and predictable demand at prices which are fixed for the duration of the project period for the various goods produced by the family farmers (see Chmielewska and Souza, 2010; and Grupo Gestor, 2010). Programmes that provide finance (such as PRONAF) and training (ATER) become more necessary or were found to have more impact in areas where these two programmes were implemented.

While prices in the public procurement programmes are set at prevailing "market prices", this was often more than what poor farmers would otherwise get in the market because of their limited bargaining power. Producers can in fact choose whether to sell their production to CONAB (Brazil's state-owned National Food Supply Company/*Companhia Nacional de Abastecimento*) if market prices are below the amount fixed in the contract or to sell in the market if prices are above this threshold.

PAA-type programmes are also found to be important in providing the space to build up capabilities to better engage with the market, and this has yielded several direct and indirect benefits, one of which is to stimulate productive investments. Studies cited in Grupo Gestor (2010) point to the following results of the PAA:

- *Direct monetary benefits*. Beneficiary farmers received three times the income of non-beneficiaries as a result of marketing produce through the PAA. Purchases made by the PAA altered the relationship between producers and intermediaries

in established markets, and helped improve conditions for non-beneficiaries. The programme provided alternatives to traditional marketing channels, helped minimise the power of middlemen, and/or ensured that farmers receive fair prices. By providing a market for products that previously had no clear market opportunities, the programme raised income and market participation levels;

- A*dditional benefits*. At least 20 per cent of farmers adopted new milking techniques in response to requirements of the PAA. The number of milk coolers installed in the particular region rose by 40 per cent, and the use of tractors, fodder, trucks and computers grew by 15 per cent, 17 per cent, 27 per cent and 35 per cent, respectively. Some 26 per cent of farmers said they have acquired new livestock that were genetically superior to those that they previously owned. There were also improvements in nutritional outcomes for the most vulnerable populations who were receiving milk from the programme.

With regard to the PAA, the annotated studies cited by Grupo Gestor also emphasised the following:

- *The importance of various institutions*. Participating organisations, cooperatives and civil society organisations played an important role in the operationalisation of the PAA by helping recipients overcome challenges related to the storage and transportation of produce. The participation of local municipalities in implementation contributed to the programme's success and led to better coordination between institutions, non-governmental organisations and other agencies, thereby so enhancing the overall impact;
- *Challenges*. The challenges included: delays in payments; outdated management systems in some regions; a lack of coordination with technical assistance; lack of support for production; weak links with other institutions and lack of planning in the application of resources ("when the farmer is ready to sell, PAA/EAP is not always ready to buy"), which pose challenges for family farmers who are interested in participating in the programme; difficulties in mapping out, qualifying and engaging partners, such that the gap is on the side of having sufficient "organised demand" in place to channel the outputs procured by the programme; and the absence of a comprehensive register for participation in the PAA, hindering the establishment of criteria to prioritise those most in need.

There are additional challenges with integration into value chains that are driven by the private sector but in which the market processes are regulated by the state as is the case of the PNPB biodiesel programme. In general the poorer farmers and participants from the "other" category—which includes indigenous groups, the Quilombola (communities of African descent), landless workers and agro-extractivists—are likely to face greater constraints on their participation in markets. Thus, in the initial phases, investments would have to be made by the public/private sector to help poor farmers to ensure consistent and better quality outputs and to scale up production.[16] This was a weakness that became evident in the PNPB, since the financial incentives provided to refineries/producers to buy castor feedstocks from widely dispersed poor family farmers in the Northeast (as opposed to better-off family farmers producing soya in the

Southeast, for example), were often considered to be insufficient to warrant participation in the programme. Some of the actors also considered training and capacity building as a "development function" best performed by the state. In the implementation of the PNPB in the Northeast, the organisation of the value-chain, provision of technical support and seeds, and purchasing, were eventually taken over by Petrobras, a public corporation.[17]

While there are certainly difficulties in incorporating poor farmers it's important that institutional expectations not be kept too low else dynamic changes that, at least, analytically appear to be possible might not materialise. Wilkinson and Herrara (2008: 50) point out "given the objective of offering new opportunities for income and employment generation and a stimulus to local/regional development, the programme would have to go beyond the simple supply of raw material and develop value-adding strategies … In addition, therefore, to the large-scale biodiesel plants of BED and Petrobras, small-scale plants for local production and consumption and primary processing plants to transform the seed into crude oil for subsequent supply to the biodiesel plants would be necessary." I.e., it's important to aim to progressively incorporate family farmers in processing activities not just in the provision of raw materials.

Whether involvement in these programmes leads to new market opportunities or whether the programmes remain the primary channel for the engagement of small family farmers depends upon whether the initiatives can stimulate investment in productive facilities, on distances from markets, and on the extent to which collective organisation can lower the transaction costs of involvement—that is, market search, transport, storage, marketing and related costs, and the need for investments. See Jonasson and Hefland (2008) on the factors conditioning the success of RNAE activities. Analysis suggests that in poor areas that are far from urban centres and where infrastructure facilities are poor, such public programmes have a valuable role to play by way of ensuring predictable demand for the products of family farmers and stimulating economic and social investments as indicated above. The demand-side stimulus (through public procurement at predictable prices) complements the more traditional supply side policies (e.g. credit, insurance, and technical assistance) in the context of a regulated market or institutional framework.

Final demand for the outputs of the programmes combined with effective provision by family farmers are core features of the programme's sustainability. E.g. the demand for the products produced for the PAA are clearly linked to addressing the food and nutritional insecurity, particularly of vulnerable groups in Brazil. The question is whether there can be an analogous structure for medicinal plants which fall under the cross-ministerial programme the *Plano Nacional de Promoção das Cadeias de Produtos da Sociobiodiversidade* (PNPSB),[18] which was launched to provide a framework for the sustainable development of environmentally and socially sustainable productive chains for socio-biodiversity products. I.e., is there publically mediated demand anticipated by the programme for the products of local and indigenous communities in addition to their possible insertion in productive chains organized by the private sector?

Some background on the PNPSB first: amongst other things, the PNPSB programme incorporates a focus on guidelines and strategic actions to promote the productive inclusion of extractivists, traditional and local communities and family farmers.[19] It builds on the PAA and earlier related initiatives aimed at family farmers. E.g. since 2008, policies for 'Guaranteed Minimum Price' included ten products which were the results of extraction and support was extended to non-food products such as andiroba, copaíba etc. Under the PNPSB, the strategic

actions in recognition of traditional knowledge include the promotion of the 'recognition of indigenous rights, and traditional Maroon communities and family farmers access to resources biodiversity and the fair and equitable sharing of benefits'. They also include actions in support of the adoption of a production chains approach and related production arrangements, by taking into account factors such as participation, territorial and systemic design and plan implementation. The PNPSB framework highlights the importance of strengthening the social and productive organization of indigenous peoples, traditional Maroon communities and family farmers and supports social and environmental added value creation to generate employment, income and social inclusion including through the establishment of a fund to facilitate management and sustainable harvesting/use in protected areas occupied by indigenous peoples and Maroons.[20]

The PNPSB is both timely and forward-looking as regards its focus area and the incorporation of a framework for the productive inclusion of indigenous and local communities as regards the products of socio-biodiversity. However, while the strategy includes a focus on medicinal plants, no clear approach appears to be outlined as to how this strategy might align with Brazil's national policies on the role of medicinal plants and herbal medicines in Brazil's Public Health System (SUS). These policies include the *National Policy of Integrative and Complementary Practice (PNPIC) in the Unified Health System* (SUS) and the *National Policy of Medicinal Plants and Herbal Medicines*. See Carvalho et. al. (2009).

While recognizing that there are health policy related issues involved where the Ministry of Health needs to take the lead, the paper views this as a missed opportunity. The next section provides a brief discussion of the medicinal plants and their potential uses in the formal and 'informal' health care systems with a view to potentially forging these linkages in the future.

4 BIODIVERSITY, TRADITIONAL MEDICINE, DRUG DISCOVERY AND HEALTH CARE

Biodiversity and traditional knowledge of its various properties and uses have long provided and continue to provide vital resources for medicine discovery and healthcare. Vast numbers of the poor in developing countries depend on traditional medicine (TM)[21] for their primary healthcare. The World Health Organisation (WHO) estimates that in some Asian and African countries the proportion is as high as 80 per cent of the population (WHO, 2008). Increasingly, scientists and pharmaceutical companies are also looking at traditional knowledge (TK) to identify new drug sources by means of "bioprospecting" and "reverse pharmacology", and ethnobotany is seen as playing a valuable role in this regard. See Patwardhan, 2009).[22]

However, as Voeks and Leony (2004) point out, a real threat is that "many of the traditional methods and general knowledge of medicinal flora is being lost to time. As healers, shamans and tribal elders age and die, their knowledge is dying with them [in areas where such knowledge has not been codified] … Seventy per cent of the plants identified as having anti-cancer characteristics by the National Cancer Institute in the United States are found in tropical rainforests and 25 per cent of the drugs used by Western medicine are derived from rainforest plants. And yet, despite all their promise, fewer than 5 percent of tropical forest plant species have been examined for their chemical compounds and medicinal value. This leaves great potential for even more discovery, but also the potential for great loss as rainforests are felled around the globe and unstudied species are lost to extinction."[23]

Moreover, while there is increasing acknowledgement of the need to draw on traditional knowledge, true recognition of the role of local communities is still very much a work in progress as far as policymaking and equitable access to benefits is concerned in practice. There are also several complicated matters confronting those seeking to make use of genetic resources. Can and should traditional knowledge be valued separately from communities that historically have been associated with such knowledge? Which communities should be viewed as associated with a particular knowledge and tradition? When more than one community is involved, and one gives prior consent and the other does not what, is to be done? For a discussion of issues with regard to access and benefit sharing, see Velez (2010).

For the most part, the potential for practitioners of traditional medicine to serve as partners in the process of drug discovery and in providing care services is not acknowledged. Information on and knowledge of herbs and protocols for treatment are well documented in some instances (traditional Chinese medicine, for example, or Ayurveda, Unani and homeopathy in India), but in other regions of the world important work remains to be done to document and systematise traditional knowledge—particularly about endemic plants—and also to ensure that TK can evolve through a living engagement with complementary sciences and therapeutic regimes, so as to produce new knowledge about herbs and thereby facilitate new, cost-effective product development and treatments. Patwardhan et al. (2009) point out that there is a need to explore ways in which "traditional medicine practitioners can be used more effectively to facilitate delivery of both western biomedical innovations and traditional therapies". In this regard, community-driven awareness raising, sustainable conservation and production efforts are proving to be vital.

4.1 SELECTED POLICY APPROACHES TO INTEGRATION AND 'MODERNIZATION' OF TRADITIONAL MEDICINE

The number of countries that have national policies for traditional medicine and/or have integrated traditional medicine into national healthcare systems is still fairly limited (see WHO, 2005), in part because of concerns about the quality, safety, efficacy and effectiveness of TM treatments in modern health systems. Recent policy analysis, however, is pointing to the need for new approaches to research and clinical trials in this area.[24] Nonetheless, regulation of TM products, practices and practitioners is difficult because of variations in how TM therapies are defined and categorised.[25]

At the same time, as mentioned above, countries such as India and China have taken effective approaches to the inclusion of TM by means of formal integration and/or linked delivery systems (for example, traditional Chinese medicine [TCM] pharmacies and the integration of TCM into China's formal healthcare system, and differentiated guidelines for registration of TCM and chemical drugs). The Chinese government attaches equal importance to the development of traditional and modern medicine. Article 21 of the country's 1982 constitution stipulates that "the state develops medical and health services, promotes modern medicine and traditional Chinese medicine, encourages and supports the setting up of various medical and health facilities by rural economic collectives, state enterprises and undertakings and neighbourhood organisations, and promotes sanitation activities of a mass character, all to protect the people's health". Both modern and traditional medicine are regulated by the Chinese Drug Administration Law, although there are different requirements for

the registration of TCM and chemical drugs (see the website of China's State Food and Drug Administration for Laws and Regulations).[26]

India's Ministry of Health and Family Welfare established a Department of Indian Systems of Medicine and Homoeopathy in 1995, which in 2003 was renamed as the Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH). The department's centres on the following objectives: (i) to upgrade educational standards in the Indian Systems of Medicines and Homoeopathy colleges; (ii) to strengthen existing research institutions and ensure a time-bound research programme on identified diseases for which these systems have an effective treatment; (iii) to draw up schemes for the promotion, cultivation and regeneration of medicinal plants used in these systems; and (iv) to devise pharmacopoeial standards for Indian Systems of Medicine and Homoeopathy drugs.[27] Pharmacopeias have been compiled for the various systems of medicine.[28] Several policy initiatives are underway to integrate Indian systems of medicine into delivery systems for conventional medicine. The National Rural Health Mission being implemented by the Ministry of Health and Family Welfare envisages the mainstreaming of AYUSH systems of medicine with conventional medical care.[29]

In India and China there are also initiatives to professionalise the practitioners of traditional knowledge. In China, for example, since the 1950s, TCM professionals have been educated at medical or pharmacy schools with similar standards and years of training as western medical professionals. In addition to TCM theories and methodology, the curriculum includes western scientific approaches, such as physiology and molecular biology, and there are formal licensing requirements for TM practitioners in both India and China.

Both countries have some provisions for the incorporation of traditional practitioners in so far as they can be shown to meet the substantive and safety requirements and provide the requisite patient care.[30] The practice of traditional medicine in a traditional manner also continues in a semi-regulated environment particularly in rural areas under-served by modern health facilities.-China also has a somewhat unique historical legacy with regard to community-based healthcare. Over 40 years ago, the Chinese government undertook basic medical and paramedical training on a significant scale to create what became known 'barefoot doctors' with the objective of bringing basic health care to rural areas in a context where trained urban doctors were not willing to migrate. These practioners focused on promoting basic hygiene and preventive health care measures and helped to treat common illnesses. They were often encouraged to use TCM to carry out treatments on the grounds that they were already more familiar with this and TCM was assumed to have smaller toxic side effects. By the 1980s, the 'barefoot doctors' were given the option to take a national exam and if they passed they became village doctors.[31] A different set of certification criteria and requirements were applied to herbal pharmacists.

China's experience in integrating TM in its health care system for the past sixty years demonstrates that the integration is feasible and effective. The market value of TM in China is increasing and production chains have been formed creating millions of jobs for both urban and rural residents. The Chinese people benefit from the integration of TM in the health care system and, in particular, TM has become a key mechanism to address chronic diseases. As regards the development of ethnic medicine and folk medicine in China, the Chinese central government also allows some degree of autonomy to ethnic groups and communities to develop their medical practices through waht are referred to as "pilot projects". These help

to showcase how ethnic medicine and folk medicine can be integrated into the formal sector. Experience suggests that while the Chinese government attaches great importance to bio technology and drug development, it also sees the value in keeping the use of TM in its original habitat setting for sustainable development of traditional medicinal materials and conservation purposes. China also periodically carries out national surveys of TM resources.[32] Based on China's experience is there is a development path for the incorporation of traditional communities, practitioners and herbal pharmacists particularly in the context of community-based preventative care?

4.2 TRADITIONAL KNOWLEDGE AND MEDICINE PRACTICES AND AREAS OF POTENTIAL CONTRIBUTION TO THE HEALTH CARE SYSTEM IN BRAZIL

Brazil has the greatest plant diversity in the world, with close to 55,000 species (See Brazil Insight Series: Environment). As Ameh et. al. (2010) point out, however, despite this fact and despite the prevalence of deeply rooted herbal traditions (derived from Amerindian, European and Yoruba traditions) surprisingly *phytotherapy* is not as established in Brazil as are Ayurveda or Homeopathy in India or TCM in China and in many other parts of SE Asia.

As traditional medicine is not extensively codified in Brazil, the government appears to be adopting a more cautious approach. The WHO points out that regulation of herbal medicine has existed in Brazil since 1967 but that important updates of the framework took place in 2000 and in 2004 (RDC 48/2004). Currently, only "herbal medicines" are regulated and can be registered. They have the same status as any other medicines and can only be produced by pharmaceutical firms that are GMP-certified. Efficacy and safety can be demonstrated by reference to literature, data, clinical and pre-clinical tests, and to some extent "by tradition of use". ANVISA's Regulation RDC 14/2010 establishes minimum requirements for the registration of herbal medicines or *fitoterápicos* (which exclude natural active compounds or associations with plant extracts). Through RDC 10/2010, ANVISA established a system for the notification of herbal drugs or *drogas vegetais* (which include medicinal plants or their parts where therapeutic action results from processing activities such as stabilization and drying, etc.) which take the form of herbal preparations but not capsules, tablets, tinctures, etc. RDC 10/2010 requires that such medicines be accompanied by information on uses and procedures for use..[33] Recent policy changes allow "a herbal drug to become the active substance in the herbal medicine if its efficacy can be clinically tested and proved". Herbal drug registration was prohibited by the preceding rule, RDC 48/2004 (see Netto, 2008; Carvalho et al., 2010 and 2009). The new regulation thus fills a gap in the existing Brazilian regulatory framework. With this, industries can register herbal drug productsbased on a list of 66 herbal species which are traditionally recognized as being both efficious and safe (Carvalho, 2010). However, to date, the current regulatory approach does not adequately cover the regulation, licensing and inclusion of herbal preparations and products produced outside a manufacturing environment and use within more traditional settings.[34] Also critical is the need to identify safety guidelines for the provision of TM outside the formal healthcare system.

The two main policies regulating the role of medicinal plants and herbal medicines in Brazil's public health system are the National Policy of Integrative and Complementary Practice (PNPIC) in Brazil's Unified Health System (SUS), and the National Policy for Medicinal Plants and Herbal Medicines (Política Nacional de Plantas Medicinais e Fitoterápicos) which was introduced by a presidential decree in 2006. The latter resulted in the creation of a

National Programme on Medicinal Plants and Herbal Medicines (Programa Nacional de Plantas Medicinais e Fitoterápicos, PNPMF).[35] The guiding principles of the PNPMF are to contribute to: the expansion of treatment options and improved health care for the users of SUS; the sustainable use of biodiversity in Brazil; the enhancement and preservation of traditional knowledge of communities and traditional peoples; the strengthening of family farming and the growth of employment and income generation, as well as the reduction of regional inequalities; social inclusion and reduction in social inequalities; community participation and social control; and technology and industry development.[36] The inter-ministerial Regulation no. 2.960 which formally approved the PNPMF also facilitated the creation of a National Committee of Medicinal Plants and Herbal Medicines with government and non-government representatives to monitor and assess implementation of the programme and policy. The committee evaluates options to ensure access to medicinal plants, herbal medicines and related services in the SUS; as well as initiatives to promote research, technology development and innovations in the various stages of the production chain. It identifies actions to promote coherence of the PNPMF with other national policies. It also has a working group that is looking into traditional and popular knowledge, practices and uses of traditional medicine in the various biomes of Brazil as well as in other countries. One of the tasks of the working group is to undertake a diagnosis and offer proposals for the implementation of mechanisms for the validation of phytotherapeutic uses of various medicinal plants by drawing on different knowledge systems— i.e., traditional, popular and scientific.

These are important steps for the promotion and integration of traditional medicine in Brazil. In 2005, a list of 237 medicinal plants with potential use in SUS was outlined. With a view to promoting research in such plants, Brazil's Ministry of Health recently published a "National List of Medicinal Plants of Interest to the Unified Health System" (RENISUS), consisting of 71 plant species which are in use domestically.[37] However, it has been noted that most of these are "exotic" plants such as pennyroyal (*Mentha pulegium*), white deadnettle (*Lamium album*) and German chamomile (*Chamomilla recutita*), for which there is an international knowledge base. Only six plants endemic to the Cerrado region of Brazil are included on the RENISUS list. This may indicate a potential gap in the knowledge about medicinal plants endemic to Brazil's various eco-regions/biomes. Until recently, moreover, finacing by the ministry of health, state governments and municipalities for SUS to officially offer herbal remedies was limited to preparations from only two medicinal plants, although as of 2010 this has risen to eight (see Frayssinet, 2009; Rossetto, 2009).

One of the priority tasks outlined by the PNPMF is thus to expand the knowledge base on phyto-therapeutical uses and the efficacy of various endemic plants, as well as to identify means to improve the recognition and knowledge of phytotherapies in the formal healthcare system. Here, there is an important role for traditional and local communities as regards the codification of the uses and properties of endemic plants. Ethnobotany and related studies and surveys drawing on traditional knowledge can inform research studies and clinical trials relating to phytotherapies and drug discovery, and contribute to assessing the effectiveness of use of phytotherapeuties in community-based healthcare. As Coelho-Ferriera (2009: 16) points out: "people from Marudá (Amazonian coastal community) know and use numerous medicinal plants and take advantage of a wide range of procedures to obtain, enhance, or attenuate the action of the ingredients in order to make these plant remedies more efficient. These results attest to the dynamism of these folk practices and a certain tendency to incorporate new concepts. Interdisciplinary studies in Amazonian phytotherapy should be pursued and

expanded, above all, with the participation of medical anthropologists and doctors. This approach could greatly help implement agendas promoting the use of medicinal plants consonant with the actual policy governing their use by Brazil's Unified Health System (SUS)".

Community-based networks of conservationists and producers of medicinal plants and related products also have an important "translation" and linking role, as well as a capacity-building role to play. As Lobato de Oliveira (2009) indicates, local communities and groups need to learn to speak the language of the state in order to be effective and empowered in policy dialogue. Hence community-based networks and non-governmental organisations (NGOs) increasingly play the role of "translators", mediators and innovators.

Articulação Pacari is one such innovative network. It was set up as a non-profit organisation by several communities involved in the production of traditional medicines and cosmetics (phytotherapies and phytocosmetics) based on medicinal plants from the Cerrado.[38] It has compiled a *Farmacopéia Popular do Cerrado* which details the management and, in particular, the uses of the various different parts of nine medicinal plant species endemic to the Cerrado. It conducted this work by setting up regional committees comprising people working with and collecting medicinal plants, as well as technicians, and by arranging an exchange of knowledge with more than 262 folk healers.[39] Given the knowledge deficits in the area of endemic plants, the pharmacopoeia is a means of registering and protecting traditional knowledge, and drawing attention to the threats to biodiversity in the area.[40] The framework can be applied to the compilation of pharmacopeias for other community groups or bioregions.[41]

Articulação Pacari has also been running small, community-based pharmacies (*farmacinhas comunitárias do Cerrado*), in which the herbal preparations are sold. There are currently 31 of these in operation.[42] They produce about 40 different types of herbal preparations and use 65 different types of medicinal plants native to the Cerrado. They use about 50 plants from the RENISUS list of which 18 are plants endemic to Brazil's different biomes and 32 are exotic. They can thus contribute to research on these plants through ethnobotony and potentially to "cohort studies" that track reactions to the herbal preparations used. The policy space to contribute to research exists within the PNPMF.

Articulação Pacari has been trying to develop practical mechanisms to guarantee the correct registration of patients' conditions and the tracking of impacts and improvements. It has not been very successful to date, mainly because of the modest levels of formal education of the people working in the *farmacinhas*. Currently, most of this information is not registered, but the results are tracked "orally", just as traditional knowledge is passed across generations. Most of the local people return to the *farmacinhas* to tell the herbalists whether their health has improved and whether the verbal preparation was effective. These are areas in which traditional knowledge could be useful in conjunction with digital-age technologies. For example, voice-to-text technologies and the inclusion of educated, unemployed youths in the initiatives could facilitate the recording of such information and the compilation of records that might be useful for studies, were it possible to involve the pharmacies. The pharmacies could also be induced to keep track of adverse reactions to drugs, herbs and preparations. The *Farmacopéia Popular do Cerrado* contains information on suggested dosages, uses of different parts of the plant, and the adverse reactions to and toxicity of medicinal plants.

Traditional healers/practitioners in each of the *farmacinhas* undertake "diagnosis" and recommend particular herbal products. For the most part, the pharmacies are staffed by three to five people, mostly women. Each employee earns about one minimum wage. These jobs are important, not only from the livelihood perspective but also because they keep traditional

knowledge alive in the local communities and facilitate the provision of valuable services for the underserved poor. The facilities treat about 7,300 patients a month and sell the herbal preparations at low prices or for free to the local community (Red de Plantas Medicinales de América del Sur, 2005). To the extent health care and medicines are free in Brazil this points to a potential role that is filled by the local pharmacies. Ironically, it is also a challenge for their growth in the future if they are not linked to the formal healthcare system. i.e. why would someone pay for traditional medicine if conventional medicine can be obtained free from the public health care system?

Currently, the pharmacies operate in an uncertain legal environment since they cannot claim that the preparations they sell are herbal medicines or provide inserts that have information on dosage or uses or that make medical claims.[43] In Brazil, as Carvalho (2009) points out, according to guideline 48/2004, plants or plant parts to be used for infusions cannot be registered as herbal medicines, even if the species is considered medicinal. According to Law 986/1969, medicinal plants can be registered as "special food", in which case "functional" or "health" claims can be made. While the *Agência Nacional de Vigilância Sanitária* (ANVISA), Brazil's equivalent of the US Food and Drug Administration (FDA), works towards developing an intermediate category, this may offer some scope to provide health information inserts similar to those for US "food supplements", which are followed by a disclaimer that "this product is not regulated by FDA".[44] ANVISA's regulations for compounding pharmacies (RDC 67/2007) which outline requirements for quality control that do not require clinical trials and pre-clinical studies and are also more appropriate for the "farmacinhas".

By focusing primarily on the industrial production of phytotherapeutic drugs, some would argue that the government seems to be potentially overlooking the complementary role that small and medium enterprises (SMEs) and community-based initiatives can play in expanding knowledge of phytotherapies and providing primary healthcare services. It can also be argued that the socioeconomic circumstances of underserved communities require a more flexible framework for the recognition of TM practitioners, as well as of their role in ensuring safe herbal preparations—especially in areas that are currently not effectively served by the public health system. E.g., *Articulação Pacari* has been active in capacity building for sustainable harvesting and cultivation, post-harvest handling, and the processing of medicinal plants. Even in the absence of a formal regulatory environment, it has put forward standards to ensure sustainable harvesting and quality control of herbal drug products. It has introduced a strategy of self-regulation (*Auto-regulação da Medicina Popular*) based on three criteria to ensure safety: ensuring the quality of the plants and materials used to make the remedy; good practices during the preparation of the remedy; and documentation of traditional knowledge about the medicinal plants used in the remedy.

Drawing on the knowledge of TM practitioners and healers, as well as technical knowledge, courses for local practitioners are also arranged, with an average 200 hours of teaching time. The courses provide basic information such as how to improve the production process, and emphasise the need to properly weigh the material and adopt safety and quality control practices. As a result of these courses, the groups collectively devise techniques to ensure quality control in the preparation of remedies in community pharmacies. Lobato de Oliveira (2009) presents a number of examples of folk healers outside the network who did not follow basic sanitary guidelines in storing the medicinal plants used for herbal preparation, thus exposing the materials to dust and other contaminants. She uses these examples to point to the important role that networks such as *Articulação Pacari* play in ensuring basic hygiene and sanitary conditions for herbal preparations.

ILLUSTRATION 1

Diagnostic and Initiatives to Overcome Identified Challenges

Capacity building: courses on best practices in handling medicinal plants and preparations; 200 hours of teaching time
Advocacy and participation in policy dialogues to ensure recognition of traditional knowledge and healing practices of the Cerrado

Source: Articulação Pacari Plantas Medicinais do Cerrado.

In the very small local communities that depend heavily on folk healers to meet their own healthcare needs, these types of 'self-regulation' are critical in the absence of formal regulatory systems. Initiatives such as *Articulação Pacari* also offer preliminary "proof of concept" of means of ensuring the safe and effective handling of herbs by community members, scope for the integration of community pharmacies in the integrated healthcare system and involvement in codifying traditional knowledge and contributing to the safe and standardised development of phtyotherapeutic drugs.

As mentioned earlier, there is also a vital role for R&D, policy and programme incubation, and testing and evaluation processes to identify opportunities for sustainable diversification and development in poor and underserved agrarian communities. Several examples are available, but the Instituto de Pesquisas Científicas e Tecnológicas do Estado do Amapá (IEPA) is singled out here because of its innovative hybrid structure, which could underpin development of the products of sociobiodiversity—phytotherapies and phytocosmetics.

First, some background on Amapa: the population of Amapá was 668,689; more than 60 per cent of the area of the state comprises forest-conservation sites (Governo do Estado do Amapá, 2010; IBGE, 2010). Several indigenous tribes, Quilombola groups and riverside communities live in the state. Traditional knowledge is part of the daily lives of Amapá's population (Fortunato, 2003), who use a variety of medicinal and aromatic plants for medicinal preparations and natural herbal cosmetics.

The region has also seen the development of commercial products that draw on traditional knowledge and culture in the region. The interaction of local communities with large organisation and/or SMEs can be a key mechanism for productive inclusion. Local communities have a lot to gain from a cooperative relationship with the private sector, including technical training, access to financial resources, a predictable demand for their products and a focus on quality. However, Bodekar (2005) cites a number of studies to point out that, in general, marketing chains tend to offer very low rates of return to gatherers: in Mexico, for example, collectors are reported to receive a mere 6 per cent of the consumer price for medicinal plants. The same author indicates that where the returns are low, there is "financial pressure to harvest

large volumes of plant material and … low prices also discourage cultivation as, with less effort, plants can be gathered for the wild and sold at the same rate." Equity in benefit sharing, therefore, in the context of integration in value chains, is not just important for poverty reduction and livelihoods but also from the viewpoint of contributing to conservation and sustainable harvesting and/or the production of medicinal and aromatic plants.

Initially, production for the market in this area took place through the self-organisational efforts of the *Cooperativa Mixta dos Produtores Extrativistas do Rio Iratapuru* (COMARU), which was set up as a cooperative of Brazil-nut collectors in the region, and through the *Cooperativa Mixta dos Agroextrativistas do Jarí* (COMAJA). Over time, multinationals such as Natura began to play a more important role because they could tap into the emerging market niche for "environmentally and socially responsible production processes and products" and could operate at scale. This new development has spurred greater attention to benefit sharing and engagement with market mechanisms in community-company partnerships. Despite Natura's clear attempts to be "socially responsible" and to facilitate productive investment, the relationship remained very asymmetrical and, unsurprisingly, the overall process of engaging with market processes was complex and difficult for local communities (see Greissing et al., 2009, for a thoughtful and detailed exploration of the issues involved).

In this regard, the work of a public research institute, the Instituto de Pesquisas Científicas e Tecnológicas do Estado do Amapá (IEPA) reveals the important contribution that public institutions can make to bringing about more equitable benefit sharing in the community-company relationship, and to serving as a business and product incubator and a broker between the community and the private sector. Through its Center for Medicinal Plants and Natural Products (CPMPN), IEPA has drawn on local knowledge and conducted research in the field of herbal medicine, with a view to confirming the efficacy of various medicinal plants and exploring the introduction of phytotherapies in the local public health system.

Created in 1993, it has played a significant role in promoting the production of drugs based on medicinal plants in the region, and in supporting the productive inclusion of local communities. Its work centres on stimulating the socioeconomic development of local communities by ensuring sustainable harvesting and preserving Amapá's traditional knowledge and biodiversity. IEPA's team of researchers conduct experiments to explore the efficacy of different medicinal plants following WHO standards. Several published papers have presented evidence of the efficacy of many local medicinal plants; on the basis of those findings, IEPA produces various herbal medicines. To date, the institute has produced 39 medicines and six phyptocosmetics using 32 different types of medicinal plants, 27 of which are native to or endemic to the Amazon rainforest. About 60 per cent of the raw materials used by IEPA for the production of medicines and cosmetics are locally supplied. The remaining 40 per cent are cultivated on a facility owned by the institute in Porto Grande municipality.

IEPA is now building its technical capacity and human resources to perform all stages of safety and efficacy testing. Successful products developed by IEPA include a wound healing gel based on a medicinal plant called Jucá (*Caesalpinia ferrea Mart. ex Tul.*). Collaborative research was undertaken with the Federal University of Amapá (UNIFAP). A multidisciplinary team comprising medical, biomedical and pharmaceutical specialists, as well as nutritionists, nurses and botanists, conducted a small clinical trial over two years on patients aged 35 to 50 who had extensive lesions, using tea and a soap-based gel (*Caesalpinia ferrea*) manufactured by the IEPA. The results were encouraging: healing of the damaged area, a decrease in local

pain and bleeding from the lesion, and elimination of any door present. The product has been proposed for use in the SUS and is already being used in a UNIFAP clinic.

Another interesting case is the Urucuri candle, which is an insect repellent made from the palm tree. It resulted in a patent and a technology transfer contract, generating benefits for the local community. The licensing of this product has yielded royalties for the local community (Women's Association of Mazagão Velho municipality). Moreover, the community was integrated into the supply chain to provide the raw materials for the production process. The company producing the Urucuri candle, L. C. Haas, is an enterprise linked to IEPA's Business Incubators Centre. This centre was created in 2004 to stimulate entrepreneurship in Amapá and to support local cooperatives.

IEPA also has a legal division to ensure that all research involving traditional knowledge, biodiversity and genetic resources conducted by the institute complies with the regulations of the Brazil Genetic Heritage Management Council (CGEN). This legal division has mediated negotiations between local communities and private firms, so as to guarantee equitable benefit sharing. In a widely reported case, IEPA's legal division intervened in negotiations between Natura and the local community of the Rio Iratapuru Reserve (Laranjal do Jari municipality)—represented by COMARU, the cooperative of local producers—over the Breu Branco perfume (see Fortunato, 2003; Belas, et al., 2009). As a result of these negotiations, a benefit-sharing agreement was signed between the local community and Natura, and the following benefits were offered to the community: (i) productive inclusion of COMARU in the supply chain of Natura's Breu Branco perfume; (ii) investment support by way of new equipment and training of local community members; (iii) access to credit; and (iv) additional orders for COMARU—for example, it began supplying other products for Natura, such as copaiba oil and chestnut.

This is critical because, although Brazilian companies such as Natura acknowledge the importance of integrating local communities into the supply chain given their expertise in sustainable harvesting and medicinal plant extraction (Costa, 2010), and although the companies have a strong desire to be associated with the image of sustainable development in the Amazon given the potential for "green" branding and to demonstrate corporate social responsibility, the asymmetrical nature of the relationships involved and the nature of the legal tools for Access Authorisation/Prior Informed Consent and Benefit-Sharing Contracts pose challenges in achieving equitable benefit sharing.[45] The contracts between firms and local communities are confidential. CGEN has the authority to demand a contract but has limited power over its substance. If the local community agrees to transfer the traditional knowledge to a private firm in exchange for a low payment, nothing can be done. Interviewed public officials pointed out that, in most cases, the local community has no clear idea of the market value of their traditional knowledge. They are sometimes ready to exchange invaluable knowledge and know-how that can generate significant returns for the private firm in exchange for a modest immediate gain, such as a small motorboat.

All of this highlights the importance of mediation by well-informed and impartial brokering institutions. It is usually only through such interventions that the playing field can be levelled and that a greater share of the benefits can be secured for local communities that operate outside of and without a knowledge of the formal market and business environment.

5 ACCESS AND BENEFIT SHARING AS REGARDS TRADITIONAL KNOWLEDGE AND TRADITIONAL COMMUNITIES

Access and benefit sharing are complex issues with regard to traditional communities. It is often difficult to identify which tribe or community is the traditional knowledge holder and who is entitled to authorise the use of the knowledge (in terms of "prior consent"). There are cases in which several different indigenous tribes have the traditional knowledge for a certain medicinal plant and it can become impossible for a firm to sign an agreement with each of them. In other cases, the traditional knowledge may have originated in a particular indigenous tribe but was then passed on across the generations by Quilombola communities. There are cooperatives representing several indigenous tribes or Quilombola communities, but sometimes there are two cooperatives legally entitled to represent the same groups, one willing to share the traditional knowledge and the other not. At the same time, "informed consent" is also an issue for indigenous communities that are often unaware of their rights and of what is involved. As Elisara (2009) points out, "the right to free, prior and informed consent is a precondition of any activity impacting on indigenous peoples and their lands and consultation is not a substitute for consent".[46]

For these reasons, the interviewed officials contended that the best solution is to create a fund for benefit sharing. The private firms could allocate a certain amount to this fund as compensation for the use of traditional knowledge. The resources would be used to benefit all communities and tribes living in the area, and perhaps to stimulate the development of sustainable production, including initiatives linked to biodiversity.[47] Such a fund is in fact anticipated in Brazil's *Plano Nacional de Promoção das Cadeias de Produtos da Sociobiodiversidade* (PNPSB) with a view to supporting the productive inclusion of local communities. As mentioned earlier, however, there is still the need for an honest broker to ensure equitable benefit sharing.

Interviews with the Ministry of Environment and at the Ministry of Development, Industry and Foreign Trade also raised a number of problems faced by Brazilian firms in accessing Brazilian biodiversity. According to public officials, it is not only local communities but also university researchers who have limited understanding of market dynamics, and they need the private sector for a better assessment of commercial potential and product development at scale. This points to the need for public entities to regulate and also to facilitate an informed understanding of emerging issues in several, related technical areas: agriculture, biodiversity, health and safety regulations, and how to address intellectual property rights and development issues (Velez, 2010; Greissing et al., 2009). As indicated throughout this paper, these efforts need to be complemented by an identification of ways through which local communities can also benefit from productive inclusion in activities that contribute to the delivery of health care and/or involve products based on natural resources.

6 CONCLUSIONS: A FOCUS ON LESSONS LEARNED AND POLICY ISSUES

To conclude, the contributions of this paper can be explored with regard to the following sets of issues:

i. Policies to address Rural Inequities and the role of productive inclusion

The attention paid to rural inequities is often part of a larger policy focus on spatial inequalities and concentrations of the poor in certain areas/sectors. To date, countries have sought to improve opportunities for the rural poor through one or more of the following channels:

a. *promoting higher agricultural productivity*, particularly among smallholders, so as to improve equity through land reform and greater access to credit and technical assistance;

b. *facilitating a shift towards non-agricultural sources of earned income* in rural non-farm or non-agricultural employment (RNFE/RNAE);

c. *fostering integration in value-added activities* and/or into productive chains based on natural resources;

d. *sectoral and territorial strategies to address deficits in public services and in economic and social infrastructure*, as well as to promote investment in previously underserved areas;

e. social transfers and programmes to tackle food insecurity and vulnerability, and to help reduce poverty and inequality; and

f. *rural-urban linkages* to facilitate sustainable migration to semi-rural/towns and urban areas.

Productive inclusion adds important implementation modalities and channels of influence to this policy mix. In particular, Brazil's approach to productive inclusion, in so far as it incorporates social assistance, integration in productive chains, and the adaptation of such programmes in the context of territorial strategies, provides a framework for exploring dynamic pathways out of poverty.

In practice, there have been a number of challenges as regards the content of the *productive* role of local communities. Inclusion does not necessarily go beyond integration at the lowest rung of the production chain: gathering/conservation activities and production of raw/unprocessed materials that are fed into production chains wherein most of the value-added benefits are reaped elsewhere, although there are examples of local enterprises working to produce more sophisticated products.

The paper explored the underpinnings of Brazil's approach to productive inclusion with a view to identifying how local communities can be integrated into market driven processes and the delivery of social services and conservation activities with greater equity. Drawing on the experience of two early productive inclusion programmes (PAA and PNPB), it pointed to the important contribution that such policies made to ensuring a 'regulated market or institutional framework' for local communities and family farmers. It also highlighted the importance of demand-side stimuli and predictable prices which these programmes offered to complement more traditional supply side policies (e.g. credit, insurance, and technical assistance) to help local communities and family farmers undertake greater market engagement and delivery of services.

ii. Conservation of biodiversity and the provision of services for the poor by the poor

The concern with climate change has added an additional imperative for rural communities: that of identifying opportunities for win-win scenarios so as to ensure that such actions not

only create economic opportunities but also contribute to mitigation and/or adaptation and conservation. In this regard there is growing recognition of the role of local communities in conserving biodiversity, and attention is being paid to how those communities can be supported in their efforts, with a view to addressing poverty while promoting biodiversity and the sustainable use of natural resources.[48] Some recent reports on reducing emissions from deforestation and forest degradation (REDD) and sustainable forestry in the Amazon have also emphasised the importance of not seeking to value carbon storage above or separately from the improvement of forest conditions and the livelihoods of local and indigenous communities (see Instituto Socioambiental, 2010).

Moreover, in the context of the emerging focus on biotechnology and "bioprospecting" or looking to natural sources, including plants, for drug discovery, attempts have also been made to address previous inequities in benefit-sharing related to genetic resources and to the use of traditional knowledge that facilitates access to genetic resources by indicating possible therapeutic and other uses of the plants in question.

Brazil's *Plano Nacional de Promoção das Cadeias de Produtos da Sociobiodiversidade* (PNPSB) which includes a focus on the productive inclusion of traditional communities and family farmers and the Programa Nacional de Plantas Medicinais e Fitoterápicos (PNPMF) which provides a framework for promoting the effective integration of traditional knowledge and medicine in Brazil's health system are thus very timely. The paper has suggested that if these new programmes are to offer a greater number of options for under-served communities they need to be anchored and informed by supportive policies in a number of related programme areas. Particularly important is the content of policies regarding the integration of complementary/traditional medicine in the public health care system. The productive inclusion framework with its demand and supply side tools may not able to operate to its full potential for poor local communities in the absence of a regulated market for the products of medicinal plants. As a result of the lack of effective integration, to date, of traditional medicine in the formal health system , the *Plano Nacional de Promoção das Cadeias de Produtos da Sociobiodiversidade* (PNPSB) can be viewed as missing out on the benefits that the provision of demand-side stimuli could provide for productive inclusion activities relating to medicinal plants and for more sustainable pharmacy services in the rural areas. The pace at which the Programa Nacional de Plantas Medicinais e Fitoterápicos (PNPMF) is able to deliver is thus a critical determinant.

The case of *Articulação Pacari* has also highlighted several key characteristics of Brazil's regulatory policies on medicinal plants that could benefit from further review. First, ANVISA's regulations tend to focus primarily on the production of phytotherapeutics on an industrial scale, overlooking the potential contribution of and need for small-scale, local-community initiatives in the production chain for medicinal plants and in the delivery of some healthcare services. The compliance requirements associated with Best Manufacturing Practices and quality standards pose a critical barrier to the productive inclusion of small-scale producers because of the financial and time costs involved, although ANVISA's regulations for compounding pharmacies (RDC 67/2007) offer some potential policy space.

In general, Brazil's policy could be viewed as under-estimating the role that traditional healers already play in providing healthcare assistance to underserved and remote populations, as well as the potential contribution of traditional knowledge to drug discovery,

by failing to provide a window for the integration of such services into the overall policy support framework. The research focus to date also appears to have been more on the incorporation of exotic medicinal plants in the National List of Medicinal Plants of Interest (Renisus) to SUS as opposed to those endemic to the region.

To the extent that these developments are still quite incipient, issues of sustainable harvesting and biodiversity preservation have not yet gained critical attention in the larger discourse on the production of herbal products. But if the scale at which firms like Natura produce was expanded, and if herbal products were incorporated extensively into the healthcare system, there would be a greater need for attention to sustainable harvesting. I.e., there could be a place for the cultivation and safe processing of herbal/aromatic plants by family farmers and local communities. This could be organized within the framework of productive inclusion and public procurement from family farmers.

iii. Institutional Mechanisms for strengthening Productive Inclusion:

Brazil's approach to productive inclusion embodies a strong multi-stakeholder component as well as cooperation between different levels of government. It explicitly incorporates a focus on cooperatives and organizations of the poor in addition to partnerships with business. The paper signalled the importance of incorporating activities such as the self-organisation and community-based networks of medicinal herb gatherers, producers and healers, in partnership with public research institutes such as IEPA, into horizontal development strategies. Local anchor institutes such as IEPA are needed. They have significant authority to negotiate with the local government and private firms, the financial and human resources to conduct research that provides scientific validation of traditional knowledge (unlike local NGOs) and could mediate meaningful participation by local communities and enhance benefit sharing in the long and short terms. More specifically, the following lessons can be drawn from the analysis of these two cases:

- The experiences analysed herein indicate that while working with small family farmers and local communities is challenging, real development gains can be harnessed. This suggests that an engagement with small producers need not entail the romanticisation of small enterprises and family farmers. Such interventions, however, have to be sensitive to the nature of the agri-ecological and production systems in which farmers and local communities are embedded.
- The public sector plays an important role in promoting the productive inclusion of family farmers and underserved communities. In each of the cases of productive inclusion studied to date, it is evident that there are "development functions" that the state is more capable of discharging. This includes helping local communities to better navigate asymmetries in market-based relationships, and providing a mix of social assistance and productive support, particularly for those communities located in poor and underserved areas. It appears that public institutions are important in: (i) conducting research that scientifically validates traditional knowledge; (ii) providing legal advice and technical assistance on benefit-sharing agreements and patent application procedures; and (iii) supporting the productive inclusion of local communities in the supply chains of large firms. This is in

addition to the development and testing of a programmatic framework, and the provision of the financing and technical support needed to make productive inclusion in this sector a reality.

- The role of local community networks is also key. The work of *Articulação Pacari* in preparing a pharmacopoeia based on the traditional knowledge of medicinal plants of Cerrado, and in promoting good harvesting and production practices in the name of self-regulation, signals an important bottom-up contribution to broader policy development and to service delivery. Initiatives of non-profit organisations such as *Articulação Pacari* and public research institutes such as IEPA can be particularly important for the Programa Nacional de Plantas Medicinais e Fitoterápicos to advance more rapidly. These organizations promote basic health and safety, and quality standards that improve the overall infrastructure and production processes for the preparation and provision of community-based herbal preparations on which the poor and underserved often depend.
- Cross-country and comparative analyses of policy frameworks, particularly in India and China (which have advanced further in the integration of traditional medicine into their healthcare systems, pharmaceuticals sectors and drug-discovery processes), can also contribute to the work of the working group related to the Programa Nacional de Plantas Medicinais e Fitoterápicos . Analysis of such experiences provide important insights about the formalisation of traditional knowledge and the development of a policy framework for the regulation and verification of herbal preparations based on traditional knowledge in Brazil and other areas where this discussion is emerging.

METHODOLOGY

The approach to productive inclusion that is outlined in this paper draws on desk research and some semi-structured interviews. It is aimed at providing some basic knowledge and encouraging discussion about this important and innovative programming framework. Additional and more detailed research on productive inclusion in the context of socio-biodiversity through the three entry points – social assistance, value chains and territorial strategies – is forthcoming. In addition to contributing to the joint desk research and interviews as with Arnaldo Anacleto de Campos, Director de Geração de Renda e Agregação de Valor at MDS/SAF, Waldemiro Junior carried out separate semi-structured field interviews with the following people: Jaqueline Evangelista Dias and Lourdes Cardozo Laureano of *Articulação Pacari*; Donald Sawyer of the Institute for Society, Population and Nature (ISPN), which provides technical assistance for several community groups and focuses on conservation in Cerrado; Katia Marzall of the Ministry of Agriculture, Livestock and Supply; Érika Spangenberg Tarré Borges and Rodrigo Moerbeck de Almeida Rego of the National Industrial Property Institute (INPI); and Henry Philippe Ibanez de Novion of the Genetic Heritage Management Council (CGEN), which is part of the Ministry of the Environment. These interviews were held to gain a better understanding of benefit sharing and practice of intellectual property regarding the commercial use of traditional knowledge. He also carried out a field visit to the facilities of IEPA in Macapá (state of Amapá), where he interviewed Benedito Vitor Rabelo, Terezinha de

Jesus M. Ferreira, Daniela Fortunato B. de Lima, Maurício José Cordeiro Souza, Alessandra Azevedo N. de Medeiros and Terezinha de Jesus Soares dos Santos. Interviews were also held with Katia Torres of the Ministry of Health. The contributions of all of the above are acknowledged with thanks.

While a number of public universities, Fiocruz and the Brazilian Enterprise for Agricultural Research (Embrapa) conduct research in related areas, the present study was limited to analysis of initiatives undertaken by IEPA, which is located in the region. Future research, however, should also consider the important role of these and other institutions.

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NOTES

1. See Jonnason, Erik and Steven M. Helfand (2010). Also see ECLAC (2007) which points out that in this region, 58 per cent of the total population and 67 per cent of the rural population is poor.

2. According to Brazil's Law 11326 of 24 July 2006, family farmers are defined as those who: (i) hold a piece of land smaller than four fiscal units (100 hectares); (ii) predominantly use labor provided by family members to operate their establishments; (iii) have a family income that derives from economic activities related to their own establishments; and (iv) run their establishments with their families. According to IFAD (2009), most of Brazil's 4 million farms are very small and many produce at the subsistence level, particularly in certain regions such as the Northeast.

3. Carvalho, Potengy and Kato (2007) indicate that in this area, 59 per cent of the farm establishments have an area of less than 5 hectares and 81 per cent have less than 20 hectares. They also point to the crisis of the old regime of production in the region to explain the current economic challenges. The old system was based on a combination of cotton production, ranching and subsistence agriculture, whereby landless and smallholder farmers produced cotton on the basis of share cropping arrangements on large cattle ranches. This system went into crisis around 1990. The cotton crisis disrupted the production system of family farmers who were deprived of income from cotton and its end-products. These contributed to their subsistence livelihoods based on small grain production and animal husbandry. In the face of this, many family farmers now practice a system of more restrained market integration except when they have better quality land and access to water, which can enable some diversification of production based on the fruits, vegetables, fish farming and the improvement of quality dairy products.

4. For a background of legal rights and institutional frameworks and policies, see the Report of the Special Rapporteur on the Situation of Human Rights and Fundamental Freedoms of Indigenous People (2009).
It points out that the Brazilian constitution was one of the first in the world to secure indigenous peoples' rights within the framework of contemporary thinking on indigenous–state relations, and that it remains one of the most progressive in this regard. Brazil has specialised agencies such as the National Indian Foundation (FUNAI), set up in 1967 and now an agency of the ministry of justice), and commissions such as its National Commission of Indigenous Policy (CNPI). Indigenous organisations and other civil-society organisations participate in these forums, which are seen as helping to ensure greater indigenous participation in the process of defining state policy on indigenous issues. There are also programmes such as the Indigenous Peoples' Social Agenda, which was launched in 2007 to advance a series of interministerial actions aimed at improving the living conditions of indigenous peoples. See Celentano et al. (2010).
For a discussion of REDD and sustainable forestry in the Amazon, see Instituto Socioambiental (2010).

5. See Farnsworth (1994).

6. Jonasson and Helfand (2008) point out that the proportion of the rural labour force engaging in rural non-agricultural employment also varies by region: e.g., ranging from 25 per cent in the Northeast which is the poorest region, to 39 per cent in the highly urbanised Southeast. On average, richer households were more likely to specialise in rural non-agricultural employment than poorer households—21 per cent of households in the lowest income quintile, compared to 37 per cent in the highest income quintile. Cassell indicates that between 2003 and 2008, the income of family farmers grew by 30 per cent and that income from labour activities contributed to 56 per cent to this growth, pensions contributed 29 per cent, and cash transfers programmes contributed 15 per cent.

7. Brazil has a strong focus on territorial strategies. For example, its *Territórios da Cidadania* ("Territories of Citizenship") aim to "to promote economic development and universal basic citizenship programmes through a strategy of sustainable territorial development". It is being implemented in 120 territories covering more than a third of Brazil's municipalities. It supports infrastructure development, productive activities, access to basic rights, and economic dynamism to enhance sustainable development. See <http://www.territoriosdacidadania.gov.br/dotlrn/clubs/territriosrurais/one-community>.

8. Many countries recognise that many of the poor are self-employed and seek to provide microcredit and related types of support, but the focus here is on potentially much broader policies. As regards social assistance, see Government of Brazil (1993), especially articles 2 and 25. See also Government of Brazil (2008), whereby Brazil's federal government promoted a National Commitment for Social Development (CNDS) in which federal, state and Federal-District authorities are expected to join forces to promote citizenship and productive inclusion. Within CNDS, MDS supports projects aimed at productive inclusion.

9. MDS has a secretariat dedicated to developing and implementing strategies for the inclusion of the beneficiaries in productive activities and integration into the world of productive work. It also carries out institutional joint actions to transform various investment opportunities or business opportunities to ensure benefits for people living in poverty. See MDS website for their approach to "productive inclusion": The starting point is to create an institutional environment conducive to productive initiatives being undertaken by the population enrolled in the Unified Social Programmes and also for independent producers, production units and family solidarity enterprises. With a view to gaining the development initiative, Brazil, aims to open up new possibilities for productive inclusion through investment and financing from public banks and private projects. Spread across different regions and involving a variety of national economic sectors, these projects are expected to foster the construction of a new sustainable and inclusive economy. Also see Lindert et al. (2007), who discuss complementary programmes for *Bolsa Família.*

10. See Secretariat for Small-Scale Family Farmers in the Ministry of Agrarian Development (MDA *Secretaria de Agricultura Familiar*).

11. MDA is a recent ministry that was created in November 25, 1999 by the Provisional Decree n° 1.911-12. It incorporates a focus on land reform and the promotion of sustainable development of family farmers.

12. See <www.territoriosdacidadania.gov.br/>.

13. See Chmielewska and Souza (2010) and Gestor (2010) on PAA; and see Garcez, Gucciardi et. al. (2009), Potengy et. al. (2007), Aldara da Silva et. al. (2010), Faria, Junia (2009), Wilkinson and Herrera (2008), and Zapta, et. al. (2010) on the PNPB.

14. The PAA is one of the actions of Brazil's Zero Hunger programme. The programme promotes the purchase of food from family farmers (this involves an exemption from public bidding processes) at prices compatible with those prevailing in regional markets. The products are fed into the food assistance network which includes community kitchens and food banks and activities involving families in situations of social vulnerability. Additionally, the foods also constitute food rations for specific population groups. It was established by Article 19 of Law 10.696/2003 and is implemented with funds from the Ministries of Social Development and Fight against Hunger (MDS) and Agrarian Development (MDA). The PAA is implemented through five modalities, in partnership with the National Supply Company (CONAB), and state and local governments. To participate in the programme, farmers must be identified as the family farmers who are qualified to receive assistance from the National Program to Strengthen Family Agriculture (PRONAF).

15. The "social fuel seal" was expected to offer incentives for the inclusion of small-scale farmers by providing various tax benefits and allowing companies to participate in ANP auctions, helping them qualify for public bank loans, and by serving as a positive marketing tool for them. In order to obtain the "social fuel seal" the companies had to reach technical cooperation agreements with small producers' cooperatives or directly with family farmers and buy at least the minimum stipulated percentages from them.

16.. For the PAA, see Grupo Gestor, 2010; for the PNBP, and with regard to the specific challenges related to the choice of feedstocks to encourage diversity and limit the dominance of soya, as well assessments of how well this approach could synchronise with the production regimes, land tenure arrangements and agro-climatic conditions in the Northeast, see Garcez, Gucciardi et al., 2009; Potengy et al., 2007; Aldara da Silva et al., 2010; Faria, 2009; and Wilkinson and Herrera, 2008 and 2010). Wilkinson and Herrara (2010) point out that "while initially the social certificate was restricted to family farm production of palm and castor oil, the law now includes all raw materials coming from family farming. Nevertheless, official data, published for the first time by the Ministry of the Mines and Energy in September 2008 and later by the National Petroleum Authority (ANP, 2009), have shown that the reality does not fit expectations. Castor oil has not been used by any [biodiesel] industry since January 2008 and palm oil participation was less than 1 percent during that year. In spite of the program's explicit goals and practical efforts, soy and animal fats dominate biodiesel production in Brazil (78 percent and 18 percent on average, respectively). According to world oil data (ABIOVE, 2009), only soybean oil and animal fats have sufficient production scale and regional distribution to support biodiesel production in the short term until other vegetable oils come online. In addition to this failure to promote typical family farming products, the goals of social inclusion have also fallen short of the target. According to the national coordinator of the biodiesel programme in MDA, around 37,000 families were working in the biodiesel value chain in 2008. The incorporation of family farmers into the programme has since slowed making it difficult to attain the goal of 200,000 families."

17. See Zapata (2010).

18. See Government of Brazil (2009) for the *Plano Nacional de Promoção das Cadeias de Produtos da Sociobiodiversidade – PNPSB* . This is a cross-ministerial programme involving the ministries of Social Development and Fight against Hunger (MDS), Agrarian Development (MDA) and the Environment (MME). The ordinance that was signed on 6/16/2009 created a Coordinating Group, comprising of representatives from the three ministries and from Casa Civil in the Presidency, which will be responsible for the coordination of government actions to implement the National Plan, the selection of priority products for production chains of socio-biodiversity and the establishment of guidelines for the development and implementation of their respective plans of action etc. In particular, the focus will be on 10 plant species, starting off with the Brazil-nut [*castanha-do-Brasil*] present in the Amazon and the Babassu [*babaçu*] present in the Transition Zone between the Amazon, Cerrado and Caatinga.

19. More generally, it seeks to recognize and take advantage of business opportunities that the Brazilian biodiversity can offer for both domestic and international markets and investments related to product development for food, cosmetics, pharmaceutical and services sector.

20. See Government of Brazil/Grupo de Coordenação: Ministério do Desenvolvimento Agrário, MDA, Ministério do Meio Ambiente, MMA, Ministério do Desenvolvimento Social e Combate a Fome, (2009). To date, there is no English translation of the document, so some sections are roughly translated and presented in some detail. With regard to productive inclusion of indigenous communities, the PNPSB framework document includes the following: strategic guidelines (section 4) to: (ii) promote recognition of indigenous rights, Maroon traditional communities and family farmers access to resources biodiversity and the fair and equitable sharing of benefits; (iii) promote appreciation and respect for cultural diversity and traditional knowledge; (v) seek social and environmental value added, generating employment, income and social inclusion; (vi) build and consolidate markets governed by values of cooperation, solidarity and ethics; (vii) adopt the approach of chains and production arrangements, by taking into account factors such as participation, territorial and systemic design, and plan implementation; (viii) promote empowerment and social control/management; (x) implement a management structure based on shared responsibilities among public, private and organised civil society. The section

on specific objectives (section 6) includes a number of action items and areas relevant to this study: (6.3) strengthen the social and productive organisation of indigenous peoples, Maroon traditional communities and family farmers; (6.4) expand, strengthen and coordinate economic instruments necessary for the structuring of supply chains; (6.5) strengthen knowledge networks integrating the actions of research, technical assistance and training; (6.6) strengthen intra/inter-agency and intersectoral networks; (6.7) adapt the legal framework so as to incorporate the specific products of sociobiodiversity action items; (section 7): (7.1.4) structuring actions to promote the production, management and sustainable extraction of sociobiodiversity products, prioritising the following areas: (i) land tenure in the territories occupied by people and traditional communities and family farmers; (ii) establishing a fund to encourage non-refundable for the annotation legal reserve and licensing of productive projects; (iii) establishing a fund to facilitate management and sustainable use in other protected areas occupied by indigenous peoples and Maroons; (iv) creation of a fund to promote the planting of native species and for the recovery of degraded areas occupied by indigenous peoples, former slaves, farmers and traditional family communities; and (7.1.7) adequacy of the regulatory framework for the sociobiodiversity products of indigenous peoples, Maroons, traditional communities and family farmers, prioritising the following actions: (i) ensuring appropriate standards in the deployment and management agroforestry; (ii) defining simplified rules for the licensing of projects relating to production by indigenous peoples, Maroons, traditional communities and family farmers; (iii) adequacy of the standards for the management of flora and fauna in line with the specificities of indigenous peoples, Maroon communities, traditional farmers and producers, as part of the approach to territorial management; (iv) adequacy of the regulatory framework so as to guarantee the right of indigenous peoples, Maroon communities and traditional farmers to produce, multiply, market and exchange seeds and seedlings of local varieties and varieties trade developed by public research institutions; (7.2.5) adequacy of the regulatory framework for specific industrial processes of products sociobiodiversity, prioritising the following actions: (i) setting standards for sociobiodiversity health products not addressed by existing legislation; (ii) defining minimum standards of manufactured goods containing sociobiodiversity products; (iii) campaigns with the municipalities to adhere to Unified Agricultural Healthcare (SUAS); (7.3.6) development and implementation of mechanisms to assess conformity, prioritising the following actions: (i) promoting the development and implementation of participatory systems for the products of sociobiodiversity; (ii) creating a social label to identify products of sociobiodiversity. (7.3.7) adequacy of the regulatory framework for specific sociobiodiversity products, prioritising the following actions: (i) reinforcement of the actions foreseen in the National Plant Medicinal and Herbal Plan and the suitability of the March regulatory framework for the marketing of medicinal plants; (ii) review the regulatory framework so as to foster greater participation in purchases of sociobiodiversity products by the government; (iii) compliance with labeling standards; (iv) adequacy of standards for transport and disposal. (7.4) strengthening social and productive organisation. (7.4.1) conducting studies and research in the area of management and organisation, prioritising the following areas: (i) development of management tools tailored to specific organisations; (ii) development of organisational models appropriate to organisations' sociocultural diversity.

21. The WHO defines traditional medicine as "the sum total of the knowledge, skills, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness". Herbal medicines include herbs, herbal materials, herbal preparations, and finished herbal products that contain parts of plants or other plant materials as active ingredients (WHO, 2008). Phytotherapy is the study of the use of extracts of natural origin as medicines or health-promoting agents.

22. See Patwardhan et al.(2009) for analysis and citations of other studies. They point out that a diminishing pipeline of new drugs is causing the focus to shift to natural products, and since the mass screening of plants is expensive and inefficient, traditional knowledge-based "bioprospecting" and reverse pharmacology appear to offer better leads for the treatment of several diseases. They say, further, that "combinatorial chemistry approaches based on natural products from traditional medicine are being used to create screening libraries that closely resemble drug-like compounds ... Since most of these compounds are part of routinely used traditional medicines, their tolerance and safety are relatively better known than other synthetic chemical entities entering first-in-human studies". For the role played by ethnobotany studies, see Voeks and Leony (2004). They point out that the "ethnobotanical method found particular support after Farnsworth's (1988) much cited work showing that 74 per cent of the plant-derived compounds currently used in western pharmaceuticals retained the same or a similar medicinal application by traditional healers … 'The ethnobotanical screen' is the most rapid and cost-efficient means of determining plant species worthy of further study."

23. See Voeks et al. (2004); see also <http://news.mongabay.com/2005/0425-tina_butler.html> and Newman et al. (2007).

24. The "western" or modern approach to drug development is to identify specific targets and to use particular drugs to achieve predefined results, whereas in most traditional medicines the body is seen as a complex and open system and TM contributes to health through a more synergistic approach. This difference in approach has made comparability difficult. The common approach has been to market TM drugs as "herbal remedies" and/or as food and dietary supplements; although it cannot legally be claimed that they cure or prevent disease, they can be said to contribute to well-being. With regard to their treatment as drugs and the "modernisation" of TM, two approaches are being followed. One is to establish a scientific evaluation system to pinpoint the active ingredients (e.g., the Shanghai Institute of Materia Medica, a subsidiary of the Chinese Academy of Sciences, has long been engaged in development of and research on plant-derived drugs for TCM modernisation and for traditional TCM treatments; it developed Artemether, a derivative of artemisinin, which is now one of the active ingredients in Novartis AG's anti-malarial therapy, Coartem. Pathwardhan et al. (2009: 809) argue that "multi-site mechanisms of action of herbal preparations from the crude extracts may offer greater chances for success where conventional single-site agents have been disappointing" and that "efforts to correlate

genotype and phenotype-based traditional methodology of classifying humans into three major Prakriti types or constitutions described in Ayurveda" open up exciting possibilities which can contribute to the progress of individualised medicine approaches. See Fønnebø, Vinjar et al. (2007); Granz et al. (2007); Patwardhan et al (2009) for suggested approaches to testing and conducting trials for traditional medicine.

25. National policies define herbal products as either as a food or dietary supplement or a herbal medicine, depending on the country and products involved. See WHO, 2008.

26. See Government of People's Republic of China (1982), websites of State Food and Drug Administration of the People's Republic of China and the policies section of the State Administration of TCM of the People's Republic of China (SATCM). On 1 October 2007, the SFDA implemented revised Provisions for Drug Registration which stipulated a standard approval procedure for TCM and natural drugs, chemical drugs, and biological products. Annex 1 of this provision sets out application dossier requirement and registration categories for TCM and natural medical products. For technical evaluation, SFDA has developed a series of TCM registration guidelines: technical guidelines for the method of preparing raw material, for extraction and purification, for general pharmacology, for acute toxic studies and so on. In January 2008, SFDA issued a Supplemental Rules for TCM Registration to reflect the characteristics of TCM. These supplemental rules indicate that the application data for marketing TCM combination preparations can be partially exempted on the basis of formulation source and their composition, function and indication, and manufacturing procedures. TCM combination preparations that can be exempted include: (i) TCM combination preparations from historic, classic and well-known recipes; and (ii) TCM combination preparations whose indication is a TCM syndrome. China has also developed standards for various forms of TCM: Chinese raw materials, prepared slices of Chinese crude drugs oil, fats and extractives; traditional Chinese patent (standardised) medicines, simple preparations and so forth. Hospitals can prepare their TCM ready-to-be use forms according to the national standard crude drug processing standard that is not subject to registration. It now has national standards for 1,000 Chinese crude drugs and national standards for 500 prepared slices of Chinese crude drugs. Source: personal communication with Yanmei Lin, a Chinese researcher involved in a forthcoming study being coordinated by UNDP. Leung (2008) points out that GAP standards only apply to registered dealers of herbs, implying that a substantial number of producers remain outside the formal regulatory framework in China. In 2008, only 5 per cent of the total was accounted for by medicinal plantations qualified to register for GAP.

27. See Government of India/Ministry of Health and Family Welfare/Department of AYUSH.

28. See, for example, pharmacopeia work undertaken by the Central Council for Research in Ayurveda and Siddha, an autonomous body of the government of India/Ministry of Health and Family Welfare/Department of AYUSH.

29. See Government of India/National Institute of Health and Family Welfare/National Rural Health Mission, in particular the "National Rural Health Mission (2005–2012) Mission Document". While this is welcome, in various instances the implementation and integration process is still a work in progress. In addition to ensuring adequate supplies and services, concerns have been raised in some quarters about the efficacy of "addressing the shortage of doctors, especially in high-focus states, through mainstreaming AYUSH manpower" and potential difficulties if AYUSH practitioners end up being assigned to allopathic hospitals without being provided with AYUSH drugs and pharmacists.

30. Both countries are moving steadily towards the professionalisation of traditional knowledge and care, and require that practitioners register in order to practice. There are means of including practitioners who have not been through formal training but who can demonstrate they have the required qualifications and knowledge, though it is increasingly difficult for traditional practitioners with only an conventional "apprenticeship education" to practice legally. For China, see Xu and Yang (2009) and Dixon (2009). For India, see Government of India/Ministry of Health and Family Welfare/Department of Indian Systems of Medicine and Homoeopathy, Central Council of Homoeopathy, and also Dixon (2008). Dixon (2008) points out that in India, graduates from accredited colleges are automatically registered but older practitioners who had been practicing for many years before the registration system was introduced were also given the opportunity to register. As for China, Dixon (2008) indicates that "besides those who graduate in traditional Chinese medicine from a recognised traditional Chinese medicine institution, qualified doctors, nurses and pharmacists who meet the necessary requirements can apply for the traditional Chinese medicine examination administered by the Ministry of Health …Those who have completed an apprenticeship of at least three years or who have practiced traditional Chinese medicine (or one of its forms) over a long period of time are required to pass an examination in order to be allowed to continue to practice."

31. See Cheng and Lin (forthcoming).

32. Based on personal communications with Yanmei Lin, a Chinese researcher.

33. Herbal products are segmented into herbal drugs, cosmetics, bioactives, and functional food. Therapeutic claims can only be made with regard to drugs/medicines. Herbal medicines, whose active ingredients must be plant extracts, tinctures, oils, or so on are defined as pharmaceutical products made by GMP-certified industry and require licensing; a traditional herbal product—a product made with plants and used therapeutically—is not licensed and is still not regulated; a medicinal plant—a plant in natura, fresh or dry, desegregated or not, used therapeutically—is not licensed; medicinal plants can be sold in pharmacies and herbal shops but their labeling cannot make therapeutic claims and they are sold as fragmented or powdered material for the purpose of making infusions and for external use; powdered plants in capsules or tablets are not permitted. Annex I of RDC 10/2010 lists medicines whose effectiveness is supported by empirical data based on traditional use as well as by relevant literature. These can be sold without a prescription to end users. The annex also lays out the types of therapeutic claims that can be made. For e.g., inserts can include text such as "traditionally used for symptomatic relief, the nature of the therapeutic claim, and then information on "

contraindications and use restrictions, "adverse effects" and "cautions and information packaging". Herbal medicines have the full status of medicines and can be sold over the counter or may need a prescription. See Netto (2008), Saad (2010) and Carvalho (2009) and (2010).

34. The approach adopted by China is more comprehensive. Xu and Yang (2009) point out that Chinese herbal medicine is currently categorised into three groups in China: raw herbal medicine (*zhong yao cai*), sliced herbal medicine (*zhong yao yin pian* or medicine that has been processed), and patent medicine (*zhong chen gyao* or medicine that is standardised). In addition to 561 herbal resource centres in China producing raw herbal medicine, there are over 1,500 manufacturers producing sliced herbal medicine and 684 manufacturers producing patent medicines. Although herbal extracts are regarded as herbal medicine, strictly speaking they are not Chinese herbal medicines since they are not based on Chinese herbology, but active ingredients or compounds extracted from herbs. They are listed as biomedicine in China.

35. National Policy of Integrative and Complementary Practice (PNPIC) in Brazil's Unified Health System [SUS] (Ministério da Saúde/Gabinete do Ministro MS/GM 971/2006) and the National Policy of Medicinal Plants and Herbal Medicines (PNPMF, Decree 5813/2006 which was approved by Ministerial Decree No. 2.960/2008). The latter allowed for the creation of a Technical Multidisciplinary Commission for the Design and Updating of National Medicinal Plants and Herbal Medicines (COMAFITO - *Comissão Técnica e Multidisciplinar de Elaboração e Atualização da Relação Nacional de Plantas Medicinais e Fitoterápicos*) which was put in place concretely by Ordinance No. 1102, 12 May 2010. See <http://www.brasilsus.com.br/legislacoes/gm/104037-1102>.

36. See Ministério Da Saúde (2009); also see the presentation in English on the 'National Policy and Program of Medicinal Plants and Herbal Medicines: Progress and Challenges' (2011).

37. For National List of Medicinal Plants of Interest (Renisus) to SUS, see Instituto Brasileiro de Florestas (IBF) notice on 16 August 2010.

38. For background on Articulação Pacari and its activities see Evangelista and Laureano (2007) and Lobato de Oliveira (2009). It has been supported by ISPN and by UNDP's GEF Small Grants Programme to help preserve Cerrado's biodiversity.

39. Approach used to develop the Farmacopéia Popular do Cerrado: Articulação Pacari sent a questionnaire to several local communities asking them to describe the medicinal plants they used. Some 264 plants were proposed for the study. Through consultations with representatives of local communities and the use of the following criteria, the list was reduced to 34 (they met three of these criteria): (i) the plant had to be cited at least five times in the questionnaires; (ii) whether the trunk's bark or/and the root of the plant should be used (indicating that the process of extraction could greatly damage the plant); (iii) plants with high commercial demand; (iv) plants that are more important in traditional medicine and are in high demand among local communities; and (v) plants that are prioritised by IBAMA in its own studies. After further meetings, the following 10 plants were decided upon: Chapéu de couro, angico, papaconha, Carapiá, Batata de Purga, Arnica, Rufão (bacupari), Imburana, Barbatimão and Pacari. Then they carried out fieldwork, conducting research with local communities in the four states (Minas Gerais, Goiás, Tocantins and Maranhão) where Articulação Pacari is located. They decided to write the detailed description of the following nine plants: in Minas Gerais—Barbatimão, Pacari, Rufão; in Goiás—Algodãozinho, Pé de Perdiz; in Tocantins—Batata de Purga, Ipê-roxo; in Maranão—Buriti; and Velame. They also tried to show the biodiversity of each region, and this was also one of the criteria that influenced their decision on the plants to be studied.

40. The Cerrado region has been classified as a biodiversity hotspot. There is growing competition from the rapid expansion of Brazil's agricultural frontier, which focuses primarily on soy and corn … as well as ranching, which is another major threat to the region. See <http://www.biodiversityhotspots.org/xp/hotspots/cerrado/Pages/default.aspx>. As pointed out by Gomes de Oliveira 40 per cent of the Cerrado has already been devastated and only 1.5 per cent of its area protected by law.

41. See article 8j of the Convention on Biological Diversity (CBD), which states that "each contracting party shall, as far as possible and as appropriate: Subject to national legislation, 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 utilization of such knowledge innovations and practices". Velez (2010) indicates that Brazil's Ministry of Culture is exploring the use the existing safeguards for intangible cultural heritage (Federal Decree 3551/2000) to apply to ATK and evaluating whether the *Farmacopéia Popular do Cerrado* can be registered as a cultural inheritance of the local traditional communities.

42. E.g., Jacqueline Evangelista Dias of Articulação Pacari indicated that while the *farmacinhas* do not have any formal interaction with SUS, in some regions there are informal interactions between the *farmacinhas* and auxiliary health workers in the Family Health Programme. The workers attend courses on traditional medicine and medicinal plants provided by the *farmacinhas*. See Sawyer and Lobato de Oliveira (2009). Sawyer gives examples of local community pharmacies (Movimento Popular de Rio Verde—MOPORV and the Quilombola community of Cedro de Mineiros), whose operations were significantly affected by health authorities. Because of legal uncertainties, some communities are discontinuing the production of phytotherapics and moving to phytocosmetics. There are other instances where, for example, the Fuliô indigenous tribe is producing herbal preparations with the support of the National Health Foundation (FUNASA). But they are unable to sell their products. Political-economy interests can also play an important role. There have been several reports of cases in which community-based pharmacies have been shut down by state-level health

authorities in Goiás (Sawyer, 2007). Interviewed health practitioners contended that surveillance may be stricter in Goiás because of pressure from pharmaceutical firms in the Anápolis municipality, which is about to become the second largest Brazilian pharmaceutical industrial cluster. In Macapá, community-based initiatives can develop under less strict governmental control, and IEPA has more freedom to commercialise its products while conducting research to complete all the steps needed to test efficacy and safety, so as to register its phytotherapics with ANVISA.

43. The *farmacinhas* deal with medicinal plants "in natura", dried plants (vegetal drugs) and herbal preparations, and they use the same name for all of them, which is "remédios caseiros". Although the National Policy on Medicinal Plants and Phytotherapics (PNPMF), approved by Decree 5.813/2006, explicitly acknowledges the need to "promote and recognise the popular use of medicinal plants and home-made drugs (remédios caseiros)" even the current changes proposed in Anvisa's regulations still do not leave space for integrating community-based initiatives on herbal preparations into the Brazilian legal framework. According to current legislation, the *farmacinhas* cannot be categorised either as herbal preparation facilities or as "*farmácias vivas*" (CP 85/2010). They do not fit into the current options available because responsibility for running the *farmacinhas* is the local community group that holds the traditional knowledge, not a pharmacist as required; the framework adopted by the *farmacinhas* is based on traditional rather than scientific knowledge. Moreover, quality control is undertaken according to the best practices of herbal preparations ("remédios caseiros"), which are supported by traditional knowledge and are not currently described in the officially recognised systems in pharmacy studies. These officially recognised systems are based on several technical experiments such as chemical markers, which are provided by laboratories. The types of herbal preparations in the two systems (the one legally recognised by Anvisa and the one adopted by the *farmacinhas*) are different. The latter use traditional mixtures, drawing on several different plants and other materials. Anvisa's legislation only allows for the use of a limited number of medicinal plants (those already approved in their regulations) and prohibits the mixing of different plants for the same herbal preparation. Finally, the tools and overall infrastructure of the *farmacinhas* are very different from the equipment specified in the regulations.

44. According to Brazilian Law 5991/1973, "dispensing medicinal plants without proper packaging and botanical classification is prohibited from pharmacies and herb stores (*ervanarias*)".

45. Bodekar (2005) cites a number of studies to point out that marketing chains tend to offer very low rates of return to gatherers (e.g. in Mexico, collectors are reported to receive a mere 6% of the consumer price for medicinal plants) and that where the returns are low, there is "financial pressure to harvest large volumes of plant material and … low prices also discourage cultivation as, with less effort, plants can be gathered for the wild and sold at the same rate.

46. See Elisara (2009).

47. See Greissing et al. (2009) on a fund set up by Natura.

48. For examples of case studies for Latin America and the Caribbean, see GEF Small Grants Programme (2006); also see Secretariat of the Convention on Biological Diversity (2010) for a more critical state-of-knowledge review.

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