



PROJECT IDENTIFICATION FORM (PIF)

PROJECT TYPE: FULL-SIZED PROJECT

TYPE OF TRUST FUND: GEF TRUST FUND

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PART I: PROJECT INFORMATION

Project Title:	Sustainable, accessible and innovative use of biodiversity resources and associated traditional knowledge in promising phytotherapeutic value chains in Brazil		
Country:	Brazil	GEF Project ID:	9449
GEF Agency:	UNDP	GEF Agency Project ID:	5792
Other Executing Partner:	Ministry of Environment	Re-Submission Date:	April 18, 2016
GEF Focal Area:	Biodiversity	Project Duration (Months)	72
Integrated Approach Pilot	IAP-Cities <input type="checkbox"/> IAP-Commodities <input type="checkbox"/> IAP-Food Security <input type="checkbox"/>		Corporate Program: SGP <input type="checkbox"/>
Name of parent program:	N/A (not applicable)	Agency Fee (\$)	543,663

A. INDICATIVE FOCAL AREA STRATEGY FRAMEWORK AND OTHER PROGRAM STRATEGIES:

Objectives/Programs (Focal Areas, Integrated Approach Pilot, Corporate Programs)	Trust Fund	(in \$)	
		GEF Project Financing	Co-financing
BD-3 Program 8 [BD3. Sustainably use biodiversity / Progr 8. Implement the Nagoya Protocol on ABS]	GEFTF	2,861,385	12,150,000
BD-4 Program 9 [BD4. Mainstream biodiversity conservation and sustainable use into production landscapes and seascapes and production sectors / Progr 9. Managing the Human-Biodiversity Interface]	GEFTF	2,861,385	12,150,000
Total Project Cost		5,722,770	24,300,000

B. INDICATIVE PROJECT DESCRIPTION SUMMARY

Project Objective: To enhance global biodiversity benefits, as well as multiple national and local co-benefits, arising from the sustainable, accessible and innovative use of medicinal plants in Brazilian ecosystems, through the strengthening of promising phytotherapeutic value chains¹, based on indigenous and local communities' traditional knowledge and in compliance with the applicable ABS regime.

Project Component	Type ²	Project Outcomes	Outputs	Trust Fund	(in \$)	
					GEF Project Financing	Co-financing
1. Strengthening phytotherapeutic value chains in indigenous and local communities (ILCs) within Local Productive Arrangements (LPAs) ³	Inv	Native medicinal plant species, found in a mosaic of Brazilian ecosystems, are sustainably used within at least 3 million hectares of better managed production landscapes linked to LPAs ⁴ , allowing ILC to access new markets and improve their livelihoods, while also safeguarding and enhancing the traditional knowledge associated with the species' genetic resources. <i>Indicators*: (i) landscape coverage and level of adoption of improved landscape-level management techniques; (ii) various production metrics, including access to markets and ecological sustainability</i>	1.1 Value chain mapping based on existing research on medicinal plant species, feasibility and sustainability analyses to guide the selection of promising phytotherapeutic chains, the location of targeted LPAs and beneficiary ILCs. 1.2 Value chains strengthened through local phytotherapeutic value chains, based on ILCs' traditional knowledge and supported in LPAs towards a quality and sustainability 'leap'. Four native species could provide	GEFTF	2,784,803	10,000,000

¹ 'Phytotherapy' is the study of the use of extracts of natural origin as medicines or health-promoting agents. Refer to attached [figures 1, 2 and 3](#) for this and other explanations on key concepts and glossary utilized in this project.

² Financing type can be either investment or technical assistance.

³ LPAs are clusters of businesses located in the same territory, which present a profile of productive specialization and maintain joint linkages, interaction, cooperation and learning from each other and with other stakeholders, as a means of promoting local development. The LPA Program is the most comprehensive and best funded local development program in Brazil.

⁴ Landscape coverage will be better assessed at PPG stage and fully confirmed once site selection has been completed. The 3 million hectares mentioned here are indicative.

Project Component	Type ²	Project Outcomes	Outputs	Trust Fund	(in \$)	
					GEF Project Financing	Co-financing
		<i>indicators; and (iii) livelihoods strengthening metrics.</i>	<p>the initial basis for value chain strengthening: <i>Schinus terebinthifolius</i> (aroeira); <i>Maytenus officinalis</i> (espinheira santa); <i>Mikania glomerata</i> (guaco); and <i>Uncaria tomentosa</i> (unha-de-gato).</p> <p>1.3 Landscape level management, Monitoring and Safeguards through biodiversity-friendly land-use plans for targeted productive landscapes within LPAs.</p>			
2. Accelerated bioprospecting and innovation with more equitable partnerships		<p>Increased public and private R&D, coupled with investments in the development of phytotherapeutic products, draw on scientific knowledge and promote innovation, often putting ILCs ‘in the driving seat’.</p> <p><i>Indicators*: a) ABS partnerships strengthened and established; b) ABS agreements signed; c) ABS products developed; and d) change in capacity of ILCs measured by: (i) the GEF ABS tracking tool and (ii) the UNDP ABS Capacity Development Scorecard. (baseline and targets to be developed during PPG).</i></p>	<p>2.1 ABS compliant community-science-industry partnerships for the development of ABS products.</p> <p>2.2 ILC’s negotiating capacity to develop and enter into ABS agreements and protocols with research institutions and private sector companies regarding genetic resources from medicinal plants is developed through focused training, exchanges and specific skill development of both leading men and women in ILCs.</p>	GEFTF	1,591,316	8,000,000
3. ABS-compliant frameworks mainstreamed into the national public health system		<p>Access to genetic resources from native plants that yield phytotherapeutic products and their use in the national public health system are significantly broadened, with ABS-aligned practices introduced, supported by ABS-compliant legal, policy and regulatory frameworks, thereby enhancing the multiple benefits from phytotherapeutic genetic resources to a large part of the Brazilian population.</p> <p><i>Indicators*: a) capacity changes of institutions and ILCs measured by the UNDP ABS Capacity Development Scorecard, and b) confidential and non-confidential registries for the protection of traditional knowledge and other tools and metrics. Baselines and</i></p>	<p>3.1 Policies & practices enable the mainstreaming of the 2015 ABS law into the public health sector.</p> <p>3.2 ABS-compliant systems and approaches for protecting traditional knowledge, innovation, practices and customary uses of biological and genetic phytotherapeutic resources in the Unified Health System (SUS).</p>	GEFTF	745,929	5,000,000

Project Component	Type ²	Project Outcomes	Outputs	Trust Fund	(in \$)	
					GEF Project Financing	Co-financing
		<i>targets will be determined during the PPG phase.</i>				
M&E	TA	n/a	n/a	GEFTF	328,209	300,000
Subtotal					5,450,257	23,300,000
Project Management Cost (PMC)					272,513	1,000,000
Total Project Cost					5,722,770	24,300,000

C. INDICATIVE SOURCES OF CO-FINANCING FOR THE PROJECT BY NAME AND BY TYPE, IF AVAILABLE

Sources of Co-financing	Name of Co-financier	Type	Amount (\$)
Recipient Government	Ministry of Environment	Grants	2,500,000
Recipient Government	Ministry of Health	Grants	3,000,000
Recipient Government	Ministry of Integration	Grants	15,000,000
Private Sector	Private sector (phytotherapeutic segment), universities etc.	Grants	3,000,000
Beneficiaries	ILCs (tentative)	In-kind	500,000
GEF Agency	UNDP	Grants	300,000
Total Co-financing			24,300,000

D. INDICATIVE TRUST FUND RESOURCES REQUESTED BY AGENCY, COUNTRY AND THE PROGRAMMING OF FUNDS

GEF Agency	Trust Fund	Country/Regional/Global	Focal Area*	Programming of Funds	(in \$)		
					GEF Project Financing (a)	Agency Fee (b) ^{b)}	Total (c)=a+b
UNDP	GEFTF	Brazil	Biodiversity	n/a	5,722,770	543,663	6,266,433
Total GEF Resources					5,722,770	543,663	6,266,433

a) Refer to the [Fee Policy for GEF Partner Agencies](#).

* Note: Given the current and planned level of allocation of STAR resources until the end of the GEF6 cycle, Brazil proposes to use remaining STAR funds in the Land Degradation focal area by making use of the marginal adjustments mechanism. The same applies to PPG resources. Land Degradation results are however not envisaged in this project.

E. PROJECT PREPARATION GRANT (PPG)

Is Project Preparation Grant requested? Yes [X]

PPG AMOUNT REQUESTED BY AGENCY, TRUST FUND, COUNTRY AND THE PROGRAMMING OF FUNDS

GEF Agency	Trust Fund	Country/Regional/Global	Focal Area*	Programming of Funds	(in \$)		
					PPG (a)	Agency Fee (b)	Total c = a + b
UNDP	GEFTF	Brazil	Biodiversity	n/a	213,303	20,264	233,567
Total PPG Amount					213,303	20,264	233,567

F. PROJECT'S TARGET CONTRIBUTIONS TO GLOBAL ENVIRONMENTAL BENEFITS

Provide the expected project targets as appropriate.

Corporate Results	Replenishment Targets	Project Targets
1. Maintain globally significant biodiversity and the ecosystem goods and services that it provides to society	Improved management of landscapes and seascapes covering 300 million hectares	3,000,000 hectares

PART II: PROJECT JUSTIFICATION

1) PROJECT DESCRIPTION

1. The global environmental and/or adaptation problems, root causes and barriers that need to be addressed.

The global environmental problems.

1. **Summary.** This project departs from the assumption that the traditions and embedded cultural knowledge of indigenous and local communities (ILCs) in Brazil can make a significant contribution the country's development efforts, in particular for what native medicinal plants are concerned. More specifically, ILC's knowledge and traditions on the use of these plants, with due consideration for their rights, form a good basis for enhancing the multiple benefits that can be derived from the country's biodiversity, while also contributing to conserving and sustainably using these assets. Phytotherapeutic value chains, which obtain their raw materials from plant species with known medicinal value, offer an excellent avenue for exploring and sharing these benefits—and for contributing to Brazil's promising 'bio-economy'—through a local and synergetic development anchor, facilitated by Local Productive Arrangements (LPAs).

2. **Core justification.** One of the 17 Megadiverse countries, Brazil is often considered the most biologically diverse country in the world. Brazil's biodiversity is a chiefly important resource for its people, not only because of the environmental services that it provides, but also due to the development opportunities that this represents. This project will explore a specific aspect of these opportunities linked to phytotherapeutic value chains, a promising segment of the Brazilian health sector—and of its emerging 'bio-economy'—where the end products are based on plants with medicinal value. The segment was worth at least \$200M in 2014, mobilizing 4% of the overall pharmaceutical market in Brazil. It has experienced solid growth in recent years.⁵ However, it is facing challenges in terms of expanding its market share and range of products, while securing a sustainable supply of raw materials. Overcoming these and other challenges would allow this segment to make a more significant contribution to the bio-economy and to the public health sector more broadly. The project proposes to address these specific challenges through a mainstreaming approach, but combining it with a strong ABS angle, given the role of ILCs as bearers of traditional knowledge on medicinal plants.

3. The latter is relevant because this project is conceived in an evolving and complex legal regime, both domestically and internationally, pertaining to genetic resources, access to them, their use and the sharing of benefits derived from them – the ABS regime under the realm of the Convention on Biological Diversity (CBD). Brazil is gearing up towards its accession to the CBD's Nagoya Protocol on ABS, adopted in 2010. In connection with it, the government enacted in May 2015 a new and comprehensive ABS Law (Lei No. 13.123/2015). It complements other legislation and regulates access to components of Brazil's genetic heritage, as well as the protection of, and access to, associated traditional knowledge. The ABS Law provides a legal regime for the fair and equitable sharing of benefits deriving from them, so that the use of these resources can contribute to the conservation and sustainable use of Brazilian biodiversity. This is also relevant because the varied properties of plants species that are used as raw materials in different industries, as well as the different compounds that they contain or can yield, are closely linked to these species' unique genetic resources. All phytotherapeutic value chains that are based on native plants have their starting point in people's traditional knowledge, or popular wisdom about the use of biodiversity. This knowledge has its origins in the cultural traditions of Brazil's ILCs, and it is still embedded in their contemporary cultural manifestations, which are diverse and scattered, as is Brazilian biodiversity. Finally, this is equally relevant, to the extent that The Nagoya Protocol makes reference to the interrelationship between genetic resources and traditional knowledge, and their inseparable nature. These elements are reflected in the 2015 ABS Law, and which furthermore legislates about the associated rights of ILCs in Brazil in the context of accessing and using genetic resources. In addition, it defines what can be considered Brazilian genetic resources, and these are by and large the raw materials used in the phytotherapeutic value chains. For these reasons, a contribution to ABS objectives is also part and parcel of this project.

4. Overall, the project will enhance global biodiversity benefits, as well as multiple national and local co-benefits, arising from the sustainable, accessible and innovative use of medicinal plants in Brazilian ecosystems, through the strengthening of promising phytotherapeutic value chains, based on the traditional knowledge of indigenous and local communities (ILCs), in compliance with the applicable ABS regime. This will be achieved in three different ways. **First**, by strengthening the supply and value-adding aspects of phytotherapeutic value chains based on native species, where ILCs are key protagonists, and with sites selected within established Local Productive Arrangements (LPAs or local clusters of businesses that are mutually strengthening and share a productive profile). The project will help LPAs towards a quality and sustainability 'leap', including in the management of productive landscapes and the safeguarding of traditional knowledge. It is expected that a large number of industry players and ILCs in phytotherapeutic value chains will find sufficient incentives for both using native plant species as raw materials (instead of non-native) and for sustainably using biodiversity and associated resources in productive landscapes. **Secondly**, this will be achieved through accelerated bioprospecting and innovation. This will involve collaborative frameworks among ILCs, science and industry, with a view to attracting both public and private finance, and by developing capacity where needed. New uses of genetic resources and derivatives can be explored and existing ones strengthened, but always by ensuring that emerging partnerships are equitable and fair in the way the benefits are shared. **Thirdly**, ABS-compliant policies, regulations and procedures will be mainstreamed into the national public health system. The access to, and use

⁵ Hasenclever *et al.* (2009) and Torres, K. R. (2015).

of, genetic resources from native plants that yield phytotherapeutic products in the public health system will be significantly broadened through ABS-aligned practices, systems and approaches.

5. **Biodiversity Significance.** Brazil's biodiversity is impressive from any of its measures. This includes e.g. the extension and importance of its terrestrial biomes (tallying 6, including two biodiversity hotspots), the diversity of vegetation types (47), the number of large marine ecosystems (3), of marine eco-regions (8) and of major river basins (12). It is estimated that Brazil hosts between 15-20% of the world's biological diversity. This also includes the greatest overall diversity of species in the world, second only to Indonesia in terms of species endemism. Brazil tops the lists for primates (55 spp.; 24% of world total) & flowering plants (55,000, 22%), and ranks 2nd in birds (1,622 spp.), 3rd in palms (387 spp), and 4th in reptiles (467 spp).⁶

6. Species diversity in Brazil includes at least 103,870 species of animals and 43,020 plant species currently known, plus on average 700 new species being recognized each year.⁷ This poses both a challenge and an opportunity with respect to this project. The sheer number and diversity of plant species is clearly an asset for the 'bio-economy' and for the medicinal plants' segment.⁸ Yet, studying Brazilian plant species in a more systematic manner and exploring their medicinal value, in view of developing potential products and value chains, would need to be considerably accelerated, before these assets can translate into benefits. Other key aspects under the topic 'biodiversity significance' are sustainability and ABS-compliance, plus the fact that Brazil is losing biodiversity very rapidly.

Root Causes and Drivers of Biodiversity Loss⁹

7. **Habitat loss through deforestation and degradation.** Across all terrestrial biomes, deforestation and degradation stand out as the most significant cause of biodiversity loss in Brazil. Deforestation and degradation patterns have been unevenly distributed across time and biomes. It is estimated that Pantanal, Amazon, Caatinga, Cerrado, Pampas and Atlantic Forest biomes hold, respectively, 83.1%, 53.4%, 51.2%, 35.6%, and 21.9% of their original vegetation. Historically, the Atlantic Forest had been the severely affected even before the 20th century, when rapid urban expansion and industrialization became the main drivers of forest loss. In the latter decades of the 20th century, deforestation accelerated and reached significant scale in the Amazon biome, where it peaked in 1994-95 (data from INPE). On the account of scale, Brazil became the largest deforester in the world between 2000 and 2005, responsible for 47% of global forest loss. The trend has been reverted since with steady decreases in deforestation rates for the Amazon and until 2013, when the annual area deforested increased again.

8. In all of Brazilian biomes, deforestation occurs mainly due to changes in land uses, driven by agriculture, in particular, cattle ranching and perennial crops (such as soybean and sugarcane), but also pushed by land market forces. Deforestation at scale results not just in the loss of the woody vegetation cover, coupled with significant CO₂ emissions, but also in the severe degradation of key ecosystem services associated with this vegetation, e.g. loss of top soil and disturbances in the water cycle. It results in pervasive habitat loss, resulting in fewer refugia, and consequently in increased threats to endemic species. Deforestation also contributes to the shrinking of entire gene pools, resulting in decreased gamma-diversity. More specifically, this impact forecloses the opportunities embedded in bioprospecting and the development of a bio-economy for Brazil, which are the inspirations for this project.

9. In the past, several authors have pointed out 'small farmers' being the main culprits of deforestation in Brazil. Current studies show that they contribute little to deforestation in aggregate terms, but with regional and other differences having significance.¹⁰ ILCs fit under the broad definition of small-farmers, but there are specificities that make them a district sub-group, including with respect to land use. Analyzing those in the local context of project sites is essential for this project, as it develops.

10. More generally, strategies for curbing deforestation and degradation should in any case be differentiated in accordance with hold-size, regional drivers and trends, but also according to the different types of land users. For instance, powerful determinants of deforestation include: plot size, plot access to road and the nearest community, and, to a high degree also, population density, with all other demographic variables included (Brondizio et al. 2009). This aspect will be important to consider in the choice of project sites among LPAs, where the goal will be to optimize the contribution of production models and value chains, viz. their contribution to biodiversity conservation and sustainable use. Even though demographic and environmental factors are implicated as drivers of deforestation, credit and land security, are also important. Finally, it is increasingly recognized, but not sufficiently studied, that rapid urbanization associated with other processes (e.g. lot turnover and land speculation in agrarian settlements) will shape the spatial pattern and rate of deforestation for years to come (Ibid.).

11. **Overharvesting.** At the level of individual species and landscapes, the overharvesting of biological resources can also have devastating effects on biodiversity. In extreme cases, it can lead overexploited species into local extinction, or into extinction altogether. The conditions under which a species' population and/or its genetic diversity will be impacted by either the intensity of resource use or

⁶ According to the [2010 Fourth National Report to the CBD](#).

⁷ Ibid, and considering review needs with respect to total number of species.

⁸ See explanations on core concepts in attached [figures 1, 2 and 3](#).

⁹ Because of the project's focus on plant genetic resources and ILCs as entry points, the threat analysis is restricted to terrestrial biomes and relevant causes only.

¹⁰ See e.g. Brondizio et al. (2009) for a detailed analysis.

the type of use, or both will be crucial for their viability and survival. In such cases, market demand for a specific natural product is also a known powerful determinant. A notable example from plant extractivism in the Amazon, where the activity has been geared towards supplying the cosmetic industry, illustrates the perils of overharvesting very well. The demand for essential oil from rosewood species *Aniba rosaedora* (pau-rosa) almost led to the species extinction in the Amazon in the 1990's. Pau-Rosa trees grow slowly and individuals of the species were naturally rare in the landscape. In addition, the species' populations were under additional pressure from habitat loss. A peak in demand for the tree's essential oil, whose repeated extraction eventually kills the tree, was the pivot of a near-extinction situation. Currently, *Aniba rosaedora* is listed in CITES Appendix II and classified as endangered in IUCN's red list. The industry had to find substitutes and current trade, even domestically, is tightly controlled. A similar fate could be experienced by medicinal plants used by the phytotherapeutic value chain, if checks and balances for sustainable harvest are not applied.

Sectoral context

12. Supplying accessible and affordable medicine to the population is a challenge that any national health sector faces worldwide. This challenge is particularly great in Brazil, where the public health services face: (i) an issue of coverage (given the size of the country and remoteness of certain areas, plus the constitutional requirement of universal coverage); (ii) issues of financial sustainability and HR capacity (which are structural, organizational and difficult to address in the short-term) and, not least also, (iii) the disease burden (given the country's predominant tropical climate). In spite of these challenges, the health sector in Brazil has developed considerably in the past few decades. This is reflected in marked improvements in key health indicators. Life expectancy of the Brazilian population increased from 69.66 years in 1998 to 74.6 years in 2012 (IBGE data). Infant mortality rates have basically decreased by one third between 1990 and 2015 (from 62 to 14 per 1000 live births, acc. to a UNICEF 2015 report).

13. The Ministry of Health (MS) is the key central entity in charge of health provision, policy development and sectoral regulation in Brazil. Service delivery happens at various levels (federal, state, municipality and local) and through a number of agencies, establishments and entities, including private. In order to improve service delivery and manage complexity, the (unified) Brazilian Health System (SUS – *Sistema Único de Saúde*) was established in 1990. The SUS has various functions and segments, a key one being the pharmaceutical, where the main challenge is to supply essential medicines to the entire population, as stated in the Brazilian constitution, at affordable prices. Under the SUS, the Brazilian Health Surveillance Agency (ANVISA) was created in 1999. ANVISA is responsible for establishing rules, and developing, monitoring, and implementing policies, guidelines and health surveillance actions. Among them, we highlight the licensing of pharmaceutical companies, large and small, and their products.

14. The mainstream pharmaceutical sector in Brazil is large, dynamic and fast growing. It was worth \$25.8 billion in 2011 and ranked as the 7th largest in the world.¹¹ The sector displayed an increase of 82.2% in retail drug sales from 2007 to 2011 and it launches several new products every year. The sector is dominated by less than 45 laboratories, which receive more than 90% of total industry sales. Many large sectoral multinationals have chosen to acquire local companies in order to enter the Brazilian market, where profits come mostly from patented medicine, which rely heavily on imported raw materials.

15. In order to keep essential medicine affordable, the government introduced 'generics' and 'similar medicines' as alternatives to the patented 'originator brand' kind of medicine, whose sales are monopolized by the sector's giants. While there is significant domestic R&D in the industry, including with government support and for biotechnology, the market's dependence on imported medicine and the locally based industry dependence on imported raw materials are issues of concern to MS. The government's preferred policy would be of producing essential drugs locally.

16. In addition, the "domestication" of health service provision in Brazil—that is, the push for the sector to incorporate into it values, practices and resources that are 'typically Brazilian', as opposed to 'imported ones'—has always been part of the sector's long-term development agenda. Within this framework, specific public policies and programs have been developed, in particular, the National Policy and Program on Medicinal Plants and Phytotherapeutic Products (*Política e Programa Nacional de Plantas Medicinais e Fitoterápicos* – PNPMF, launched in 2006 and in 2008, respectively). Both the policy and the program share the same objective: to ensure safe access to, and rational use of medicinal plants and phytotherapeutic products by the Brazilian population, by promoting the sustainable use of biodiversity, the development of productive chains, and of a truly domestic industry.

17. Historically, it should be recalled that 'herbal medicines' (*fitoterápicos*) were the 'mainstream' type of medicine in use in Brazil for many centuries, including into the early 20th century, when modern medicine, synthetic drugs and mass production methods eventually achieved dominance. Phytotherapeutic medicine has been the only type of medication used by indigenous populations that maintain their traditions and avoid contact with the remainder of the Brazilian society, and the one mostly available to local/traditional communities that live in isolated areas (among them *extrativistas*, *ribeirinhos*, *quilombolas*). Phytotherapeutic medicine is still very important for all ILCs. The PNPMF can therefore be regarded as an effort towards reviving historically and culturally important Brazilian traditions, by applying scientific methods for quality and efficacy control and by creating policy incentives for a bio-economy around

¹¹ Main source for this paragraph is PCW (2013).

them to flourish. The production of, and trade in, phytotherapeutic products is therefore an economic segment of interest to the Brazilian public health sector.

18. There are both a formal segment sustaining the phytotherapeutic value chain, and a less formal one. The latter is highly local, its products are not standardized and agents often operate at the margins of government control. As part of the informal economy, their most common points of distribution are the popular '*farmacinhas*' (small local pharmacies), which may or may not be subject to oversight and licensing by municipal authorities. The quality and medicinal benefits of products in the informal segment are variable and the raw materials are, for the most part, collected in the wild. In turn, the formal phytotherapeutic segment includes registered companies of varied sizes and, more importantly, established and structured supply chains that reach pharmacies in urban and rural centers, as well as public hospitals, even far away from the points of production. Some companies are engaged in export and import.

19. A comprehensive analysis of the formal phytotherapeutic segment in Brazil showed that there are approximately 100 laboratories that manufacture and sell phytotherapeutic products, though the majority of them manufacture also non-phytotherapeutic ones (Hasenclever *et al.* 2009). In 2006, a total of 367 phytotherapeutic products have traded by these labs. The market is dominated by 5-7 companies, located primarily in the state of São Paulo, and which are responsible for approximately half of both volumes of sales and total revenue (Ibid.). The segment is small but dynamic. There are probably more monopolistic tendencies in phytotherapeutic segment than in the mainstream pharmaceutical one. Some 20 companies are responsible for the 85% of the phytotherapeutic production value (Ibid.), as opposed to 45 and >90% in the mainstream segment (PCW 2013).

20. There has been a steady increase in sales in the phytotherapeutic segment in Brazil: from \$128 million in 2003 to \$260 million in 2006 (Hasenclever *et al.* 2009). In spite of an impressive growth in sales (an average of 27% per year for that period), this rate is similar to one observed for the entire pharmaceutical sector (Ibid). This suggests that there has been little change in the overall market share for phytotherapeutic medicine, which has remained between 3% and 4% of all pharmaceutical sales in Brazil.¹² Prices and goods are generally elastic and there is therefore room for additional growth in the phytotherapeutic segment. The number of ANVISA registered phytotherapeutic products increased to 382 in 2011 (Torres 2015) from 362 in 2006. While there has been some level of product diversification and innovation, the use of Brazilian native plants by the sector is still very limited. The government then started creating incentives to address this situation.

21. The Ministry of Environment (MMA) and ANVISA (the latter under MS), are the main actors regulating the use of medicinal plants in Brazil. Since 2008, ANVISA has reviewed and created a number of rules aiming at establishing procedures and good practices for the development of medicinal plants and phytotherapeutic products.¹³ In 2012, the Ministry of Health supported the structuring, consolidation and strengthening of 14 Local Productive Arrangements (LPA) that focus on medicinal plants. These actions also sought to support pharmaceutical care in municipalities and states, promoting health and the well-being of the population, and encouraging biodiversity conservation. The selected LPAs are spread in all five Brazilian geographical regions: North, Northeast, Center, South and Southeast. A model LPA with focus on medicinal plants would integrate on a geographical basis ILCs, other small farmers, research institutions, large and small companies from the health sector, in addition to public health services. The model has excellent conditions to be up-scaled, if specific local and market conditions can be better understood and the use of biodiversity and landscapes be more sustainable and ABS compliant.

Indigenous and Local Communities (ILCs), their traditional knowledge and sustainability

22. The more than 200 indigenous peoples in Brazil, speaking 170 languages, are recognized by elements such as self-identification, descent from original occupants of the territory, common history, language, and culture regulated by customary laws that are distinct from national cultures, and possession of a common land. Besides indigenous peoples, ILCs in Brazil encompass various other groups under the 'local communities' sub-category, among them extractivists, colonists, agroextractivists, *quilombolas*, family farmers, collectors, and traditional fishers. Production systems adopted by ILCs include a gradient from very intensive, diverse and agronomically sophisticated to extensive, opportunistic and unproductive systems.

23. Many ILCs live in poverty, in isolated areas, with limited economic opportunities and insecure land tenure. In general, it may be said that ILCs have an important role in the management of biodiversity. Yet, understanding the contextual specificities pertaining to each community' interactions with their ecosystems is the key. Only then, can we determine the extent to which their production and extractive systems have good chances of being sustainable or not. E.g. indigenous peoples have sometimes caused extinctions and degraded environments. At other times, they were regarded as the 'guardians of the forests'. Historical evidence from various parts of the world show that indigenous groups have often persisted for millennia in their territories by using detailed adaptive knowledge.¹⁴

¹² Ibid. In comparison, the segment has witnessed significant growth in other countries, e.g. the US and Germany, also according to same report.

¹³ Among them: Instrução Normativa (IN) no. 2008; IN no. 5/2010; Resolução da Diretoria Colegiada (RDC) no. 14/2010; RDC no 17/2010; RDC no 95/2008; RDC no 10/2010; RDC no 13/2013; RDC no 14/2013; and Consulta Pública (CP) no 85/2010.

¹⁴ Mauro (1999).

24. The cross-generational persistence of indigenous and traditional land uses of ILCs and their adaptability appear to be an important determinant of sustainability. Current hard data evidence from deforestation monitoring systems, including from Brazil, underscore this statement. For instance, a recent report by WRI and the Rights and Resources Initiative found lower rates of deforestation in areas where governments protect communities' rights.¹⁵ Furthermore, the current self-conscious approach of Brazilian ILCs to both land stewardship and their indigenous knowledge rights offer an opportunity for strengthening sustainability, provided that socio-economic conditions can concomitantly be improved and pressure from competing and destructive land-uses attenuated.

Barriers

25. There are **three major constrains** to be overcome, before phytotherapeutic value chains can effectively contribute towards exploring and widely sharing multiple benefits from Brazil's immense plant genetic diversity, with due consideration for the rights of ILCs, while also contributing to local development:

26. Barrier 1: The phytotherapeutic segment in Brazil is still modest, not always sustainable and may face challenges in adapting its practices to new ABS legislation.

27. There are complex productive processes involved in any phytotherapeutic value chain, particularly with respect to procuring a stable supply of raw materials and maintaining standards of quality, but also in terms of exploring new markets and launching new products. While the downstream part of the phytotherapeutic segment (manufacturing and distribution) is well developed and reasonably regulated, the upstream one (supply of raw materials) remains poorly mapped and weakly surveilled by the authorities. For the sector to expand and diversify its range of products, more attention to the upstream element is needed. For instance, the number of species used in the approximately 380 phytotherapeutic products that are currently traded by the 100+ labs remain surprisingly small and largely non-native. Of all phytotherapeutic medicinal products registered at ANVISA in 2011, only a mere 98 species provided the raw materials to them (Torres 2015). Of these, only 18.4% of the species were said to be 'distributed across Brazil' (Ibid.), meaning that several of the species used in the value chain happened to be 'exotic', 'naturalized' or 'cultivated'. This suggests that non-native species still hold a place of chief importance in the national phytotherapeutic segment. Brazil, as a country, is missing out on a major opportunity to better use its own biodiversity through this segment.

28. Along the same lines, we know that small farmers in general play an important role in supplying the phytotherapeutic value chain. However, structured and comprehensive data on this is missing. We can safely assume that a specific role for small-farmer populations that qualify as ILCs, and who detain traditional knowledge on the medicinal properties of native plants, remains largely unexplored. This is also a major untapped opportunity, where the main initial barrier for ILCs stronger participation in phytotherapeutic value chains is one of simply expanding the knowledge base and taking the initiative.

29. If the above-mentioned initial barrier can be overcome, there would still be land use barriers with regards to the sustainability of supplies, with strong livelihoods drivers behind them. ILCs will not shift from cattle ranching or food crop agriculture to mostly cultivating or harvesting medicinal plants, unless it is technically feasible and economically profitable to them. Plot size could be limiting factor. Many, if not most, small farmers (ILCs included) depend on negotiations with middleman to sell their products, a system that significantly decreases their economic return per unit produced, independent of their success and productivity with the crops. Furthermore, the lack of industrial and semi-industrial facilities nearby to process agricultural goods and natural resources condemns many ILCs to sell their products as unprocessed or only partially processed raw materials. This perpetuates the pattern, under which value added is mostly concentrated in the hands of the final player in the supply chain.

30. Another key challenge for sustainability is that growth in the phytotherapeutic segment may bring significant revenues and jobs, but it may also fuel deforestation or resource overharvesting, which were identified as the main direct causes of biodiversity loss. This project will not, under any circumstance, support value chain development, if this is the likely outcome. Both the harvesting of plants in the wild and the cultivation of species for the supply chain may have negative impacts on biodiversity and ecosystems. Establishing and enforcing parameters of sustainability is currently a 'missing link' in the upstream part of the phytotherapeutic supply chain. Given that these parameters are highly contextual (depend on the species, its life cycle features, the fluctuations in demand, etc.) a key barrier is the absence of useful business data. Another one the need for adopting investment standards and safeguards by the public sector to avoid negative environmental and social consequences.

31. Finally, the collection of plant samples *in situ* should pay close attention to the new ABS law in place. Due consideration to access procedures outlined by the law, including the scope of utilization of genetic resources and derivatives, Prior Informed Consent (PIC) and mutually agreed terms (MTA) should be taken, when proposals for exploring the genetic properties of medicinal plant resources that are based on the traditional knowledge of ILCs. Clear institutional and specialized roles for strengthening, structuring and overseeing the downstream element of the phytotherapeutic economic segment are needed. In addition, the interaction between ILCs and

¹⁵ See e.g. <http://www.wri.org/blog/2014/10/3-maps-show-importance-local-communities-forest-conservation>

industry and government players should be permeated by trust and mutual benefit. Not always is this the case. The segment could see improvements by investing in it, or it could become a potential barrier.

32. Barrier 2. The scientific knowledge about both medicinal plants and the potential products that they could yield is still limited; it is not, in any measure, on par with the scale and diversity of Brazil's immense richness in plant species.

33. In 2009, the Ministry of Health (MS) published the National List of Interesting Medicinal Plants for the SUS (RENISUS – *Relação Nacional de Plantas Medicinais de Interesse ao SUS*), which lists the 71 medicinal plants that have potential to lead to plant drug development. Among the listed species, it is unfortunate that only 31 are native from Brazil. In addition, MS published in 2012 the National List of Essential Drugs (RENAME) which lists the drugs (medication), including plant drugs, to be prescribed by physicians under SUS. Species and plant drugs listed in both RENISUS and RENAME are those that they have undergone thorough research and testing, and were considered safe for human use, including in phytotherapeutic products. In spite of all these efforts, only 12 plant drugs (“*droga vegetal*”) are listed on RENAME, of which only four are native from Brazil and show promise for value chain development, due to prior experience with them and the existence of market at scale, and in some cases also an export market. They are: *Schinus terebinthifolius* (aroeira); *Maytenus officinalis* (espinheira santa); *Mikania glomerata* (guaco); and *Uncaria tomentosa* (unha-de-gato). This is a very small number and not compatible in any shape or form with the richness of plant species in Brazil.

34. Although at least three of the above listed native species represent a selection that is ready for value chain development, e.g. under Component 1 of this project, there is no doubt that both RENISUS and RENAME are very limited lists for what the medicinal value of native plants are concerned. Also, considering the speed at which new species of Brazilian biodiversity are discovered every year (~700 among plant and animal species, plus micro-organisms), there is a dire need to accelerate R&D in this area. R&D and product development is costly, risky and time consuming. Yet it is the only known pathway for innovation and technological development, in particular in the pharmaceutical sector. As it is, both the pharmaceutical sector in Brazil and the government are investing heavily in R&D, the latter through universities, federal institutes and *incubadoras*. The greatest barrier to achieving more success in this endeavor is the difficulty with “cutting corners” for achieving faster results, e.g. by “knowing where to look”, when the universe of potentially bioactive plants is so vast and scattered. There are, in addition, other barriers linked to the patenting process, which will not be addressed by this project, but which it should be aware of.

35. Indigenous and traditional knowledge on plant species and their medicinal use could be a major accelerator in this context. What is rarely seen though is for ILCs to actually take the initiative for kick-starting R&D. Their engagement, either as kick-starters or as participants would involve, in most cases, access to genetic resources or access to associated traditional knowledge, imposing the need for compliance with the Brazilian ABS legal regime. Besides that, nothing, in theory, would impede a stronger participation of these groups in R&D, besides capacity constraints and the need for strengthening partnerships.

36. Barrier 3. Limited understanding of the impact of the 2015 ABS Law on the national public health system.

37. The public health sector in Brazil is particularly challenged due to structural, organizational and capacity problems. Adequately dispensing medicine that is accessible, affordable and effective to a large portion of its population of 200+ million people is only one of the challenges. The role that phytotherapeutic products could potentially play in helping address these challenges show promise. Yet, a number of conditions need to be in place for sustainability and full compliance with ABS and related legislation.

38. The Genetic Heritage Management Council (CGEN) is the Brazilian National Authority responsible for regulating access to genetic resources and the associated traditional knowledge.¹⁶ It was established in 2001, and is composed by representatives from 19 federal organizations. In order to adequately playing its role, CGEN has to both enforce and navigate a complex framework of laws, regulations and policies. Brazil's first legal instruments on ABS comprised 4 Decrees, 43 Resolutions, and 10 Technical Guidelines, which are complex. ABS procedures and related regulations established prior to 2015 were very complex and time consuming, inhibiting the development of products based on Brazilian biodiversity, among them plant-based drugs. The new 2015 ABS Law brings clarity on rights and obligations. The law defines utilization of genetic resources as encompassing the genetic information from living organisms that fall under the definition of Brazilian biodiversity, including substances derived from these organisms and their metabolism. The definition of genetic resources is broad. It also includes cultivated and “spontaneous” populations of non-native species, as long as they are found in situ within the Brazilian territory. Article 1 of the Law defines this, but also stresses that, what is considered ‘Brazilian genetic resources’ are assets for ‘the shared use of the people’. Unfortunately, the scope of utilization of genetic resources under the law may have a negative impact on the development of Phytotherapeutic products, which are essential for a strong and fully functional national public health system. Currently, the main barrier is lack of experience with implementation of the 2015 ABS Law.

39. Regulation is a major concern in the production of plant drugs in Brazil. In order to develop a well-established market for medicinal plants based on access to genetic resources, it is key that the SUS allows and stimulates Brazilian physicians to prescribe

¹⁶ As legislated in the Brazilian first ABS law, *Medida Provisória* no 2.186-16 (MP), currently repealed by the 2015 ABS Law, though the permanence of CGEN is maintained.

phytotherapeutic medicine to their patients and that these practices became gradually institutionalize in the SUS. Many efforts have been undertaken by the Brazilian government in this regard. Ultimately, an expansion of RENISUS and RENAME towards including native species and more phytotherapeutic medication is desired, along with a stronger uptake of results from R&D and value chain development. Capacity, information and collaboration seem to be a main barrier.

2. The baseline scenario or any associated baseline projects.

40. The status quo. More specifically to this project, the country faces a number of challenges when it comes to the implementation of an ABS regime and the use of native species within phytotherapeutic value chains. In its recent development path, Brazil is carving its niche in the world as an emerging economy with excellent natural endowments, though facing profound regional, social and economic disparities. Embracing the bio-economy is a long-term vision for the country that shows potential. Currently, realizing this vision may face conjunctural challenges, linked to the prevailing economic situation in the world and Brazil's position in it. Still, investments in this long-term view are being made, including in biodiversity protection, sustainable use, local development and national capacity building. This constitutes a strong baseline for this project.

41. The financial baseline. MMA and the IFC have signed a contract to develop an analysis of economic, regulatory and governance aspects for developing of the 'biodiversity market business case'¹⁷ in view of strengthening the dialogue on ABS with the private sector. Eight workshops were conducted and two studies developed. From the economic perspective, it was found that 71 species of plants, animals, or microorganisms are used by industry in Brazil, of which 24 are native from Brazil. It was also found that factors such as logistics and the possibility of substitution by synthetic products are essential to the use of biodiversity species in production. Finally, it was shown that there is great potential for the use of biodiversity in sectors that seek to replace the mineral raw materials base for raw materials of plant origin. Along with other (non-GEF) investments from MMA in landscape level management, knowledge on biodiversity and its components, and in biodiversity planning, a total baseline from MMA corresponds to **\$3 million** for the next 5-6 years (2016 plus the project duration).

42. Since 2008, and as a cross sectoral initiative, the implementation of PNPMF (with reference to the program) is being rolled out at the federal level under the leadership from the Ministry of Health (MS).¹⁸ This included the financing of several relevant actions by MS focusing on promoting the use of medicinal plants in Brazil: 436 actions were defined and implemented and 17 guidelines developed. These actions are related to the following axis, all of which are directly relevant to the project: regulation, human resources, R&D, information and communication within the SUS on medicinal plants, traditional knowledge, cultivation and handling of medicinal plants, production of phytotherapeutic products, marketing, financing, and supply chain. During 2008 and 2015, it was estimated that MS has allocated more than R\$ 53M to actions related to PNPMF. As these programs will continue, we considered a baseline of at least **\$22.5 million** from MS for the period relating to the project duration (2016 plus 6 years).

43. The Ministry of National Integration (MI) also invested significantly in local development, and particularly in the strengthening of LPAs throughout the country. For the past few years, a total of 14 LPAs that focus on phytotherapeutic value chains have been supported by the Ministry of National Integration (MI) as part of baseline activities. These 14 LPAs are located in 16 different states, part of all 6 administrative regions and representing 5 of the 6 Brazilian biomes¹⁹. A total of 45 municipalities have been included in the synergies promoted by the 14 mentioned LPAs and they still are. Among them, there is a predominance of LPAs in Southeast and South Brazil, which are the most developed regions of the country. Currently, only 3 of the 14 LPAs have experience with native species, an aspect that is proposed changed by the project. In all the 14 LPAs, there was co-participation from MS. Between 2012 and 2015, a number of infrastructural, public service provision and capacity development investments were made by MI across the entire LPA program, reaching R\$ 120-150M per year and approximately R\$ 500M over 4 years. The LPA program is far-reaching and claimed to have generated more than 3 million direct jobs to date. It encompasses a universe of 670+ LPAs throughout the country, 59 productive economic segments, covering 40% of the 5000+ Brazilian municipalities. The 14 LPAs with phytotherapeutic value chains are only a small part of this larger program. Approximately half of the productive segments supported by MI's LPA Development Program were considered to have either relevance to conservation/sustainable use of biodiversity at the landscape level, or to the health sector—and hence to the project more generally.²⁰ A cursory analysis indicated that approximately a third of the LPA investments could be considered either directly or indirectly relevant to the project's baseline. We assessed a relevant baseline value of R\$ 166M for the past period. As the program will continue, we assess a baseline of **\$83 million** from MI for the period 2016 plus 6 more years.

44. Finally, the investments in R&D from both government and private sector that would be directly relevant to this project (e.g. focused on medicinal plants) were initially assessed through a cursory analysis at \$10 M per year, though this is likely an understatement.

¹⁷ A proxy of the bio-economy, a term used in this project.

¹⁸ Other entities include: Executive Office of the President of Brazil (Casa Civil); Ministry of Agriculture, Livestock and Food Supply (MAPA); Ministry of Science, Technology and Innovation (MCTI); Ministry of Agrarian Development (MDA); Ministry of Social Development and Fight against Hunger (MDS); Ministry of Development, Industry and Foreign Trade (MDIC); Ministry of National Integration (MI) and the Ministry of the Environment (MMA).

¹⁹ Only Pantanal has not benefited from the initiative.

²⁰ Besides the phytotherapeutic segment, we mention e.g. apiculture, biotechnology, environmental protection services, forestry, among many others.

Yet, this amount would comprise a baseline of **\$60 million** for the duration of the project from diverse entities, including universities, pharmaceutical companies and others.

45. The total financial baseline estimated refers to past and projected expenditures that are most directly relevant to this project in connection with biodiversity management, PNPMF implementation, LPA development, and R&D. They sum up approximately **\$167.2 million** in total baseline that contributes to all three components of the project. A break-down per component with a more detailed baseline analysis will be prepared at PPG stage. Co-financing from MS, MMA and MI proposed for this project is considered new and leveraged, and referring to the period from 2016 on and, investments that are primarily public and which will be fully aligned with the project objectives.

3. The proposed alternative scenario, GEF focal area strategies, with a brief description of expected outcomes and components of the project

46. The project aims to enhance global biodiversity benefits, as well as multiple national and local co-benefits, arising from the sustainable, accessible and innovative use of medicinal plants' in Brazilian ecosystems. The project will do so by strengthening phytotherapeutic value chains in LPAs located throughout the country, with the full participation of ILCs. The phytotherapeutic economic segment has shown good signs of growth and profitability for the past few years. It was chosen as an entry point because it can potentially contribute to the sustainable use of biodiversity and to strengthening the implementation of the current ABS legal and policy regime in Brazil.

47. The country's impressive diversity of plants and the traditional knowledge of ILCs on their medicinal value form a good basis for expanding the multiple benefits sought by the project, provided that three key conditions are fulfilled:- (i) that the industry is able to rely more on native plants as raw materials for its product range, including by working with government, the scientific community and ILCs in expanding the applicable lists of species and medicine being used in value chains; (ii) that sustainability parameters can be established and upheld for the different species being used in the supply chain and in the landscapes that produce them; and (iii) that, whenever genetic resources are accessed and used by industry and/or science in this context, the associated traditional knowledge held by ILC's is respected in accordance with the Nagoya Protocol and Brazil's emerging ABS legal regime. The proposed GEF alternative scenario is presented side by side with the baseline and global benefits' description in a section [further down](#).

48. GEF focal area strategies. The project taps into two GEF BD programs, namely #8 and #9, on ABS and Mainstreaming respectively with equal amounts from each program. Program 8 (BD3. Sustainably use biodiversity / Program 8. Implement the Nagoya Protocol on ABS) is relevant to the extent that the project directly strengthens Brazil's implementation of its ABS regime, by building the capacity of key stakeholders for it, and where the health sector, medicinal plants and ILCs, science and industry are at the heart of it. Contributions are mostly to Components 2 and 3, but Component 1 also has an ABS angle in connection with the introduction of safeguards in the phytotherapeutic value chains. Program 9 (BD4. Mainstream biodiversity conservation and sustainable use into production landscapes and seascapes and production sectors / Program 9. Managing the Human-Biodiversity Interface) is equally relevant and has its entry point in Components 1, through landscape level management and related activities, and in Component 3, with focus on sectoral aspects and with respect to the mainstreaming of ABS into the public health sector. In the latter, policies, regulations, practices and systems are at the heart of the approach. Three components are foreseen:

49. **Component 1. Strengthening phytotherapeutic value chains in indigenous and local communities (ILCs) within Local Productive Arrangements (LPAs)**. Three outputs are foreseen under Component 1:

50. The first output is foundational (**Output 1.1 Value Chain Mapping**). It will build on existing research on phytotherapeutic value chains, taking the results from research further and complementing them in an accelerated manner. As a result, a solid knowledge base is expected to produce tangible and scalable results within the project's lifetime. This will include knowledge on the current activities of ILCs located both within or outside established LPAs²¹, their location, the boundaries and features of targeted of landscapes, where management of biodiversity resources will be improved through value chain development, and the extent to which different ILCs are well positioned to participate in the value chains that will be supported by the project. A key focus will therefore be on the feasibility and sustainability analyses of value chains, including by screening and categorizing different products with respect to market viability and benefit generation potential. Currently four native species with proven medicinal value and an existing market appear as promising and ready for value chain strengthening. They fulfil the following criteria: (i) the species occur and can be cultivated in various parts of Brazil; (ii) products (either intermediary or final) can achieve a good price and has growing demand for raw products in the phytotherapeutic economic segment; (iii) the species can be collected in the wild or cultivated sustainably, without negatively impacting biodiversity. These species are *Schinus terebinthifolium*, *Mikania glomerata*, *Maytenus officinalis* and *Uncaria tomentosa*. They are part of the current 'promising value chains'. The work will start during the PPG with baseline studies and will be concluded by end of year 1, when site selection is expected to have been finalized. The results of this output will provide guidance both to the value chain strengthening work in Output 1.2 and to the R&D work under Component 2. By project end, and on the basis of the coordinated work under this and other

²¹ For example, if there are prospects for linking them up to an LPA.

outputs, it is expected that the list of promising value chains has been expanded to reach at least 15 species with at least 5 value chains fully developed.

51. The second output (**Output 1.2 Value Chains Strengthened**) will mobilize most of the funding under this Component and it will include a broad set of activities that will support engaged ILCs within LPAs towards a quality and sustainability ‘leap’. The two-fold aim is to improve the ILC’s livelihoods and create a key incentive for the sustainable management of landscapes that supply the raw materials and harbor medicinal plant species. Targeted ILCs will be selected through a balanced approach towards regional and biome representation and to the extent that they offer the best conditions for value chain strengthening. The following activities are envisaged under Output 1.2: (a) Availing machinery and equipment to LPAs benefitting from the project, with a view to promoting equity (including of gender, regional and ethnic), fostering innovation, environmental responsibility and socio-economic development; (b) Establishing sustainable harvesting limits and thresholds of potential concern for the in-situ harvest of targeted species in the promising phytotherapeutic value chains (yield studies, regeneration surveys, harvest assessments and harvest adjustments); (c) Improving the capacity of targeted LPAs to adopt best practices for high quality sustainable production, with due gender and ethnic considerations; (d) Developing business plans with engaged ILCs for enhancing multiple benefits in the supply and value chains (including social and livelihoods related), while safeguarding the sustainability of resource use; and finally, by taking advantage of scale, synergies and ‘capacity multipliers’ that are a key comparative advantage of LPAs, (e) fostering and developing links between LPAs and promising markets, including current, new and export ones.

52. The third output (**Output 1.3 Landscape level management, Monitoring and Safeguards**) will work with relevant stakeholders through the LPA program to develop biodiversity-friendly land-use plans for the productive landscapes targeted by the project. The aim is to better manage current and emerging threats to biodiversity at the landscape level, introduce more sustainable land uses, enhance the yields of ecosystem services and increase ecological connectivity where needed. ILCs involved in the phytotherapeutic value chain will be the entry point. They will work in collaboration with LPA coordinating entities/focal points, the authorities (local, state and federal within their respective spheres of competence) and the relevant economic sectors. The output will also yield a database, as an essential supporting tool for stakeholder decision-making with respect to landscape-level management. It will capture and analyze information from the ‘Value Chain Mapping Exercise’ and allow for a much more systematic monitoring of activities under Output 1.2, as well as the application of relevant socio-environmental safeguards. This is important because the need for safeguards on potential socio-environmental impacts and concerns may need be dynamically identified as they emerge (and not *a priori*). The database will be comprehensive, geo-located and it will help in that regard. It will focus on: the production landscapes, their ecological and land-use features, links to synergistic services in LPAs, the presence and socio-economic features of ILCs and their traditional knowledge on native medicinal plants, along with a number of production, productivity and commercialization related data. The establishment and management of this database will also ensure that the use of genetic resources from medicinal plants and the associated traditional knowledge have been accessed in accordance with prior informed consent, and that mutually agreed terms have been established between ‘knowledge holders’ and ‘knowledge users’ at various levels using FPIC tools. Strong socio-environmental safeguards be consistently applied to relevant contexts in project supported activities, in particular FPIC measures will apply to indigenous knowledge and peoples.

53. **Component 2. Accelerated bioprospecting and innovation with more equitable partnerships.** Two mutually complementary outputs, that also have linkages to Component 1 activities, are foreseen under Component 2:

54. The first (**Output 2.1 ABS compliant Community-Science-Industry Partnerships**) focuses on R&D, investments and on the strengthening of collaboration among key stakeholders within a bio-economy, including by putting ILCs ‘in the driving seat’, whenever there is an opportunity. Due consideration for ABS laws and rules will be consistently applied. The goal is to see that technical and scientific analyses contribute in much more systematic way to the development of value chains based on Brazilian medicinal plants. Requests for research on the genetic and/or biochemical composition of these plants may either come from ILCs or from government, in full compliance with the ABS regime. Focused studies will be executed by universities, centers of excellence and *incubadoras*, with a strong involvement of, and under the advice from CNPq. It is expected that the results of these studies will infuse innovation into phytotherapeutic and related value chains, and that this will create good conditions for attracting both public and private investment capital into the bio-economy. It should be noted that the research will focus on plant species and their medicinal value and that it is not possible to determine *a priori* what types products can be derived from them (with reference to attached [figures 2 and 3](#)). While the scope of this project relates to the specific phytotherapeutic value chain and segment, the development of intermediary and end-products from medicinal plants, as a result from Output 2.1 work, will not necessarily be restricted to the narrow definition of phytotherapeutic products. Also, where relevant, the R&D work may include the application of biotechnology and the development of products from genetic resources and derivatives. Government co-financing and, where relevant, industry co-financing, will be brought to bear in the mix for financing activities, including beyond the project’s lifetime, given the relatively long R&D time for products in the pharmaceutical sector.

55. The second output under this Component (**Output 2.2 ILC’s negotiating capacity**) will focus on strengthening the capacity of ILCs when bargaining their share of the benefits from phytotherapeutic resources. Key ILC stakeholders will be capacitated and exposed to essential experience in this field, so that they are better prepared to enter into more equitable agreements and protocols with either research institutions or private sector companies. Activities will include training, exchanges and specific skill development of both leading men and women in ILCs.

56. **Component 3. ABS-compliant frameworks mainstreamed into the national public health system.** The aim here is to broaden the use of genetic resources from native plants in the national public health system, in particular through the adoption of phytotherapeutic products, and in full compliance with the ABS regime. Two key outputs are foreseen and they focus on the interface between biodiversity and health in the emergence of a bio-economy:

57. First, the project will strengthen the relevant frameworks (**Output 3.1 Policies, regulations and procedures enable the mainstreaming of the 2015 ABS law into the health sector**). This implies an assessment of the implications of the 2015 ABS Law on the development of phytotherapy products which are essential for the public health sector. This assessment will allow the development of policies and practices to mitigate such impact and the gradual but systematic removal of policy and regulatory barriers for achieving wider benefits from phytotherapeutic resources within the public health sector. The work here will also strengthen the ‘systemic uptake & learning’ based on results from components 1 and 2. It will involve the review of legislation, regulations and of their application, including when it comes to the informal phytotherapeutic segment, referred to in the baseline description. Because this output focuses on the interface between various sectors in the bio-economy, there will be a key focus on enhancing cross-sectoral intra-governmental collaboration, involving environment, health and national integration. It could be proposed that working groups and relevant commissions are supported in their mainstreaming work. Key stakeholders will be capacitated and consulted in the process.

58. **Output 3.2 ABS-compliant systems and approaches for protecting traditional knowledge, innovation, practices and customary uses of biological and genetic phytotherapeutic resources.** This output will have a specific focus on the Unified Health System (SUS) and in close collaboration with the Brazilian Health Surveillance Agency (ANVISA). This will include support for the technical scrutiny, dynamic review and update of lists of phytotherapeutic products and species, their descriptions and authorized uses, so as to better reflect the diversity of Brazil’s native plant species. As a result of this work – and of the project altogether – the list of species with interest to the public health sector, the RENISUS should be expanded and have a much stronger focus on native species. Traditional knowledge may be protected through a combination of confidential and non-confidential registries managed by SUS in close collaboration with ANVISA.

4. Incremental/additional cost reasoning and expected contributions from the baseline, the GEFTF, LDC, SCCF, and co-financing. and

5. Global environment benefits (GEFTF) and/or adaptation benefits (LDCE/SCCF).

<i>Current Baseline</i>	<i>Alternative</i>	<i>Global benefits</i>
<p>Brazil has impressive biological diversity, comprising 15-20 % of all global biodiversity, including the largest diversity of plants in the world.</p> <p>Brazil is also home to a significant number of indigenous and local communities (ILCs) which translate into significant cultural diversity and traditional knowledge associated with genetic resources.</p> <p>These are major assets for the country, as it strives to achieve multiple development benefits for its 200+ million-strong population.</p> <p>Currently, Brazil is not only losing terrestrial biodiversity very rapidly, but also under-utilizing these assets, more specifically with respect to medicinal plants value, which ILCs are bearers of specific and useful knowledge on.</p> <p>A key development challenge for Brazil’s health sector is to secure access to affordable and essential medicine to a large portion of its population, given the limited alternatives to ‘originator brand’ medicine or to medicine that relies on imported raw materials.</p> <p>Phytotherapeutic medicines based on native medicinal plants offer an alternative. Brazil has both policies and programs on this matter, which could enhance multiple benefits from the interface between biodiversity and health.</p> <p>However, the phytotherapeutic economic segment in Brazil is still modest, not always sustainable and may face challenges in adapting its practices to new ABS legislation.</p>	<p>The alternative provided by this GEF project will enhance global biodiversity benefits, as well as multiple national and local co-benefits, arising from the sustainable, accessible and innovative use of medicinal plants in Brazilian ecosystems. It will do so by strengthening promising phytotherapeutic value chains, based on indigenous and local communities’ traditional knowledge, in full compliance with the applicable ABS regime.</p> <p>The work under the project will be in three interrelated fronts:</p> <p>First, by strengthening the supply and value-adding aspects of phytotherapeutic value chains based on native species, where ILCs are key protagonists, and with sites selected within established LPAs. and by working on a few selected native species that show promise. The project will help LPAs towards a quality and sustainability ‘leap’, including in the management of productive landscapes and the safeguarding of traditional knowledge.</p> <p>Secondly, this will be achieved through accelerated bioprospecting and innovation. This will involve collaborative frameworks among ILCs, science and industry, with a view to attracting both public and private finance, and by developing capacity where needed. New uses of species and new derivatives can be explored and existing ones strengthened, but always by ensuring that</p>	<p>The project will enhance the achievement of global biodiversity benefits as follows:</p> <p>(1) at the level of landscapes linked to targeted LPAs and with a total coverage currently assessed at 3 million ha, where landscapes will be better managed for protecting, sustainably using and safeguarding biodiversity;</p> <p>(ii) at the level of plant species, and in particular with respect to the genetic resources of those with medicinal value; and</p> <p>(iii) by strengthening the interrelationship between genetic resources and traditional knowledge, and their inseparable nature.</p> <p>Landscapes are located within at least 5 of the 6 Brazilian biomes, all of which are rich in biodiversity, they harbor rare habitats, endangered species, protected areas and they include among them two globally significant hotspots (Atlantic Forests and the Amazon).</p> <p>Many of Brazil’s medicinal plants remain undiscovered. Several are yet to be thoroughly studied and remain</p>

<i>Current Baseline</i>	<i>Alternative</i>	<i>Global benefits</i>
<p>At the same time, the scientific knowledge about medicinal plants and their potential use is still limited and not on par with the scale and diversity of Brazil's immense richness in plant species.</p> <p>Altogether, the public health sector is not fully realizing the potential benefits that Brazilian biodiversity could offer.</p>	<p>emerging partnerships are equitable and fair in the way the benefits are shared.</p> <p>Thirdly, ABS-compliant policies, regulations and procedures will be mainstreamed into the national public health system. The access to, and use of, genetic resources from native plants that yield phytotherapeutic products in the public health system will be significantly broadened through ABS-aligned practices, systems and approaches.</p>	<p>underutilized. It can be assumed that a number of these species can be at risk from the degradation of their gene pool, and, in some cases, from extinction, in case they are endemic or rare within the landscape. The project will seek to change these patterns, through sustainable use and by helping Brazil advance with the implementation of its ABS regime.</p>

6. Innovation, sustainability and potential for scaling up.

59. This project will promote the sustainable and ABS-compliant use of biodiversity in Brazil through the development of phytotherapeutic value chains with the full involvement of ILCs. It will also help the national health sector find innovative alternatives to address challenges in its pharmaceutical segment. In this light, the project has its niche in the interface between health and the diversity of Brazil's natural and cultural endowments. Traditional knowledge embedded in ILCs' use of biodiversity will have a privileged place in it. This approach is innovative and has not been tried before. Innovation is also being directly fostered by the science-industry-ILC bioprospecting partnerships to be developed under Component 2.

60. The project will multiply its benefits through Brazil's most comprehensive local development program – the Local Productive Arrangements (LPAs) – which is, on itself, a breeding ground for innovation. The landscape-level management work under Output 1.3 has great potential to be adopted as a valid and cost-effective tool by the LPA Program to be applied in several other segments and LPAs. This can potentially scale up biodiversity benefits and have a very large national outreach beyond the LPAs directly targeted by the project.

61. Brazil counts on a defined, robust, and functioning institutional and legal framework in regards to sustainable use and protection of the environment. This will assure the continuity and sustainability of any achieved outcomes from this project. Within this framework, we also mention the ABS legislation. Although the ABS regime is not new in Brazil, the novelty with the 2015 ABS Law, is that it brings legal certainty into the relevant relationships, processes and transactions, allowing businesses, scientists and ILCs to reap and share the benefits from Brazil's genetic resources more broadly. This will likely accelerate and scale up bio-discoveries in a sustainable way, including beyond the lifetime of the project.

2) STAKEHOLDERS

Will project design include the participation of relevant stakeholders from civil society and indigenous people? (yes)

62. The main governmental stakeholders for this project are: The Ministry of Environment (MMA), which is the project lead; the Ministry of Health (MS), due to its role in the implementation of the PNPMF and of Component 3, and within MS, linked institutions such as the SUS and ANVISA; the Ministry of National Integration (MI), due to its role in the implementation of the LPAs Program; as well as the Ministry of Science, Technology and Innovation, with CNPq as a linked institution, due to their role in Component 2. Key protagonists will include ILCs. This implies engaging organizations representing Brazil's 238 indigenous peoples occupying 678 separate indigenous lands; and organizations representing Brazil's multiple categories of non-indigenous traditional communities. Also at government level, a key entity for indigenous matters is the National Indian Foundation (FUNAI). For the roll-out of Output 1.2 activities, ILCs are proposed to be supported by the Institute for Society, Population and Nature (ISPN), a non-profit organization currently implementing the graduated GEF Small-Grants Program in Brazil, and to the extent that ISPN can provide a coordination role with respect to the selection of ILCs, LPAs and value chain strengthening, and a more general oversight of Component 1 implementation. In addition, the project will involve all agencies members of the National Genetic Heritage Council (CGEN) and its permanent observers (representing indigenous and local communities, sub-national environmental management agencies, the biotechnology and business sectors, the scientific community, non-governmental organizations and the federal prosecution service). Beyond the lead federal ministries already mentioned (MMS, MS and MI), we also mention various other federal, state and municipal entities involved in the implementation of both the LPA program and the PNPMF, and in the management of the conservation units within the national protected area system (SNUC). Others still may include institutions responsible for science, technology and innovation (among them universities, research institutions, federal technical institutes), as well as government supported funding agencies (e.g. BNDS) and representative organizations of relevant R&D and business sectors, non-governmental and other specialist organizations with interests or expertise in ABS matters, medical and pharmacological professional associations and the Brazilian media.

3) GENDER CONSIDERATIONS

Are gender considerations taken into account? (yes)

63. Gender relations will be considered every step of the way, in particular in the social organization of the selected ILCs and in how Component 1 activities will roll out the phytotherapeutic value chain development work. Gender relations can play a key role in the access to, and use of, biological resources, as well as their management within production landscapes. Women and men often have different knowledge about, and preferences for, plants and animals. Women's role in seed selection, seed saving, and use of wild plants for food and medicines plays a major role in biodiversity conservation. The consultations and capacity building to be carried out under the project will ensure that women and men are equally involved. Care will be taken to recognize the different roles woman and men may play in identifying and conserving genetic resources and in generating and transmitting knowledge of these, and to frame consultation and capacity building activities accordingly.

64. Attention will also be paid to identifying and promoting appropriate forms of benefit sharing, probably equally likely to be non-monetary than monetary, that acknowledge and reward the differing contributions of women and men to the conservation and identification of the genetic resources, in each case where benefits are to be shared

4) RISK

65. Risk 1 (Medium): Low engagement of indigenous and local communities. The project aims at changing the way ILCs deal with their productive landscapes. It is possible that they do not easily engage to proposed changes in land-use, or preferred crops, or in the way they share their knowledge on medicinal plants. In order to address this, the project will count on local leaders and specialized facilitation so as to positively influence local communities. We will also present success cases on developing sustainable production chains and strengthen them through a suit of Output 1.2 activities. Particular care will be taken in communities of indigenous people to ensure facilitation is undertaken in the languages and timeframes appropriate for their culture and where appropriate apply FPIC. During further project development (PPG) more in-depth analysis on the best ways to engage communities and IPs will be undertaken to ensure the full scale project adequately addresses this risk. Also, strong socio-environmental safeguards and FPIC will apply to relevant contexts under all outputs and will be specifically rolled out through Output 1.3.

66. Risk 2 (Low): Failure in the long-term sustainability of the proposed actions under the project. For Component 1, this could mean that ILCs should have access to reliable credit lines to finance e.g. the purchasing of new machinery and equipment in order to sustain their activities in the long-term. Government involvement will facilitate this. Under Component 2, it could mean that several R&D efforts supported by the project may end up being fruitless (i.e. not producing any viable new products), given that bioprospecting and product develop is a risky, lengthy and complex business. To mitigate this, the project will focus on targeted research that can be accelerated by ILCs' knowledge. Finally, under Component 3, this could mean that the SUS may not find viable ways of changing its preferences for the use of non-native species as raw materials of phytotherapeutic products and lists such as RENAME and RENISUS remain largely unchanged by project end on that account. The project will build on results from Components 1 and 2 to address this issue under Component 3 in close collaboration with SUS and AVISA.

67. Risk 3 (Low): Competing land uses and prevailing unsustainable practices in LPAs undermine the goals of Component 1. It is possible that competitors in areas near those of ILCs will attempt to impose their non-sustainable practices to on ILCs and contrary to the project's guiding principles. The project will introduce safeguards and landscape level planning under Output 1.3 in order to consistently address this risk.

5) COORDINATION

68. The Brazilian Agricultural Research Corporation (EMBRAPA) is developing the GEF funded project "Mainstreaming Biodiversity Conservation and Sustainable Use into non-timber forest products (NTFP) and agro-forestry systems (AFS) production practices in Multiple-Use Forest Landscapes of High Conservation Value" (GEF ID: 5091). The project seeks to address deforestation driven by small-scale farmers by up-scaling sustainable agricultural practices such as NTFP and AFS in the Amazon, Caatinga and Cerrado biomes. The mentioned NTFP project is preparing regulations (e.g. safeguards, best practices) and will propose differential policies for products derived from selected species according to their harvesting limits. It will also undertake the identification and mapping of 12 species of the Amazon, Cerrado and Caatinga in high biodiversity landscapes of forest ecosystems and production landscapes. Based on the information generated, the project will provide technical support to the ongoing programs of the MMA and MDA to support the development of productive chains to increase production volume, improve quality of products and reduce costs as well as the MAPA policy for minimum prices. Our proposed project takes a similar approach although it is focused on the development of phytotherapeutic products that are based on access to Brazilian plant genetic resources. It also takes it a step further, as it will directly provide ILCs the necessary equipment for transforming plant species, adding value to their product and improving their livelihoods. The potential for synergies and collaboration between these two projects is significant and will be explored with the involvement of key partners.

69. The Ministry of Environment is developing, in collaboration with the Inter-American Development Bank-IADB and funded by the GEF a new project called "Capacity Building and Institutional Strengthening on the National Framework for Access and Benefit Sharing under the Nagoya Protocol" (GEF ID: 5760). The project is in its preparation phase (PPG) and it aims to develop and implement

a national legal and regulatory framework and administrative procedures that enable Brazil to fulfill the ABS provisions of the CBD and Nagoya Protocol. Our project will benefit from the new ABS framework supported by the IADB-GEF project. Differently from the latter, our proposed project will fulfill gaps on the existing actions already carried out by PNPMF to promote well-established markets for plant drugs and related product, with a focus on enhancing ILCs' livelihoods. It has therefore a much more specific focus on the health-biodiversity interface. Both projects will collaborate on what policy and legislation aspects are concerned, as well as with respect to mutual learning and synergies.

6) CONSISTENCY WITH NATIONAL PRIORITIES.

Is the project consistent with the National strategies and plans or reports and assessments under relevant conventions? (yes [X])

70. Project activities will support and complement national policies being implemented, among them the implementation of the NBSAP, the expansion and management of the national conservation units' system, support to scientific research on biodiversity, and implementation of national and sub-national science, technology and innovation strategies. It will also specifically support the PNPMF (national policy of 2006 and the program from 2008) and the new ABS Law. More specifically, Brazil's NBSAP is currently being revised, with the validation process currently pending. Yet, given that Brazil's previous biodiversity planning processes have been so comprehensive, strategic and forward looking²², it has been decided that the NBSAP being finalized should be narrowly focused on the program of work of the national Secretariat for Biodiversity and Forests (SBF) under MMA, in terms of forming national biodiversity-relevant policies and on guiding the sub-national level on implementation. The project will support NBSAP implementation on the two domains it is concerned with, namely mainstreaming and ABS. For the former, this relates to the strengthening the sustainable use of biodiversity into landscape-level management and in phytotherapeutic value chains, where the role and safeguarding of native biodiversity will be on focus. As for the latter, it pertains to strengthening the implementation of the ABS Law. With focus on the development of phytotherapeutic value chains, this implies the project helping lift barriers for the attribution of traditional knowledge on genetic resources, so that benefits obtained can be more widely fairly shared, in accordance with the Nagoya Protocol.

7) KNOWLEDGE MANAGEMENT

71. All data produced by this project will be made public in user-friendly forms.²³ Reports will be available at the Ministry of the Environment website. The results of this project will also be made available for: Organizations representing Brazilian ILCs; Chico Mendes Institute for Biodiversity Conservation (ICMBio), FUNAI, research institutes; Brazilian Agricultural Research Corporation (Embrapa), CNPq, MS, Ministry of Agricultural Development (MDA); Ministry of Science, Technology and Innovation (MCTI) and MI. The project takes a pragmatic and equitable approach to knowledge management. With respect indigenous and traditional knowledge on genetic resources, full safeguards for equitable and fair access and prior informed consent under the ABS regime will apply.

PART III: APPROVAL/ENDORSEMENT BY GEF OPERATIONAL FOCAL POINT AND GEF AGENCY


A. RECORD OF ENDORSEMENT OF GEF OPERATIONAL FOCAL POINT (S) ON BEHALF OF THE GOVERNMENT(S):

(Please attach the [Operational Focal Point endorsement letter](#)(s) with this template. For SGP, use this [SGP OFP endorsement letter](#)).

NAME	POSITION	MINISTRY	DATE (MM/dd/yyyy)
Marcelo Moises DE PAULA	General Coordinator for External Financing	Ministry of Planning, Budget and Management	March 04, 2016

B. GEF AGENCY CERTIFICATION

This request has been prepared in accordance with GEF policies and procedures and meets the GEF criteria for project identification and preparation under GEF-6.

Agency Coordinator, Agency name	Signature	Date (MM/dd/yyyy)	Project Contact Person	Telephone	Email
Adriana Dinu, UNDP-GEF Executive Coordinator.		3/22/2016	Helen Negret, Regional Technical Advisor	(507) 302-4508	helen.negret@undp.org

ATTACHED FIGURES 1, 2 AND 3, + BIBLIOGRAPHY

<http://bit.ly/21lhLmh>

²² We mention e.g. the work on the 2010 targets, the on-going and comprehensive process of implementing the [2002 National Policy on Biodiversity](#) (the [PAN-Bio](#)), along with related work by the Chico Mendes Institute on Biodiversity ([ICMBIO](#)), IBAMA that are .

²³ Except, of course, the content of confidential registries for the protection of traditional knowledge.