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Phytomedicine Value Chain Development Report

September 2017

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Important concepts and definitions

Phytomedicine

Phytomedicine is defined as an herbal-based traditional medicinal practice that uses various plant materials in modalities considered both preventive and therapeutic (www.drugs.com /July 2017).

Phytomedicine is also referred to as herbal medicine or herbal remedy, herbal product, herbal medicinal product, phytotherapeutic agent and phytopharmaceutical (Nigel et al., 2013).

Medicinal plant

Medicinal plant is considered as any plant that contains one or more substances capable to be used for therapeutic needs or which are precursors in synthesis of useful drug (Sofowora et al., 2013). A complete definition of medicinal plants should include the following clauses (Sofowora, 1996):

- Plants or parts of plants with medicinal properties used using in pharmaceuticals (obtained by decoction, maceration, infusion...).
- Plants used for pure substances isolation either for direct medicinal using or for synthesis of medicinal compounds.
- Foods, spices and perfume plants for medicinal using.
- Microscopic plants (e.g. fungi) using for pharmaceutical plant isolation, in particularly antibiotics.
- Plant with fibre, as cotton, flax, jute used to prepare surgery dressing.

Phytomedicines can be found on market either as (Okigbo and Mmeka, 2006):

- Raw material, mostly powdered or fragmented plant samples;
- Finished product which are registered and needs a marketing authorization and
- Dietary supplement mostly used to prevent various diseases.

Medicinal plants are the future of medicine. Phytomedicines are coming to equal prominence with orthodox medicines worldwide. However, some medicinal plants are becoming endangered species. Many active principles have been found in various plants, but these compounds are not going to clinical trials and then ultimately to pharmacy (Afolabi et al., 2014). The focal point of phytotherapy research should be drug development from medicinal plants. The synergistic bioactivity of phytochemicals in plant extracts often is touted as an advantage that is difficult to replicate by single synthetic drugs (Afolabi et al., 2014).

Traditional medicine

Traditional medicine means the total combination of knowledge and practices, whether explicable or not, used in diagnosing, preventing or eliminating a physical, mental or social imbalance and relying on practical experience and observations handed down from generation to generation, whether verbally or in writing (WHO, 1976).

Traditional medicine practitioner

Traditional medicine practitioner or “tradipracticians” / Traditional medicine healer means a person recognized by the community as competent to provide health care, using medicinal plants animal or mineral substances and certain other methods, based on the sociocultural and religious background as well as on the knowledge, attitudes and beliefs that are prevalent in the community regarding physical, mental and social well-being and the causes of disease and disability.

Value chain development

In a broad sense a value chain describes the sequence of activities required to make a finished product from its initial starting material (e.g. from field crop or gathered wild material) (Chopra and Meindl, 2004 cited by Anthony et al., 2012). Value chain research focuses on the nature of the relationships among the various participants involved in the chain, and on their implications for development. In practical terms, value chains are descriptions of the transactions and processing of a product until it reaches its end market, and will include various kinds of processing, transportation and branding.

The impetus for value chain work arose from the increasingly varied value chains that can be seen for many products, both in terms of the addition of value (e.g. from simple, undifferentiated agricultural commodities to highly- processed, branded products) and the geographic distances that they cover (e.g. from very localised markets to international ones). A fundamental distinction in the value-chain literature is between producer-driven chains and buyer-driven chains (Gereffi, 1994). The value chain we address here relates to the creation of products and value from local ethnopharmacological resources and its relevance for research on medicinal plants.

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Abbreviations

CPD	Continuous Professional Development
DMRS	Domestic Market Recapturing Strategy
EDPRS	Economic Development and Poverty Reduction Strategy
GAPs	Good Agriculture Practices
GBD	Global Burden Disease
GMPs	Good Manufacture Practices
ISO	International standards organisation
KOICA	Korea International Cooperation Agency
LABOPHAR	Laboratoire Pharmaceutique du Rwanda
HSSP	Health Sector Strategy plan
MINAGRI	Ministry of Agriculture and Animal Resources
MINEACOM	Ministry of Trade, Industry and East Africa Community Affaires
MINICOM	Ministry of Trade and Industry
MINIREMA	Ministry of Natural Resources
MoH	Ministry of Health
NIRDA	National Industrial Research and Development Agency
RDB	Rwanda Development Board
REMA	Rwanda Environmental Management Authority
RNRA	Rwanda Natural Resources Authority
RSB	Rwanda Standards Board
SMEs	Small and Medium Enterprises
UNIDO	United Nations for Industrial Development Organization
UR	University of Rwanda
WHO	World Health Organization

1. Background

1.1 Introduction

Rapid technical change and accelerating globalization are radically changing the context for economic development in every country. These changes offer developing countries both significant opportunity – of massive productivity increase and more access to new resources and markets – and significant risk – of economic dislocation, stagnation and marginalization.

International competitiveness is at the core of industrial success, and is taking new forms. Trade liberalization is forcing enterprises to face unprecedented global competition in domestic as well as foreign markets. The falling "costs of distance" make this competition more immediate and intense than in the past. Rapid technical change forces producers to constantly upgrade their process technologies and introduce new products. It also changes patterns of trade, with product segments based on research and development growing faster than less technology-intensive segments.

The main reasons for the growing importance of international competitiveness are technological. The rapid pace of innovation – and the resulting promise of productivity increase – makes it costlier to insulate economies from international trade and investment. Since new technologies benefit all activities, traded and non-traded, rapid access to such technologies in the form of new products, equipment and knowledge becomes vital for national welfare. Insulation from global markets and technologies is no longer a viable option for any developing country.

Technology is therefore vital to developing countries, even though it is clear that they are not "innovating" at the frontier. They import new technology, equipment, and patents from more advanced countries, but they have to learn to use these inputs effectively.

There is clear evidence that research and development is a core element in the economic growth of developed countries. This might suggest that simply increasing research and development expenditure in developing countries will lead to rapid economic growth. However, the innovation needs of developing countries are both simpler and more complex than those of developed countries: simpler because to a large extent developing countries can attain increases in productivity by making effective use of existing knowledge¹; more complex, because the key requirements of technology-driven development are not just new knowledge. In addition, technology-driven development requires education, packages of technical skills, and a whole series of institutions, networks and capabilities which

¹ For developing countries which are behind the "technological frontier", acquisition of existing knowledge may be expected to yield higher increases in productivity than would flow from a similar scale investment in R&D or other efforts to push back the technological frontier. There are many means of technology transfer for private goods. Direct foreign investment, licensing, technical assistance, importation of technology as embodied in capital goods, components or products, copying and reverse engineering, and foreign study are the key channels.

enable the effective use of existing knowledge and must be part of, or even precede, any serious effort to create new knowledge.

Innovation in the context of developing countries is not so much a matter of pushing back the frontier of global knowledge, but more the challenge of facilitating the first use of new technology in the domestic context. Innovations should be considered broadly as improved products, processes, and business or organizational models. Developing countries should therefore be more interested in technology knowledge through its acquisition, adaptation, dissemination, and use in diversified local settings rather than in pure research and development and the creation of knowledge.

Using new technologies is not an automatic or simple process. It entails the conscious building of "technological capabilities", a mixture of information, skills, interactions and routines that firms need in order to handle the tacit elements of technology. Once imported, using technology efficiently is not easy, costless or automatic.

The efficient dissemination of knowledge requires appropriate mechanisms to educate potential users in the benefits of the related technology through the provision of technical information using explicit training, pilot demonstration projects, or technical assistance on how to use the technology.

In this context of rapid development and dissemination of new knowledge, innovation is becoming a more critical element of competitiveness. Firms have to be constantly innovating to avoid falling behind. This does not necessarily mean that they have to be moving the technological frontier forward. Only the most advanced firms do that. However, all firms need to be at least fast imitators and adopt, use and improve existing technologies in order not to fall behind. This puts a great deal of pressure on firms' technological capabilities. Moreover, innovation is not just a matter of new products or new processes and ways to produce them, but also better organization and management techniques, and better business models which facilitate doing business.

NIRDA's strategy is aimed at increasing the competitiveness of Rwandan enterprises through:

- Ensuring they have knowledge of the technologies that could improve their competitiveness
- Supporting them to identify and acquire specific existing technologies which can improve their competitiveness
- Developing purpose-built solution where existing technologies needed to improve competitiveness either do not exist or inappropriate to the Rwandan nosiness environment
- Ensuring that demonstrated success of pilot projects in replicated by a large number of enterprises to achieve impact at scale.

NIRDA cannot operate at significant scale: it cannot hope to be polytechnic in aiming to service wide-ranging customer needs across the whole spectrum of Rwanda's industrial economy. It certainly cannot go beyond the provision of technology support services into broader business development services for enterprises: it has neither the skills or capabilities to do this and this would only deflect from achievement of its main goal.

It must focus and specialise on those areas where it can have most impact and adopt matrix structures to allow it to be flexible and responsive rather than develop "knowledge silos" which reduce its agility.

A critical first phase of this process is to determine which value chains offer the best prospects of achieving NIRDA's objectives goal (either increased exports or import substitution) in the most cost effective and efficient manner. NIRDA will review value chains considering the potential for:

- Upgrading (actions to help Rwanda enterprises move to a higher value added component of a value chain);
- Extending (actions to broaden an existing value chain to increase its full potential job creation and value-added impact);
- Optimising (actions to improve operation of certain links of the value chain to achieve greater value added);
- Targeting (identification of a new value chain or sector that Rwanda has the required endowments for but that has not been developed, or adequately developed).

In general, Rwanda's manufacturing sector has been experiencing a rapid growth but there is still need for significant efforts in the pharmaceutical sector. In this strategic sector, Rwanda depends largely on imports: over 98% of medicines used in Rwanda are imported causing then a huge trade imbalance. As example, over the five-year period 2009 –2013, Rwanda imported about US\$ 45.8 million worth of medications per annum (Ministry for Trade and Industry, 2015). The government of Rwanda has prioritized investment in the pharmaceutical sector and the creation of NIRDA in 2013 was one of the strategies to accelerate industrial and export growth.

In order to enable the Rwandan population to obtain high quality medicines at an affordable price, the manufacture of the drugs based on local raw materials must be one of priority of a research institution like NIRDA. This is still valuable not only in health domain but also for all new industries. Within the framework of the integrated development of the country it is more than urgent, that such work gets support from national and international organizations particularly those who have health in charge.

Nowadays, using natural products can lead to the development of a new pharmaceutical industry which will help to reduce as much as possible the expenses made for the importation of pharmaceutical products (save foreign currency) and offer to Rwandan population efficient and safe medicines at an accessible price in the next years (Nkurunziza, 2004). Within this framework UNIDO decides to support NIRDA in providing technological support to selected value chains among which phytomedicine value chain.

It is in this context that phytomedicine products has been determined to be a priority sector worthy of investigation. This report undertakes the first phase of that investigation.

1.2 Phytomedicine in Rwanda

Phytomedicine and the flora of Rwanda form a national richness, which is not sufficiently exploited at present. Currently, exploitation is undertaken almost entirely by the village population (which is the most significant percentage of Rwanda's overall population) and constitutes the domain of the traditional practitioners or "tradipracticians" (also called traditional healers).

As is the case in most other developing countries, traditional healers are the practitioners of traditional medicine and the most common type of traditional medicine is phytomedicine or herbal medicine (National Policy on Traditional Medicine and Regulation of Herbal Medicines, 2015). In Rwanda,

traditional medicine plays an important role in health care; it is estimated that between 60 and 80 % of the population initially consult a traditional healer before considering more formal health care or hospital facilities (Balick et al., 1996; Barnes et al., 1996 cited by Muganga et al., 2012). Considering the significant percentage of the population that consults – as a first priority - traditional practitioners, improvement is essential in order to ensure the effectiveness and the non-toxicity of traditional remedies (Nkurunziza, 2004). Even if phytomedicine use is continually expanding in both industrialized and developing nations (Drew et al., 1993), limited scientific data on its effectiveness and safety are available (Best et al., 2015).

Research on Phytomedicine in Rwanda began in 1972 and was formalized ten year later with the establishment of the Centre for Research in Phytomedicines and Life Sciences (by the then Institute of Scientific and Technological Research which became NIRDA). One of the objectives of the centre was to develop techniques for producing medicines, pesticides and other products from local plants for commercial sale: meaning that it should evaluate scientifically how traditional medicine can contribute to the Rwandan health care system. Various phytomedicines - as ameliorated traditional remedies - were put in place and were generally appreciated. However, since 2006 the production of such phytomedicines has been decreasing.

1.3 Phytomedicine value chains

Based on the recent developments in the global markets of medicinal plants, value chains that originate in some Asian countries and especially in India and China are of particular interest (Kala et al., 2006). Generally a traditional healer has detailed knowledge about the plants and he/she is able to identify it properly as well as ascertaining whether it is of a culturally acceptable composition and quality. Very often such traditional healer rely on some form of small-scale local trade to secure the material they are prescribing or processing. Clearly this has an impact on the quality of a product, how this quality is monitored, and how value-added is generated from it. It may also have important implications on the sustainability of use and impact on a species' availability as a commodity. Obviously, this also impacts on the value of the product and the economic benefits obtained from it and its cost to the patient (Anthony et al., 2012).

In India, several thousand, mostly quite small companies, including numerous neighbourhood pharmacies that compound ingredients to make their own remedies, produce phytomedicines. Kala and collaborators (2006) assert that of the 17,000 higher plants to be found in India, 7500 are known for medicinal uses with Ayurvedic medicine claiming to use 2000 of these, most of which are collected from the wild (Kala et al., 2006). More than 60 species are in great demand and the so-called tribal belt of India is abundant in these plants and the area's minorities (ethnic groups) mainly depend on this trade for their livelihoods. To avoid adulteration and contamination, the supply of good quality raw materials is important.

In Phytomedicine, the improvement of quality, the adoption of standards and quality controls along the whole value chain has to be ensured.

Indeed, the need for a new and more efficient governance of the Phytomedicine's sector is necessary to prevent its decline. Key action and investments along the value chain can include (Juan, 2010):

Phytomedicine Value Chain Report

- Quality improvement in the upstream value chain of wild plants, training harvesters on sustainable collection of medicinal plants, establishing community dryers/sorting facilities and community-based auctions, where necessary, to contrast the uncontrolled procurement of raw materials.
- More organic efforts to introduce medicinal plants cultivation, training agronomists, producing extension material and establishing an in-country production of quality seedlings
- Improving quality controls and introducing traceability of products in the downstream part of the value chain. In particular, a quality control facility for essential oil should be established and traceability of raw materials ensured, to prevent overexploitation of natural resources.
- Investments in governance (i.e. defining standards, restructuring the system of quotas and controls for raw materials collection, giving a role to public institutions in quality control of essential oils etc.) are also quite important.

According to Criss (2006), the phytomedicine value chain involves five levels of actors:

- Producers;
- Collectors;
- Processors;
- Wholesalers (domestic and export markets);
- Domestic retailers.

To those levels, we can add another level of patients or consumers as end users.

2. Project Brief

2.1 Key tasks and deliverables for the assignment

The tasks of this assignment were split into two clear phases with the following deliverables:

Phase 1

- Produce a report on the availability of high-quality raw materials for production of phytomedicine and other pharmaceutical products in Rwanda
- Produce a database of all enterprises engaging in herbal health care in Rwanda
- Produce a detailed report on technological capacity, production methods, and the needs of SMEs/Companies/Cooperatives engaging in the phytomedicine value chain.
- Summary, conclusions and justification to whether the sector is one in which NIRDA should intervene with technological support aimed at improving exports/reducing imports

Phase 2

- Provide guidelines for an open Call for Project Proposals for projects in the phytomedicine value chain with a covering report justifying all recommendations
- Create awareness raising material including a report on available phytomedicine value chain technologies relevant to the Rwandan context aimed at raising the interest of Rwanda enterprises in applying for support from NIRDA with the introduction of relevant cost-effective technologies and processes to support upgrading or modernization of the phytomedicine value chain in Rwanda.
- Hold two dissemination workshops with actual and potential phytomedicine developers in appropriate locations in Rwanda
- Budget justifying overall allocation of funding for first open call including an Assessment of the total amount of funds that should be allocated from the NIRDA-KOICA-UNIDO project to co-finance the call the first open call.
- Advisory report to the NIRDA Selection Committee for the applications received through the call for phytomedicine value chain.

Progress to Phase 2 can only be commenced following the approval of the Project Steering Committee to progress following their review of this Phase 1 report.

3 Methodology

3.1 Introduction

This chapter reports how all activities related to the undertaking of the fieldwork and data collection process were performed. It provides the information about how the study was designed, what data were collected and how this was done (tools used and procedures), how data were analysed and limitations of the study.

3.2 Study design

The research plan and methodology was discussed and approved by both UNIDO and NIRDA. This study was conducted on the whole territory of Rwanda (see the annexed road map) and targeted all individuals (mainly traditional healers); enterprises or cooperatives and industries dealing with phytomedicine.

An interview guide was prepared and tailored to facilitate the collection of all relevant phytomedicine information (see annex 1). The database of all concerned enterprises was obtained from the Rwanda Development Board (RDB), the Ministry of Health and from the coordinators of traditional healers associations in Rwanda. However, this database is not complete and appropriate. To maximise the number of enterprises in our study, we also requested contact persons from known enterprises to provide us the name and address of other relevant phytomedicine enterprises whose existence they were aware of.

3.3 Data collection process and analysis

Data were collected using a structured interview guide containing general information, human resources, productivity and economic data, process description, product information, technological capacity, quality control & standards, challenges, collaboration, future trends and forecasts individuals, SMEs/Companies/Cooperatives operating in the Phytomedicine products value chain (see annex 1 for details). Filled form has been checked for any missing variable of the research and additional questions were asked when needed.

In order to perform and maintain quality data control, all information was properly collected and recorded from the field and then hard copies and soft copies stored. Data were recorded using Microsoft Excel and then were interpreted. The data was interpreted by using tabulation with the detail explanation.

The following figure shows the geographic spread of the phytomedicine enterprises analysed. The major phytomedicine enterprises are located in eastern, western and Kigali province.

Figure 1: Geographic spread of analysed enterprises



3.4 Challenges and limitations of the study

The database of phytomedicine enterprises obtained from Rwanda Development Board (RDB) was not adequate and complete. We were obliged to contact each enterprise to be sure that it is engaged in phytomedicine sector and to know if it was still functional. We decided then to contact the coordinators of traditional healers' associations and the Ministry of Health.

Many enterprises were operating illegally in the phytomedicine sector and had been obliged to close some months before this study commenced: this was as a result of a communication from the Minister of Health to local governments requesting them to close all illegal medical practices.

This increased difficulties in the study, as, some people were reluctant to meet us thinking we sought to close their business or to check if they were still working illegally. In some regions, local governments discouraged us from meeting people dealing with phytomedicine stating that they were untrustworthy. Therefore, it was impossible to visit all enterprises and cooperatives engaged in phytomedicine: some refused to meet the team and others simply delayed meeting until such meeting was impossible.

Many interviewed enterprises were uncomfortable with some questions (such as their annual turnover or current cost of cultivation, production capacity etc.), but this did not significantly affect the quality of collected data. The fieldwork was undertaken in three weeks and it was practically impossible to visit all districts of Rwanda during such a short period of time.

Nevertheless, we managed to visit all provinces and each category of enterprises was represented.

4.1 Output 1: Report on availability of high-quality raw materials for production of phytomedicine and other pharmaceutical products in Rwanda

Cultivation of medicinal plants is very important to the development of the phytomedicine sector (so that the sector can secure both the availability and quality of raw material that it needs). However, it is crucial to know the name and estimated volume of plant materials we have in Rwanda which can be utilized for the production of phytomedicine.

4.1.1 Estimated volume and therapeutic values of some medicinal plants available in Rwanda

According to the data from this study and available resources, the most commonly available medicinal plant in Rwanda is *Eucalyptus species* which cover around 256,065.01 hectares (almost 10 % of Rwanda surface area) followed by coffee (\pm 50,000 ha), tea (\pm 18,000 ha), Pinus (17,790.15 ha), *Melanoxylon spp* (\pm 978.96 ha), *Callitris spp* (\pm 957.56 ha), *Grevillea robusta* (\pm 411.36 ha), Cypress (*Pinus spp*) (\pm 213.19 ha), *Jacaranda spp* (\pm 104. 58 ha), Cinchona (\pm 100 ha), *Alnus spp* (\pm 78.15 ha), Pyrethrum (*Chrysanthemum spp*) (40 ha), Geranium (*Pelagonium graveolens*) (\pm 32 ha), Patchouli (*Pogostemon cablin*) (\pm 11 ha), *Artemisia annua* (\pm 8 ha), Lemongrass (*Cymbopogon citratus*) (\pm 8 ha), Black wattle (7.34 ha) and *Tetradenia riparia* (\pm 3 ha), lippia (1 ha) and *Rosmarinus officinalis* (1 ha) (MINIRENA – RNRA, 2012).

Figure 2 Some medicinal plants coverage at country level. The percentage is calculated based on the volume of plant plantation and the value for surface area in Rwanda (26,340 sq. km)

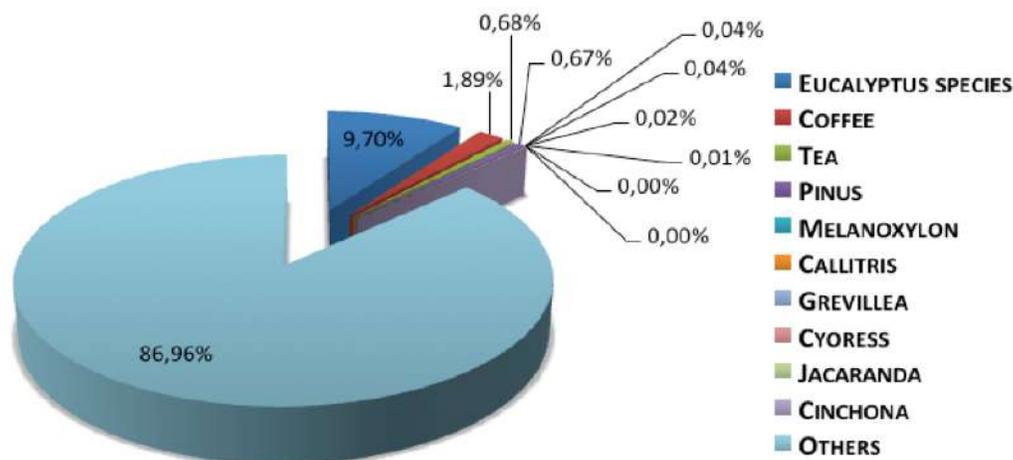
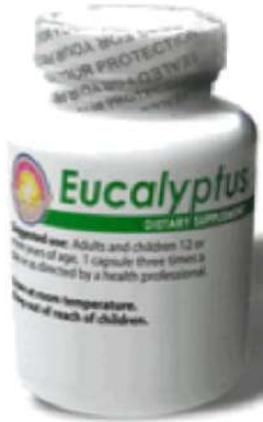


Figure 3: Phytomedicine from *Eucalyptus* available on Rwandese market



In Rwanda there are 69 species of *Eucalyptus species* but only 12 are disseminated countrywide. *Eucalyptus species* possess various biological effects, such as antibacterial, antihyperglycemic (Grayand and Flat, 1998) and antioxidant (Lee and Shibamoto, 2001) activities. Many pharmaceutical products are available worldwide and some are available in Rwanda. This is the case of Eucalyptus® indicated for respiratory track conditions.

The leaf of *Eucalyptus species* contains essential oil mainly 1,8-cineol also called eucalyptol. An important quantity of *Eucalyptus* leaf available in Rwanda is used as a source of wood and energy, but it can be used for the extraction of essential oil. This is the case of *Eucalyptus* used in tea factories for energy production. As already mentioned, the coverage of *Eucalyptus species* is around 10 % of the Rwanda surface area. So we should ask our selves why no reliable

phytomedicine is locally produced?

Therapeutic activities of coffee and tea are well known and the possible value addition local produced products are discussed in below.

The other plants mentioned above have also interesting biological effects: *Pinus spp* have anti-inflammatory, antifungal and antibacterial activities (Salem et al., 2014); *Callitris spp*, antimicrobial and antifungal activity (Sadgrove and Jones, 2014); *Grivillea robusta* leaf, antimicrobial activity (Sharif et al., 2014); *Jacaranda spp* (back and leave), antioxidant antidepressant, antimicrobial, anticancer, anti-leishmanial, anti-protozoal, hypotensive and anti-hypertriglyceridemic activities (Nada et al., 2014); *Alnus* (leaf), antimicrobial activity (Altinyan et al., 2015); Black wattle (*Acacia mearnsii*): insect pests and source of gum used in pharmaceutical industries (Ono et al., 2014) and *Dalbergia melanoxylon*, antimicrobial activity (Mohapatra et al., 2009).

This list of medicinal plants is not exhaustive, further study may provide more details. It should be taken in consideration that many medicinal plants are cultivated in a disparate way and it is not easy to estimate the volume. This is the case of *Tetradenia riparia*: a famous Rwandese medicinal plant which is found in many home places but not cultivated at large scale. Similarly, Geranium, Lemongrass and *Rosmarinus officinalis* are cultivated in various small gardens, meaning that the aforementioned volumes correspond only to the plantations from surveyed enterprises or individuals.

We should also mention the inestimable rich biodiversity of flora from the protected natural resources such as Akagera National Park which covers 120,000 ha in eastern Rwanda, Nyungwa National Park (around 97,000 hectares) and its large swamp, Kamiranzovu, the largest peat bog in Continental Africa representing a large flat basin of about 850 hectares surface surrounded by hills covered with mountain forest and Gishwati (1,439.72 hectares).

4.2 Output 2: A database of all enterprises engaged in the phytomedicine value chain in Rwanda

4.2.1 The categorisation of enterprise types

Based on the production process and technology used, the phytomedicine value chain in Rwanda can be mainly classified into 3 categories. The three main categories are:

- **Category A:** comprises all enterprises and individuals dealing with home-based preparations which make no use of machinery in any form: all steps of the production process are undertaken manually. This category is divided into two types A1 & A2;
- **Category B:** includes Small and Medium enterprises (SMEs) operating with phytomedicine. This category is also divided into two types B1 (small enterprises) and B2 (medium enterprises);
- **Category C:** this is a category of industrial-scale production which is also divided into 2 types C1 & C2.
- The nature of these categories is explained in more detail below.

Beside these three categories, we identified another category “D” of people dealing only with the cultivation of medicinal plants. However, this category contains very few enterprises. It should be noted that some traditional practitioners prefer to sell cultivated or collected medicinal plants, but also prepare their own processed products.

The different types of phytomedicine enterprises are described and illustrated below:

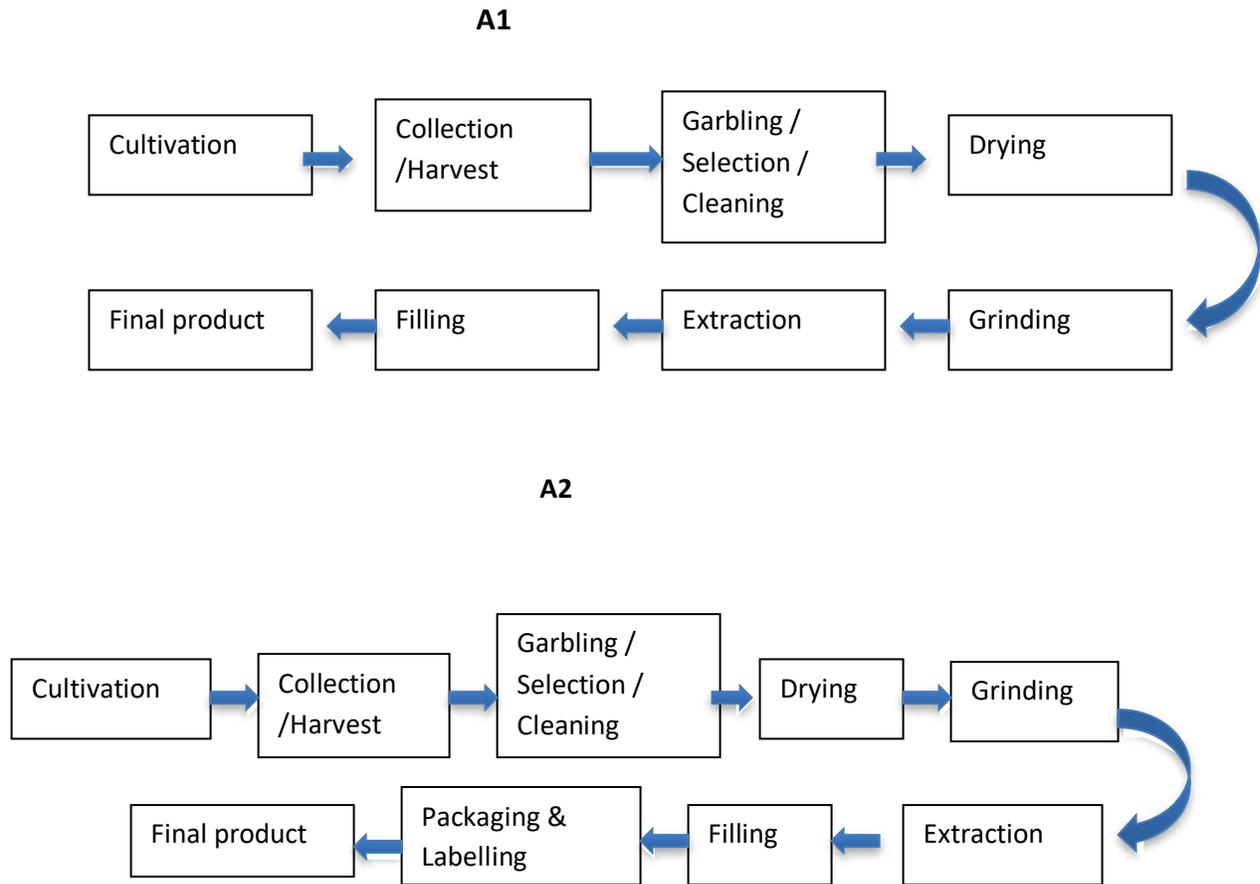
A1 Local traditional healers’ chain (home-based preparations)

The steps are:

- A1. Cultivation - Collection/ harvest – traditional processing (cleaning, garbling, drying, grinding, extraction, filling) – Final product (treating): all steps are done manually. No added value. This category comprises all authentic traditional healers who prepare their traditional preparations when they have a patient.
- A2. Cultivation - Collection/harvest–traditional processing (drying, grinding, extraction, packaging) – Final product – Selling/ treating. Packaging is done manually using mainly second-hand materials

This category comprises all traditional healers who are on the whole business-oriented, but undertake all production steps manually.

Figure 4: Value chain for Category A enterprises



B SMEs

The steps are:

- B1. Cultivation – and/or buying of raw materials – Collection/ Harvest - processing using medium-level technology (cleaning/garbling, drying, grinding, extraction, filling, packaging, labelling) – Final product – Selling on the national and/or international market. Packaging is done manually using mainly second-hand materials which are sealed. They do not meet the requirements of either Good Agriculture Practices (GAPs) or Good Manufacturing Practices (GMPs).
- B2. Cultivation / and or buying – harvest / collection, processing using advanced technology (cleaning / garbling, drying, grinding, extraction, filling, packaging, labelling) – raw material – Selling – on the national and/or international market. Filling and packaging is done manually and/or automatically. Packaging materials are new materials which are sealed. This is the category of medium enterprises which is trying to meet GAPs and GMPs.

Note: For the two categories mentioned above, some plant materials are cultivated, some collected in non-cultivated lands or forests and some are purchased, but very few depend exclusively on their own cultivated medicinal plants.

C Industrial-scale enterprises

The steps are:

- C1. Cultivation and/or buying of raw materials - Collection/buying - processing using advanced technology (drying, grinding, extraction, packaging, labelling) – Final product – Selling to the national and/or international market. This is the category of enterprises which meet standards but their products need additional value added.
- C2. Buying raw material- packaging, labelling and selling - Final product. This category of enterprises meets the required standards but do operate a complete phytomedicine production chain.

All those steps are not always followed: it depends on the nature of their final product. As many producers only produce powdered plant material, this may not involve any extraction.

The categories A2, B1, B2 and C1 have quite similar steps but utilise different machineries and technologies. However, category B2 and C1 may have additional steps depending on the pharmaceutical product that they want to produce.

Similarly, for category D, plant materials can be sold as fresh (selected and cleaned) or dried materials (powdered or not).

Based on the profile and flow sheet of all visited phytomedicine enterprises, it is clear that in Rwanda there is no existing phytomedicine plant that meets both GAPs and GMPs. Some enterprises in category B2 could be upgraded to meet international norms and standards. Enterprises classified in this category C are generally working well, but they are more focused on the production of tea which is mostly consumed as beverage rather than a phytomedicine. However, all visited enterprises are interested in the production of green tea as a phytomedicine as long as the market is assured.

4.2.2 The database

Table 1 provides a database of all visited phytomedicine enterprises and their respective stage in terms of value chain development. This database is not exhaustive. Indeed, accordingly to the coordinators of traditional healers' associations, there are more than 3,000 traditional healers in Rwanda. In Rwanda, the phytomedicine sector is not yet developed: no comprehensive list of companies or individuals in this sector is available either from the Rwanda Development Board (RDB) or from the Ministry of Health. However, we managed to visit all categories of enterprises dealing with phytomedicines to have a general picture of the phytomedicine value chain development in Rwanda.

According to the results presented in table 1, most of visited enterprises are in category A2 (46.59 %) followed by the category B1 (20.45 %) and A1 (18.18 %).

However, even if the category A2 is largely well represented, most of individuals, SMEs/Companies/Cooperatives operating in the Rwandan phytomedicine products value chain are in category A1, comprising mainly typical traditional healers.

Phytomedicine Value Chain Report

Table 1: Database of enterprises across the various stages of the phytomedicine value chain in Rwanda

	COMPANY/ ENTERPRISE/ NAME	CONTACT PERSON	SEX	CONTACT PERSON PHONE NUMBER	ADDRESS (SECTOR, DISTRICT)	CATEGORY
1	KANKINDI CANDIDE	Kankindi Candide	F	0783585885	Kamembe, Rusizi	A1
2	INGABIRE ESPERANCE	Ingabire Esperance	F	0782379261	Kamembe, Rusizi	A1
3	MPUNGENIBO ISIDORE	Mpungenibo Isidore	M	0783552277	Rugerero, Rubavu	A1
4	KAMANAZI BERTH	Kamanazi Berth	F	073099898	Kanjongo, Nyamasheke	A1
5	NDIMURWANGO P CÉLÉSTIN	Ndimurwango Pierre Célestin	M	0782023903	Nyamyumba, Rubavu	A1
6	NDENGERANISHIMWE	Twambazimana Dieudonné	M	0788236091	Busogo, Musanze	A1
7	GAHUTU INNOCENT	Gahutu Innocent	M	0783010860	Nyakiriba, Rubavu	A1
8	KANYAMAHANGA PIERRE CÉLÉSTIN	Kanyamahanga Pierre Célestin	M	07832556949	Kanama, Rubavu	A1
9	AKIMANAZINYE AGNES	Akimanazinye Agnes	F	0786460466	Ririma, Bugesera	A1
10	SAFETY WORK AND HEALTH MANAGEMENT AUTHORITY	Nshamihigo Ange Safari	M	0784343109	Kicukiro, Nyarugenge	A1
11	KABONSINGE BIBIANE	Kabonsinge Bibiane	F	078880403	Nyagatare, Nyagatare	A1
12	MUKAZITONI JACQUELINE	Mukazitoni Jacqueline	F	0783392753	Birenga, Ngoma	A1
13	UMUBYEYI JOLY	Umubyeyi Joly	F	0787779921	Nyagatare, Nyagatare	A1
14	MUSINE VINCENT	Musine Vincent	M	0785458691	Mutenderi, Ngoma	A1
15	KABUYE FATMA	Kabuye Fatma	F	0785459563	Nyarugenge, Nyarugenge	A1
16	TABARA COOPERATIVE	Twagiramungu Marc	M	0781570303	Kanjogo, Nyamasheke	A1
17	RUHUKA COOPERATIVE	Rwangirahe Marc	M	0785283037	Rusizi, Rusizi	A2
18	INEZA HERBAL MEDICINE – KABUGA	Habumugisha Jotham	M	0789651555	Rusororo, Gasabo	A2

Phytomedicine Value Chain Report

	COMPANY/ ENTERPRISE/ NAME	CONTACT PERSON	SEX	CONTACT PERSON PHONE NUMBER	ADDRESS (SECTOR, DISTRICT)	CATEGORY
19	ERAYON RWANDA TRADITIONAL MEDICINE	Rutazihana Alphonse	M	0783084922	Nyamabuye, Muhanga	A2
20	IMBARAGA Z'IBIMERA	Munyankindi Innocent	M	07788863221	Kimisagara, Nyarugenge	A2
21	IFUMBA Y'UBUZIMA	Gafaranga Daniel	M	0783934040	Kabeza, Kanombe	A2
22	MAWAZO MARGERIT	Mawazo Margerit	F	0786437129	Kagano, Nyamasheke	A2
23	GARDEN FOR LIFE	Mugisha Flugence	M	0788325237	Gihango, Rutsiro	A2
24	NUNU COFFEE	Dushimimana Isac	M	0787073617	Nyamyumba, Rubavu	A2
25	JAMIITIBA	Kalisa Emmanuel	M	0788753859	Muhoza, Musanze	A2
26	NKERAMIHIGO FAUSTIN	Nkeramihigo Faustin	M	0788732850	Nyange, Musanze	A2
27	SILOWAMU	Nyirarukundo Esther	F	0788566265	Kacyiru, Gasabo	A2
28	INKUNGA Y'UBUZIMA	Mutabaruka Nathan	M	0783778540	Rugarama, Burera	A2
29	NGAYABAREZI JEAN NEPOMUSCÈNE	Ngayabarezi Jean Nepomuscène	M	0786407803	Nyakiriba, Rubavu	A2
30	RWAJEKARE ALEXIS	Rwajekare Alexis	M	0783671839	Nyamyumba, Rubavu	A2
31	HINDEM POLYCLINIC NATURAL MEDICINE	Nyirahakizimana Françoise	F	0789682564	Kimisagara, Nyarugenge	A2
32	AFRICAN CULTURE MEDICINE	Sibomana Jean Bosco	M	0788 835 329	Kimisagara, Nyarugenge	A2
33	ABAHARANIRUBUZIMA	Mukarugagi Léocadie	F	0788517951	Muhima, Nyarugenge	A2
34	UWIHANGENYE ETIENNE	Uwihangenyé Etienne	M	0781098363	Ririma, Bugesera	A2
35	MUKARWABUSISI GAUDENSIA	Mukarwabusisi Gaudensia	F	0788506017	Ikazu, Birenga	A2
36	AFRICAN NATURAL TRADITIONAL MEDICINE NETWORK	Ndahayo Alex	M	0783771751	Nyagatare, Nyagatare	A2

Phytomedicine Value Chain Report

	COMPANY/ ENTERPRISE/ NAME	CONTACT PERSON	SEX	CONTACT PERSON PHONE NUMBER	ADDRESS (SECTOR, DISTRICT)	CATEGORY
37	NATURAL LIFE CENTER	Byagatonda Gad	M	0783775955	Rwamiyaga, Nyagatare	A2
38	GATE HEALTH CENTRE	Cyiza Théogène	M	0788590902	Nyagatare, Nyagatare	A2
39	MUKANDENGO EGIDIA	Mukandengo Egidia	F	0788779010	Nyagatare, Nyagatare	A2
40	NGIRABAKUNZI FRODUARD	Ngirabakunzi Froduard	M	0785915066	Nyagatare, Nyagatare	A2
41	AGASABIKO HUMURA	Ntampaka Fontaine	M	0788620999	Muhima, Nyarugenge	A2
42	UBUVUZI BW'UMUCO	Nsabimana Emmanuel	M	0785981039	Muhima, Nyarugenge	A2
43	MAYIDENI	Nkundiyamuremye Appolinaire	M	0785201140	Nyamirambo, Nyarugenge	A2
44	UBUVUZI BUTANGAJE BUKORESHA IBIMERA	Mukanshimiye Colette	F	0788856512	Busasamana, Nyanza	A2
45	IBIMERA COPERATIVE	Ruhumuriza Thacien	M	0788296181	Rugabano, Rutsiro	A2
46	IRAME LTD	Ngayampoze Michel	M	0781042798	Mukamira, Nyabihu	A2
47	MBONABIHAMA PHÉNIAS	Mbonabihama Phénias	M	0785495365	Mukamira, Nyabihu	A2
48	UWIMANA MARIE JEANNE	Uwimana Marie Jeanne	F	0780276386	Kanama, Rubavu	A2
49	NGIRENTE GASPARD	Ngirente Gaspard	M	0788607317	Rurembo, Nyabihu	A2
50	ZIRIMWABAGABO	Zirimwabagabo	M	0786015150	Kanama, Rubavu	A2
51	NDAGIJIMANA OSÉE	Ndagijimana Osée	M	0782738537	Nyakiriba, Rubavu	A2
52	NYIRIBAMBE JACQUELINE	Nyiribambe Jacqueline	F	0788601847	Gisenyi, Rubavu	A2
53	BAGAZA THEOPHILE	Bagaza Theophile	M	0783440757	Nyamwumba, Rubavu	A2
54	MUNYARUKIKO JEAN PIERRE	Munyarukiko Jean Pierre	M	0788729850	Kanama, Rubavu	A2
55	RWASIZIKI CÉLÉSTIN	Rwasiziki Céléstin	M	0788310496	Rurembo, Nyabihu	A2
56	UMWIGISHA	Sebagenzi Etienne	M	0788882692	Busugo, Musanze	B1
57	NIYIREMA LIFE COMPANYY	Niyirema Gaudiose	F	0788498755	Gasaka, Nyamagabe	B1

Phytomedicine Value Chain Report

	COMPANY/ ENTERPRISE/ NAME	CONTACT PERSON	SEX	CONTACT PERSON PHONE NUMBER	ADDRESS (SECTOR, DISTRICT)	CATEGORY
58	RELAX LIFE CENTRE	Habakubaho Denise	F	0788302368	Remera, Gasabo	B1
59	GAFUNZO AGRO PROCESSING CENTRE	Uhoranimana Clementine	F	0788682349	Mwendo, Ruhango	B1
60	ISHANGI	Tugirimana Victor	M	0722508252	Ruhango	B1
61	UMUCYO IWACU	Manirabona Innocent	M	0785593013	Nyabimata, Nyaruguru	B1
62	ZIRUMUZE COOPERATIVE	Nyakarundi Samuel	M	0788863221	Muhima, Nyarugenge	B1
63	RENGERUBUZIMA	Gasana John	M	07838047284	Kacyiru, Gasabo	B1
64	IVURIVANZE	Twagirimana Jeremy	M	0788485435	Kimisagara, Nyarugenge	B1
65	NATURAL MEDICINE POWER	Gapasi Serushago Innocent	M	0788624935	Kacyiru, Gasabo	B1
66	INEZA HERBAL MEDICINE – RWAMAGANA	Ndayishimiye Alfred	M	0725331710	Kigabiro, Rwamagana	B1
67	AMIZERO HERBAL MEDICINE	Nsengimana Schadrack	M	0784726301	Rusororo, Gasabo	B1
68	ISOKO LIFE CENTRE	Uzaribara Innocent	M	0788358895	Kigabiro, Rwamagana	B1
69	UMURAGE W'UBUMENYI GAKONDO	Kayiranga Musa	M	0785444477	Nyamata, Bugesera	B1
70	NAIVERA CAMPANY Ltd	Mbinigaba Alex	M	0788454054	Kimisagara, Nyarugenge	B1
71	RAMIRUBUZIMA	Maniriho Emmanuel	M	0788612295	Muhima, Nyarugenge	B1
72	BODY CARE PROFESSIONAL	Kayitare John	M	0783210624	Kimisagara, Nyarugenge	B1
73	PERFECT THERAPY & HEALTHFUL PRODUCTS	Ndayishimiye Filbert	M	0786982300	Nyamirambo, Nyarugenge	B1
74	IBANGA RY'UBUZIMA	Rugema François	M	0788241630	Kicukiro, Kicukiro	B1
75	HUYE COFFEE INVESTMENT	Rudahungwa Abdoul	M	0788305706	Simbi, Huye	B2

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	COMPANY/ ENTERPRISE/ NAME	CONTACT PERSON	SEX	CONTACT PERSON PHONE NUMBER	ADDRESS (SECTOR, DISTRICT)	CATEGORY
76	NICE DREAM CANDLES	Kiroha Guido	M	0788526687	Ndera, Gasabo	B2
77	CYAHINDA COFFEE	Niyonsaba Betty Scheba	F	0788735844	Cyahinda, Nyaruguru	B2
78	EDEN BUSINESS CENTRE	Rekeraho Emmanuel	M	0784186585	Runda, Kamonyi	B2
79	SMGF Ltd	Ndahimana Emmanuel	M	0788300170	Masaka, Rwamagana	B2
80	SORANA Ltd	Abizeye Jean Marie	F	0788878877	Muhoza, Musanze	B2
81	RWANDA MOUNTAIN TEA LTD - KITABI TEA FACTORY	Nkurikiyinka Jean Nepomuscène	M	0788522031	Kitabi, Nyamagabe	C1
82	RWANDA MOUNTAIN TEA – MATA TEA FACTORY	Mungwakuzwe Yves	M	0788555095	Mata, Nyaruguru	C1
83	RWANDA MOUNTAIN TEA LTD – RUTSIRO TEA FACTORY	Thushara Pinidiya	M	0786182956	Gihango, Rutsiro	C1
84	HORIZON – SOPYRWA	Bizimungu Gabriel	M	0788229181	Ruhengeri, Musanze	C1
85	AGROPY	Nyirigira Emmy	M	0788384846	Ruhengeri, Musanze	C1
86	RWANDA TEA PARCKERS	Kabagambe Hamim	M	0788302537	Gikondo, Nyarugenge	C2
87	BAKUNDUKIZE JOSEPH	Bakundukize Joseph	M	0726206647	Nyamata, Bugesera	D
88	Environmental Museum	Munyaneza Emmanuel	M	0788683288	Bwishyura, Karongi	D

The majority of all visited phytomedicine enterprises are private companies belonging to the health sector and the majority (around 53.4 %) are registered under the Rwanda Development Board (RDB).

It should be noted that typical traditional healers (who are normally not business-oriented) manage most of the non-registered enterprises.

However, a not negligible number of enterprises in other categories (particularly category A2 and B1 as defined above) are illegally engaged in phytomedicine and are supposed to close their businesses.

All provinces were represented in our survey, but the majority of companies or enterprises come from Kigali province ($\pm 30.68\%$), Western province ($\pm 25.0\%$) and Ester province ($\pm 17.04\%$).

Many contact persons in these enterprises ($\pm 38.63\%$) have benefitted from both short training programmes in phytomedicine in addition to the traditional medicine information that they have obtained from their parents or other relatives.

4.3 Output 3: A diagnostic report on phytomedicine production in Rwanda

4.3.1 Productivity and economic data

Table 2 presents the key productivity and economic information on surveyed enterprises. Even if the majority of all visited enterprises are cultivating medicinal plants (approximately 55.68 %), only 12 enterprises (13.63 %) are solely using their own cultivated plants.

Few enterprises have adopted organic farming (49.91 %) and only 12.5 % are meeting full Good Agriculture Practices (GAPs). It should be noted that the use of GAPs is very important for the cultivation of medicinal plants (Hosein et al., 2015).

It should also be noted that a phytomedicine plant can operate using medicinal plants from another company: what is important is to be able to guaranty the quality of the raw material.

Phytomedicine Value Chain Report

Table 2: Key productivity and economic data from visited enterprises

Category/Data (%)		A1	A2	B1	B2	C1	C2	Total
Source of plant material	Cultivation + other sources	15.9	27.3	17.0	4.54	3.41	N/A	55.68
	Cultivation only						N/A	13.63
	Outsources + other sources	12.5	19.4	7.95	1.13	0	N/A	27.27
	Buying + other sources	5.68	19.4	11.4	3.41	5.68	N/A	35.22
	Buying only							15.9
Cultivation practice	Organic farming	13.6	17.0	12.5	2.27	4.54	N/A	49.9
	Chemical	0	1.13	1.13	1.13	1.13	N/A	4.54
	None	2.27	4.54	2.27	0	0	N/A	9.08
GAPs	YES	0	0	1.13	5.69	5.68	N/A	12.5
	NO	18.2					N/A	77.5
Area of cultivation	> 1 hecter	11.4	27.3	13.6	1.13	0	N/A	53.43
	1 – 10 hecters	2.27	3.41	2.27	3.41	0	N/A	40.09
	< 10 hecters	0	0	1.13	0	4.45	N/A	5.58
Available infrastructure	YES	0	0	3.64	6.81	5.68	1.13	16.14
	NO	18.2	46.6	9.06	0	0	0	73.86
Survey done before	Marketing survey	0	19.3	18.2	6.81	5.68	1.13	51.14
	Feasibility study	0	0	0	2.29	5.68	1.13	9.1
Add value	YES	0	46.6	20.5	6.81	5.68	1.13	80.72
	NO	18.2	0	0	0	0	0	18.2

Although the majority of visited enterprises (53.43 %) have less than one hectare to cultivate medicinal plants, it is significant that many traditional healers have now started to cultivate medicinal plants as historically this was not the norm.

Table 2 above shows also that the majority of visited enterprises / companies or cooperatives (73.86 %) do not have infrastructure specifically allocated to the production of phytomedicine. From the remaining enterprises having infrastructures specifically for phytomedicine production (22.14 %) only 13.63 have an electrical generator (results not shown). In addition, few enterprises conducted a marketing survey (51.14 %) or a technical feasibility study (only 9.1 %) at either local or international level before starting their business.

Moreover, only 17.05 % companies undertook a marketing survey at international level before they commenced and these were mostly enterprises in category C: very few enterprises in category B (results

not shown) did so. Parallely, only enterprises in category C (less represented in Rwanda) undertook a technical feasibility study to international standards.

The majority of enterprises (81.12 %) do add value to their phytomedicines but need to add more. Although we did not receive the information about the income generation for all enterprises, it is interesting to note that even some enterprises in category B can have an annual turnover ranging from 5,000,000 to 50,000,000 Rfw per year.

In category C, the annual turnover is between 500,000,000 and 1,000,000,000 Rfw.

Even if the production capacity is limited for the majority of visited enterprises, cost-effectiveness and cost benefits of phytomedicine is evident especially in category B and C.

4.3.2 Process description and product information

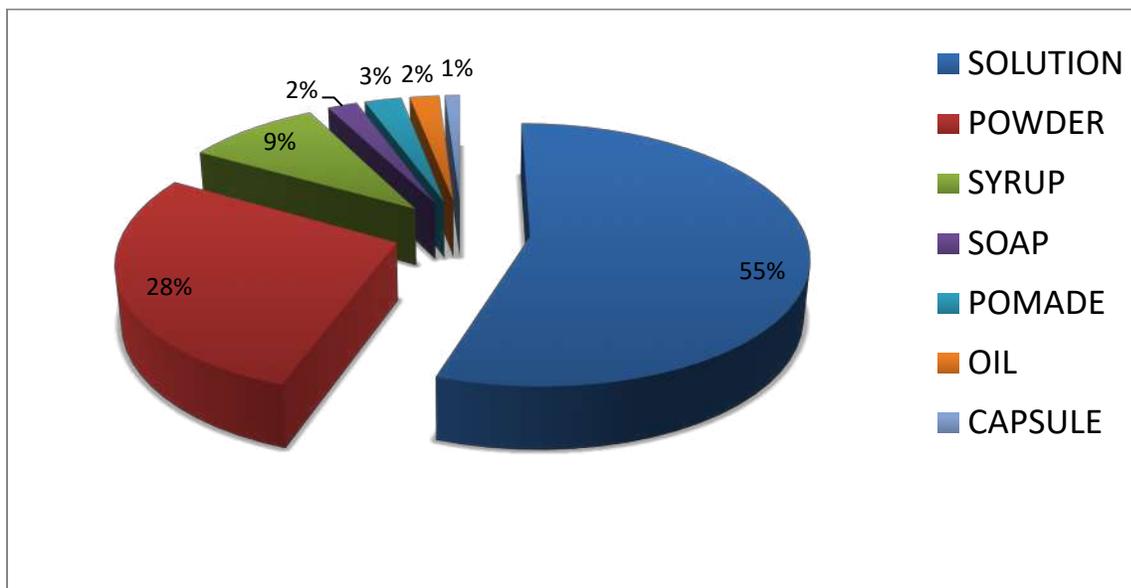
As already mentioned, not all steps of production process are followed by every phytomedicine enterprise.

Many enterprises (80.68 %), mostly in category A2 and B1, conduct all steps from cultivation, harvest to the final product, but others just undertake some steps. Very few enterprises (mostly in category B and C) operate an automatic machine for filling and packaging (6.81 % and 5.68 % respectively) indicating clearly that this sector is still underdeveloped in Rwanda.

Almost all locally produced phytomedicines are neither registered with RDB nor with the Ministry of Health. The few products registered with RDB are from category C enterprises only.

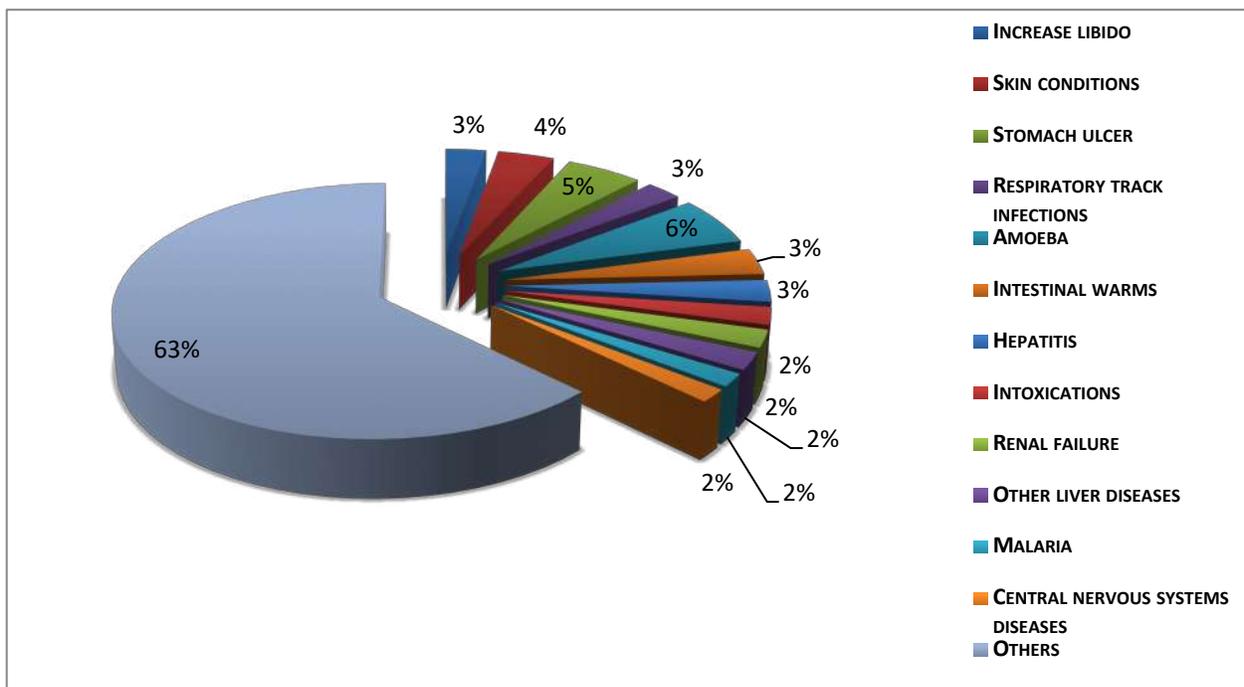
The most produced pharmaceutical dosage forms are solutions mainly for oral administration (56.18 %) followed by powder (28.35 %) and syrups (9.27 %). The percentage of solutions is actually even higher if we consider that what people describe as syrups are really solutions. Indeed, to the true sense of the world, syrup is primarily composed of a solution of sugar in water, which is not the case for those “syrups” locally prepared.

Figure 5: Pharmaceutical dosage forms made by surveyed enterprises



More than 355 diseases and conditions are treated using phytomedicines according to our inventory with the most common being treatments against amoebae (6,20%), stomach ulcers (5.35 %), skin conditions (3,94 %), intestinal worms (3.38%), hepatitis and to increase libido (sexual desire) (2.82 %) and respiratory track infections (2.54 %). Therefore, it is strongly indicating that phytomedicine is playing a major role in health system. Indeed, as it is in other developing country, Rwandese population is still suffering from conditions caused by poor sanitation like infections and parasitosis (MoH, 2011) and the majority of the population (60 to 80 %) use to initially consult a traditional healer before going to health care or hospital facilities (Balick et al., 1996; Barnes et al., 1996). Moreover, phytomedicines for respiratory track infections are commonly found on the market (see Figure 6 below) and these diseases which are among the most common diseases and the first cause of death in Rwanda (GBD, 2015). We find also on market phytomedicines used to treat other top ten causes of death like diarrhoeal diseases and preterm birth complications.

Figure 6: Diseases treated by phytomedicines made by surveyed



4.3.3 Technology information

This section provides information about the existing technology and machinery used in the production of local phytomedicines and identifies the main gaps in processing.

In general there is a lack of the technology and machinery in the commercial production of phytomedicines. In category A, phytomedicines are traditionally produced using simple materials and equipment (see Figure 4 below) which limits production quantity significantly. In addition, phytomedicine are normally produced in non-hygienic conditions and are also exposed to cross contamination.

Figure 7:Materials and work flow for category A enterprises

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The most commonly used machineries were extraction machines (found in 12.5 % of all enterprises), grinding machines (11.36 %), and drying and packaging machines (4.54 %). Such machines are found only in category B2 and C enterprises. Most of machines found in category B1 were simple grinding machines (to powder plant material) or juice maker machines. We found also some sealing, packaging and labelling machine but most of these were manual. It should be noted that technology and machineries depend on the pharmaceutical dosage form to be produced and on production scale.

Most of promoters use technology for phytomedicine production (87.5 %), cosmeceutical products (22.72 %) or health care products and agroceutical product (11.36% and 4.54 % respectively).

For all categories of enterprises, gaps in processing were found mainly for materials (82.94 %) and machinery (81.81 %), but also with respect to labour (technicians) involved in the production process.

In addition, very few enterprises (4.54 %) and only in category C meet Good Manufacturing Practice (GMPs).

Phytomedical solutions produced mainly by enterprises in Category A and B suffer often from precipitation of plant materials (see figure 8).

Figure 8: An example of locally produced solutions demonstrating precipitation issues



Those solutions present a precipitation of plant ingredients (see bottom of the bottle on the right). Ideally, those solutions should be homogenised and the use of second-hand bottles is not recommended to avoid possible contamination.

The problem of precipitation in solutions can be addressed. The precipitation can result from exceeding the saturation point (the capacity of water to dissolve more substance is exceeded) or the fact that there are some ingredients which are not soluble in water. In the event that we know that all active ingredients are soluble in water, we can then filter the solution to avoid precipitation. However, in the event that the precipitate contains active compounds, surfactants can be used to obtain a homogenized solution.

The following figures show examples of production machinery in use in Rwanda at present.

Figure 9: Machinery and products from enterprise category B1



Figure 10: Rwandan-made grinding machine (used by enterprises in category B1)



Figure 11: Pressure machine used in Rwanda (category B)



Figure 12: Manual capsule-filling machine used in Rwanda (on the left) used by category B1 and automatic capsule-filling machine (on the right)



The manual capsule-filling machine used in category B1 presents many disadvantages amongst which we can cite are source of contaminations; the contents may not be standardized, time consuming etc. and such approach does not meet GMPs.

Figure 13: Machinery for distilling essential oil machines in category B1 (on left), B2 (on right) and in Category C1



The current essential oil distilling machines produced in Rwanda do not have a pressure control switch: this is very important to avoid accidents and it is not easy to separate water and oil after distillation. Additionally, the whole system should be in stainless steel so as to avoid contamination. In general, enterprises in categories A and B1 are missing all technologies and machineries needed in phytomedicine, whilst categories B2 and C possess most essential machinery.

Figure 14: Machines and products from category B2



Figure 15: Some steps in the production of tea in Rwanda: note manual packaging and filling (bottom right)



Figure 16: Tea parker machinery in Rwanda, Category C2



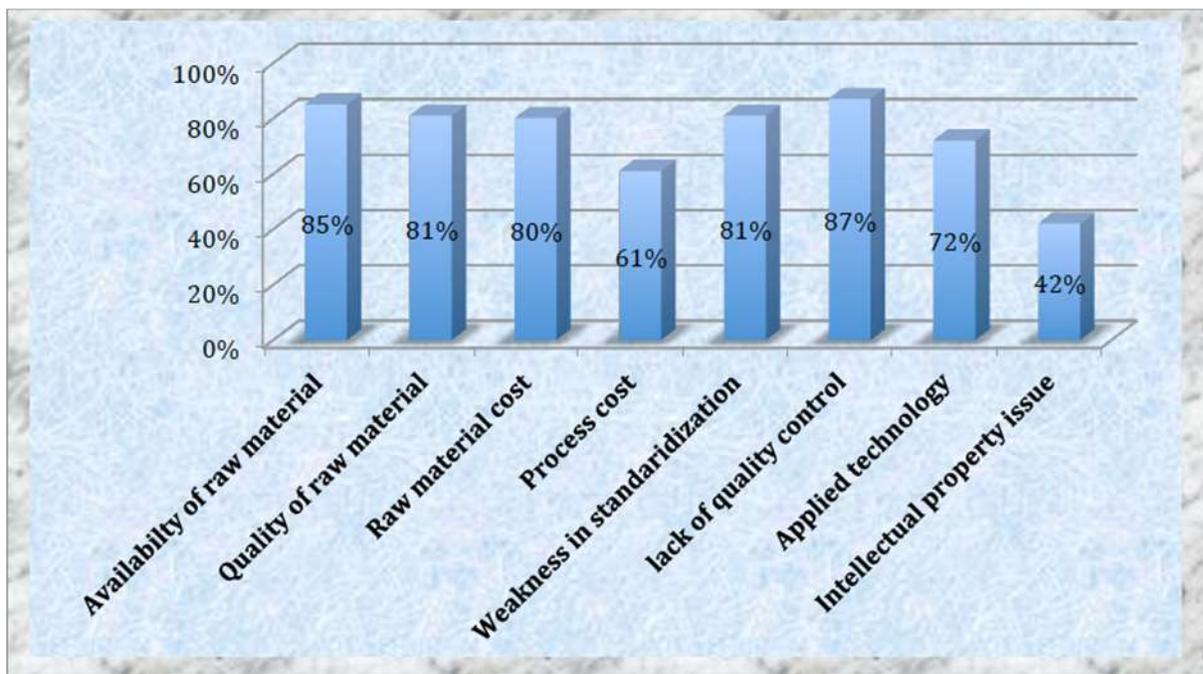
4.3.4 Quality control and Standards

As is the case for all modern medicines, quality control and achieving defined standards plays a critical role in the production of phytomedicines. Quality control should completely satisfy the product specifications (or at least the basic specifications or partial product specifications). According to the results of the present study, few enterprises undertake quality control or meet such standards. Indeed, only 9.09% apply quality control procedures and only 10.22% commission quality control of their products by an external organisation. Similarly, only 9.09 % meet required standards or have certification.

4.3.5 Challenges

As is illustrated in Figure 15 below, the most common challenges identified by visited enterprises are product quality (as a result of the lack of quality control), weakness in standardization and applied technology (87.5, 81.81 and 72.72 % respectively), low availability of raw material (85.22 %), the quality of raw materials (81.81 %), high product costs (mostly caused by the cost of raw materials) (80.68 %), process costs (61.36 %) and intellectual property issues (42.04%).

Figure 17: The main challenges faced by visited enterprises



3.3.6 Collaboration, future trends and forecasts

Regarding collaboration, 32.95% of phytomedicine enterprises declared that they participate in a collaboration programme whereas all enterprises stated that they were interested in entering into a formal collaboration with NIRDA. Their expectations from NIRDA are mainly technology support and training (96.59 %), quality control of their products (85.22 %) and helping in innovation (64.77 %). Other important expectations from NIRDA are, for example, improving access to appropriate machinery and equipment, financial support and advocacy.

The regulation issue mentioned, as one of the most commonly faced challenges, is a serious and general concern in the Rwanda Health system (MOH, 2015). Indeed, the phytomedicine sector cannot be developed as long as there is no clear regulation. However, this crucial challenge will be soon resolved, because MoH has recently published a traditional medicine policy and traditional medicine law is being

reviewed by Law reforming commission at Ministry of Justice and will be available soon.

The most important requirements to instigate the development of the phytomedicine sector are:

- improvement in the production of phytomedicines
- closure of illegal phytomedicines shops
- appearing of false and illegal traditional healers
- new requirements to be registered as traditional healers
- climate change, some herbal medicines are disappearing in regions.

Phytomedicine products are largely marketed through ethical promotion (stressing the social and environmental benefits of the product). However, commercial advertising is also undertaken especially for category A2, B and C enterprises.

The following figures (Figure 15 – 25) illustrate what we were expected to see in terms of phytomedicine value chain for different pharmaceutical dosage forms found. This will help to understand possible value addition we are discussing below.

Figure 18: Example of flow chart expected in Phytomedicine



Figure 19: Schema – Phytomedicine value addition – liquid formulation

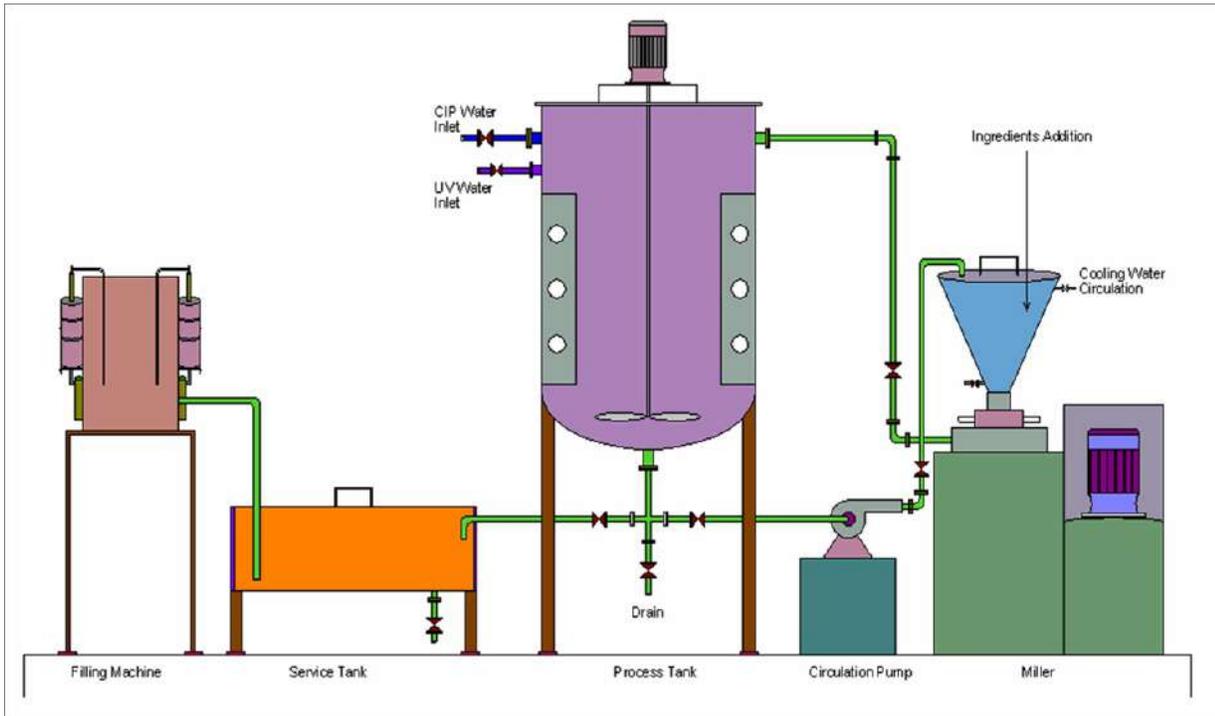


Figure 20: Phytomedicine value addition for Powder/Capsule Formulation

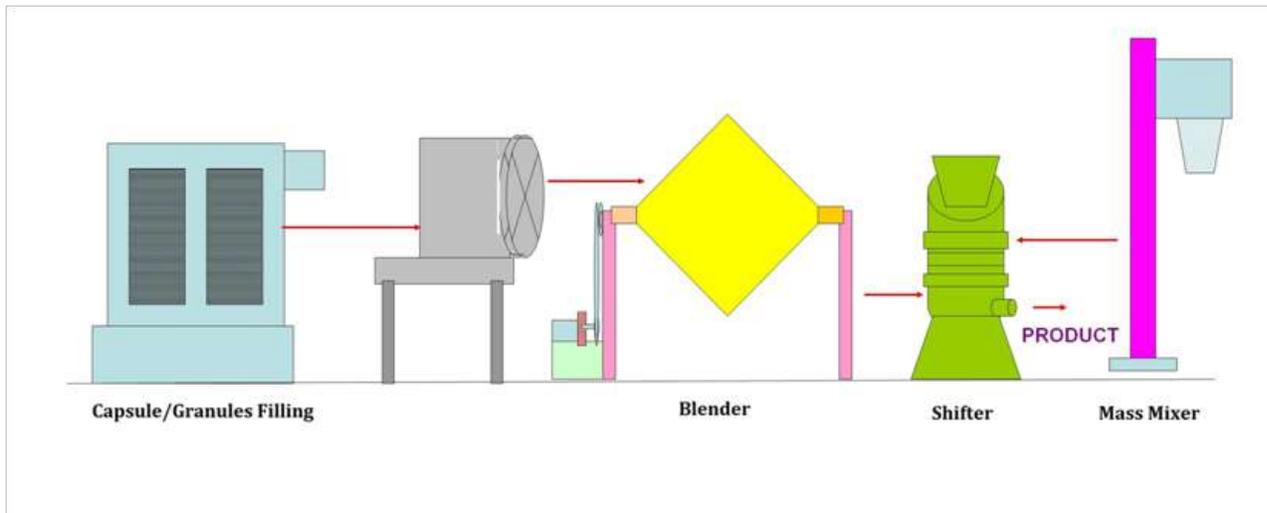


Figure 21: Phytomedicine value addition for Pomade Formulation

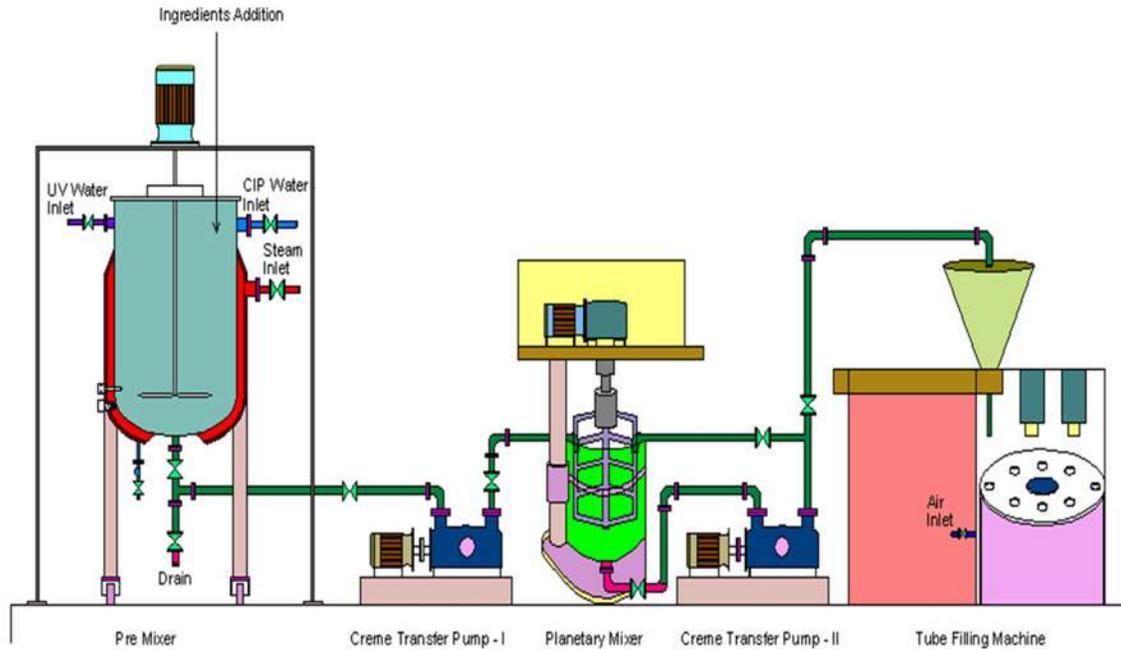


Figure 22: Phytomedicine value addition for Oil Formulation

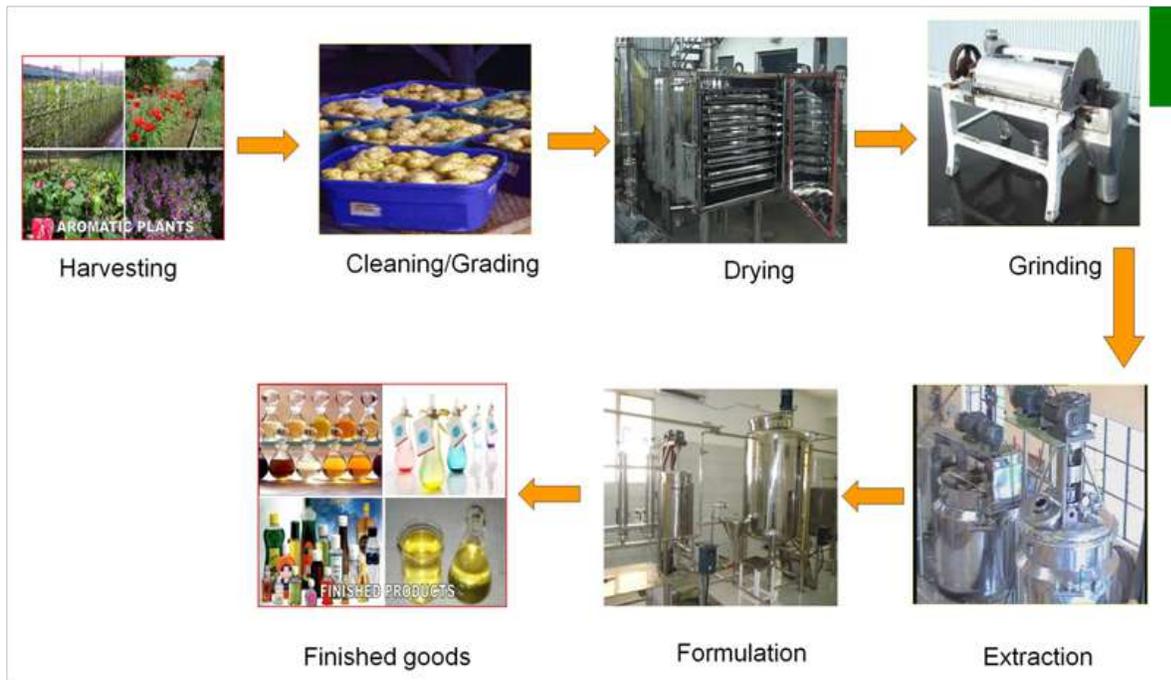


Figure 23: Schema - Phytomedicine value addition for Oil Formulation

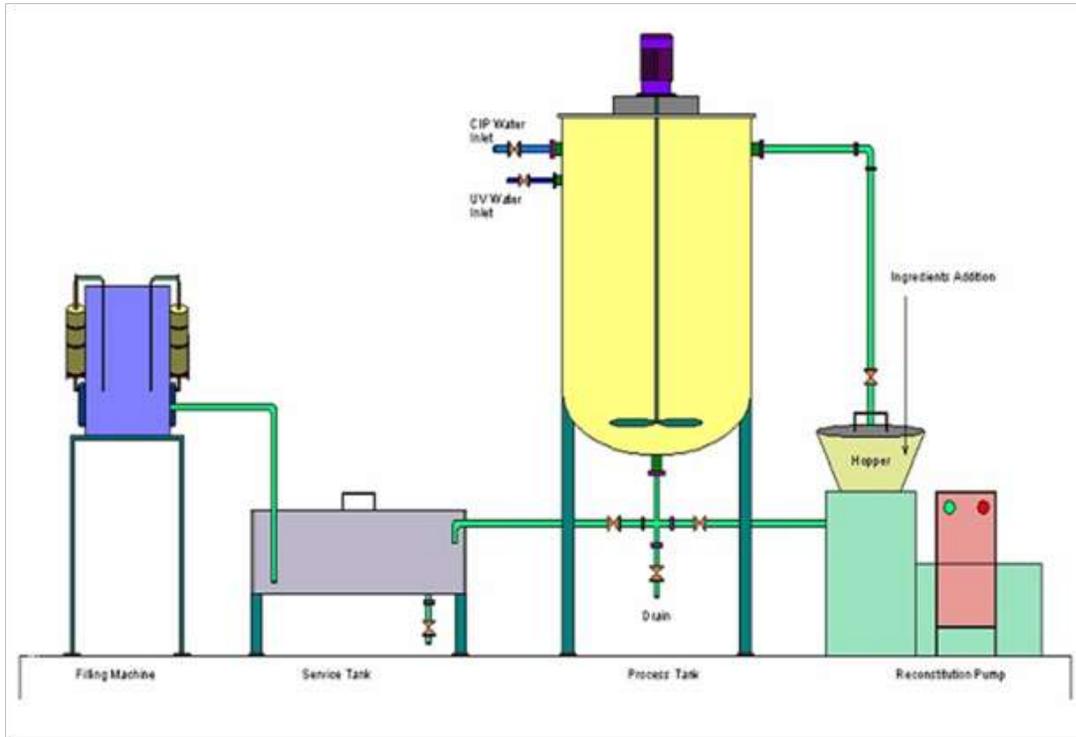
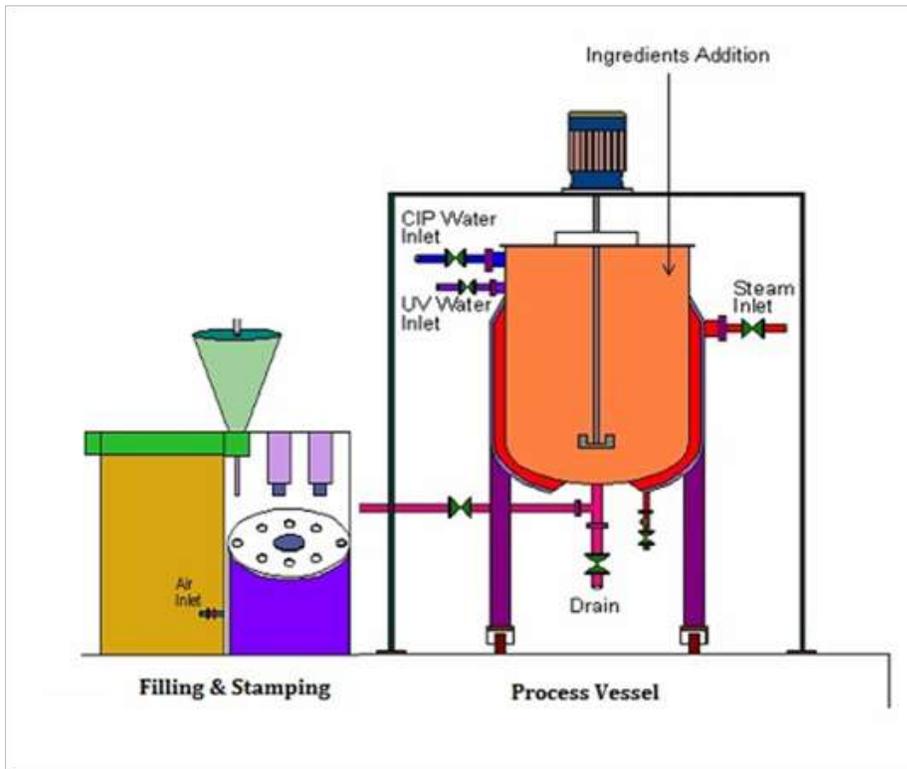


Figure 24: Phytomedicine value chain for Soap Formulation



Figure 25: Schema - Phytomedicine value addition for soap formulation



3.3.7 Value chain development

This section discusses all activities or steps undertaken in the value chain from the cultivation of medicinal plants to the availability of herbal medicine (final product). It highlights the possible actions surveyed enterprises may take to improve the quality and added-value of their products.

Cultivation has various different steps: the identification and authentication of cultivated medicinal plants, identification of cultivation conditions etc. For the cultivation of medicinal plants we should avoid the use of chemical fertilizers and chemical pesticides because they can seriously affect the quality of phytomedicines that are produced.

Having visited some coffee factories, we determined that no chemical testing is undertaken on their product. Coffee is normally consumed as a beverage, but it has interesting therapeutic effects (Lilly and Pizano, 2003). The determination of the level of active ingredients, especially caffeine and phenolic compounds will help to use coffee rationally. In addition, coffee waste is not properly managed (see Figure 28 below). Coffee pulp can be converted into nutrient-rich compost used to enrich fields and thus reduce

the need for synthetic fertilizers. Moreover, coffee wastewater (from the fermentation process) can be converted to biogas or renewable natural gas (Figuroa et al., 2016). This has a dual purpose: production of energy and reduction of pollution. The phytomedicine sector in Rwanda is facing environmental and energy management challenges. As an example, one tea factory can consume around 100 tonnes of wood per year to generate the energy needed in tea production. This has a significant environmental impact; the use of less environmental polluting energy sources such as renewable energy from agriculture waste or green energy should be encouraged.

Some natural pesticides, such as pyrethrum, *Azadirachta indica*, *Zanthoxylum chalybeum*, *Tagetes minuta*, *Tetradenia riparia* etc., are available in Rwanda and can efficiently replace chemical pesticides. According to AGROPY staff, there is a need to educate people about the benefits of using natural pesticides.

Figure26: Some steps in coffee production process: unused coffee waste (down left side)



The quality and possible value addition for phytomedicines from different categories needs to be discussed.

Product quality and standardisation is a cross-cutting issue in all categories of enterprises already described.

The development of local quality control laboratories specific for phytomedicine is highly recommended. Beside the standardisation of phytomedicine production process especially in A & B categories, value addition can be achieved through pharmacological and toxicology tests. This will help to scientifically

prove that the product is efficient, safe and can be registered by MoH. Proper packaging (in appropriate materials) and labelling of herbal medicine are key requirements for the development of all phytomedicines. At present, most of enterprises are using second hand packaging material and the cleaning process before reuse is probably inadequate. In addition, the most common packaging materials are transparent plastic bottles which may lead to the degradation of active ingredients sensitive to sun light exposure. Some plastic material can also react with the product or release potential harmful chemicals. This is case with bisphenol A (BPA) - found in consumer goods - which may cause human health problems.

It should be noted that plastic containers can still be used for some phytomedicines. One simple phytomedicine form is infusion, herbal tea or tisane. After the standardisation of the production process and estimation of adequate dose, fragmented plant material can be packed simply in plastic material. Preparation method as well as the dose for that herbal tea should be described on the label (see Figure 29).

Figure 27: An example of fragmented plant material available on the South Africa market from which an infusion used to treat asthma is made



Value addition is also needed for many enterprises producing essential oils. This is the case with SOPYRWA which has sufficient machineries and adequate technology in the production of various essential oil in raw form. Essential oils have various health benefits: they can be used in medicine for their different therapeutic activities (antiseptic, antibacterial, diuretic, antispasmodic, antidepressant etc.), in cosmetics (to balance and revitalise the skin), in cleaning and dentistry (for their antiseptic activity), and as flavouring, perfume or for their repellent activity, etc. Our survey identified only one enterprise making essential oil candle diffusers but also for some essential oil.

Tea factories, classified in category C, constitute the most developed value chain among all enterprises visited. However, even if some visited factories are ISO certified, they produce tea in raw form and this tea needs to be packaged by another company located in Kigali. Considering the fact that tea, particularly

green tea, is very rich in polyphenolic compounds having variable therapeutic activities, analysing and describing the level of total polyphenolic compounds and tannins and/or antioxidant activity from produced tea would act to add value². The laboratories in those tea factories should also be sufficiently well equipped to undertake microbiological tests.

² Another possible add value is to mix green tea with other active ingredients to obtained a needed therapeutic effect.

4.4 Output 4 – Conclusions and recommendations

4.4.1 Conclusions

The present study shows that the production of phytomedicines in Rwanda is at a very early stage of development and that production, with the exceptions of tea and coffee, is on the most rudimentary scale.

There is no enterprise in Rwanda which operates a modern, completely equipped phytomedicine plant which meets good manufacturing practice standards.

Enterprises operating in the phytomedicine sector can be classified into 3 categories based on the nature of their production processes and technology used – but the vast majority operate using entirely manual process without any form of automation. All categories of phytomedicines undertake some level of cultivation of medicinal plants, but the cultivation is often under-developed and makes use neither of GAPs nor organic farming precepts.

The private sector is the key player in the phytomedicine value chain with most enterprises seeking to add value to their respective products. Technology used in production of phytomedicine is still low (especially in small enterprises whose processes are often entirely manual or make use of low levels of automation). However, larger and more sophisticated enterprises (mainly in categories B2 and C) expressed interest in investing in new technology to meet GMPs.

In general, phytomedicines available on the market are well matched with the most common health problems in Rwanda.

The phytomedicine sector lacks effective quality control, standardization of products, or effective use of applied technology.

Additionally, the value chain suffers from the limited availability of raw materials, the low quality of raw materials, and the high cost of those raw materials. These input issues create irregularity of production and high production costs.

The sector is currently not well regulated, but MoH is planning to address this issue in the near future.

To summarise:

- Many phytomedicines are available on Rwandan market - but they are of low quality and are poorly packaged
- Many enterprises are operating in the phytomedicine value chain with limited or no machinery and technology – and the level of value-added is small
- Phytomedicine production has been demonstrated in other countries to be cost-effective source of medicines

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- Many phytomedicines are imported but similar products could be locally made – provided a higher quality, assured production of raw materials could be achieved.

The need to improve raw material production before significant processing growth could be achieved means that impact in reducing the import of medicines is a long-term goal. However, steps should be taken to support the sector as:

- The government of Rwanda has a “Made in Rwanda” policy to reduce the large gap between import and export
- The Government considers that phytomedicines have an important role to play in the health sector in Rwanda;
- WHO has identified the quality of traditional medicine as a priority in its health policy;

4.4.2 Recommendations

Recommendations for NIRDA

Recommendation	Justification
Recommendation 1: Pilot the use of machinery/technology to improve the productivity and competitiveness of phytomedicine production enterprises	Many people operating in phytomedicine sector do not have enough skills and experience in new machinery and technology used in the production of phytomedicines
Recommendation 2: Improve collaboration and networking with other national and international institutions involved in phytomedicine development and monitor trends in the phytomedicine sector.	NIRDA collaborates already with different institutions and organisations. However, there are other national and international organisations engaged in phytomedicine NIRDA could partner with to develop this sector.
Recommendation 3: Encourage knowledge and technology transfer in phytomedicine production to the private sector	According to the results from this study, the private sector is massively engaged in phytomedicine and the majority of visited SMEs expect technology support from NIRDA. Therefore, technology transfer is a good alternative NIRDA can use in supporting this sector. This can be done through Public Private Partnership (PPP) advocated by the government of Rwanda.

Recommendations for other Government Agencies

Recommendation	Justification	Agency
To initiate the standardization³ of phytomedicines	Standardization will help to adjust and harmonize the herbal drug preparation to a defined content of a constituent or a group of substances with known therapeutic activity by adding excipients or by mixing herbal drugs or herbal drug preparations	NIRDA, RBS & UR
To develop quality control laboratory for phytomedicine	Quality control will allow to get qualified phytomedicines which can be then registered under MoH	MoH, RBS, NIRDA & UR

³ Standardization of herbal medicines is the process of prescribing a set of standards or inherent characteristics, constant parameters, definitive qualitative and quantitative values that carry an assurance of quality, efficacy, safety and reproducibility

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Recommendation	Justification	Agency
To select some phytomedicines based on real local health problems	Local phytomedicine should be able to treat the most common diseases in Rwanda or diseases for which no or few efficient medicines are available	MoH
To establish clear regulation specific for phytomedicine	MoH has so far published traditional medicine policy but law and strategic plan are also needed to regulate this sector	MoH
To create a database of all SMEs and individuals engaged in phytomedicine	For better regulation a complete database of all individuals operating in phytomedicine is needed. So far none knows the total number of people dealing with phytomedicine and this sector plays a major role in health sector	MoH and MINICOM
To promote phytomedicine sector by integrating traditional medicine in health system as recommended by WHO	To efficiently promote phytomedicine sector, the integration of traditional medicine in health system is needed as recommended by WHO (WHO, 2013)	MoH
To compile a complete and relevant database of all SMEs really operating in phytomedicine. In contrast to the database from MoH should contain all individuals engaged in Phytomedicine sector whereas the database from RDB should include only companies or enterprises running a business in phytomedicine	So far, RDB doesn't have an adequate and complete database of all enterprises or companies doing business in phytomedicine	RDB
To sensitization and apply intellectual property in phytomedicine sector	RDB has a unit dealing with intellectual property but people like traditional healers are not aware and protected by this right.	RDB and NIRDA
To protect endangered medicinal plant species	According to traditional healers in Rwanda many herbal medicines are disappearing, strategy or program to protect and sustain them are highly recommended.	REMA
To apply the Nagoya protocol⁴ at all levels	Rwanda has signed Nagoya protocol but the implementation of it is still at embryonic stage	REMA
To promote agro-processing technologies to convert agricultural waste into value added products	Agriculture wastes are not properly managed and can be used to produce organic fertilizers or source of renewable energies which are more environmental friendly	MINAGRI and NIRDA

⁴ <https://www.cbd.int/abs/text/>

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Recommendation	Justification	Agency
To improve policies and strategies for conservation, proper harvesting, cost-effective cultivation and marketing of raw materials in order to protect, sustain and develop this phytomedicine sector	Policy and strategy related to conservation, harvest and cost-effective cultivation of medicinal plants will assure the availability of qualified raw material in phytomedicine sector	MINAGRI MINIREMA & RNRA
To educate and encourage the use of organic farming and natural pesticides in cultivation of medicinal plants	Organic farming and use of natural pesticide affect positively the quality of medicinal plants	MINAGRI, MINIRENA & REMA
To train people implicated in phytomedicine in GAPS and GMPs	Many people engaged in phytomedicine are not applying GAPS and GMPs which are needed to get qualified phytomedicine products	MINAGRI (RAB), UR and RSB

Perspectives – proposed possible NIRDA interventions to selected SMEs operating in Phytomedicine sector

As already mentioned, the purpose of this study is to clearly justify whether Phytomedicine sector is one in which NIRDA should intervene with technological support aimed at improving exports/reducing imports, and conclusion and recommendation section provides enough clarifications and advices. However, it is important to provide some guidelines on which SMEs NIRDA would technically support and how. This section provides possible interventions and some SMEs operating in Phytomedicine sector NIRDA could technically support.

NIRDA would not support all enterprises, just few SMEs were selected based on the probability an enterprise has to easily register his finish phytomedicine product under MoH, infrastructure and equipment and human resources.

Phytomedicine product registration under MoH is very important and should be taken in consideration. Indeed, no local produced phytomedicine will compete imported products if is not recognised and accepted by MoH in charge of pharmaceutical sector regulation. The registration of any pharmaceutical product including phytomedicine necessitates a list of requirements (on quality, efficacy, stability, safety and security, indication, side effects, contraindications, etc.) which are not easy to meet especially for a new product. However, registration process is less complicated for phytomedicine products from plant already recognized by pharmacopoeia and for food supplement or fortified food from plants.

The proposed interventions can be done in three ways:

- Supporting SMEs whose product(s) are already registered under MoH;
- Supporting SMEs in producing qualified dietary supplements or fortified food and;
- Supporting SMEs in improving the quality and productivity of raw material, which may be used to make a phytomedicine finished product.

SMEs whose product(s) are already registered or under registration process

In this category there is one society called SMGF Ltd, the only large-scale producer of Spirulina in Rwanda and having qualified staff especially in Research and Development unit. Spirulina contains interesting active ingredients and nutritional elements; it can be used as food, dietary supplement and nutritional supplement or as natural health product. This product is already on market, by the time we conducted this study the product was still under registration process as dietary supplement at MoH. Very recently, MoH approved the product, spirulina can be now legally used in Rwanda in case of malnutrition and related conditions. The society is looking now for RSB certificate to export local produced spirulina (see Figure 28). To improve the productivity and the quality of spirulina from SMBF, NIRDA can support by

providing adequate drying and grinding machines and facilitating in quality control especially the establishment of in house microbiological test laboratory to assure the safety for each produced batch.

NIRDA submitted already four phytomedicine-finished products (Calendular®, Rusendina®, Bantakor® and Gifurina®) for registration under MoH. Those products are in pharmacopoeia and are likely to be approved. However, NIRDA doesn't have mandate to produce pharmaceutical products as it is, but it can intervene through Public Private Partnership (PPP) advocated by the government of Rwanda. Within this framework, a PPP can be established between the farmer LABOPHAR drug factory particularly its non sterile drugs production unit and NIRDA on one public side and any private company willing to invest in the sector on the other side. LABOPHAR is public pharmaceutical plant having a capability to produce infusions as well as several types of non-sterile drug products like tablets, capsules, syrups, ointments and suppositories. This plant is no longer fully functional because of GMPs issue which can be handled. NIRDA has equipment and machineries which can be used also to produce some pharmaceutical dosage forms and supplement existing equipment and machineries from LABOPHAR. This proposed PPP convenes well with Domestic Market Recapturing Strategy (DMRS), Government's National Industrial Policy and National Export Strategy aiming at reducing Rwanda's trade deficit. NIRDA has the mandate to implement those strategies. Various studies have been already conducted on LABOPHAR and would help. A more specific technical study can be done to determine which phytomedicine(s) can be produced based on available infrastructure and equipment and on local need. We used to discuss with MoH stakeholders and NIRDA Pharmaceutical and Chemical Industries Division Manager, all of them are willing to valorise LABOPHAR production capacity in collaboration with private sector. Moreover, the results from this study show that private sector is massively implicated in phytomedicine sector. We know that some people propose to privatize LABOPHAR for production of modern medicines. However, based on the status of this plant, particularly its non-sterile drugs production unit we are now interested in, it can't compete with new upcoming pharmaceutical plants in Rwanda. This intervention is likely to impact on the importation of phytomedicines in Rwanda as it can help to establish the first typical phytomedicine plant in Rwanda.

SMEs producing dietary supplements or fortified food

The registration of dietary supplements or fortified food is easy since it require less drastic conditions. In this category we can select one SMEs, EDEN Business Centre which has already interesting infrastructure and equipment for the production of liquid forms (see Figure 16). NIRDA can intervene in standardization, quality control and by availing cost effective machineries specifically packaging machine.

Improving the quality and productivity of phytomedicine raw material

In this category we have:

- IKIREZI Natural Products producing organic essential oils for export. The produced essential oils will serve as raw material for the production of many finished products like medicines, cosmetics etc. This company has already interesting machineries and more than 10 years experience in production of qualified organic essential oil. NIRDA

Similarly, NIRDA may plan for the establishment of phytomedicine incubation centre. This process should come up with a registered product which can be "sold" to private sector for large scale production. Although there is no large-scale private producer of phytomedicines except tea companies, private companies will not hesitate to invest in since they will be dealing with legal products. Indeed, this sector clearly interests the private sector. However, the development of this incubation centre doesn't match with the Open Call process that is the basis of NIRDA's approved approach and would definitely involve another financial support.

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Annex 1: Technology needs forecasting information – interview guide

.	COMPANY GENERAL INFORMATION	
1	Company/ cooperative Name	
2	Legal status	Proprietor / Partner / Pvt. Ltd. / Public Ltd. / Cooperative Body / Others (specify) Registered YES NO
3	Sector/subsector	Health Bioagro
4.	Address Company: Company office	Sector District Province Sector District Province
5	Promoter name/phone	
6	Qualifications:	
7	Experience	Cultivation/Trading/ MFG/ phytomedicine /No experience
8	Promoters net worth	Mobil / fixed assets
9	Contact person name/position / telephone	
	HUMAN RESOURCES	
10	Number of employees Permanent employees Casual workers:	R&D planning: Sales/ marketing: Administration: Production
11	Qualification/number	University Technical school Other
12	CPD program	YES NO
	PRODUCTIVITY AND ECONOMIC DATA	
13.	Source of plant material	Cultivation / outsources / buying
14	Place of Cultivation (location of proposed land)	Sector District Province
15.	Cultivation practice	Organic farming/ chemicals / none
16.	GAPs	YES NO

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30	Suggested technology / machineries	1 2 3	
31	Promoters wants technology for	Phytomedicine / cosmoceutical / Health care/ agroceutical	
32	Main gaps in processing GMPs	Machineries Materials YES	Technicians NO
33	Technology target	New technology personnel Process Qualification Education / training	Specialized
34	Product improvement	New technology process Education/ training/ specialization	Novel product
35	For how many products technology required	(a) Cosmetic (b) Medicinal (c) Health care	No. of Products: No. of Products: No. of Products:
36	Express your future plan in improving technology	Internal R & D Training or hiring a specialized personnel R & D in collaboration with other institutions R & D contracted to external organization Purchase of know-how New equipment purchase Other (specify)	
37	Hindrances to develop innovative solutions	Information training Financing : self financing/collaboration/ subsidies Technology Others (specify)	Lack of
38	Participation in R&D financed projects foreseen	Pilot extraction purification Pharmaceuticals processing	Active ingredient
	QUALITY CONTROL		
39	The applied quality control	YES	NO
40	The applied quality control will satisfy	Totally the product specifications The basic specification Partially the product specification	

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		/ Sole Selling Agent/ Buyback arrangement
	FORECASTS	
57	Competition	YES NO
58	Evolution of the company	YES NO
59	Technological modernization	YES NO
60	Annual turnover	YES NO
61	Added value	YES NO
62	Product distribution	YES NO

Declaration

I/we solemnly declare that the information provided above are true to best of our knowledge and request **NIRDA** to suggest a suitable and technical support based on above information

Signature :
Name :

Date:

Place:

Stamp

*Above details and information are required to exactly assess and propose a suitable and profitable project and will be kept strictly confidential.

Note: You can avail additional shifts wherever it is necessary. Company structure and Diagram / Graphic Representation of the Production Process to be employed are annexed.

ADDITIONAL INFORMATION

Company structure (Organigram)

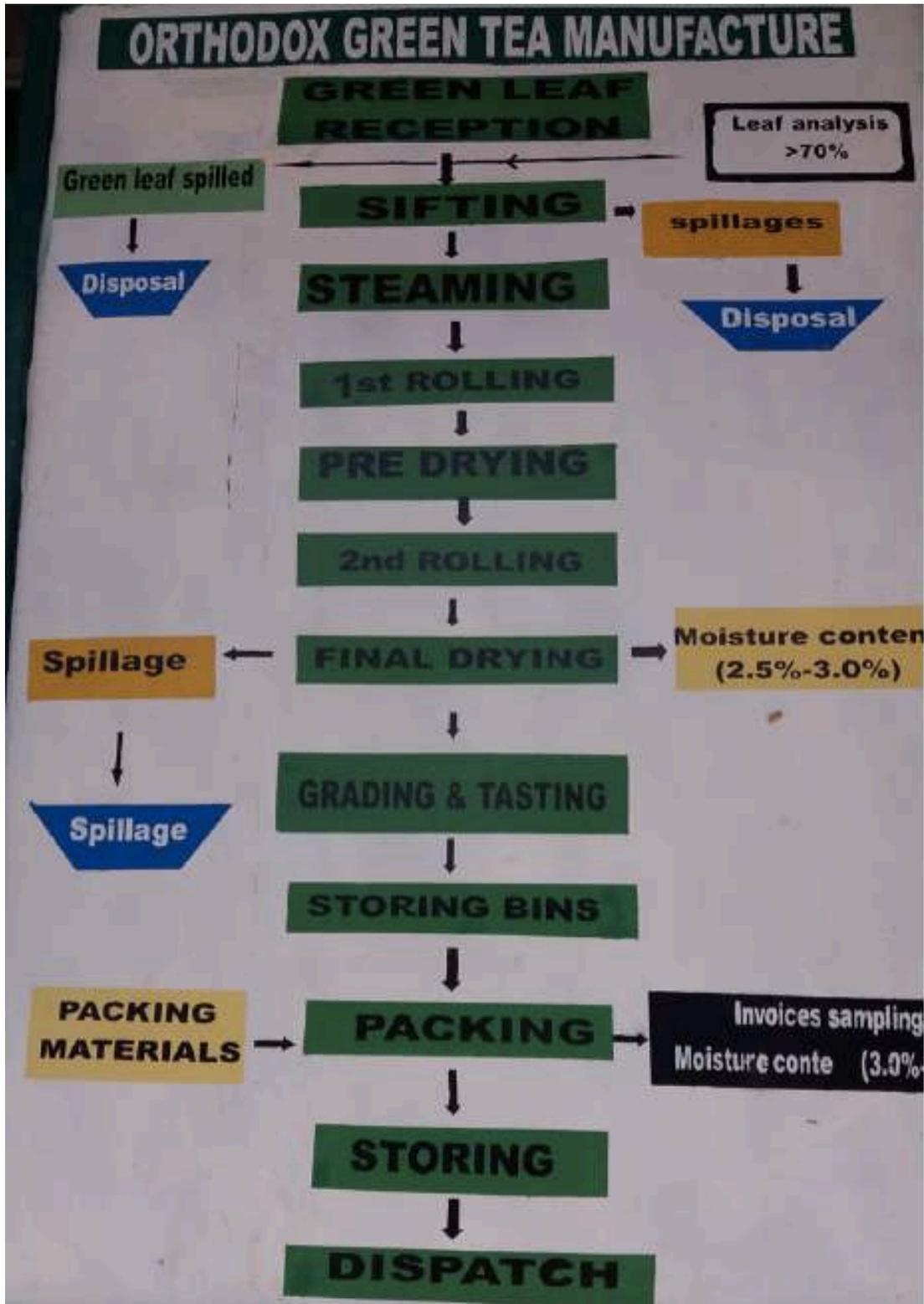
**Flow sheet
(Diagram / Graphic Representation of the Production Process to be employed)**

ANNEX 3: Letter from Ministry of Health suspending all illegal medical practices

Annex 2: Implementation schedule of field visits

Day	Starting point	Destination	Stay
Thursday 20/07/17	Huye	Huye - Nyaruguru	Huye
Friday 21/07/17	Huye	Ruhango - Muhanga	Huye
Monday 24/07/17	Huye	Kamonyi Kigali	Kigali
Tuesday 25/07/17	Kigali	Kigali Kabuga	Kigali
Wednesday 26/07/17	Kigali	Kigali	Kigali
Thursday 27/07/17	Kigali	Musanze Burera Pfunda	Rubavu
Friday 28/07/17	Rubavu	Nyabihu	Huye
Monday 31/07/17	Huye	Maraba Kitabi Gisakura	Rusizi
Tuesday 01/08/17	Rusizi	Kamembe Nyamasheke, Karongi	Karongi
Wednesday 02/08/17	Karongi	Karongi, Rutsiro, Kigali	Kigali
Thursday 03/08/17	Kigali	Kigali, Huye	Huye
Monday 07/08/17	Huye	Kigali	Kigali
Tuesday 08/08/17	Kigali	Kigali Rwamagana Kayonza	Ngoma
Wednesday 09/08/17	Ngoma	Ngoma	Kayonza
Thursday 10/08/17	Ngoma	Nyagatare	Kigali
Friday 11/08/17	Kigali	Kigali Bugesera	Kigali
Saturday 12/08/17	Kigali	Kigali Nyanza	Huye

ANNEX 3: Flow chart used in the production of green tea (category C)



ANNEX 4

