Study on Quality Issues of Medicinal and Aromatic Plants (MAPs) Sector in Nepal

A report submitted to,

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December 2013

Acknowledgments

I am deeply obliged to The Physikalisch-Technische Bundesanstalt (PTB) for the assignment provided me to conduct this study. I would like to express special appreciations to a number of individuals for their support and kind cooperation during the study period.

Firstly, I would like to express my sincere thanks to Dr. Julia Micklinghoff- Project Coordinator, Technical Cooperation in Asia (PTB), Dr. Ulrike Lechner (PTB) and Poonam Thapa (PTB) for their assistance, suggestions and feedback during the entire study period.

I am grateful to Anne Marie Saget (Independent-perfumer and active ingredients consultant, France), Alexandre Skibniewski (Biocosmethic, France) and Klaus Piotrowski (KruegerGourmet, Germany) and Walter De Boeck (Nateva, France) for providing me with the information on the quality requirements of MAPs and its products in EU.

I would like to acknowledge Jyoti Joshi (Bhatta) - Head, NPRL; Minoba Yonzon and Usha Rijal (HPPCL) for providing with the laboratory related information for the testing and analysis of MAPs and its products in Nepal.

My heartfelt thanks go to Dipesh Pyakurel for the information on MAPs trade and distillation units located at Taplejung and Rasuwa districts. Similarly, thanks are due to Bharat Basnet (Jhapa), Hem Narayan Chaudhary (Dang), Durga Datta Regmi (ELAM/Helvetas), Sheela Nepali (Jajarkot) and Purna Bohra (Jumla) for providing the information on distillation units and essential oils production in eastern and western Nepal.

At last but not least, I would like to thank MAPs farmers, collectors, processors and traders of Nepal who assisted me during my field visits during 2000-2013.

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December 2013

Table of contents

Abbreviations and acronyms

AEC: Agro Enterprise Centre

ANSAB: Asia Network for Sustainable Agriculture and Bioresources

APC: Advance Payment Certificate

ASTA: American Spice Trade Association

BS: Bikram Sambat

CAS: Chemical Abstracts Service

CBO: Community Based Organizations

CFUGs: Community Forest User Groups

CITES: Convention on International Trade of Endangered Species of Fauna and Flora

CNI: Confederation of Nepalese Industries

CO: Certificate of Origin

COA: Certificate of Analysis

COC: Chain of Custody

CPT: Custom Point Transit

CTD: Custom Transit Declaration

DDA: Department of Drug Administration

DFO: District Forest Office

DOF: Department of Forest

DPR: Department of Plant Resources

EIA: Environmental Impact Assessment

EINECS: European Inventory of Existing Commercial chemical Substances

ENPHO: Environment and Public Health Organization

ESA: European Spice Association

ESON: Ethnobotanical Society of Nepal

EU: European Union

FECOFUN: Federation of community forest user group, Nepal

FIFO: First in First out

FNCCI: Federation of Nepalese Chambers of Commerce and Industry

FSC: Forest Stewardship Council

FTIR: Fourier Transform Infrared Spectroscopy

GACP: Good Agricultural and (Wild) Collection Practices

GAP: Good Agricultural Practices

GC-MS: Gas Chromatography-Mass Spectrometry

GHP: Good Handling Practices
GLC: Gas Liquid Chromatography
GMP: Good Manufacturing Practices
GSP: Generalized System of Preference
HACCP: Hazard Analysis and Critical Control Point
HDPE: High Density Polyethylene
HPLC: High Performance Liquid Chromatography
HPLC-MS: High Performance Liquid Chromatography-Mass Spectrometry
HPPCL: Herbs Production and Processing Company Limited
HPTLC: High Performance Thin Layer Chromatography
ICIMOD: International Center for Integrated Mountain Development
IEE: Initial Environment Examination
IMO: Institute of Marketecology
INCI: International Nomenclature of Cosmetic Ingredients
IR: Infrared Spectroscopy
IUCN: The World Conservation Union
JABAN: Jadi Buti Association of Nepal
JAS: Japanese Agriculture Standards
L/C: Letter of Credit
LC: Liquid Chromatography
LC-MS: Liquid Chromatography-Mass Spectrometry
M/S: Mild Steel
MAPDON: Medicinal and Aromatic Plants Database of Nepal
MAPPA: Medicinal and Aromatic Plants Program in Asia
MAPs: Medicinal and Aromatic Plants
MEDEP: Micro-Enterprise Development Programme
MNS: Market News Service
MSDS: Material Safety Data Sheet
NASAA: National Association for Sustainable Agriculture, Australia
NAST: Nepal Academy of Science and Technology
NCC: Nepal Chamber of Commerce
NEHHPA: Nepal Herbs and Herbal Products Association
NESS: Nepal Environment and Scientific Services Private Limited
NMR: Nuclear Magnetic Resonance

NPQP: National Plant Quarantine Program
NPRL: Natural Products Research Laboratory
NRs: Nepalese Rupees
NTFP: Non Timber Forest Products
NTIS: Nepal Trade and Integration Strategy
OPLC: Over-Pressured Layer Chromatography
OSHA: Occupational Safety and Health Administration
OTL: One-Time-Lock
PAN: Permanent Account Number
PC: Phytosanitary Certificate
PRA: Pest Risk Assessment
PTB: Physikalisch-Technische Bundesanstalt
PTWI: Provisional Tolerable Weekly Intake
QI: Quality Issues
QTLC: Quantitative Thin Layer Chromatography
R&D: Research and Development
RA: Rainforest Alliance
REACH: Registration, Evaluation, Authorization and Restriction of Chemicals
RECAST: Research Center for Applied Science and Technology
S/S: Stainless Steel
SHP: Sustainable Harvesting Practices
SOP: Standard Operating Procedures
TDS: Technical Data Sheet
TEPC: Trade and Export Promotion Centre
TIA: Tribhuvan International Airport
TLC: Thin Layer Chromatography
UEBT: Union for Ethical BioTrade
UNDP: United Nations Development Program
US: United States
USDA-NOP: United States Department of Agriculture-National Organic Program
UV-VIS: Ultraviolet-Visible
VC: Value Chain
WFEN: Wildlife Friendly Enterprise Network
WHO: World Health Organization

CHAPTER ONE

1.1 Introduction

A medicinal plant is any plant used in order to relieve, prevent or cure a disease or to alter physiological and pathological process or any plant employed as a source of medications or their precursors. Aromatic plant refers to a plant with elevated level of volatile oil or essential oil. Essential oils in addition to being therapeutic value have wide applications in cosmetics and beauty products, flavors, fragrances and perfumery.

Nepal harbor rich flora due to altitudinal variation, climatic differences, varied topography and abundant ecological habitats. Nepal host around 7000 species of flowering plants (Press *et.al*, 2000). About 246 flowering plant species are endemic to Nepal. High altitude places, mostly alpine and sub-alpine regions, have the major share of the endemic plants. These regions possess around 131 endemic plants (Shrestha and Joshi, 1996).

In 1970, Nepal Government's Department of Plant Resources (DPR- previously known as Department of Medicinal Plants) published the first detailed survey of the medicinal plants found in Nepal and the number of the medicinal and aromatic plants (MAPs) species was estimated to be 483 (DPR, 1970). The medicinal and aromatic plants data base of Nepal (MAPDON) puts the number of MAPs in the wild, cultivated, imported and naturalized found in Nepal as 1624 (Shrestha *et.al*, 2000). A more recent publication records the number of the medicinal and aromatic plants found in Nepal as high as 1792 (Baral and Kurmi, 2006). Records of Department of Forests (DOF) reveal the total number of MAPs in trade to be 110. In general, the number of MAPs is considered to be 700 which is 10% out of estimated 7000 plant species.

In Nepal, the sub-tropical (54%) and tropical (49%) regions possess highest share of the MAPs followed by the temperate (36%), sub-alpine (18%) and alpine (7%) zones (Malla and Shakya, 1984).

The medicinal plants belonging to the sub-alpine and alpine regions are prized for their high medicinal values as well as their export potentialities. In these areas, these medicinal plants and herbs offer the subsistence income for the poor and marginalized community groups as well as contribute the revenue from their collection to the government.

Nepal has the long tradition of Ayurvedic medicinal practice. Besides Ayurveda, there are other important traditional medical systems such as Unani, Homeopathy and Tibetan medicine for health care delivery of the common people. Plants form the primary bulk of medicines in such traditional medical systems.

Continuous supply of the medicinal plants is crucial for manufacture of the medicines in such systems. High Himalaya to low Terai region has been contributing useful plants to such traditional medicinal systems since time immemorial.

On the other hand, Nepal is home to more than 59 culturally rich ethnic and indigenous groups. Majority of them have their own medical practices which were handed over to them orally from generation to generation. As in the scholarly traditional medical systems, plants form the mainstay of the folk medicine. In fact, the folk medicine employs more number of the plants than the plants used in the scholarly medical systems.

Medicinal plants constitute a source of raw materials for both traditional systems of medicine (such as Ayurvedic, Chinese, Unani, Homeopathy, and Siddha) and modern medicine. Nowadays, plant materials are employed throughout the industrialized and developing world as home remedies, over-the-counter drugs, and ingredients for the pharmaceutical industry and cosmetic industry. As such, they represent a substantial proportion of the global drug market. Most rural populations, especially in the developing world, depend on medicinal herbs as their main source of primary health care. Although most medicinal herbs are not, in their natural state, fit for administration, preparations suitable for administration are made according to pharmacopeia directions. The therapeutic potential of herbal drugs depends on its form: whether parts of a plant or simple extracts, or isolated active constituents. Herbal remedies consist of portions of plants or unpurified plant extracts containing several constituents, which often work together synergistically.

Despite all these potentialities of MAPs, quality control in every steps of value chain is equally essential for the efficacy and safety of herbal products. Quality has always been the issues for the effective promotion and marketing of MAPs and its products from Nepal. Therefore, the current study entails the detailed study on quality issues in MAPs sector to provide a reliable basis for further decisions regarding the activities and support of The Physikalisch-Technische Bundesanstalt (PTB) in MAPs sector in Nepal. PTB is the national metrology institute of Germany providing scientific and technical services. PTB measures with the highest accuracy and reliability-metrology as the core competence.

1.2 Objectives

The overall objective of the study is to assess the quality issue in each step of value chain of MAPs and provide necessary quality control steps to be adopted in Nepal. The specific objectives are as follows:

1. To provide a general overview of MAPs sector in Nepal.
2. To assess the quality issues in each step of value chain of MAPs.
3. To highlight the necessary quality control steps in the value chain for ensuring the high quality MAPs products.
4. To study the testing and analysis facilities for MAPs in Nepal.
5. To study the testing requirements of buyers vs analytical services provided in Nepal.
6. To study additional requirements from international buyers.

7. To recommend further steps to be taken to address the quality issues of MAPs in Nepal.

1.3 Methodology

The following methods were adopted during the study on quality issues of MAPs:

a. Literature review and compilation of the related documents

The relevant documents including WHO standards and guidelines, monographs, EU regulations and standards, related reports and research articles on MAPs, publications, legal/policy related documents, etc. were consulted and reviewed.

b. Discussion with MAPs value chain actors

Formal and informal interactions were conducted with MAPs value chain actors including- farmers involved in MAPs cultivation, collectors, traders at various levels, those involved in distillation/processing, exporters and manufacturers of herbal health care products etc. regarding the practices and procedures that they are adopting to find out the gaps to be fulfilled to conform with the accepted quality standards.

c. Interaction with quality testing bodies

MAPs and herbs products quality testing laboratories based in Kathmandu, such as Natural Products Research Laboratory (NPRL) at Department of Plant Resources (DPR), Natural Products Laboratory at Nepal Academy of Science and Technology (NAST), Herbs Production and Processing Company Ltd (HPPCL), and few private laboratories were visited and discussion was carried out regarding the available testing and analytical services and their planning to launch further tests as per the requisite for promotion of MAPs. Other private laboratories were consulted via telephone and e-mail.

d. Consultation with overseas buyers

Few EU and US based companies who deals with herbs, spices, essential oils, ingredients and cosmetic producers were consulted via e-mail to assess their quality and documentation requirements from suppliers.

CHAPTER TWO

2.1 Overview of MAPs in trade

MAPs and the processed products have both domestic as well as international markets. Three level of trading avenues for the medicinal plants have been identified. The first level is the national market where MAPs and products are traded. The second trade avenue is the informal trade of the MAPs and products across the national borders. The third avenue is the formal export trade of the MAPs and the processed products. Demand for the medicinal plants comes from the following sectors.

a. *Pharmaceutical companies*

Pharmaceutical companies require medicinal plants and herbs to process them into medicine. This is done through several ways. Medicinal plants are subjected to the separation process to obtain purified single drug. The drugs such as morphine/codeine (analgesics), emetine (emetic), quinine (antiparasitic), vinblastine/vincristine/taxol (antineoplastic), atropine (anticholinergic), artemisinin (antimalarial), etc. are all obtained in pure form from the plant sources.

At times, the compounds isolated from the plant will be made starting material in order to produce even more pharmacologically active substances. As early as in 1985, it was shown that there were 119 single component drugs derived from the medicinal plant in use worldwide. Interestingly, most of these medicinal plants had been identified by their use in the century old ethnomedical practices (Farnsworth *et.al*, 1985).

Natural products derived drugs occupied respectable position in worldwide selling of top 35 ethical drugs, 40% in 2000, 24% in 2001 and 26% in 2002. From 2000 to 2005, 20 new drugs either obtained or inspired from natural sources were marketed worldwide (Chin *et.al*, 2006).

Every so often, plant standardized extracts with the known active ingredients in almost fixed amount also serve as medicines. For example, Ashwagandha (*Withania somnifera*) containing active ingredients withanolides as adaptogen is widely used. For the production of such important medicines, substantial amount of the MAPs are traded globally.

b. *Traditional medical system*

Traditional medical systems such as Ayurveda, Traditional Chinese Medicine, Unani, Siddha, Tibetan, Kampo, etc. utilize the medicinal plants to produce traditional medicines. Up to 6000 medicinal plants are reported to have been used in the traditional Chinese medicine; however, commonly used plants range from 500- 600. In Ayurveda, around 1250-1400 plant species are used in the preparation of the medicines. Similarly, in Tibetan medicine 1106−3600 species, in Unani 342 species and in Siddha 328

species are likely to be used (Gewali, 2008). With the equal status given to the traditional Chinese medicine as the allopathic medicine in China and growing popularity of Ayurveda in the Indian sub-continent as well as the increasing universal attraction of the other forms of traditional medicine, one can visualize that the volume of the global requirement these medicinal plants will swell over the years.

c. *Folk medicine*

Folk medicines usually practiced by the indigenous and ethnic communities also require vast amount of medicinal plants for the production of the folk medicines. In comparison to the scholarly medical systems such as the Ayurveda and the traditional Chinese medicine, more numbers of plants are used in folk medicines for the health care.

d. *Alternative medicines*

Alternative medicine, also known as, complementary medicine has taken ground root in western countries. In such system, scientific evidence is sought for the traditional medical uses. Health foods, herbal teas and herbal tonics are in great demand in the western countries and Japan. Usually in order to avoid complex and expensive process of obtaining license as medicine, these products are sold as the health products or dietary supplements. Dietary supplements include vitamin, mineral, herb, amino acid, metabolite or plant extract. Nutrition providing products commonly known as nutraceuticals are in vogue. Foods are enriched with nutrients which are not natural to the food. There is growing demand for herbal creams, soaps and shampoos. For the preparation of such products, there is a global demand of the MAPs- worth about US$ 8.2 billion (Freedonia Group Inc., 2001(a)) annually.

e. *Aromatherapy*

Aromatherapy is the treatment or prevention of disease by use of essential oils. All essential oils are antiseptic; some have antiviral and anti-inflammatory properties as well. Essential oils promote natural healing by stimulating and reinforcing the body's own healing mechanism. For instance, Chamomile oil is credited for the ability to stimulate white blood cell production which helps to fight against diseases. Lavender oil has the ability to stimulate the regeneration of skin cells.

Essential oils also act on the central nervous system; some oils help the body to relax (Chamomile oil, Lavender oil), others act as stimulants (Basil oil, Rosemary oil). Few essential oils have the ability to normalize; Garlic oil can raise low blood pressure as well as lower high blood pressure.

Essential oils have three distinct modes of action with regard to how they interrelate with the body systems; pharmacological, physiological and psychological. The pharmacological effect is concerned with the chemical changes that take place when an essential oil enters the bloodstream and reacts with the hormones, enzymes, etc.

Physiological mode starts when an essential oil affects the system of the body, whether they are sedated or stimulated. The psychological effect takes place when an essence is inhaled and an individual responds to its odor. This implies that, it is not simply the aroma that works, but also the chemical interaction between the oil and the body which results the physical changes in the body. Now a days aromatherapy is widely practiced worldwide and regarded as a complementary modality for the treatment.

2.2 Worldwide trade of MAPs

Worldwide trade of the MAPs is overwhelming. Out of more than 50,000 medicinal plant species used globally, around 2500 species are estimated to be in trade. In 2010, the botanical and natural ingredient export trade reached approximately $33 billion, according to the Market News Service (MNS) “Medicinal Plant and Extracts” report, published in the MNS December 2011 bulletin. The total amount of money transaction of global MAPs and their products trade is believed to be in the range of US$ 70.5 billion with annual growth rate of 10 to 12%. By 2015, the international herb supplement and remedies market is expected to reach $93 billion, according to a report by San Jose, CA-based Global Industry Analysts, Inc.

European Union takes about 45% of world’s total share amounting to about US$ 32 billion. United States holds about 20% of the market share. Japan is shown to have around 11% of the total trade share; while the rest of Asia 17% and other 7%. The global trade of MAPs and their products is estimated to reach US$ 5 trillion by the year 2050.

2.3 Trade of MAPs in Nepal

Collection, processing, value addition and trading of MAPs have created employment opportunity and income generation in remote rural areas and also at the trading points in Nepal. Despite the fact that there is no exact figure on the employment generation in MAPs sector, it is estimated about 250,000 people are involved in the value chain of MAPs in Nepal (including both full time and part time employment).

Considering the fact that substantial amount of the MAPs trade is through informal channel and considerable trade figure does not end up in the Government record, exact figure of the trade is difficult to obtain. However, the data obtained from Department of Forest (DOF) reveals that a total of 58-85 MAPs species were in trade during fiscal year 2005/06 to 2011/012. Moreover, 1,675 tons to 3,336 tons of MAPs were traded generating the revenue of NRs. 13.97 to NRs 37.90 million during fiscal year 2005/06 to 2011/012.

Table 1. Traded volume and revenue of MAPs during 2005/06 to 2011/012

SN	Fiscal year	No. of species in trade	Trade volume (Kg)	Total Revenue (NRs)
1	2068-069 (2011/012)	58	1,675,450.452	13,979,566.95

2	2067-068 (2010/011)	66	2,833,808.449	23,987,266.00
3	2066-067 (2009/010)	63	2,098,936.265	19,118,024.90
4	2065-066 (2008/09)	74	2,092,279.665	37,905,195.10
5	2064-065 (2007/08)	85	3,336,606.10	27,594,829.80
6	2063-064 (2006/07)	78	2,573,206.06	15,706,370.50
7	2062-063 (2005/06)	82	2,766,922.10	14,318,553.50

Source: Department of Forest (2005/06-2011/012)

Approximately, 112 distillation units are in operation throughout Nepal distilling both wild harvest and cultivated aromatic herbs. Most of the distillation units are located in Terai regions which distill mostly cultivated aromatic herbs and few wild harvest aromatic plants harvested nearby forests (and community forests) and also transported from mid hills and high Himalayas. More than 100 distillation units are in operation in western Terai (Banke, Bardiya and Kailali) without registration. Field visits in distillation unit sites and also information provided by producers, traders and exporters revealed that - 21 items of essential oils are produced commercially in Nepal (which comprises of 11 items from wild harvest and 10 items from cultivated aromatic herbs). In average, it is estimated that 75 tons of essential oils (13 tons of Wild harvest essential oils and 62 tons cultivated essential oils) are produced every year in Nepal. Approximately 10% of crude herbs and essential oils are consumed in domestic market to be used in the production of ayurvedic products, health care products and other personal care products.

2.4 Procedures on MAPs collection and trade

Forest Act-1993 and Forest Regulation-1995 regulates the MAPs harvesting, processing and its commercial trade. Wild herbs are generally harvested from National forest and Community forest. District Forest Office (DFO) issues collection permit for the collection of MAPs from government forest or in pasture land and Community Forest User Groups (CFUGs) issue the permit for their collection from Community forest. For this, applicant has to submit an application containing details on the types of herbs, origin, collection quantity and purpose of the collection (domestic use or export). After getting permission from DFO, collectors and/ or traders can collect and store the same MAPs and quantity mentioned in the permission letter.

Collectors and/ or traders have to pay royalty of the collected quantity of MAPs to the DFO for release permit. This release permit is a proof of royalty payment by the traders for the domestic transportation. DFO only gives permit to those MAPs which are not prohibited for export/local commercial trade in raw or unprocessed form. If the MAPs are intended to export then exporter has to apply for the recommendation from the DFO to the concerned customs office at Nepal-India boarder.

For the export of processed MAPs (essential oils, extracts or it's by products), exporters need to obtain certification from Department of Plant Resources (DPR). Based on

laboratory analysis of the samples and applicants information, the containers are sealed and if the result is equivalent and satisfactory then DPR issues certification letter to concerned custom office to allow export of consignment.
Similarly, for the CITES (Convention on International Trade of Endangered Species of Fauna and Flora) listed species (or processed products), Department of Forest (DoF) issues CITES permit for the export.
As per the Plant Protection Act-1972 and Plant Protection Rules-1975, Phytosanitary certificate (PC) is mandatory for the export of MAPs from Nepal. Plant Quarantine Office issues Phytosanitary certificate before exporting MAPs. To obtain Phytosanitary certificate exporter has to submit an application to Plant Quarantine Office along with supporting documents like enterprise registration certificate, a release letter of DFO etc. Plant Quarantine Office makes arrangements to send its staff to the ware house for necessary sanitary examination of MAPs.
Phytosanitary certificate can be obtained from different Plant Quarantine Offices located at the Customs posts of Kakarvita, Biratnagar, Birgunj, Tatopani, Bhairahwa, Nepalgunj, Kanchanpur and Kathmandu (Tribhuvan International Airport).

2.5 Transportation of MAPs

Transportation inside the country from the collection centre to Road head or Terai trade centers have to pass through several check posts. These check posts examine the collected/harvested MAPs and the respective documents (DFO permit, release letter/CFUG's letter). If the transporter has necessary documents which match with transported MAPs only then MAPs are allowed to move further. If not both the transporter and goods are detained for further investigations. Multiple check points have been established just to verify the transporting of MAPs. Transit/Export permits of unprocessed MAPs has to be obtained from DFO.

2.6 Trading channels of MAPs

In general, trade channel of MAPs begins from the harvesters/collectors (CFUGs, herders, farmers), who function as the primary suppliers of the herbs. Herbs from the collectors then decentralize to the different tiers of stakeholders. Collectors have good knowledge on the available local resource, whose assistance in the marketing chain improves the economics of collection and increases the volume of the trade. After harvesting, MAPs are then transported to collection points (on man's back or by horse or mule) up to the road and air accessible areas located nearby the forest or sometimes 4-5 days walking distance from collection sites.
In remote north-western mountainous parts of Nepal MAPs from difficult steep dry slopes are transported to the collection point, the domestic airstrips which fly to south plain of the country. The major airstrips of MAPs are Gamgadi, Simikot, Jumla-Khalanga, Jufal and Jomsom in western Nepal. Except some exceptions from Jomsom almost all MAPs from these regions are transported to Nepalgunj and Surkhet airport.

Whereas, the collected MAPs from north-eastern parts are transported to Kakarvitta and Biratnagar via the trade points Ilam, Basantapur and Lahan.
From east to west Nepal, MAPs wholesalers are based in Kathmandu and the Terai plain cities at the Nepal-India boarder where road and air transportation facility is common. From Nepalgunj MAPs are transported to central wholesalers based in cities in Nepal Terai and some mid hills cities including Kathmandu.
Supply chain of MAPs between Nepal and China also takes place via the transit boarder of Taplejung, Sankhuwasabha, Dolakha, Sindhupalchok, Rasuwa, Gorkha, Mustang, Dolpa, Mugu, Humla and Darchula districts.
Taken from different intermediaries, Kathmandu based traders also supply many species of MAPs in national and international markets in various forms.
Between the source and the International markets, MAPs and herbs based products are handled by intermediaries at four levels. Village traders, road-head traders and Terai traders all three located in Nepal while fourth intermediaries are in India or overseas.

2.7 Value chain of MAPs

Major functions involved in the value chain of MAPs are input supply, production and local processing at farmers level (for cultivated items); collection, domestic trading and exporting at traders level (for wild harvest); and processing and manufacturing for value addition at processors/manufactures' level. The function of final processing and manufacturing is in limited form within Nepal. Some manufacturing companies involved in Ayurvedic productions, herbs based personal care producers, health care herbal products producers, etc. have been using MAPs and processed products as an ingredient in their various products.
In a value chain, the actors include the value chain operators and the operational service providers together. Those functionaries who are directly involved in transaction or directly support the actors who involved in transaction are the value chain actors.

a. *Input suppliers*: Input suppliers are those who provide inputs for the production of MAPs. Seed/seedlings, farm yard manure and labour are the major inputs for MAPs farming and are usually managed by farmers themselves. Chemical fertilizers (if used) are provided by fertilizer dealers existing in nearby market centres of farmers. Government agencies and non-governmental agencies provide technical knowhow and inputs in some extent to the farmers; however, the flow of information and inputs is not satisfactory.

b. *Farmers*: Farmer is the person or his/her family members who are engaged in growing, collecting and selling MAPs. Small commercial farmers are involved in small production volume but still targeting the market and large-scale farmers produce commercial production. The produce from small farmers generally does not enter the market directly. Small and large-scale commercial farmers sell most of their produce to

various market intermediaries. Farmers are also engaged in local processing of the MAPs such as essential oils.

c. *Collectors*: Collectors are the village farmers and/or members of community forest user groups who harvest MAPs from community or government forests. Collectors do the cleaning, drying and preliminary grading of MAPs they harvested

d. *Local processors*: Some farmers distil essential oils from cultivated aromatic herbs and also from few wild crafted herbs in distillation units and sell to the road-head traders or national traders.

e. *Road-head traders*: Road-head traders are those who are located at road-head and collect the MAPs from farmers and collectors. Road-head traders are usually from the local community and conducts trading activity of various goods including retailing of grains and foodstuffs. Most of the MAPs from road-head traders go to exporters who supply to India and some quantity goes to national traders.

f. *National traders*: National traders are those who have been active in trade of MAPs and products in national/domestic market. They get goods both from cooperative and road-head traders. Besides supplying goods to national markets, they also supply to exporters and national processors/manufacturer. Sometimes national traders directly provide goods to Indian commission agents.

g. *National processors/manufacturers*: National processors/ manufacturers are the firms which are engaged in producing herbs based products such as Ayurvedic products, herbs based personal care products, health care products and other products using MAPs as one of the ingredients. The products using MAPs as an ingredient like Ayurvedic medicine and health care products are sold locally to wholesalers or to wholesalers in India. Dabur Nepal, Gorkha Ayurved Company, Singh Durbar Vaidyakhana, Himalayan Bio Trade Pvt. Ltd etc. are some of the examples of the processors and manufactures.

h. *Exporters*: Exporters are those firms who have been doing export business of MAPs and its products. Major volume of MAPs and its products are exported to India and China, while few quantities are exported to overseas.

i. *Commission agents*: Most of the MAPs exported to India initially go to Indian commission agents who are based in major market hubs of India and border cities of Nepal. These commission agents usually take 5-6% as commission on the total sales amount. Depending upon the relationship with the exporters, payment of 50% is made

by the commission agent during delivery of goods. Rest of the payment is paid once the goods are sold completely by deducting the commission.

j. *Wholesalers*: Wholesalers are those who sell MAPs to retailers, products manufacturers, industries, and institutional users. MAPs wholesaler in Kathmandu is based in Kilagal.

k. *Retailers*: They are the traders who purchase MAPs from wholesalers and sell to end consumer. In Kathmandu most of the retailers of MAPs are based in Kilagal and Boudha areas and Krishna mandir area in Patan.

2.8 Exportable MAPs of Nepal

MAPs and herbs based products are one of the major export items from Nepal. Nepal's export of MAPs and products estimated over NRs. 2.5 billion per year contributing 4% of the total contribution of forestry sector to the national economy.
In terms of both volume and value, almost 80% of the crude herbs are exported to India and China through various southern and northern borders. Similarly, 80% of essential oils (approx. 60 tons of annual production) are exported to India, EU, USA. And approximately 10 tons of vegetal oils are exported to EU and USA annually.
Of the total 5000-7000 tons of exported MAPs resources from Nepal, most traded species includes: Chirayito (*Swertia chirayita*), Jatamansi (*Nardostachys grandiflora*), Kaulo (*Persea odoratissima*), Kutki (*Neopicrorhiza scrophulariiflora*), Majitho (*Rubia manjith*), Padamchal (*Rheum australe*), Pakhanved (*Bergenia ciliata*), Rittha (*Sapindus mukorossi*), Rudrakshya (*Elaeocarpus sphaericus*), Satavari/Kurilo (*Asparagus racemosus*), Satuwa (*Paris polyphylla*), Tejpat (*Cinnamomum tamala*), Timur (*Zanthoxylum armatum*) and Yarshagumba (*Cordyceps sinensis*) made up more than 80% of the total export. In addition to that illegal trade of the MAPs is rampant.
Similarly, the essential oils items that are exported to overseas market includes: Abies oil (*Abies spectabilis*), Anthopogon oil (*Rhododendron anthopogon*), Chamomile oil (*Matricaria recutita*), Citronella oil (*Cymbopogon winterianus*), French basil oil (*Ocimum basilicum*), Jatamansi oil (*Nardostachys grandiflora*), Juniper oil (*Juniperus indica*), Lemongrass oil (*Cymbopogon flexuosus*), Mint oil (*Mentha arvensis*), Palmarosa oil (*Cymbopogon martinii*), Wintergreen oil (*Gaultheria fragrantissima*), Zanthoxylum oil (*Zanthoxylum armatum*), etc. Vegetal oils that are exported include Chiuri butter (*Diploknema butyracea*) and Dhatelo oil (*Prinsepia utilis*).

2.9 Producers and exporters of MAPs

Almost 90% MAPs are harvested from wild. Major wild harvested MAPs includes: Atis (*Aconitum heterophyllum*), Jatamansi (*Nardostachys grandiflora*), Kutki (*Neopricrorhiza scrophulariiflora*), Padamchaal (*Rheum australe*), Satuwa (*Paris polyphylla*), Chirayito

(*Swertia chirayita*), Kurilo (*Asparagus racemosus*), Timur (*Zanthoxylum armatum*), Rittha (*Sapindus mukorrosi*), Yarshagumba (*Cordyceps sinensis*), Guchhi chyau (*Morchella conica*/*M*. *esculenta*), Pakhanved (*Bergenia ciliata*), etc.
On the other hand, few MAPs are being cultivated in private lands and community forests, mostly in low lands (Terai) of Nepal. Some cultivated MAPs include: Mentha (*Mentha arvensis*), Lemongrass (*Cymbopogon flexuosus*), Citronella (*Cymbopogon winterianus*), Palmarosa (*Cymbopogon martinii*), Chamomile (*Matricaria recutita*), French basil (*Ocimum basilicum*), Tejpat (*Cinnamomum tamala*), Chirayito (*Swertia chirayita*), Timur (*Zanthoxylum armatum*), Rittha (*Sapindus mukorrosi*), Kurilo (*Asparagus racemosus*), *Aloe vera*, etc.
Collectors harvest MAPs from community or government managed forest. In some locations, cooperatives or traders have established distillation units for the production of essential oils from few aromatic wild harvest herbs and cultivated MAPs. Whereas, the manufacturers of Ayurvedic products, herbal health care products and personal care products are based in urban areas.
Most of the exporting firms/companies market MAPs and products to India and China. Few companies exports MAPs and processed products to third countries. Exporters are located in Nepalgunj, Krishnanagar, Kathmandu. While, few of traders of high mountains and Terai regions export MAPs and essential oils to border areas of China and India these days. Lists of producers and exporters of MAPs and products are given in Box 1.
On the whole, there is no direct link between producers and importers.

Box 1: Major exporters of MAPs and herbal products

Major exporter of MAPs and herbal products

Aarya Aroma
P O Box: 4035, Kamaladi, Kathmandu
www.essencenepal.com

Alternative Herbal Products Pvt. Ltd
Balkhu, Kathmandu
www.alternative.org.np

Annapurna Aroma
Naya baneswor, Kathmandu
www.annapurnaaroma.weebly.com

Bahubali Herbal Essence and Extracts Pvt. Ltd.
Surkhet Road-2, Nepalgunj
www.nepalessence.com.np

Bheri Kirana Stores
Ward No. 5, Nepalgunj

Chaudhary Biosys (Nepal) Pvt. Ltd
P O Box No.: 8975 EPC 1352, Khumaltar-15, Lalitpur
www.biosysnepal.com

Classical Herbal Products Pvt. Ltd
Balaju, Banasthali Chowk, Kathmandu
www.ayuveda.com.np

Discover Nepal Exports Pvt. Ltd
Banasthali, Kathmandu
www.dnexports.trustpass.alibaba.com

Everest Aroma Industries Pvt. Ltd
Chabahil, Kathmandu

Fauz Mohamad and Company
Ward No. 5. Ghosi Tole, Nepalgunj

Gajurmukhi Herbal Pvt. Ltd
Mechi Municipality-10, Jhapa

Gorkha Exim Pvt. Ltd
Balaju-16, Kathmandu
www.gorkhaexim.com

Gyan Herbal Products Pvt. Ltd
PO Box: 1991, Charkhal, Dillibazar, Kathmandu
www.kldugargroup.com

Herbs Production and Processing Co. Ltd
Koteswor, Kathmandu

Himalayan Bio Trade Pvt. Ltd
P O Box: 8941, Dhapasi-7, Block No.: 108, Kathmandu
www.himalayanbiotrade.com

Himalayan Herbs Traders P. Ltd
P O Box: 7823, Baluwatar, Kathmandu

Khaptar Aroma Industries
P O Box: 3149, Putali sadak, Kathmandu
www.khaptarherbs.com

Male' International Pvt. Ltd
P O Box: 20279, Kusunti, Lalitpur
www.male.com.np

Natural Products Industries
Jawabhari-3, Kapilbastu

Natural Resource Industries Pvt. Ltd
P O Box: 410, Purano Baneswor, Kathmandu
www.essentialoil.com.np

Rapti Herbals Wood and Food Traders
Karkandu-5, Nepalgunj

Satya International
Gaganganj-8, Peepal Chowk, Nepalganj
www.satyaherbs.com

Shambhala Herbal and Aromatic Industry Pvt. Ltd
P O Box: 4794, Boudha Mahankal, Kathmandu
www.shambhala.com.np

Simko Traders/Jain Exporters
Nepalgunj

Unique Himalayan Herbs International Pvt. Ltd
P O Box: 23162, Mitranagar, Bauddha, Kathmandu
www.herbsonweb.com

Wild Earth Pvt. Ltd.
P O Box: 2187, Kathmandu
www.wildearthnepal.com

2.10 Procedures for the export of MAPs

a. *Export via land/sea*

MAPs exporting to India is not much complex. Clearance at the customs offices and checking posts at the boarder are sufficient.

- For third countries export via India, requires further clearance procedures at Nepal/India boarder, Kolkata port and Bangladesh port.
- From Nepal/India boarder export of the materials to the destination normally undertaken by authorized agents.
- Exports are permitted only against Advance Payment or Letter of Credit (L/C) to ensure that the payment for the MAPs and its product is received in Nepal. L/C copy or Advance Payment Certificate (APC) should be authenticated by the concerned Nepalese commercial bank.
- Nepal customs release export shipments only after verifying the bank Certificate of Advance Payment or L/C copy certified by a commercial bank.
- On all exports, Certificate of Origin (CO) should be submitted to Nepal customs at boarder. CO is issued by Nepal Chamber of Commerce (NCC), Federation of Nepalese Chambers of Commerce and Industry (FNCCI) or Confederation of Nepalese Industries (CNI).

b. *Documents for the Nepal boarder customs*

Exporter has to submit following documents for the Nepal boarder customs:

- Custom Transit Declaration (CTD) in quadruplicate duly endorsed by Nepal customs office (yellow copy)
- Nepal Customs Export Declaration
- Commercial Invoice
- Packing List
- L/C or Certificate of Advance Payment
- Certificate of Origin
- Generalized System of Preference (GSP) or Form A
- Certification from Department of Plant Resources (for processed products and by-products)
- Enterprise Registration Certificate
- Income Tax Registration Certificate/Permanent Account Number (PAN)
- Phytosanitary Certificate (PC)
- Authorization letter in the name of forwarding agent.

After checking all the necessary documents with the consignment, the Nepal customs office endorses the CTD. Exporter has to pay the custom charges to get clearance. Only then cargo moves to Indian boarder customs office.

c. *Documentation for Indian custom office*

Exporter or clearing agent has to submit following documents in the Indian custom office at the Indian boarder:

- The declaration included in CTD duly endorsed by the Nepal Customs
- Original Invoice
- Packing List
- Authority letter of clearing agent in the name of forwarding agency
- Certified copy of L/C or Certificate of Advance Payment

The One-Time-Lock (OTL) of containerized cargo towards third country is checked and if found intact is allowed further transportation.

- As to the non-containerized goods, such goods is verified and examined on the basis of CTD. If found correct the consignment is cleared for further transportation.
- All the four copies of CTD are endorsed by the Indian boarder customs. Out of the four, two copies (second and third) are sent to the Kolkata customs. The first copy is returned to the exporter/clearing agent and the fourth copy is retained with the customs office for the record.
- After full examination container moves to Kolkata port, the main exit for overseas.
- At Kolkata all the related files endorsed by Nepal-India boarder custom office are filed and compared to the original CTD with the duplicate and triplicate copies received in a sealed envelope taken by clearing agent.
- After documents are cleared by the Kolkata Customs, Custom Point Transit (CPT) approval is obtained for taking the cargo inside the port.
- The cargo is then taken inside the port where the customs checks seals and locks on the wagons or containers and packages, and compares with the declaration made on CTD.
- Then the cargo is handed over to the ship's agent inside the port. After necessary endorsements, customs gives back the original, duplicate and triplicate copies of CTD to clearing agent who takes them again to the Kolkata customs.
- After Kolkata customs makes necessary entries on all copies, the original is handed back to clearing agent for submission to the border customs, the triplicate copy is sent to the border customs and the duplicate copy retained for records.

d. *Export via air*

Tribhuvan International Airport (TIA), Kathmandu, is the only international gateway for exporting goods by air in Nepal.

Following documents has to be submitted by exporter or clearing agent for customs examinations at TIA:

- Nepal Customs Export Declaration
- Original Invoice
- Packing List

- Certified copy of L/C or Certificate of Advance Payment
- Certificate of Origin
- Generalized System of Preference (GSP) or Form A
- Enterprise Registration Certificate
- Certification from Department of Plant Resources (for processed products and by-products)
- Income Tax Registration Certificate/Permanent Account Number (PAN)
- Phytosanitary Certificate (PC)

Based on the examination of necessary documents provided by exporter or clearing agent, the cargo is sealed and cleared for storage by customs. For loading of the cargo into a container, exporter has to reserve space with the concerned airlines. Only after that loading of the cargo into a container truck is allowed. After checking and sealing of the container truck by the customs, the cargo is transported to the apron area and unloaded there.

2.11 Major markets of MAPs

The major importing countries of the MAPs (herbs and spices), essential oils and vegetal oils of Nepal include: India, China (including Hong Kong), Pakistan, Bangladesh, Singapore, UAE, Japan, Korea, Taiwan, Australia, New Zealand, Germany, Switzerland, France, Sweden, Finland, Czech Republic, Hungary, Spain, Italy, Netherlands, Belgium, UK, Canada, USA, etc. Majority of the buyers are the ingredients suppliers and few are manufacturers of health care products, personal care and beauty care products.

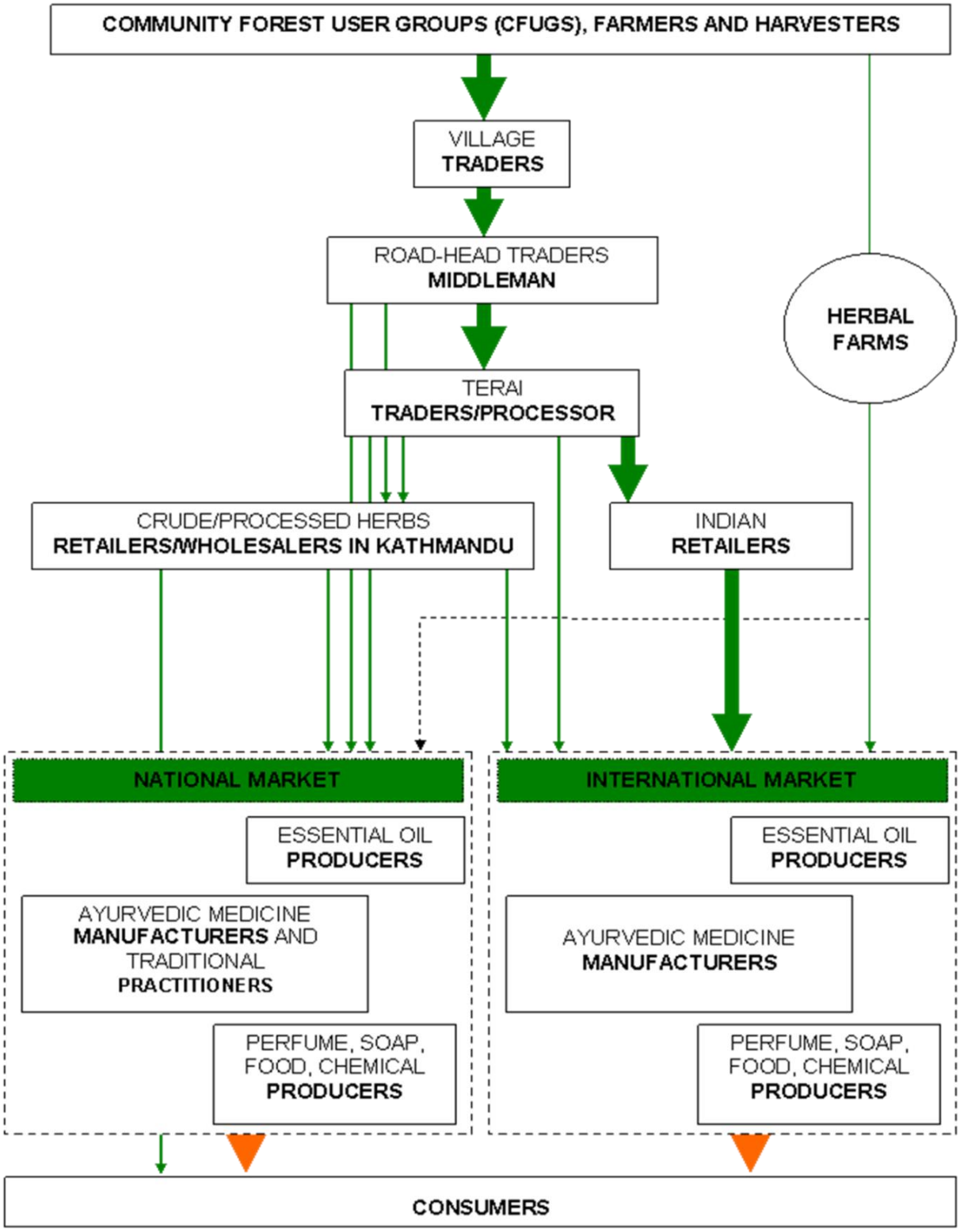

Figure 1: Conventional market chain of MAPs in Nepal

CHAPTER THREE

3.1 Policies and regulations

In 1993, the World Health Organization (WHO) sponsored a symposium on the use of medicinal plants. The result was a standard guideline for the assessment of herbal medicines and a recommendation that governments of the world should protect medicinal plants, improve regulation of herbal medicines, and respect traditional medicine approaches.

With proper enforcement of regulations, more products that are legitimate will enter the market and the consumers will see justifiable claims on labels. In fact, it is predicted that appropriate regulations will rejuvenate the market in response to growing concerns about the regulatory environment for herbal remedies.

3.2 Legislation and policies related to MAPs in Nepal

Acts and policies related to collection, processing, trade and export of MAPs in Nepal are as:

- Convention on International Trade of Endangered Species of Flora and Fauna (CITES), 1975
- Customs Act, 2064 (2007)
- Environment Protection Act, 2053 BS (1997)
- Environment Protection Rules, 2054 BS (1998)
- Export Import Regulations, 1997
- Forest Act, 1993 and Forest Regulation, 1995
- Forest Inventory Guidelines, 2057 BS (2000)
- Herbs and Non Timber Forest Products (NTFP) Development Policy, 2004
- IEE/EIA Review Guidelines for Forestry Sector, 2060 BS (2003)
- Industrial Enterprise Act, 2049 BS (1992)
- Industrial Regulation, 2070 BS (2013)
- National Drug Policy, 1995
- National Parks and Wildlife Conservation Act, 1993
- Nepal Biodiversity Strategy, 2002
- Nepal Trade and Integration Strategy (NTIS), 2010
- NTFPs Inventory Guidelines, 2012
- Patent, Design and Trademark Act, 2022 BS (1965)
- Plant Protection Act, 2029 BS (1972)
- Plant Protection Act, 2064 (2007)
- Plant Protection Rules, 2031 BS (1975)
- Procedural Guidelines for the sale of Forest Products, 2060 BS (2003)
- Trade Policy, 2009

3.3 Regulation of herbal products

In accordance with the Nepal Drug Act- 1978, all the pharmaceutical products including herbal medicines are regulated. Department of Drug Administration (DDA) under the Ministry of Health and Population is the national regulatory authority. In addition, for regular testing, analysis and research of the pharmaceutical products, the Government has established a National Reference Laboratory. As far as the registration of domestic pharmaceutical products are concerned, the requirements include a letter of recommendation for establishing a drug industry and obtaining product license, registration for manufacture and sale of the products in compliance with national guidelines for good manufacturing practices (GMP). For the imported products, the registration of the sale and distribution of the products as well as a letter of recommendation for import of drugs in compliance with WHO good manufacturing practices (GMP) guidelines are required.

3.4 Ayurveda health policy

With objectives to improve the health condition of the people at large and making them self-reliant on health service by exploiting huge natural medicinal resources available in the country, Ayurveda Health Policy came into existence in 1996. It has committed to improve upon qualitatively and quantitatively the Ayurveda related infrastructures such as Department of Ayurveda, central and district Ayurvedic hospitals, Singh Durbar Vaidya Khana, the Ayurvedic dispensaries and other private organizations. The policy has emphasized on herb farming, production of herbal medicines and development of herbal medicine based enterprises. Ayurvedic human resources of high quality in the fields of education, health and preparation of medicines are envisaged to be produced. The policy points out the necessity for establishing an international standard Ayurvedic research institute for doing meaningful and useful Ayurvedic researches.

Government of Nepal, Department of Ayurveda in collaboration with WHO has published "The Ayurvedic Pharmacopoeia of Nepal" in 2003.

Some widely referred international pharmacopoeias are given in Box 2.

Box 2: Some international pharmacopoeias

International pharmacopoeias:

- The Ayurvedic Pharmacopoeia of India, Government of India, Ministry of Health and Family Welfare Department of Ayush.
- *Pharmacopoeia of India*, New Delhi, The Controller of Publications, 1985.
- *European Pharmacopoeia*, 5th ed. Strasbourg, European Directorate for the Quality of Medicines, Council of Europe, 2004.
- *The Japanese Pharmacopoeia*, 14th ed. (English ed.). Tokyo, Ministry of Health,

Labour and Welfare, 2001.
- *The Korean Pharmacopoeia*, 8th ed. (English ed.). Seoul, Korea Food and Drug Administration, 2002.
- *Pharmacopoeia of the People's Republic of China. Vol. I* (English ed.). Beijing, Chemical Industry Press, 2005.
- *Pharmacopoeia of the People's Republic of China. Vol. 2* (English ed.). Beijing, Chemical Industry Press, 2005.
- *Thai Herbal Pharmacopoeia*, *Vol. 1*. Bangkok, Department of Medical Sciences, Ministry of Public Health, 1998.
- *Thai Herbal Pharmacopoeia*, *Vol. 2*. Bangkok, Department of Medical Sciences, Ministry of Public Health, 2000.
- *The United States Pharmacopoeia 28 and the National Formulary 23*. Rockville, MD, The United States Pharmacopoeia Convention, Inc., 2004.
- *British Herbal Pharmacopoeia,* Part 2, London, British Herbal Medicine Association, 1979.

3.5 Research, development and promotional institutions and associations

There are several government, non-governmental, academic institutions, associations and private organizations involved in research, development and promotional activities of the MAPs in Nepal. The following are some of the major organizations:

a. *Academic institutions*

In the academic sector, four universities in one way or the other are in the MAPs teaching and research. Tribhuvan University established in 1959 is the oldest and the largest university of Nepal. The major departments that are engaged in the MAPs teaching and research in Tribhuvan University are Central Department of Botany, Central Department of Chemistry, Central Department of Microbiology, Central Department of Environmental Science and Research Center for Applied Science and Technology (RECAST). Kathmandu University is a private university established in 1990 and its Pharmacy Department runs programs in natural products teaching and research. Similarly, newly established universities such as Purbanchal University and Pokhara University have programs related to the medicinal plants studies and research. Nepal Sanskrit University has been cultivating medicinal plants since long time.

b. *Nepal Academy of Science and Technology (NAST)*

Nepal Academy of Science and Technology (NAST) is an autonomous apex body for the development and promotion of science and technology in Nepal. Its MAPs related activities include bioprospecting of the Himalayan medicinal plants and *in situ*

conservation of germplasm of medicinal and aromatic plants, development of cultivation techniques and transfer of appropriate technology to the local communities.

c. *Department of Plant Resources (DPR)*

Department of Plant Resources (DPR) previously known as Department of Medicinal Plants was established in 1960. This institute is the leading Government body for providing services in research and development of the plant resources in the country. The major responsibilities of Department of Plant Resources include surveying and collecting of plant resources and preserving the specimens in the National Herbarium, maintaining botanical gardens, carrying out chemical and biological researches with an aim to optimum utilization of MAPs and other plant resources, conducting biotechnology research to improve the plants of economic value and developing agro technology on plants and providing services to the farmers on techniques of commercial cultivation of important MAPs.

d. *International Center for Integrated Mountain Development (ICIMOD)*

Established to work towards economically and environmentally sound mountain development as well as to improve living standards of mountain communities, ICIMOD has taken over Medicinal and Aromatic Plants Program in Asia (MAPPA). MAPPA's activities are geared towards creating a system of long-term sustainable and equitable uses of the MAPs resources in Hindu Kush Himalayan regions.

e. *Asia Network for Sustainable Agriculture and Bioresources (ANSAB)*

The Asia Network for Sustainable Agriculture and Bioresources (ANSAB) is an independent, not for profit, international organization based in Kathmandu, Nepal established in 1992. Focusing on natural resource management and economic development, ANSAB is working towards sustainable use and management of non-timber forest products (NTFPs) supporting the development of viable community based forest enterprises.

f. *Ethnobotanical Society of Nepal (ESON)*

With the aim of enhancing the study and promoting the proper utilization of plant resources in Nepal, a group of Nepali ethnobotanists established Ethnobotanical Society of Nepal (ESON) in 1997. ESON is working to promote plant based research activities through information exchange among plant scientists and institutions at national and international levels; increase public awareness on different issues related to indigenous knowledge and ensure intellectual property rights; strengthen community's capacity through training programs for both skill and leadership development and cultivate MAPs of economic importance.

g. *The World Conservation Union, IUCN, Nepal*

IUCN, Nepal is in the conservation arena in Nepal since late 1960s, working with the objectives to promote biodiversity conservation, environmental justice and sustainable livelihood. IUCN, Nepal has published *National Register of Medicinal Plants* in 2000.

h. *Jadi Buti Association of Nepal (JABAN)*

Jadi Buti Association of Nepal (JABAN) is an umbrella organization of herbs and herbs based products traders, established in Nepalgunj (western Nepal) in 1995. Nepalgunj is major trade center of herbs in western Nepal. JABAN strives for the conservation of the natural resources and provides support to the rural communities for the MAPs cultivation. It works for the production of quality materials as well as prompt and efficient services and supply for the buyers. JABAN has more than 300 members.

i. *Nepal Herbs and Herbal Products Association (NEHHPA)*

Nepal Herbs and Herbal Products Association (NEHHPA) is an umbrella organization of herbal entrepreneurs, established in 2002. Advocating the advantages associated with herb and herbal business, NEHHPA intends to participate in the economic development of the nation through the medium of sustainable business of herbs and medicinal plants. It organizes herb related seminars and workshops, publishes a magazine *Prakrit* and lobby on herb related policy issues with the Government agencies. About 40 members are affiliated to NEHHPA.

j. *Nepal Traditional Ayurvedic Medicinal Practitioners Association*

The association aims to work towards passing valuable traditional practices to the new generations through well managed Ayurvedic institutions, campaign to generate awareness and knowledge about the efficacies of the herbs, reduce adulteration in the herb and herbal products and assist the Government for preparing and implementing the policies that address the conservation of traditional practices and the potential herbs. This association has membership of 55 traditional Ayurvedic practitioners and manufacturers from all over Nepal.

k. *Himalayan Amchi Association*

Himalayan Amchi Association was established in 1998 with the aim of preserving and consolidating the knowledge and skills represented by traditional Himalayan healers and Tibetan medicine in order to provide local communities with an effective health care system. Its major activities are to campaign for the recognition and support of the Tibetan medicine, provide trainings and other forms of medical education, put effort to provide efficient health care delivery to the communities, work towards conservation, cultivation and sustainable utilization of medicinal plants, undertake activities on

documentation and research of the medical practices and associated knowledge and to work towards protection of intellectual property.

l. *Trade and Export Promotion Centre (TEPC)*

Trade and Export Promotion Centre (TEPC) is established under Ministry of Commerce and Supplies with the objective of promoting foreign trade in general and export trade in particular of the country.

m. *Agro Enterprise Centre/Federation of Nepalese Chambers of Commerce and Industry (AEC/FNCCI)*

FNCCI has created AEC as an autonomous unit in 1991. It has its own optimal guidelines, policies and program approval is given by a separate board comprising of FNCCI executive members, representative from District Chambers of Commerce & Industry, commodity associations, permanent invitees from various related government agencies and donors. The mission of AEC is to expand and strengthen market oriented private sector driven agro enterprises in order to increase the value and volume of high-value products marketed domestically and internationally.

n. *Micro-Enterprise Development Programme (MEDEP)*

Micro-Enterprise Development Programme (MEDEP) is a multi-donor funded poverty reduction initiative implemented by the Government of Nepal with the technical and financial support of United Nations Development Program (UNDP), started in 1998. The programme helps to improve the livelihood of the poor and excluded communities by creating various income generating opportunities through skill development trainings and support to establish small business enterprises.

CHAPTER FOUR

4.1 Quality issues in the value chain of MAPs

Quality is the status of a product that is determined by identity, purity, content, and other physical, chemical, or biological properties, or by the manufacturing processes. Quality control refers to processes involved in maintaining the quality and validity of a manufactured product.

Strict guidelines have to be followed for the successful production of quality products. The quality of a MAP product is determined by the prevailing conditions during growth, and accepted Good Agricultural Practices (GAP) can control this. These include seed selection, growth conditions, use of fertilizers, harvesting, drying and storage. In fact, GAP procedures are, and will be, an integral part of quality control.

Factors such as the use of fresh plants, age and part of plant collected, period, time and method of collection, temperature of processing, exposure to light, availability of water, nutrients, drying, packing, transportation of raw material and storage, can greatly affect the quality, and hence the therapeutic value of herbal products.

Apart from these criteria, factors such as the method of extraction, contamination with microorganisms, heavy metals, and pesticides can alter the quality, safety, and efficacy of herbal products. Sometimes the active principles are destroyed by enzymatic processes that continue for long periods from collection to marketing, resulting in a variation of composition. Thus proper standardization and quality control of both the raw material and the herbal preparations should be conducted.

In this regard producers/collectors, processors, and traders of MAPs or herbal products have an obligation and a role to play. The manufacturers and suppliers of herbal products should adhere to quality control standards and good manufacturing practices.

4.2 Good agricultural practices for MAPs

A general guideline on good agricultural practices for medicinal plants (WHO, 2003) is widely accepted for the cultivation of MAPs. It describes general principles and provides technical details for the cultivation of MAPs and also describes quality control measures.

1. *Identification/authentication of cultivated MAPs*

1.1 Selection of MAPs

MAPs selected for cultivation should be the same species as that specified in the national pharmacopoeia or recommended by other authoritative national documents of the end-user's country. In the absence of such national documents, MAPs should be

selected as specified in the pharmacopoeia or other authoritative documents of other countries.

Practice in Nepal: *MAPs selected for cultivation is based on the practice of the adjoining states of India. Sometimes the species are not properly identified. Furthermore, species are not properly identified during domestication from wild.*

1.2 Botanical identity

The botanical identity- scientific name (genus, species, variety) - of selected MAPs under cultivation should be verified and recorded. If available, the local and English common names should also be recorded.

Practice in Nepal: *The botanical identity of cultivated MAPs is not recorded. DPR has only recorded the species that are cultivated in demonstration plots.*

1.3 Specimens

A voucher botanical specimen of selected MAPs should be submitted to a regional or national herbarium for identification and comparison to that of an authentic specimen.

Practice in Nepal: *There is no awareness among farmers about the voucher specimen of MAPs to be submitted to national herbarium at DPR for identification.*

2. *Seeds and other propagation materials*

Seeds and other propagation materials should be specified, and suppliers of seeds and other propagation materials should provide all necessary information relating to the identity, quality and performance of their products. The propagation materials should be as free as possible from contamination and diseases in order to promote healthy plant growth. Seeds and other propagation materials used for organic production should be certified as being organically derived.

Practice in Nepal: *Farmers are not receiving enough information on the seeds and propagation materials, as a result the yield are lesser than it is claimed and product quality may be inferior. There are no organic certified seeds and propagation materials of MAPs supplier in Nepal.*

3. *Cultivation*

If scientific published or documented cultivation data of selected MAPs are not available, traditional methods of cultivation should be followed. Otherwise a method should be developed through research. Conservation agriculture techniques should be followed where appropriate, especially in the build-up of organic matter and conservation of soil humidity.

Practice in Nepal: *Traditional methods are followed for cultivation of MAPs in Nepal. No research has been developed for cultivation of MAPs.*

3.1 Site selection

Soil type, climate and other factors such as past land uses history should be taken into consideration while selecting site for the cultivation. Risks of contamination as a result of pollution of the soil, air or water by hazardous chemicals should be avoided.

Practice in Nepal: *Farmers tend to cultivate in their own land or lease land available in community and leaseholds forests- regardless of soil type and climatic conditions.*

3.2 Ecological environment and social impact

The quality and growth of MAPs can also be affected by other plants, other living organisms and by human activities. The introduction of non-indigenous MAPs into cultivation may have a detrimental impact on the biological and ecological balance of the region.

The social impact of cultivation on local communities should be examined to ensure that negative impacts on local livelihood are avoided.

Practice in Nepal: *Ecological environment and social impact are not assessed during the introduction of exotic MAPs in Nepal.*

3.3 Climate

Climatic conditions such as duration of sunlight, average rainfall, average temperature, including daytime and night-time temperature differences, also influence the physiological and biochemical activities of plants, and prior knowledge should be considered.

Practice in Nepal: *Farmers are knowledgeable on the climatic conditions but they are not aware on its influence on the physiological and biochemical activities on the exotic species.*

3.4 Soil

The soil should contain appropriate amounts of nutrients, organic matter and other elements to ensure optimal growth of MAPs and its quality. Optimal soil conditions, including soil type, drainage, moisture retention, fertility and pH, will be dictated by the selected MAPs. It is necessary to ensure that correct types and quantities of fertilizers- preferably organic fertilizers should be used.

Human excreta must not be used as a fertilizer owing to the potential presence of infectious microorganisms or parasites. Animal manure should be thoroughly composted to meet safe sanitary standards of acceptable microbial limits and destroyed by the germination capacity of weeds. Any applications of animal manure should be

documented.

Practice in Nepal: *Only few farmers conduct the soil test before the application of suitable nutrients in the soil. Most of the farmers use chemical fertilizers (such as urea, DAP, etc.) in soil readily available in market. There is also practice of applying animal manure and compost in the soil-but not documented.*

3.5 Irrigation and drainage

Irrigation and drainage should be controlled and carried out in accordance with the needs of the individual MAPs species during its various stages of growth. Water used for irrigation purposes should comply with national quality standards.

Practice in Nepal: *Basically underground water and also water from canal is used for irrigation in MAPs cultivation. But the farmers do not test the water quality in laboratory.*

4. Plant protection

The timely application of measures such as topping, bud nipping, pruning and shading may be used to control the growth and development of the plant to improve the quality and quantity of the MAPs being produced. Integrated pest management should be followed where appropriate. All applications should be documented.
Growers and producers should comply with maximum pesticide and herbicide residue limits, as per the national regulatory authorities of both the growers' and the end-users' countries. International agreements such as the International Plant Protection Convention and Codex Alimentarius should also be consulted on pesticide use and residues.

Practice in Nepal: *Farmers apply all the possible plant protection measures for the growth and development of MAPs during cultivation. Most of the farmers use pesticides without knowing the maximum limits. Integrated pest management is rarely followed.*

5. Harvest

MAPs should be harvested during the optimal season or time period to ensure the production of plant materials and finished herbal products of the best possible quality. The time of harvest depends on the plant part to be used. Detailed information on the appropriate timing of harvest is available in national pharmacopoeias, published standards, official monographs and major reference books.
The best time for harvest (quality peak season/time of day) should be determined according to the quality and quantity of biologically active constituents rather than the total vegetative yield of the targeted plant parts. During harvest, care should be taken to ensure that no foreign matter, weeds or toxic plants are mixed with the harvested plant materials.
MAPs should be harvested under the best possible conditions, avoiding dew,

rain or exceptionally high humidity. If harvesting occurs in wet conditions, the harvested material should be transported immediately to an indoor drying facility to expedite drying so as to prevent any possible deleterious effects due to increased moisture levels, which promote microbial fermentation and mould.
Cutting devices, harvesters, and other machines should be kept clean and adjusted to reduce damage and contamination from soil and other materials. They should be stored in an uncontaminated, dry place or facility free from insects, rodents, birds and other pests, and inaccessible to livestock and domestic animals.
Contact with soil should be avoided to the extent possible so as to minimize the microbial load of harvested plant materials. If the underground parts (such as the roots, tubers or rhizomes) are used, any adhering soil should be removed from the plant materials as soon as they are harvested.
The harvested raw plant materials should be transported promptly in clean, dry conditions. They may be placed in clean baskets, dry sacks, trailers or other well-aerated containers and carried to a central point for transport to the processing facility or warehouse.
All containers used at harvest should be kept clean and free from contamination by previously harvested plants and other foreign matter. When containers are not in use, they should be kept in dry conditions, in an area that is protected from insects, rodents, birds and other pests, and inaccessible to livestock and domestic animals.
Decomposed plant materials should be identified and discarded during harvest, post-harvest inspections and processing, in order to avoid microbial contamination and loss of product quality.

Practice in Nepal: *Harvesting is done in appropriate period depending on the MAPs species. The harvesting devices are cleaned thoroughly with water and sun dried. The foreign matters are carefully separated. Before transportation, the baskets or sacs are cleaned properly. But there is lack of appropriate drying facilities and warehouse which affects the quality of MAPs.*

6. Personnel

Growers and producers should have adequate knowledge of the MAPs on botanical identification, cultivation characteristics and environmental requirements (such as soil type, soil pH, fertility, plant spacing and light requirements), as well as the means of harvest and storage.
All personnel (including field workers) involved in the propagation, cultivation, harvest and post-harvest processing stages of MAPs production should maintain appropriate personal hygiene and should have received training regarding their hygiene responsibilities.
Only properly trained personnel, wearing appropriate protective clothing (such as overalls, gloves, helmet, goggles, face mask, etc.), should apply agrochemicals.

Practice in Nepal: *MAPs growers and producers lack adequate knowledge on cultivation, harvest, proper storage and processing. The personal hygiene is not maintained during processing MAPs (except few cases).*

4.3 Good collection practices for MAPs

Adoption of good collection practices of medicinal plants (WHO, 2003) ensures the long term survival of wild populations and their associated habitats. Management plans for collection should provide a framework for setting sustainable harvest levels and describe appropriate collection practices that are suitable for each MAP species and plant part used (roots, bark, leaves, flowers, fruits, etc.). Collection of MAPs raises a number of complex environmental and social issues that must be addressed locally on a case by case basis.

1. Permission to collect

Collection permits and other documents from government authorities and landowners must be obtained prior to collecting any plants from the wild. Sufficient time for the processing and issuance of these permits must be allocated at the planning stage. National legislation, such as national “red” lists, should be consulted and respected. For medicinal plant materials intended for export from the country of collection, export permits, phytosanitary certificate, Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) permits (for export and import), CITES certificates (for re-export), and other permits must be obtained as per required.

Practice in Nepal: *Collection permit of MAPs is obtained from DFO (for the collection from government managed forests) and CFUGs (for the collection from community forests) and release permit from DFO for the transportation. Forest acts and regulations and also CFUG's management plan is respected during issuing permits. Export certification, phytosanitary certificate and for CITES listed species- CITES permit are issued by DPR, Plant Quarantine Office and Department of Forest respectively.*

2. Technical planning

Prior to collection expedition, the geographical distribution and population density of the target MAPs should be determined. When the collection sites have been identified, local and/or national collection permits should be obtained.
Essential information on the target species (taxonomy, distribution, phenology, genetic diversity, reproductive biology and ethnobotany) should be obtained as far as practicable. Data about environmental conditions, including topography, geology, soil, climate and vegetation at WHO guidelines on good agricultural and collection practices (GACP) for medicinal plants the prospective collecting site(s), should be collated and presented in a collection management plan.

Copies of photographs and other illustrations of the target MAPs from books and herbarium specimens, and ethnographical information (common or local names) of the target species and plant parts are useful field instruments. Rapid, safe and dependable transportation to carry equipment, supplies and collected MAPs materials should be arranged in advance.
A collection team familiar with good collecting techniques, transport, and handling of equipment and medicinal plant materials, including cleaning, drying and storage, should be assembled. Training of personnel should be conducted regularly. The responsibilities of all those involved in collection should be clearly set out in a written document.

Practice in Nepal: *CFUG permits only particular site (block) for the collection of MAPs each year on rotational basis as per the management plan. However, in government managed forests, collection of MAPs takes place unsystematically. Few collectors are knowledgeable on the target species while others are not. More or less the environmental conditions of the particular community forest are incorporated in CFUG management plan. The collectors are familiar with the ethnographical information of the target species. CFUGs train the collectors on the sustainable collection practice. Transportation and storage are pre-planned or plan after collection depending on the quantity of MAPs collected.*

3. Selection of MAPs for collection

MAPs selected for collection should be the same as that specified in the national pharmacopoeia or recommended by other authoritative national documents of the end-user's country. In the absence of such national documents, the selection of species specified in the pharmacopoeia or other authoritative documents of other countries should be considered.
Collectors of MAPs and producers of medicinal plant materials and herbal medicines should prepare botanical specimens for submission to regional or national herbaria for authentication. The voucher specimens should be retained for a sufficient period of time, and should be preserved under proper conditions. The name of the botanist or other experts who provided the botanical identification or authentication should be recorded. If the medicinal plant is not well known to the community, then documentation of the botanical identity should be recorded and maintained.

Practice in Nepal: *There is no national herbal pharmacopoeia in Nepal. Collection of MAPs is dictated by the traders or middleman. Therefore, the species may not be always the same as specified in the publication by DPR, DFO and academic and developmental institutions. Collectors do not prepare botanical specimens and submit for the authentication in national herbarium. And there is no record of the documentation of the botanical identity.*

4. Collection

The population density of the target species at the collection sites should be determined and species that are rare should not be collected. To encourage the regeneration of source plant materials, a sound demographic structure of the population has to be ensured. Management plans should refer to the species and the plant parts (roots, bark, leaves, fruits, etc.) to be collected and should specify collection levels and collection practices.

MAPs should be collected during the appropriate season or time period to ensure the best possible quality of both source materials and finished products. The best time for collection (quality peak season or time of day) should be determined according to the quality and quantity of biologically active constituents rather than the total vegetative yield of the targeted medicinal plant parts.

Only ecologically non-destructive systems of collection should be employed. This will vary widely from species to species. MAPs should not be collected in or near areas where high levels of pesticides or other possible contaminants are used or found, such as roadsides, drainage ditches, garbage dumps and industrial facilities which may produce toxic emissions. In addition, the collection of MAPs in and around active pastures, including riverbanks downstream from pastures, should be avoided in order to avoid microbial contamination from animal waste.

Efforts should be made to remove parts of the plant that are not required and foreign matter, in particular toxic weeds. Decomposed plant materials should be discarded.

Collected raw MAPs should not come into direct contact with the soil. If underground parts (such as the roots) are used, any adhering soil should be removed from the plants as soon as they are collected. Collected material should be placed in clean baskets, mesh bags, other well aerated containers or drop cloths that are free from foreign matter.

After collection, plant materials may be subjected to appropriate preliminary processing, including elimination of undesirable materials and contaminants, washing (to remove excess soil), sorting and cutting. The collected plant materials should be protected from insects, rodents, birds and other pests, and from livestock and domestic animals. If the collection site is located some distance from processing facilities, it may be necessary to air or sun-dry the raw medicinal plant materials prior to transport.

If more than one medicinal plant part is to be collected, the different plant species or plant materials should be gathered separately and transported in separate containers. Cross-contamination should be avoided at all times. Collecting implements and mechanical tools should be kept clean and maintained in proper condition.

Practice in Nepal: *CFUGs as well as DFO carry out the inventory of traded MAPs within their territories to determine the overall stock of species and plant parts. Roots, barks and leaves are collected ensuring regeneration. Whereas, flowers, fruits and seeds are collected after maturation. Sometimes pre-mature collection is done as there*

is competition among collectors for the most demanded MAPs (such as Satuwa; Botanical name: Paris polyphylla rhizome collection in Nepal).Soon after the collection, soil and other contaminants are removed and also cleaned by washing. Separate species are placed in separate baskets or sacks. If the collection site is far away from storage area, MAPs are sun dried and then transported to storage site. On the other hand, if collection site is nearby the storage area, MAPs are transported and dried in storage area. Collection implements and tools are cleaned and maintained.

5. Personnel

Local experts responsible for the field collection should have formal or informal practical education and training in plant sciences and have practical experience in fieldwork. They should be responsible for training any collectors who lack sufficient technical knowledge to perform the various tasks involved in the plant collection process. They are also responsible for the supervision of workers and the full documentation of the work performed. Field personnel should have adequate botanical training, and be able to recognize medicinal plants by their common names and ideally by their scientific names.

All collectors involved in the collection operation should have sufficient knowledge of the species targeted for collection and be able to distinguish target species from botanically related or similar species. Collectors should also receive instructions on all issues relevant to the protection of the environment and the conservation of plant species, as well as the social benefits of sustainable collection of MAPs.

The collection team should take measures to ensure the welfare and safety of staff and local communities during all stages of MAPs sourcing and trade. All personnel must be protected from toxic and dermatitis-causing plants, poisonous animals and disease-carrying insects. Appropriate protective clothing, including gloves, should be worn when necessary.

Practice in Nepal: *CFUGs and/or district federation of community forest user group, Nepal (FECOFUN) and/or DFO provides training on sustainable collection of MAPs for the collectors. But training documentation is lacking. Lead collectors are knowledgeable on the identification of target species by local name/Nepali common name/trade name, but not familiar with botanical name. For new collectors, sometimes it is difficulty in proper identification of target MAPs due to the availability of other similar species and lack of sufficient knowledge. There is no practice of wearing protective clothing during collection and transport.*

4.4 Common technical aspects of GACP for MAPs

WHO guidelines on good agricultural and collection practices (GACP) for medicinal plants (WHO, 2003) should be followed for the post-harvest handling and processing of MAPs.

1. Post-harvest processing

1.1 Inspection and sorting

Raw MAPs should be inspected and sorted prior to primary processing. The inspection may include:

- visual inspection for cross-contamination by untargeted MAPs and/or plant parts;
- visual inspection for foreign matter;
- organoleptic evaluation such as: appearance, damage, size, colour, odour, and possibly the taste.

Practice in Nepal: *The collectors do the preliminary visual inspection for cross contamination and foreign matter at the collection sites and also at the storage sites. But they do not evaluate organoleptic properties.*

2. Primary processing

Primary processing includes washing, cutting before drying, fumigation, freezing, distillation, drying, etc. All of these processes must conform to regional and/or national regulations.

- On arrival at the processing facility the harvested MAPs/product has to be promptly unloaded and unpacked. Prior to processing, the material should not be exposed directly to the sun, except in cases where there is a specific need, and must be protected from rainfall and moisture.
- MAPs that are to be used in the fresh state should be harvested/collected and delivered as quickly as possible to the processing facility in order to prevent microbial fermentation and thermal degradation.
- MAPs can be dried in a number of ways: in the open air (shaded from direct sunlight); placed in thin layers on drying frames, wire-screened rooms or buildings; by direct sunlight, if appropriate; in drying ovens/rooms and solar dryers; by indirect fire; baking; microwave; or infrared devices.
- When possible, temperature and humidity should be controlled to avoid damage to the active chemical constituents. The method and temperature used for drying may have a considerable impact on the quality of the resulting MAPs.
- In the case of natural drying in the open air, medicinal plant materials should be spread out in thin layers on drying frames and stirred or turned frequently. In order to secure adequate air circulation, the drying frames should be located at a sufficient height above the ground.
- Drying MAPs directly on bare ground should be avoided. If a concrete or cement surface is used, medicinal plant materials should be laid on an appropriate cloth or sheeting.
- Drying directly on the ground or under direct exposure to the sunlight should be avoided unless specifically required. Attempts must be made to achieve uniform drying of the MAPs and thus avoid mould formation.

- Except in the case of open air drying, the drying conditions such as temperature, duration etc. must be selected taking into consideration the medicinal plant part such as root, leaf or flower and the nature of its active constituent.
- The source of heat in direct drying should be limited to natural gas and temperatures should be kept below 60°C. If other sources of fire are used, contact between those materials, smoke and medicinal plant material should be avoided.
- All materials must be inspected and where necessary sieved in order to eliminate sub-standard product and foreign bodies. Sieves must be maintained in a clean state and should be serviced regularly.
- Clearly marked waste-bins should be available, emptied daily and cleaned.
- All processed medicinal plant materials should be protected from contamination and decomposition as well as from insects, rodents, birds and other pests, and from livestock and domestic animals.

Practice in Nepal: *Primary processing of MAPs in Nepal includes cleaning, cutting (depending on the MAPs), grading and distillation of aromatic herbs. This is carried out in collection sites, storage area and processing facilities as well.*
Storage conditions in village level as well as in trading centers are poor and difficulty in protection from contamination and from insects, rodents and pests.
Drying is carried out in open area (mostly in plastic or cloths or bamboo mats) in direct sun (and rarely in temporary drying facilities) and therefore temperature and moisture level may not be maintained.

3. Packaging and labeling

- Early packaging should be done in order to protect the plant material/product and to reduce the risk of pest attacks and other contamination.
- Continuous in-process quality control measures should be implemented to eliminate sub-standard materials, contaminants and foreign matter prior to and during the final stages of packaging.
- Processed medicinal plant materials should be packaged in clean, dry boxes, sacks, bags or other container.
- Materials used for packaging should be non-polluting, clean, dry and in undamaged condition. Fragile medicinal plant materials should be packaged in rigid containers.
- Re-usable packaging material should be well cleaned and perfectly dried prior to use. No contamination should occur through re-using of bags.
- Packaging materials must be stored in a clean and dry place that is free of pests and inaccessible to livestock and domestic animals. It must be assured that no contamination of the product occurs by the use of packaging materials, particularly in the case of fiber bags.
- Label should clearly indicate the scientific name of MAPs, plant part, place of origin, collection date as far as practicable.

- Label should bear the production batch, weight, assignment number and date.

Practice in Nepal: *For raw herbs, mostly packaging is done at the time of transportation. Packaging materials includes re-used jute sacks, and also plastic sacks. Whereas, plastic containers are used for packaging essential oils and vegetal oils at the processing facilities. The exporters used Aluminum and/or HDPE containers or epoxy-coated metal containers for shipment.*
The traders and processors do not use label in the packaging. Sometimes they write trade name in the packaging sacks and containers. Labels with all the contents are used only after transportation to the exporters' warehouse and at the time of shipment.

4. Storage and transportation

- Packaged dried MAPs and products should be stored in a dry, well-aerated building, in which daily temperature fluctuations are limited and good aeration is ensured. Fresh medicinal plant materials/products should be stored between 1^0C and 5^0C, while frozen products should be stored below -18^0C (or below -20^0C for long term storage).
- In the case of bulk transport, it is important to secure dry conditions. Furthermore, in order to reduce the risk of mould formation or fermentation it is advisable to use aerated containers. As a substitute, the use of sufficiently aerated transport vehicles and other aerated facilities is recommended.
- Fumigation against pest attack should be carried out only where necessary and must be carried out exclusively by licensed personnel. Only registered chemicals must be used. Any fumigation against pest attack should be reported in the documentation.
- For fumigation of warehouses, only substances permitted by the regional and/or national regulations should be used.
- When frozen storage or saturated steam is used for pest control, the humidity of the material must be controlled after treatment.

Practice in Nepal: *In village level, no separate store rooms for MAPs and products are allocated. Collectors/processors and traders store in the extra room in their house where available and sometimes they rent rooms for storage. In trading centers, traders rent separate rooms or house for storage of MAPs and products. The temperature may not be maintained during storage conditions.*
For bulk transportation, trucks are used while for the transportation of small quantity routine vehicle (like passengers bus) are used. There is no practice of fumigation and used of steam for pest control.

5. Equipment

- Equipment and utensils used in the handling of MAPs should be made of materials that do not transmit toxic substances, odour or taste, non-absorbent, resistant to corrosion and capable of withstanding repeated cleaning and disinfection.

- Use of wood and other materials that cannot be adequately cleaned and disinfected should be avoided.

Practice in Nepal: *For the distillation of aromatic herbs- both mild steel (M/S) and stainless steel (S/S) distillation units are used. Further, for expelling vegetal oil both wooden traditional expeller and M/S expeller are used.*

6. Documentation

Standard operating procedures (SOP) should be adopted and documented. All processes and procedures involved in the production of MAPs and the dates on which they are carried out should be documented.
The types of information that should be collected include:
- seeds and other propagation materials
- propagation
- cultivation or collection site
- crop rotation at the site
- application of fertilizers, growth regulators, pesticides and herbicides
- unusual circumstances that may influence the quality of the medicinal plant materials
- harvest or collection
- all processing
- transportation
- storage
- application of fumigation agents.

Practice in Nepal: *Documentation has always been the poor part in each step of value chain of MAPs in Nepal. But exporters maintain all those required documentations (which is also mandatory for obtaining organic certification).*

7. Health, hygiene and sanitation

All production of medicinal plant materials by agriculture and collection should conform to national and/or regional regulations on safety, materials handling, sanitation and hygiene. All those involved in the handling and processing of cultivated or collected MAPs should in all processing procedures comply with national and/or regional regulations on hygiene.
Personnel should be protected from contact with toxic or potentially allergenic herbs by means of adequate protective clothing, including gloves.

a. Illness and injuries

Personnel with open wounds, skin diseases should be suspended from work or required to wear protective clothing and gloves until full recovery. Persons suffering from known air-borne or food-borne communicable diseases should be suspended from work in all areas of production and processing.

Any personnel who have cuts or wounds and are permitted to continue working should cover their injuries with suitable water-proof dressings.

b. Personal cleanliness

Personnel who handle medicinal plant materials should maintain a high degree of personal cleanliness, and, where appropriate, wear suitable protective clothing and gloves, including head covering and footwear.
Personnel should always wash their hands at the start of handling activities, after using the toilet, and after handling medicinal plant materials or any contaminated material.

c. Personal behavior

Smoking and eating should not be permitted in medicinal plant processing areas.
Personnel who handle medicinal plant materials should refrain from behaviors that could result in contamination of the materials such as spitting, sneezing or coughing over unprotected materials.

Practice in Nepal: *Health, hygiene and sanitation is poor in rural parts where MAPs cultivation and collection takes place. Persons involved in cultivation, collection and processing of MAPs do not wear protective clothing. Personal cleanliness and behavior do not comply with the minimum required standards.*

8. Building and facilities

Buildings used in the processing of harvested MAPs/products must be clean, as well as thoroughly aerated and must never be used for housing livestock. They must provide adequate protection for the harvested MAPs/products against birds, insects, rodents and domestic animals. In all storage and processing areas suitable pest control measures such as baits and electric insect killing machines must be operated and maintained by professionally qualified staff or contractors.
It is recommended that the packaged MAPs/products be stored:
- in buildings with concrete or similar easy to clean floors,
- on pallets,
- with a sufficient distance from the wall,
- well separated from other herbal products to avoid cross-contamination.
- organic products must be stored separately.

Buildings where plant processing is carried out must have changing facilities as well as toilets including hand-washing facilities.

Practice in Nepal: *Processing facilities for essential oils and vegetal oils in rural areas are usually open, no permanent buildings are constructed. But the processed products are stored in rooms in own house/or rented house. Whereas, processing and storage of Ayurvedic products in urban areas takes place in good facilities. Organic certified MAPs/products (as essential oils) are stored separately.*

CHAPTER FIVE

5.1 Quality assurance in production

1. Quality assurance in the manufacture of MAPs products

In addition to the use of modern analytical techniques, quality assurance also requires the control of starting materials, storage and processing (WHO, 2007). For this reason, an appropriate quality assurance system should be applied in the manufacture of MAPs products.

2. Sanitation and hygiene

- MAPs materials may contain microbiological contaminants. During the course of harvesting and processing, MAPs products that may be especially prone to microbiological contamination are produced. To avoid alterations and to reduce contamination, a high level of sanitation and hygiene is necessary during manufacture.
- Water supply to the manufacturing unit should be monitored, and, if necessary treated appropriately to ensure consistency of quality.
- Waste from the manufacturing unit should be disposed of regularly so as to maintain a high standard of hygiene in the manufacturing area. Clearly marked waste-bins should be available, emptied and cleaned as needed, but at least daily.

3. Qualification and validation

- Qualification of critical equipment, process validation and change control are particularly important in the production of MAPs products. In this case, the reproducibility of the production process is the main means for ensuring consistency of quality, efficacy and safety between batches.
- The written procedure should specify critical process steps and factors (such as extraction time, temperature and solvent purity) and acceptance criteria, as well as the type of validation to be conducted (e.g. retrospective, prospective or concurrent) and the number of process runs.

4. Complaints

- The person responsible for handling complaints and deciding on the measures to be taken to deal with them should have appropriate training and/or experience in the specific features of the quality control of MAPs products.
- The complaints should be recorded in detail and the causes thoroughly investigated (such as by comparison with the reference samples kept from the same batch). There should also be written procedures to describe the action to be taken.
- Reports of any adverse reaction/event should be entered in a separate register in accordance with national and international requirements. An investigation should be

conducted to find out whether the adverse reaction/event is due to a quality problem and whether such reactions/events have already been reported in the literature or whether it is a new observation. In either case, complaint records should be reviewed regularly to detect any specific or recurring problems requiring special attention and possible recall of marketed products.

5. Product recalls

- The product recall procedure depends on the national regulations. There should be a standard operating procedure (SOP) for storage of recalled MAPs products in a secure segregated area.

6. Contract production and analysis

- The contract partner should have adequate premises and equipment for the production of MAPs products. Validated methods should be applied for cleaning the equipment and premises carefully before using them to produce different products.
- Technical aspects of the contract should be drawn up by competent persons suitably knowledgeable on the specific characteristics of MAPs products, including their production and quality control testing.

7. Self-inspection

- At least one member of the self-inspection team should possess a thorough knowledge of MAPs products.

8. Personnel

- The release of products should be authorized by a person who has been trained in the specific features of the processing and quality control of MAPs materials, herbal preparations and finished herbal products.
- Personnel dealing with the production and quality control of MAPs products should have adequate training in the specific issues relevant to products.

9. Training

- The personnel should have adequate training in appropriate fields such as pharmaceutical technology, taxonomic botany, phytochemistry, pharmacognosy, hygiene, microbiology and related subjects such as ethnobotany.
- Training records should be maintained and periodic assessments of the effectiveness of training programs should be made.

10. Personal hygiene

- Personnel entrusted with the handling of MAPs products, herbal preparations and finished herbal products should be required to have a high degree of personal hygiene

and to have received adequate training in maintaining appropriate standards of hygiene. The personnel should not work, if they have infectious diseases or skin diseases. Written procedures listing the basic hygiene requirements should be made available.
- Personnel must be protected from contact with toxic irritants and potentially allergenic plant materials by means of adequate protective clothing. They should wear suitable gloves, caps, masks, work suits and shoes throughout the whole procedure from plant processing to product manufacture.

11. Premises

Premises should be designed, located, constructed, adapted and maintained to suit the operations to be carried out according to *WHO good manufacturing practices (GMP) for pharmaceutical products: main principles (2003)*.
- Because of their potential for degradation and infestation with certain pests as well as their sensitivity to microbiological contamination, production, and particularly storage, of MAPs materials and herbal preparations assume special importance.

a. Storage areas

- Storage areas should be well organized and tidy. Special attention should be paid to cleanliness and good maintenance. Any accidental spillage should be cleaned up immediately using methods that minimize the risk of cross contamination of other materials, and should be reported.
- The set-up of storage areas depends on the type of materials stored. The areas should be well labeled and materials stored in such a way as to avoid any risk of cross-contamination. An area should be identified for the quarantine of all incoming MAPs materials.
- Storage areas should be laid out to permit effective and orderly segregation of the various categories of materials stored, and to allow rotation of stock. Different MAPs materials should be stored in separate areas.
- To protect the stored material and reduce the risk of pest attacks, the duration of storage of any MAPs material in unpacked form should be kept to a minimum.
- Incoming fresh MAPs materials should be processed, unless specified otherwise, as soon as possible. If appropriate, they should be stored between 2°C and 8°C, whereas frozen materials should be stored below -18°C.
- Where materials are stored in bulk, to reduce the risk of mould formation or fermentation it should be stored in aerated rooms or containers using natural or mechanical aeration and ventilation. These areas should also be equipped in such a way as to protect against the entry of insects or animals, especially rodents. Effective measures should be taken to limit the spread of animals and microorganisms brought in with the plant material and to prevent cross-contamination.

- MAPs materials, even when stored in fibre drums, bags or boxes, should be stored off the floor and suitably spaced to permit cleaning and inspection.
- The storage of plants, extracts, tinctures and other preparations may require special conditions of humidity and temperature or protection from light as per *WHO GMP: updated supplementary guidelines for the manufacture of herbal medicines (2006);* appropriate steps should be taken to ensure that these conditions are provided, maintained, monitored and recorded.
- MAPs materials, including raw materials, should be kept in a dry area protected from moisture and processed following the principle of “first in, first out” (FIFO).

b. Production areas

Production areas should comply with the general requirements of *WHO good manufacturing practices (GMP) for pharmaceutical products: main principles (2003)*. As a rule, campaign work in their processing is necessary.
- The use of dedicated premises is encouraged. Moreover, the special nature of the production of MAPs products requires that particular attention be given to processing products that generate dust. When heating or boiling of the materials is necessary, a suitable air exhaust mechanism should be employed to prevent accumulation of fumes and vapors.
- To facilitate cleaning and to avoid cross-contamination, adequate precautions should be taken during the sampling, weighing, mixing and processing of medicinal plants.

12. Equipment

Processing of MAPs materials may generate dust or material which is susceptible to pest-infestation or microbiological contamination and cross contamination. Effective cleaning of the equipment is therefore particularly important.
- Vacuum or wet-cleaning methods are preferred. If wet-cleaning is done, the equipment should be dried immediately after cleaning to prevent the growth of microorganisms. Cleaning with compressed air and brushes should be done with care and avoided if possible, as these methods increase the risk of product contamination.
- Non-wooden equipment should be used unless tradition demands wooden material. Where it is necessary to use traditional equipment (such as wooden implements, clay pots, pallets, hoppers, etc.), this should be dedicated, unless otherwise justified. When such equipment is used, it is advisable that it does not come into direct contact with chemicals or contaminated material. If the use of wooden equipment is unavoidable, special consideration must be given to its cleaning as wooden materials may retain odors, be easily discolored and are easily contaminated.

13. Materials

- All incoming MAPs materials should be quarantined and stored under appropriate conditions that take into account the degradability of materials and herbal preparations.
- Only permitted substances should be used for fumigation, and allowable limits for their residues together with specifications for the apparatus used should be set according to the national regulations.

14. Reference samples and standards

The reference standard for MAPs product may be a botanical sample of the MAPs material; a sample of the herbal preparation such as extract; or a chemically defined substance such as a known active constituent, a marker substance or a known impurity.

- The reference standard should be of a quality appropriate to its purpose. If the MAPs product is not described in a recognized pharmacopoeia, a herbarium sample of the flowering or fruiting top of the whole medicinal plant or part of the medicinal plant should be available.
- All reference standards should be stored under appropriate conditions to prevent degradation. Their expiry and/or revalidation date should be determined and indicated.

15. Documentation

The general principles for documentation are set out in the *WHO good manufacturing practices (GMP) for pharmaceutical products: main principles (2003)*.

a. Specifications

Consistent quality for finished herbal products can only be assured if the starting materials are defined in a rigorous and detailed manner. In some cases more detailed information may be needed on aspects of collection or agricultural production. Their characterization (which also includes a detailed evaluation of the botanical and phytochemical aspects of the medicinal plant, manufacture of the herbal preparation and the finished herbal product) is therefore essential to allow the establishment of specifications which are both comprehensive and relevant.

For this reason the specifications for MAPs/herbal materials should include the following information as far as possible:

i. Herbal materials

- The family and botanical name of the plant used according to the binomial system. It may also be appropriate to add the vernacular name and the therapeutic use in the country or region of origin of the plant.
- Details of the source of plant, such as country and/or region of origin, whether it was cultivated or collected from the wild and, where applicable, method of cultivation, dates and conditions of harvesting, collection procedures, collection area, and brand.

- Whether the whole plant or only a part is used. For dried plant material, the drying system should be specified, if applicable.
- Description of the plant material based on visual (macroscopic) and/or microscopic examination.
- Suitable identity tests including identification tests (such as thin layer chromatography (TLC) or other chromatographic fingerprint) for known active ingredients or markers. A reference sample should be available for identification purposes.
- Details of the assay of active constituents or markers, where appropriate.
- Limit tests such as dry residue of liquids, ash value (total ash, and ash insoluble in hydrochloric acid), water-soluble extractives, moisture/water content and loss on drying.
- Suitable methods for the determination of possible pesticide contamination and the acceptable limits for such contamination in herbal materials or herbal preparations used in the manufacture of MAPs/herbal products.
- Tests for toxic metals and for likely contaminants, foreign materials and adulterants.
- Tests for fungal and/or microbiological contamination, fumigant residues (if applicable), mycotoxins, pest-infestations.
- Other appropriate tests such as particle size, residual solvents in herbal preparations and biological fingerprints.
- Specifications for starting materials should include, if applicable, reference to a pharmacopoeial monograph.
- Qualitative and quantitative information on the active ingredients or constituents with known therapeutic activity in MAPs/herbal materials and herbal preparations should be given.

ii. Finished herbal products

- Tests for microbiological contamination and tests for other toxicants.
- Uniformity of weight (such as for tablets, single-dose powders, suppositories, capsules and herbal tea in sachets), disintegration time (for tablets, capsules, suppositories and pills), hardness and friability (for example uncoated tablets), viscosity (for internal and external fluids), consistency (semi-solid preparations), and dissolution (tablets or capsules), if applicable.
- Physical appearance such as color, odor, form, shape, size and texture.
- Loss on drying, or water content.
- Identity tests, qualitative determination of relevant substances of the plants (for example fingerprint chromatograms).
- Quantification of relevant active ingredients, if they have been identified, and the analytical methods that are available.
- The control tests and specifications for the finished herbal product should be such as to allow the qualitative and quantitative determination of the main active constituents. If the therapeutic activity of constituents is known, these

constituents should be indicated in the documentation. If such substances are not known the constituents useful for assessing the quality should be identified as markers. In both cases, the assay specifications should be defined.
- If either the final product or the herbal preparation contains several herbal materials and a quantitative determination of each active ingredient is not feasible, the mixture of several active ingredients may be determined.

iii. Herbal preparations

The specifications of herbal preparations consist of the relevant items of the specifications for herbal materials or for finished herbal products.
- The processing instructions should describe the different operations to be performed on the plant material, such as drying, crushing, milling and sifting. They should also include the time and, if applicable, temperatures required in the drying process, and the methods to be used to control fragment or particle size. Instructions on removing foreign matter and other unwanted materials should also be given.
- The drying conditions chosen should be appropriate to the type of plant material processed. These depend on both the character of the active ingredients (for example essential oils) and the type of plant parts collected (for example root, leaf or flower). Drying by direct exposure to sunlight is possible, but drying on the ground should be avoided. If the plant should be processed fresh, without drying, the reasons and criteria determining the use of fresh material should be stated.
- For the production of processed extracts, the instructions should specify details of any solvent that may be used, the durations and temperatures needed for extraction and any concentration stages and methods that may be required.
- The permissible environmental conditions such as temperature, humidity and standard of cleanliness, should be stated.
- Any treatment, such as fumigation, used to reduce fungal or microbiological contamination or other infestation, together with methods of determining the extent of such contamination and potential residues, should be documented. Instructions on the conduct of such procedures should be available and should include details of the process, tests and allowable limits for residues together with specifications for apparatus used.
- Steps in the processes of blending and adjustment to reach defined contents of pharmacologically active constituents should be clearly documented.
- The rules that apply to the disposal of spent herbal material after processing should also be elaborated.

5.2 Good practices in production

To ensure the quality, safety and efficacy of MAPs/herbal products, it is essential that the steps in their production are clearly defined as recommendation by *WHO guidelines on good manufacturing practices (GMP) for herbal medicines (2007)*.

1. Selection of the first production step

For MAPs, which are either cultivated or collected from the wild, and which may be used in crude form or subjected to simple processing techniques (such as cutting or comminuting), the first critical step of their production should be clearly designated. The rationale for this designation should be stated and documented. However, for processes such as extraction, fermentation and purification, this rationale should be established on a case-by case basis.

- Collection/cultivation and/or harvesting of MAPs should follow other relevant guidance such as the *WHO guideline on good agriculture and collection practices (GACP) for medicinal plants (2003).*
- Generally, the post-harvest processing including primary cutting is covered by GACP. If further comminuting is carried out in the manufacturing processing, it should be covered by GMP. If cutting and comminuting considerably reduce the probability of detection of adulteration or mix-up of MAPs materials, application of supplementary guidelines may be extended to encompass these steps.
- When the active ingredient consists exclusively of comminuted or powdered MAPs, application of these guidelines starts at the physical processing following primary cutting and comminuting, and includes packaging.
- When MAPs extracts are used, the principles of these guidelines should apply to any production step following post-harvest processing.
- In the case of finished herbal products manufactured by fermentation, application of GMP should cover any production step following primary cutting and comminuting.

2. General considerations

- On arrival at the processing facility, the MAPs material should be promptly unloaded and unpacked. During this operation, the material should not come into direct contact with the soil. It should not be exposed directly to the sun (except in cases where this is a specific requirement) and it should be protected from rain and microbiological contamination.
- Attention should be paid to classification of clean area requirements taking into account the possible high degree of initial microbial contamination of MAPs materials.
- Specific and detailed requirements should be developed to cover microbial contamination of equipment, air, surfaces and personnel, and also for rest rooms, utilities, ancillary and supporting systems.
- Washing dried MAPs materials with water is generally inappropriate. When it is necessary to clean them, an air duster or air shower should be employed. In cases when immersion of MAPs materials in water or other appropriate agents (such as disinfectants) for cleaning is unavoidable (such as to eliminate suspected coliform bacteria), it should be kept to a minimum.

- The presence of plant materials from different species and varieties, or different plant parts should be controlled during the entire production process to avoid contamination.

3. Mixing of batches and blending

- MAPs products with constituents of known therapeutic activity are often standardized. The methods used to achieve such standardization should be documented. If another substance is added for these purposes, it is necessary to specify the quantity that may be added. Blending different batches of a specific MAPs material (for example before extraction) or by mixing different lots of similar MAPs preparations may also be acceptable. Records should be maintained to ensure traceability. The blending process should be adequately controlled and documented and the blended batch should be tested for conformity with established specifications where appropriate.
- Batches should be mixed only if it can be guaranteed that the mixture will be homogeneous. Such processes should be well documented.
- Out-of-specification batches of MAPs products should not be blended with other batches for the purpose of meeting specifications, except for standardization of the content of constituents with known therapeutic effect. Every batch incorporated into the blend should have been manufactured using an established process and should have been individually tested and found to meet appropriate specifications prior to blending.
- The expiry date of the blended batch should be chosen according to the date of manufacture of the oldest batch in the blend.

5.3 Good practices in quality control

The personnel of quality control units should have the necessary expertise in MAPs products to enable them to carry out identification tests and recognize adulteration, the presence of fungal growth or infestations and lack of uniformity in a consignment of materials.

The quality control of the MAPs material, herbal preparations and finished herbal products should establish their quality, but does not imply the control of every single constituent. *WHO guidelines on good manufacturing practices (GMP) for herbal medicines (2007)* provides good basis for adopting good practices in quality control.

1. Sampling

As MAPs materials are an aggregate of individual plants and/or different parts of the same plant and thus have an element of heterogeneity, sampling should be carried out with special care by personnel with the necessary expertise.

2. Testing

The identity and quality of MAPs material, herbal preparations and of finished herbal products should be tested as described in the *WHO: Quality control methods for*

medicinal plant materials (1998 and 2011). Each country should develop this basic requirement for technical equipment further according to its own needs.
- MAPs material, herbal preparations and finished herbal products can be categorized as follows:
a. the active constituents are identified, and may be quantified as such;
b. the main group of components which contribute to the activity (such as the constituents with known therapeutic activity) are known and can be quantified as a total (such as essential oils) or calculated using a representative substance belonging to the group (such as flavonoids);
c. the former is not identified and/or not quantifiable, but marker substances are;
d. others, where quantification (such as specification for a certain quantity of a constituent) is not applicable or feasible.
- Identification methods may be based on:
a. physical, macroscopic (organoleptic) and microscopic tests;
b. chromatographic procedures (TLC, high performance liquid chromatography (HPLC), high performance thin layer chromatography (HPTLC) or gas liquid chromatography (GLC)), spectrometric techniques such as ultraviolet-visible (UV-VIS), infrared spectroscopy (IR), nuclear magnetic resonance (NMR).
- The identification test methods should be specific for the MAPs material, herbal preparation or finished herbal product and ideally should be capable of discriminating between the required MAPs material and potential substitutes or adulterants that are likely to occur.
- Reference samples of MAPs materials should be made available for use in comparative tests, such as visual and microscopic examination and chromatography.

3. Stability test
- If the expiry date for a MAPs material or herbal preparation is given, some stability data to support the proposed shelf-life under the specified storage conditions should be available. Stability data are always required to support the shelf-life proposed for the finished herbal products.
- Finished herbal products may contain several MAPs materials or herbal preparations, and it is often not feasible to determine the stability of each active ingredient.
- The fingerprint methods used for the stability studies should be as similar as possible to those used for quality control purposes.
- For identified active ingredients, constituents with known therapeutic activity and markers, widely used general methods of assay, and physical and sensory or other appropriate tests may be applied.
- The stability of preservatives and stabilizers should be monitored. When these are not used, alternative tests should be done to ensure that the product is self-preserving over its shelf-life.

- Samples used for stability studies should be stored in the containers intended for marketing.

4. Packaging materials and labeling

- All packaging materials, such as bottles and other materials should be stored properly. Controls on the issue and use of these packaging materials should be adequate to ensure that incorrect labels and cartons are not used.
- All containers and closures should be thoroughly cleaned and dried before being used to pack the products.
- There should be adequate information on the label (or the package insert) to inform the users of the composition of the product (in addition to the brand name, if any), indications or actions, directions for use, cautions and adverse reactions if any, and the expiry date.
- Finished herbal products may contain several MAPs materials and/or herbal preparations. The full quantitative composition of the herbal ingredients should be stated on the product label. If this is not possible, at least the main ingredients should be stated on the label while the full qualitative composition could appear on the package insert.
- The qualitative and quantitative particulars of the active ingredients in MAPs materials and herbal preparations should be expressed in the following ways:

• For MAPs materials and herbal preparations consisting of comminuted or powdered herbal materials:

a. the quantity of the MAPs material must be stated or, if constituents with known therapeutic activity are unidentified, the quantity of the MAPs material/herbal preparation should be stated; or

b. the quantity of the MAPs material/herbal preparation should be given as a range, corresponding to a defined quantity of constituents with known therapeutic activity.

5.4 Cosmetics products

The following is the widely accepted standard which covers the quality aspects for the production, control, storage and shipment of cosmetics products as per *Cosmetics - good manufacturing practices (GMP) - guidelines on good manufacturing practices* (2007) and *Guidance for industry: cosmetics good manufacturing practices (*2008).

1. Premises

Premises should be located, designed, constructed and utilized so as:

a) to ensure protection of the product;

b) to permit efficient cleaning, sanitizing and maintenance;

c) to minimize the risk of mix-up of products, raw materials and packaging materials.

- Premises design decisions should be based on the type of cosmetic product produced, existing conditions, cleaning and sanitizing measures used.

2. Types of area

Separate or defined areas should be provided for storage, production, quality control, ancillary, washing and toilets.

a. Space

Sufficient space should be provided to facilitate operations such as receipt, storage and production.

b. Flow

Flow of materials, products and personnel through the building should be defined in order to prevent mix-ups.

c. Floors, walls, ceilings, windows

- Floors, walls, ceilings and windows in production areas should be designed or constructed for ease of cleaning and sanitization and be kept clean and in good repair.
- Windows should be of non-opening design where ventilation is adequate.
- New construction of production areas should incorporate considerations for proper cleaning and maintenance.

d. Washing and toilet facilities

Adequate, clean, washing and toilet facilities should be provided for personnel. The washing and toilet facilities should be differentiated from production areas.

e. Lighting

Adequate lighting, that is sufficient for operations, should be installed in all areas.

f. Ventilation

Ventilation should be sufficient for the intended production operations.

g. Pipework, drains and ducts

- Pipework, drains and ducts should be installed in such a manner so that drip or condensation does not contaminate materials, products, surfaces and equipment.
- Drains should be kept clean and should not allow back flow.

h. Cleaning and sanitization

- Cleaning and sanitization should be carried out to achieve the objective of protecting each product.
- Cleaning and sanitizing agents to be used should be specified and effective.
- There should be cleaning and sanitization programs corresponding to specific needs of each area.

i. Maintenance

Premises used in activities should be maintained in a good state of repair.

j. Consumables

Consumables used for premises should not affect the quality of the product.

k. Pest control

- Premises should be designed, constructed and maintained so as to restrict access to insects, birds, rodents, pests and other vermin.
- There should be a pest control program appropriate for the premises.
- Measures should be taken to control the exterior of the premises to prevent attracting pests.

3. Equipment

Equipment should be suitable for the intended purpose and capable of being cleaned, sanitized and maintained.

a. Equipment design

- Production equipment should be designed to prevent contamination of the product.
- Bulk product containers should be protected from air contaminants, such as dust and moisture.
- The material used in the construction of equipment should be compatible with products and the cleaning and sanitizing agents.

b. Installation

- The design and the installation of equipment should ease its drainage in order to facilitate cleaning and sanitization.
- Equipment should be placed so that movement of materials, mobile equipment and personnel do not pose a risk to quality.
- Major equipment should be readily identifiable.

c. Calibration

- Laboratory and production measuring instruments that is important for the quality of the product, should be calibrated regularly.
- If results of calibration are out-of-acceptance criteria, measuring instruments should be appropriately identified and removed from service.

d. Cleaning and sanitization

- All equipment should be subjected to an appropriate cleaning and sanitization program.
- Cleaning and sanitizing agents should be specified and effective.
- Equipment should be cleaned and sanitized at appropriate intervals, where equipment is assigned to continuous production.

e. Maintenance

- Equipment should be regularly maintained.

- Maintenance operations should not affect the quality of the product.
- Defective equipment should be identified accordingly, excluded from use and isolated.

f. Authorizations

Equipment used in production and control should be accessed and used by authorized personnel.

4. Raw materials and packaging materials

Purchased raw materials and packaging materials should meet defined acceptance criteria relevant to the quality of finished products.

a. Purchasing

- The purchase order, the delivery note and the delivered materials should match.
- The integrity of the raw materials and packaging materials shipping containers should be checked visually.

b. Identification and status

- Containers of raw materials and packaging materials should be labeled in order to identify the material and the batch information.
- Raw materials and packaging materials showing defects that might affect product quality should be held pending a decision.
- Raw materials and packaging materials should be identified in an appropriate way according to their status such as accepted, rejected or quarantined.
- Identification of raw materials and packaging materials should contain:

i) name of the product marked on the delivery note;
ii) name of the product as given by the company, and/or its code number;
iii) date or number of receipt;
iv) supplier's name;
v) batch reference given by the supplier.

c. Release

- Physical system should be set up to ensure that only released raw materials and packaging materials are used.
- The release of materials should be carried out by the authorized personnel responsible for quality.
- Raw materials and packaging materials can be accepted on the basis of the supplier certificate of analysis only if there are established technical requirements, experience and knowledge of the supplier, supplier audit and agreed supplier's test methods.

d. Storage

- Storage conditions should be appropriate for each raw material and packaging material.

- Raw materials and packaging materials should be stored and handled according to their characteristics.
- Specific storage conditions should be respected and monitored.
- Containers of raw materials and packaging materials should be closed and should be stored off the floor.
- When raw materials and packaging materials are repacked, they should carry the same labeling as at origin.
- When raw materials and packaging materials are quarantined or rejected, they should be stored in their respective physical locations.
- Stock rotation should ensure that the oldest released stock is used first.

5. Quality of water used in production

- The water treatment system should supply a defined quality of water.
- Water quality should be verified by either testing or monitoring of process parameters.
- The water treatment system should permit sanitization.
- Water treatment equipment should be set up so as to avoid stagnation and risks of contamination.
- Materials used in water treatment equipment should be selected to ensure that water quality is not affected.

6. Production

At each stage of manufacturing operations and packaging operations, measures should be taken to produce a finished product that meets the defined characteristics.

a. Availability of relevant documents

- Relevant documentation should be available at each stage of manufacturing operations.
- Manufacturing operations should be carried out according to manufacturing documentation, including:

i) suitable equipment;
ii) formula for the product;
iii) list of all raw materials identified according to relevant documents indicating batch numbers and quantities;
iv) detailed manufacturing operations for each stage (such as addition of raw materials, temperatures, speeds, mixing times, sampling, cleaning and sanitizing of equipment, and bulk product transfer).

b. Assignment of a batch number

A batch number should be assigned to each batch of manufactured bulk product.

c. Identification of in-process operations

- In accordance with the formula, all raw materials should be measured or weighed, into clean and suitable containers labeled with appropriate identification or directly into the equipment used for manufacturing.

- At all times, it should be possible to identify major equipment, containers of raw materials and containers of bulk products.

- Identification of containers of bulk products should indicate:

a) name or identifying code;

b) batch number;

c) storage conditions when such information is critical to assure the quality of the product.

d. Bulk product storage

- Bulk product should be stored in suitable containers, in defined areas, and under appropriate conditions.

- The maximum bulk product storage duration should be defined.

- When this duration is reached, the bulk product should be re-evaluated before use.

e. Re-stocking raw materials

If raw materials remain unused after weighing and are intended and deemed acceptable to return to stock, their containers should be closed and properly identified.

7. Packaging operations

a. Availability of relevant documents

- Relevant documentation should be available at each stage of packaging operations.

- Packaging operations should be carried out according to packaging documentation including:

i) suitable equipment;

ii) list of packaging materials defined for the intended finished product;

iii) detailed packaging operations such as filling, closing, labeling and coding.

b. Start-up checks

Before starting any packaging operation, it should be ensured that:

i) the area has been cleared of materials to avoid mixing with materials from previous operations;

ii) all documentation relevant to the packaging operations is available;

iii) all packaging materials are available;

iv) suitable equipment is available for use, in working order, cleaned and sanitized;

v) any coding to permit identification of the product is defined.

c. Assignment of batch number

- A batch number should be assigned to each unit of finished product.

- This number does not need to be identical with the batch number that appears on the label of the bulk product.

d. Packaging line identification

It should be possible to identify the packaging line with its name or identifying code, the name or identifying code of the finished product and the batch number.

e. Re-stocking of packaging materials

If packaging materials remain unused after packaging operations and are intended to return to stock, their containers should be closed and properly identified.

f. Identification and handling of work-in-process

Filling and labeling is usually a continuous process. Special measures including segregation and identification should be applied so that no mix-ups or mislabeling can occur.

8. Finished products

Finished products should meet the defined acceptance criteria. Storage, shipment and returns should be managed in a manner so as to maintain the quality of finished products.

a. Release

- Prior to being placed on the market, all finished products should be controlled in accordance with established test methods and should comply with acceptance criteria.
- Product release should be carried out by the authorized personnel responsible for quality.

b. Storage

- Finished products should be stored in defined areas under appropriate conditions for an appropriate length of time. Finished products should be monitored while stored as per necessity.
- Storage areas should permit organized storage.
- When finished products are released, quarantined or rejected, they should be stored in their respective physical locations.
- Identification of finished product containers should indicate:

i) name or identifying code;
ii) batch number;
iii) storage conditions when such information is critical to assure the quality of the product;
iv) quantity.

- Measures should be set up to ensure stock turnover. Stock rotation should ensure that the oldest released stock is used first.
- Periodic inventory checks should be performed to:

i) ensure inventory accuracy;
ii) ensure that acceptance criteria are met.

9. Shipment

- Measures should be taken to ensure the shipment of the defined finished product.
- Precautions should be taken to maintain the finished product quality.

a. Returns

- Returns should be identified in an appropriate way and stored in defined areas.
- Release should be given before placing returns on the market again.
- Measures should be established to distinguish any reprocessed return.

10. Quality control laboratory

- Principles described for personnel, premises, equipment, subcontracting, and documentation should apply to the quality control laboratory.
- The quality control laboratory is responsible for ensuring that the necessary and relevant controls are carried out for sampling and testing so that materials are released for use and products are released for shipment, only if their quality fulfills the required acceptance criteria.

a. Test methods

- The quality control laboratory should use all test methods necessary to confirm that the product complies with acceptance criteria.
- Controls should be performed on the basis of defined, appropriate and available test methods.

b. Acceptance criteria

Acceptance criteria should be established to specify the requirements to be met for raw materials, packaging materials, bulk products and finished products.

c. Results

All results should be reviewed. After this review, a decision should be made, notably in terms of approval, rejection or pending.

d. Out-of-specification results

- Out-of-specification results should be reviewed by authorized personnel and properly investigated.
- There should be sufficient justification for any re-testing to be performed.
- After the investigation, a decision by authorized personnel should be made, notably in terms of deviation, rejection or pending.

e. Reagents, solutions, reference standards and culture media

Reagents, solutions, reference standards, culture media, etc. should be identified by the following information:

i) the name;
ii) its strength or concentration;
iii) expiration date;
iv) the name and/or signature of the person who prepared it;
v) opening date;
vi) storage conditions.

f. Sampling

- Sampling should be performed by authorized personnel.
- Sampling should be defined in terms of:

i) sampling method;
ii) equipment to be used;
iii) amounts to be taken;
iv) any precautions to be observed to avoid contamination or deterioration;
v) identification of sample;
vi) frequency.

- Samples should be identified by:

i) the name or identifying code;
ii) the batch number;
iii) the date of sampling;
iv) the container from which the sample was taken.

g. Retain sample

- Samples of finished product should be retained in an appropriate manner and in designated areas.

- Sample size of finished products should allow analyses to be carried out in accordance with the regulations.

- Retain samples of finished product should be kept in their primary package for an appropriate time under the recommended storage conditions.

- Samples of raw materials may be retained according to company practice or in accordance with the regulations.

11. Treatment of product that is out of specification

a. Rejected finished products, bulk products, raw materials and packaging materials

- Investigations of rejected product or materials should be performed by the authorized personnel.

- Decisions to destroy or to reprocess should be approved by the personnel responsible for quality.

b. Reprocessed finished products and bulk products

- If all or part of a batch of finished product or bulk product does not meet the defined acceptance criteria, a decision to reprocess in order to obtain the defined quality should be approved by personnel responsible for quality.
- The method of reprocessing should be defined and approved.
- Controls should be performed on the reprocessed finished products or bulk products.
- Results should be reviewed by authorized personnel in order to verify the conformity of the finished product or bulk product with the acceptance criteria.

c. Wastes

Wastes should be disposed of in a timely and sanitary manner.

d. Flow

- The flow of waste should not impact on the production and laboratory operations.
- Appropriate measures should be taken concerning collection, transportation, storage and disposal of wastes.

e. Containers

- Containers of waste should be properly identified as to contents and other information, as appropriate.

f. Disposal

- The disposal of waste should be performed in an appropriate way with an adequate level of control.

12. Sub-contracting

A written contract or agreement should be established, mutually confirmed and controlled between the contract giver and the contract acceptor covering sub-contracted activities. The sub-contracting can be provided for:
i) manufacturing;
ii) packaging;
iii) analysis;
iv) cleaning, sanitization of premises;
v) pest control;
vi) equipment and premises maintenance.

a. Contract giver

- The contract giver should assess the contract acceptor's ability and capacity to carry out the contracted operations. Further, the contract giver should ensure that the contract acceptor has all the means available to carry out the contract.

- The contract giver should provide the contract acceptor with all the information required to carry out the operations correctly.

b. Contract acceptor

- The contract acceptor should ensure that they have the means, experience and competent personnel to meet the contract requirements.
- The contract acceptor should not pass to a third party any of the work entrusted to them in the contract without the contractor giver's prior approval and consent.
- The contract acceptor should inform the contract giver of any changes that may affect the quality of the services or products provided prior to implementation unless otherwise specified in the contract.

c. Contract

- A contract or agreement should be drawn up between the contract giver and the contract acceptor which specifies their respective duties and responsibilities.
- All data should be kept or made available to the contract giver.

13. Complaints and recalls

a. Product complaints

- Authorized personnel should centralize all complaints.
- Any complaints concerning a product defect should be kept with the original details and follow-up information.
- Appropriate follow-up on the concerned batch should be completed.
- Complaint investigations and follow-up should include:

i) steps to prevent recurrence of the defect;
ii) checking other batches in order to determine whether they are also affected;

- Complaints should be reviewed periodically to check for trends or recurrence of a defect.

b. Product recalls

- The authorized personnel should coordinate the recall process.
- Product recall operations should be capable of being initiated promptly and in a timely manner.
- The appropriate authorities should be notified of recalls which could have an impact upon consumer safety.
- Recalled products should be identified and stored separately in a secure area while awaiting a decision.

14. Internal audit

An internal audit is a tool which is designed to monitor the implementation and the status of the cosmetics GMP and to propose corrective actions.

a. Approach

- Competent personnel should conduct internal audits in an independent and detailed manner, regularly or on demand.

- All observations made during the internal audit should be evaluated and shared with appropriate management.

b. Follow-up

Internal audit follow-up should confirm the satisfactory completion or implementation of corrective action.

15. Documentation

Each company should establish, design, install and maintain its own system of documentation that is appropriate to its organizational structure and to the type of products. An electronic system can be used to prepare and manage documents.

a. Writing, approval and distribution

- Documents should be defined and describe the operations to be carried out, precautions to be taken and measures to be applied in all activities.

- The title, nature and purpose of documents should be stated.

- Documents should be:

i) written in a legible and comprehensive way;

ii) approved, signed and dated by authorized persons before being used;

iii) prepared, updated, withdrawn, distributed, classified;

iv) referenced to ensure that obsolete documents are not used;

v) accessible to appropriate personnel;

vi) removed from the job area and destroyed if they are outdated.

- Records which require the entry of handwritten data should:

i) indicate what is to be entered;

ii) be written legibly with permanent ink;

iii) be signed and dated;

iv) be corrected, leaving the original entry still readable.

b. Revision

Documents should be updated and the revision number indicated. The reason for each revision should be retained.

c. Archiving

- Only original documents should be archived and only controlled copies should be used.

- The storage of original documents should be properly secured.

- Documents may be archived as either electronic or hard-copies and their legibility should be ensured.

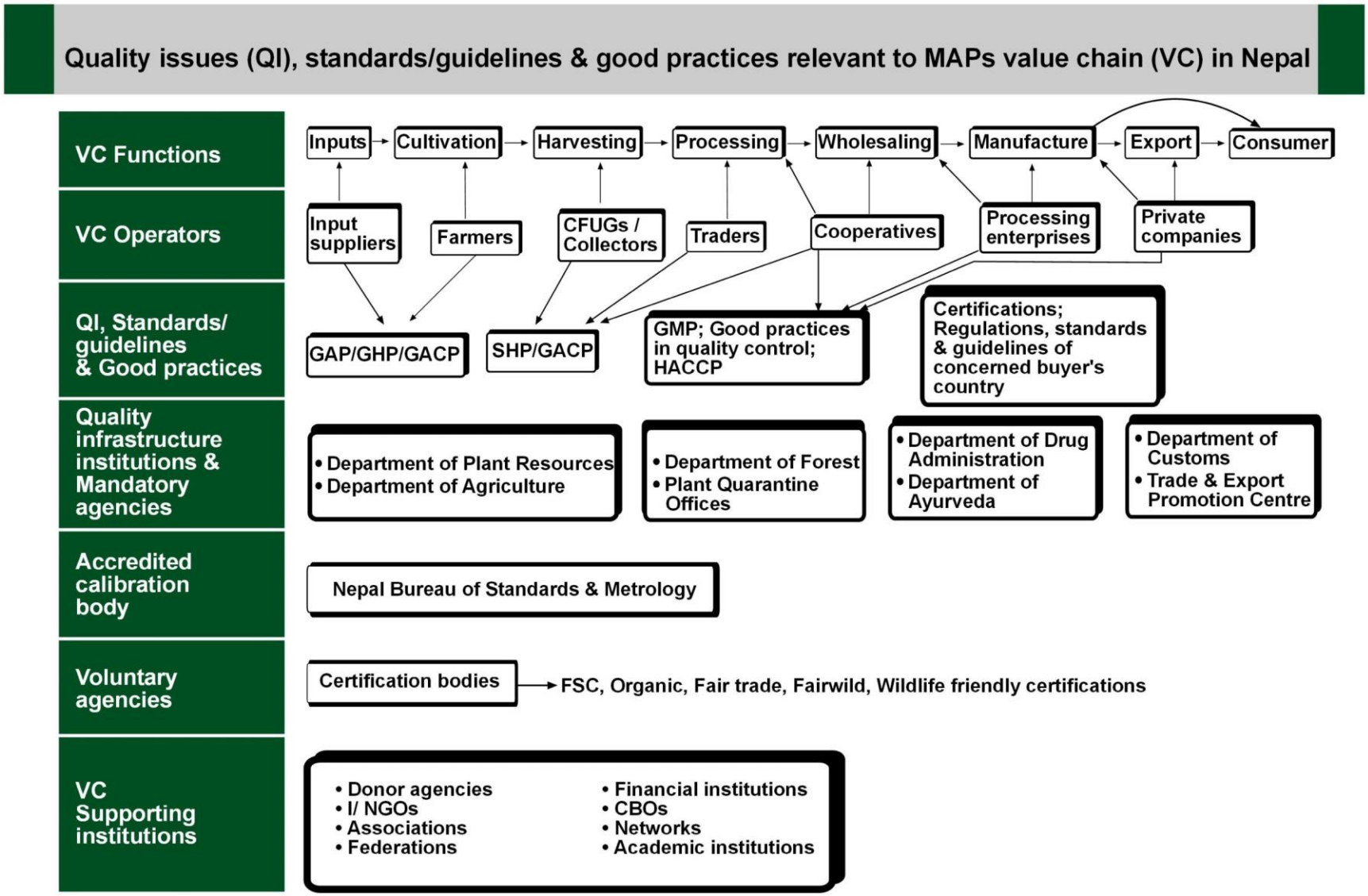

Figure 2: Quality issues, standards/guidelines & good practices relevant to MAPs value chain in Nepal

CHAPTER SIX

6.1 WHO quality standards and testing requirements for MAPs

Compliance with GACP and GMP is crucial for the production of good quality MAPs and MAPs products. The entire production process, starting from cultivation and ending with the sale of the products, must adhere rigorously to these two sets of practices.

1. Parameters for quality control of MAPs and it's products

a. Microscopic evaluation

Microscopic evaluation is indispensable in the initial identification of MAPs, as well as in identifying small fragments of crude or powdered MAPs, and detection of foreign matter and adulterants. Microscopic analysis is needed to determine the correct species and that the correct part of the species is present.

b. Determination of foreign matter

MAPs products should be made from the stated part of the plant and be devoid of other parts of the same plant or other plants. They should be entirely free from mould or insects, including excreta and visible contaminant such as sand and stones, poisonous and harmful foreign matter and chemical residues. Animal matter such as insects and microbial contaminants are also among the potential contaminants of MAPs products. Macroscopic examination can easily be employed to determine the presence of foreign matter.

c. Determination of ash

Total ash is the measure of the total amount of material left after burning and includes ash derived from the part of the plant itself and acid-insoluble ash.

d. Determination of heavy metals

Contamination by heavy metals such as mercury, lead, copper, cadmium, and arsenic in herbal remedies can be attributed to many causes, including environmental pollution, and can pose clinically relevant dangers for the health of the user and should therefore be limited. The potential intake of the toxic metal can be estimated on the basis of the level of its presence in the product and the recommended or estimated dosage of the product. This potential exposure can then be put into a toxicological perspective by comparison with the so-called provisional tolerable weekly intake values (PTWI) for toxic metals.

e. Determination of microbial contaminants and aflatoxins

MAPs may be associated with a broad variety of microbial contaminants, represented by bacteria, fungi, and viruses. This microbiological background depends on several environmental factors and exerts an important impact on the overall quality of MAPs

products and preparations. Risk assessment of the microbial load of MAPs has therefore become an important subject in the establishment of modern hazard analysis and critical control point (HACCP) schemes.
MAPs products normally carry a number of bacteria and molds, often originating in the soil. Poor methods of harvesting, cleaning, drying, handling, and storage may also cause additional contamination. While a large range of bacteria and fungi are from naturally occurring microflora, aerobic spore-forming bacteria frequently predominate. The presence of fungi should be carefully investigated and monitored, since some common species produce toxins, especially aflotoxins. Aflatoxins in MAPs products can be dangerous to health even if they are absorbed in minute amounts. Aflatoxin-producing fungi sometimes build up during storage.
In addition to the risk of bacterial and viral contamination, herbal remedies may also be contaminated with microbial toxins as such bacterial endotoxins and mycotoxins.

f. Determination of pesticide residues

It is important that MAPs and MAPs products are free of pesticides and fumigants or at least are controlled for the absence of unsafe levels. MAPs products/herbal medicines are liable to contain pesticide residues, which accumulate from agricultural practices such as spraying, treatment of soils during cultivation, and administering of fumigants during storage. However, it may be desirable to test MAPs products for broad groups rather than for individual pesticides. Many pesticides contain chlorine in the molecule, which can be measured by analysis of total organic chlorine. Insecticides containing phosphate can be detected by measuring total organic phosphorus.
Samples of MAPs material are extracted by a standard procedure, impurities are removed by partition and/or adsorption, and individual pesticides are measured by GC-MS.

2. Analytical methods

MAPs or MAPs extract can be evaluated by various biological methods to determine pharmacological activity, potency and toxicity. A simple chromatographic technique such as TLC may provide valuable additional information to establish the identity of the plant material. This is especially important for those species that contain different active constituents.
TLC fingerprinting is of key importance for MAPs products made up of essential oils, resins, and gums, which are complex mixtures of constituents that no longer have any organic structure.
HPLC is the preferred method for quantitative analysis of more complex mixtures. Though the separation of volatile components such as essential and fatty oils can be achieved with HPLC, it is best performed by GC or GC-MS.

TLC, HPLC, GC, quantitative thin layer chromatography (QTLC), and HPTLC can determine the homogeneity of a plant extract. Over-pressured layer chromatography (OPLC), infrared and UV-VIS spectrometry, MS, GC, liquid chromatography (LC) used alone, or in combinations such as GC-MS, LC-MS and nuclear magnetic resonance (NMR), electrophoretic techniques, especially by hyphenated chromatographies, are powerful tools, often used for standardization and to control the quality of both the raw material and the finished product. The results from these sophisticated techniques provide a chemical fingerprint as to the nature of chemicals or impurities present in the plant or extract.

3. Adulteration of MAPs products

Adulteration usually includes the practices in which MAPs products are substituted partially or fully with other inferior products. Due to morphological resemblance to the authentic MAPs, many different inferior commercial varieties are used as adulterants. This practice is most common in the case of volatile oil-containing materials, where the dried exhausted material resembles the original materials but is free of the essential oils. Foreign matter such as other parts of the same plant with no active ingredients, sand and stones, manufactured artifacts, and synthetic inferior principles are used as substitutes.

The practice of intentional adulteration is mainly encouraged by traders who are reluctant to pay premium prices for MAPs of superior quality, and hence are inclined to purchase only the cheaper products. This encourages producers and traders to sell MAPs of inferior quality. Rarity of MAPs is another factor that influences adulteration. In the absence of proper means of evaluation, authentic MAPs products partially or fully devoid of the active ingredients may enter the market. Factors such as geographical sources, growing conditions, processing, and storage are all factors that influence the quality of the MAPs products.

Physical factors such as air (oxygen), humidity, light, and temperature can bring about deterioration directly or indirectly. These factors, alone or in combination, can lead to the development of organisms such as moulds, mites, and bacteria. Oxidation of the constituents of a product can be brought about by oxygen in the air, causing some products, such as essential oils, to resinify or to become rancid. Moisture or humidity and elevated temperatures can accelerate enzymatic activities, leading to changes in the physical appearance and decomposition of the MAP.

Dried MAPs are particularly prone to contamination with spores of bacteria and fungi present in the air. Bacterial growth is usually accompanied by the growth of moulds, whose presence is evidenced by changes in appearance, breakdown of the plant material, and smell. Mites, nematode worms, insects/moths, and beetles can also destroy MAPs products during storage.

Control measures to protect against deterioration include the use of airtight containers made up of materials that do not interact physically or chemically with the material being stored. Storage in ventilated, cool, dry areas prevents deterioration of MAPs and products.

4. Toxicity of MAPs products

Traditionally, MAPs and MAPs/herbal products have been considered to be non-toxic and have been used by the general public and traditional medicinal doctors worldwide to treat a range of ailments. The fact that something is natural does not necessarily make it safe or effective.

MAPs and herbal preparations can cause toxic adverse effects, serious allergic reactions, adverse drug interactions, and can interfere with laboratory tests. Two kinds of side effects have been reported for MAPs based medicines. The first is mainly related to predictable toxicity due to toxic constituents of the MAPs ingredients and over dosage, and the second is allergy.

The major problem with regard to the safety of MAPs products is related to the manufacturing practice, including contamination, substitution, incorrect preparation and dosage, intentional addition of unnatural toxic substances, drugs, and herbal medicines, either intentional or unintentional mislabeling, and the presence of natural toxic contaminants.

5. Screening of MAPs products

Once the botanical identity of a MAP is established, the next step is phytochemical screening, which involves bioassays, extraction, purification, and characterization of the active constituents of therapeutic importance.

6.2 Quality testing requirements of buyers

International buyers mostly based in EU and United States require various quality tests in compliance with World Health Organization (WHO) standards (WHO, 1999, 2002, 2007 and 2009). The quality requirements for MAPs/herbs and/or spices, essential oils and vegetal oils are as per given Tables 2-4:

MAPs and spices: The required quality analysis parameters for MAPs and spices are presented in Table 2.

Table 2: Quality analysis parameters for MAPs and spices

SN	Quality analysis parameters
1	**Organoleptic properties** - Color - Odour - Taste
2	**General identity tests**

	- Macroscopic test - Microscopic test - Thin layer chromatography analysis
3	Extraction
4	**Purity tests** - Foreign matter - Total ash - Acid insoluble ash - Moisture - Pesticides residues - Heavy metals
5	**Microbial tests** - Fungi (moulds) - *Staphylococcus aureus* - *Candida albicans* - *Escherichia coli* - *Salmonella* spp, etc.
6	**Chemical assays** - Thin layer chromatography (TLC) - Gas liquid chromatography (GLC) - High performance liquid chromatography (HPLC)

Essential oils: The required quality analysis parameters for essential oils are presented in Table 3 as per Gurung (2009, 2010 and 2012).

Table 3: Quality analysis parameters for essential oils

SN	Quality analysis parameters
1	**Organoleptic tests** - Color - Aroma - Appearance
2	**Physical properties** - Specific gravity - Optical rotation - Refractive index - Solubility - Boiling point - Melting point - Flash point
3	**Chemical properties** - Acid number - Aldehyde content - Ester value - Ester value after acetylation

4	**Chemical analysis/constituents** - GC-MS - LC-MS - HPLC-MS - Fourier transform infrared spectroscopy (FTIR)
5	**Microbiological tests** - Antimicrobial - Anti-inflammatory
6	Toxicity test
7	Pesticide residue test

Vegetal oils: The required quality analysis parameters for vegetal oils are presented in Table 4.

Table 4: Quality analysis parameters for vegetal oils

SN	Quality analysis parameters
1	**Organoleptic tests** - Aspect - Color - Flavor
2	**Analytical tests** - GC analysis - Fatty acid profile
3	**Physico-chemical analysis** - Specific gravity - Acid value - Peroxide value - Iodine value - Saponification value
4	**Purity tests** - Irradiation detection - Total heavy metals - Water content - Phosphorus content
5	Composition of unsaponifiables
6	**Microbiological tests** - Total plate count - Yeast and moulds - *Staphylococcus aureus* - *Candida albicans* - *Escherichia coli* - *Salmonella* spp

6.3 Quality infrastructure and testing/analytical services in Nepal

Natural Products Research Laboratory (NPRL) under Department of Plant Resources (DPR) is the government laboratory established with the aim of research and development in the field of phytochemistry, medicinal plants, and technology development for the production of herbal products, standardization and quality control of drugs, medicinal plants and plant products. NPRL is only the government authorized body for testing/analysis and issuing the recommendation letter for export of herbs and essential oils and by-products. According to the provision of Custom Directive- 2057 BS (2000 AD), certification letter from NPRL/DPR is mandatory for the export of extract and by-products of herbs and plants. Tables 5 and 6 indicates the existing laboratory services at NPRL/DPR and other laboratories in Nepal.

Table 5: Existing laboratory services at NPRL/DPR

SN	Services provided by NPRL	Remarks
1	**Public analysis service**	
i	Identification of Silajit sample	Within 7 days
ii	Yield determination of fixed (vegetal) oil	Within 7 days
iii	Extractative value of MAPs	Within 7 days
iv	Identification of Chiretta extract	Within 7 days
v	Determination of bitter principle	Within 15 days
vi	Determination of physico-chemical parameter of essential oils - Acid value - Ester value - Ester value after acetylation	Within 7 days
vii	Determination of essential oil yield	Within 7 days
viii	Qualitative test by TLC	Within 7 days
2	**Phyto-chemical analysis service**	
i	Phyto-chemical screening of herbs	Within 30 days
ii	Plant extract preparation	Within 7 days
3	**Pharmacological analysis**	
i	Acute toxicity test	Within 15 days
4	**Pharmacognosy service**	
i	Identification of plant, plant parts and nomenclature	Within 7 days
ii	Identification plant powder sample	Within 7 days
5	**Instrumental analysis service**	
i	UV/VIS Spectrophotometer	Within 7 days
ii	IR	Within 7 days
iii	GLC/TLC	Within 7 days
iv	HPLC	Within 7 days
v	Polarimeter	Within 7 days

The quality tests for MAPs and herbal products need to be conducted for the preparation of specifications and technical data sheet (TDS) prior sampling to buyers

and export markets. The tests include organoleptic properties, physical properties, chemical properties, Gas Chromatography-Mass Spectrometry (GC-MS), etc.

Table 6: Quality tests and testing laboratories in Nepal

SN	Quality analysis parameters	Laboratory facilities in Nepal
1	Determination of foreign matter	NPRL, Herb Production and Processing Company Limited (HPPCL), NAST
2	Thin layer chromatography	NPRL, NAST, HPPCL
3	Determination of pesticides residue	Nepal Environment and Scientific Services Pvt. Ltd (NESS), Environment and Public Health Organization (ENPHO), NAST
4	Determination of heavy metals	NESS, CEMAT, ENPHO
5	Microbiological tests	NAST, NPRL, CEMAT, ENPHO
6	**Organoleptic properties**	
a	Color	NPRL, HPPCL
b	Odor	NPRL, HPPCL
c	Appearance	NPRL, HPPCL
7	**Physical properties**	
a	Specific gravity	NPRL, HPPCL, NESS
b	Optical rotation	NPRL, HPPCL, NESS
c	Refractive index	NPRL, HPPCL, NESS
d	Solubility	NPRL, HPPCL, NESS
e	Flash point	NPRL
f	Melting point	NPRL, HPPCL, NESS
g	Boiling point	NPRL, HPPCL, NESS
h	Solubility	NPRL, HPPCL, NESS
8	**Chemical properties**	
a	Saponification	NESS
b	Acid number	NPRL, HPPCL
c	Aldehyde content	NPRL, HPPCL
d	Ester value	NPRL, HPPCL
e	Ester value after acetylation	NPRL, HPPCL
f	Acid value	NPRL
g	Peroxide value	NPRL
h	Gas Chromatography (GC)/ Mass Spectrometry (MS), (GC-Infrared Spectrophotometry (IR)	NPRL, NAST, Water Engineering and Training Centre Pvt. Ltd
i	Ultraviolet and Visible Spectrophotometry (UV-VIS)	NPRL
j	Structure	NAST

6.4 Laboratories services and analysis outside Nepal

The exporters of MAPs or products send the sample representing the lot to the overseas importers/buyers. Depending on the buyers, they conduct the required tests and analysis of particular MAPs or products in their own laboratory or their contract/sub-contract laboratories. If the MAPs or products meet the requirements of buyers then they negotiate for purchase.

Few exporters conduct laboratory tests and analysis of some selected MAPs and products (such as essential oils and vegetal oils) in India (Kanauj and Delhi) and also in EU (mostly France and Italy). The cost of tests and analysis is expensive in EU laboratories and therefore, exporters based in Nepal cannot afford the associated cost. Box 3 shows the average cost of sample analysis of MAPs and products in EU laboratories.

Box 3: Average rate of sample analysis in EU laboratories

Average rate of sample analysis in EU labs (per sample):

Raw herbs:
Water content: 9-12€
Ashes: 33-40€
Dry matter: 45-48€

Essential oils:
Physico-chemical analysis: 150-160€
GLC: 68-72€
Acid value: 11-13€
Gravity: 11-13€
Refractive index: 27-30€
Optical rotation: 27-30€
Peroxide value: 11-15€
Flash point: 150-160€

Vegetal oils:
Physico-chemical analysis: 160-170€
Acid value: 11-13€
Peroxide index: 11-15€
UV spectrometry : 25-30€
Saponification value: 50-75€
Fatty acids content: 72-85€
Microbiological analysis: 700-800€
GC: 68-75€
Unsaponifiable matters content: 69.50-80€
Unsaponifiable matters composition: 107-115€

6.5 Accreditation of parameters relevant for MAPs

In order to approach markets and buyers, exporters should provide specification, technical data sheet (TDS) and certificate of analysis (COA) of products along with product samples. It is equally important that the testing and analysis has been conducted in accredited laboratory for the reliability of the test and analysis results. The Table 7 indicates the accreditation of parameters relevant for MAPs and processed products.

Table 7: Accreditation of parameters relevant for MAPs and products

SN	Parameters for raw MAPs	Parameters for essential oils	Parameters for vegetal oils
1	**General identity tests** - Macroscopic test - Microscopic test	**Physical properties** - Specific gravity - Optical rotation - Refractive index - Solubility - Boiling point - Melting point - Flash point	**Physical properties** - Specific gravity - Boiling point - Melting point - Flash point
2	**Purity tests** - Foreign matter - Total ash - Acid insoluble ash - Moisture - Pesticides residues - Heavy metals	**Chemical properties** - Acid number - Aldehyde content - Ester value - Ester value after acetylation	**Chemical properties** - Acid value - Peroxide value - Iodine value - Saponification value
3	**Analytical tests** - Thin layer chromatography - Gas liquid chromatography - High performance liquid chromatography	**Analytical tests** - Gas chromatography/Mass spectrometry - High performance liquid chromatography/Mass spectrometry	**Analytical tests** - Gas chromatography - Fatty acid profile
4	**Microbiological tests** - *Salmonella* spp - Fungi (moulds) - *Escherichia coli*	**Microbiological tests** - Antibacterial - Antifungal	**Microbiological tests** - Total plate count - Yeast and moulds - *Staphylococcus aureus* - *Candida albicans* - *Escherichia coli* - *Salmonella* spp
5		**Purity test** - Pesticide residue test	**Purity tests** - Heavy metals - Water content - Phosphorus content

6.6 Constraints of the laboratories and testing services in Nepal

Natural products research laboratory (NPRL) is only the government authorized body for testing, analysis and issuing the certification for export of herbs and essential oils and by-products in Nepal. According to the provision of Custom directive (2000), certification letter from NPRL/DPR is mandatory for the export of extract and by-products of herbs and plants. Therefore, exporters have no option than to rely on NPRL/DPR for the test and analysis services. Constraints of the NPRL testing services are summarized below:

a. Infrastructure

NPRL is located within the same building at DPR. The laboratory rooms are not well furnished. There is no alternative power supply during load shedding, whereas, 24-hours electricity is necessary to operate the laboratory. No lab grade water is used while operating instruments and the water supply system at laboratory is poor.
Instruments are not calibrated and many of them are not in operation. Reference literatures, reference library and reference chemicals and/or standards are lacking due to which majority of the compounds in essential oils and extracts are not identified.

b. Human resource

Chemists specialized in various fields of chemistry are needed to operate the required tests and analyses for herbs, essential oils and vegetal oils. NPRL lacks analytical (basically instrumental) and natural products chemists who are responsible for R&D of natural products.

c. Training

Chemists at NPRL are conducting tests and analyses of herbs, essential oils and vegetal oils as part of their routine work. Advance trainings on operation of instruments and methods of tests and analysis parameters for MAPs and herbs based products have not been conducted to NPRL chemists at Nepal or abroad. Therefore, only few basic tests and analyses are being carried out in NPRL.

d. Documentation

There is no documentation on tests and analyses of MAPs, essential oils and vegetal oils conducted by NPRL and do not provide analysis report (certificate of analysis) of essential oils and vegetal oils to exporters at the time of shipment. Therefore, due to unavailability of certificate of analysis and also lack of handling procedures for essential oils and vegetal oils, exporters have to depend on the secondary sources for the preparation of material safety data sheet (MSDS), basically for essential oils and vegetal oils.

Overview of quality control / quality assurance of MAPs & products

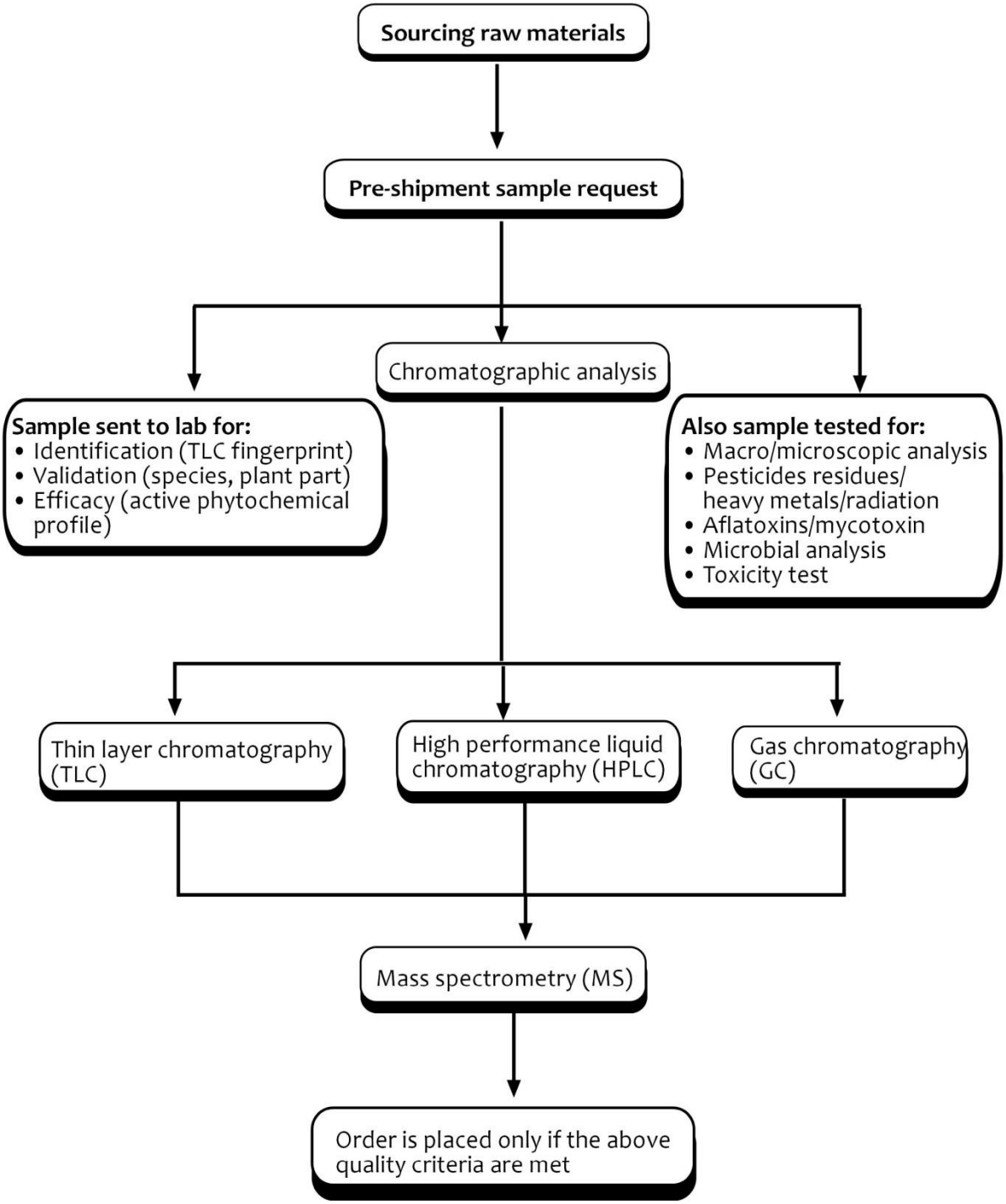

Figure 3: Overview of quality control/quality assurance of MAPs and products

CHAPTER SEVEN

7.1 Voluntary standards and additional requirements

There is a requirement for certifications in the trade of MAPs and products in international markets. There is an increasing need for safety documentation, traceability and assurance of quality. Certification is a way of ensuring buyers that certain standards have been maintained. In an increasingly competitive market, certification may provide an advantage in consumer choice, as Organic certified, FSC certified, Fair trade certified, etc. may prove a tipping point in a consumers mind to purchase the product. The only stipulation is the cost to maintain the certification may outweigh the benefits in sales. Sale price premium is a good way to identify whether certification has a positive cost-benefit ratio.

Certification has been an important step in the assurance of a quality product as well as assurance of traceability, environmental integrity, social integrity, labeling and packaging.

a. Organic certification

From the marketing perspective, there is a greater emphasis on Organic certification for MAPs and products such as essential oils and it has been proved to be a useful tool to approach international buyers. The well-known Organic certification bodies in Nepal are ECOCERT (France), NASAA (Australia), OneCert (USA), SGS (Switzerland), LACON GmbH (Germany) and IMO (Switzerland) etc. Different Organic standards need to be fulfilled for the access to various markets. For example, European Organic Standards (Council Regulation EEC No: 2092/91) needs to comply for the access to markets within the European Union. For those wishing to access the Japanese market needs to comply with all aspects of Japanese Agriculture Standards (JAS). Similarly, for the access to US markets, the suppliers must comply with USDA-NOP Standards of Organic Food Products Act, 1990.

b. Fair Trade Certification

There is also an established market in EU and US for the Fair trade certified products such as essential oils over the conventional oils. Some well-known Fair trade certification bodies are FLO CERT (Germany), ECOCERT (France) and IMO (Institute of Marketecology, Switzerland). However, in Nepal FLO CERT is the only certification body for Fair trade certification for the producers/or traders/ or organizations and the products.

c. FSC certification

Some environmentally conscious buyers also preferred FSC certified forest based products such as MAPs and processed products as essential oils, sourced from well managed forests. Rainforest Alliance (RA)/SmartWood (USA) and SGS are the FSC

accredited certification body in South Asia Region. In case of Nepal, RA/SmartWood has certified 35 community forests and 5 enterprises have been awarded Forest Stewardship Council (FSC)/ Chain of Custody (COC) certifications.

d. FairWild Certification

The FairWild certification implies to wild plant collection operations wishing to demonstrate their commitment to sustainable collection, social responsibility and fair trade principles.

Compliance with the FairWild standard ensure the continued use and long-term survival of wild species and populations in their habitats, while respecting the traditions and cultures, and supporting the livelihoods of all stakeholders, in particular collectors and workers. FairWild Foundation, based in Switzerland awards the FairWild certification.

e. Wildlife Friendly Certification

Wildlife Friendly certification ensures the protection of wildlife in wild habitats by certifying enterprises that assure people and nature coexist and thrive.

The Wildlife Friendly Enterprise Network (WFEN) based in US, works with its members to promote wildlife conservation through facilitation and certification of responsible production practices, enterprise development, education and branding.

f. Ethical Bio Trade Standards

The Union for Ethical BioTrade (UEBT) promotes the 'Sourcing with Respect' of ingredients that come from biodiversity. Trading members commit to gradually ensuring that their sourcing practices promote the conservation of biodiversity, respect traditional knowledge and assure the equitable sharing of benefits all along the supply chain. This commitment is measured through the implementation of the Ethical BioTrade standard in their business practices. The secretariat of Union for Ethical BioTrade is based in Netherlands.

7.2 Additional information required by the buyer/importing countries

The main concern of international buyers can be summarized as product quality, traceability and reproducibility. Quality can greatly affect the ability to market products internationally. In terms of the product quality, MAPs and products such as essential oils of Nepal are recognized as the highest quality in international markets. However, international buyers expect a high level of quality and this entails more than simply a good quality product. The aspects of high level quality includes: timeliness and an ability to meet deadlines, the traceability of a product (knowing where the product is at all times during the value chain process), compliance with industry standards, labeling and packaging that includes all pertinent information (MSDS, weight, volume, technical specifications), environmental integrity (whether the product minimize the impact on the

environment through the value chain), social integrity (whether the products benefit the livelihood of people in the rural communities), and overall customer satisfaction (whether the buyer is satisfied with the overall transaction).

1. Ingredients specifications needed for Flavor/Fragrance and Cosmetics based buyers

a) Facility controls: Suppliers shall have a documented Hazard Analysis Critical Control Point (HACCP) plan (or similarly recognized industry program) for each ingredient/or product.

b) Utility controls: Utilities shall be adequately controlled to ensure ingredients/or products are not contaminated with foreign material and/or undesirable microorganisms.

c) Pest controls: A documented pest control program shall be in place to effectively prevent pest activity in the facility or surrounding area.

d) Sanitation controls: The supplier shall have and maintain a documented sanitation program that meets regulatory standards.

e) Housekeeping controls: The supplier should have a designated person inspect their facility at a set frequency (at least monthly) to evaluate conditions that may impact ingredient safety or quality.

f) Weight controls: The supplier shall have a weight control program that complies with all applicable regulatory requirements.

g) Product certificate of analysis: A Certificate of analysis, per lot number, must accompany or precede each shipment. The Certificates of analysis shall comply with the terms/requirements stated on purchase order.

h) Microbiological analysis: Suppliers must have effective monitoring, detection, and control systems in place to ensure all ingredients are safe, wholesome, and void of undesirable microorganisms.

i) Foreign material/Adulteration: All plant personnel, visitors, and outside contractors shall comply with good manufacturing practice (GMP) requirements. All ingredient shipments must be free of foreign material, infestation, and rodent contamination in accordance with GMP.

j) Pesticide usage: Procedures shall be in place to ensure that products shipped have not been exposed to illegal pesticides and do not contain pesticide residues which exceed legal tolerances.

k) Allergens: Suppliers shall have controls in place to prevent the presence of unlabeled allergens in products. All raw materials used in the production of each ingredient/or product shall be reviewed to determine if allergens are present.

l) Regulatory: For materials that may pose a health or safety hazard to workers, safety information must be provided to buyer's receiving location. For US, Material Safety Data Sheet (MSDS) as defined by the United States Occupational Safety and Health Administration-OSHA: CFR 1910:1200 or a letter stating that an MSDS is not required, must be available to the receiving plant. For EU buyers, MSDS as accordance to Commission Regulation (EU) No. 453/2010 is generally required with delivered goods. Notification of fumigation and the type of fumigation must be included with every applicable shipment.

m) Packaging/Containers: Packages must be appropriate to the ingredient contained therein. They must be of such material and construction that the ingredient's integrity is maintained and that the ingredient is usable throughout its shelf life at the production plant.

n) Labeling: The labeling should be readily visible and must include:
- Supplier's lot number
- Date of manufacture, and expiration date or use by date
- Supplier's product name and generic name, if applicable
- Name and address of supplier
- Gross, tare, and net weight per container
- Ingredient listing: All ingredients, preservatives, processing aids, conditioning agents, incidental additives, undeclared ingredients, must be accurately, completely, and legibly labeled.
- Other information as required (such as storage requirements, purchase order number, etc.).

o) Traceability: The supplier must have the capability for 100% traceability through their manufacturing and distribution network for any specified lot(s). This shall include identification of all materials, rework, process conditions, and the customer(s) to whom the lot(s) was distributed.

p) Quality audits: Suppliers of ingredients/or products shall permit buyer's quality auditors', and/or accredited third party auditors on their behalf to review of records, processes, controls and facilities that demonstrate that ingredients/or products produced meet the expectations and specifications.

q) Additional documentations: Additional documentation on "Certificate of conformity with EU 1223/2009 for cosmetic products" and Certification "Not tested on animals" are also required.

2. Ingredients specifications needed for herbs and spices buyers

American Spice Trade Association (ASTA) and European Spice Association (ESA, 2011) have developed specification of quality minima for herbs and spices. The required specification includes:

a) Extraneous matter: Herbs- maximum of 2% and Spices- maximum of 1%
b) Foreign matter: Maximum of 2%
c) Total ash: Maximum of 8%
d) Acid insoluble ash: Maximum of 0.5
e) Moisture: Maximum of 10%

g) Packaging: Jute and sisal packaging material should not be used as they are the source of product contamination, with loose fibres from the sacking enters the products.

h) Heavy metals: Should comply with national or EU legislation. WHO maximum limit of heavy metals in herbs- 0.3mg/kg Cadmium and 10mg/kg Lead; According to European Monograph Herbal Drugs (2008), the acceptable limits of heavy metals in herbs- 0.1mg/kg Mercury; 0.5mg/kg Cadmium and 5mg/kg Lead.

i) Pesticides: Shall be utilized in accordance with manufacturers recommendations and good agricultural practices (GAP) and comply with existing national and/or EU legislation (WHO maximum residue limit- 0.05mg/kg).

j) Treatments: Use of any EC approved fumigants in accordance with manufacturers' instructions, to be indicated on accompanying documents. Irradiation should not be used.

k) Microbiology: *Salmonella* spp should be negative; Yeast and Moulds: 10^5/g target; *Escherichia coli*: 10^2/g target.

l) Off odors: Shall be free from off odors and taste.

m) Infestations: Should be free from live and/or dead insects, insect fragments and rodent contamination visible to the naked eye.

n) Aflatoxins: Should be grown, harvested, handled, and stored in such as a manner so as to prevent the occurrence of aflatoxins, or minimize the risk of occurrence. If found, the level should comply with existing national or EU regulations.

o) Volatile oil: Minimum of 1.5ml/100g

p) Adulteration: Shall be free from adulteration.

q) Documents: Should provide details of any treatments the product has undergone, name of product, weight, country of origin, lot identification/batch number, year of harvest.

7.3 Additional tests in EU/US by the importers

The additional tests, basically for cosmetics and perfumery use, have to be undertaken by the importers for the quality assessment of MAPs and/or products for further use in products and to develop comprehensive product documentation such as technical data sheets, stability testing, allergic reaction testing, efficacy testing, material safety data sheets, analysis reports, REACH registration for market promotion. Additional tests and evaluation includes:

- *Establishing the composition parameters of each product*
- *Stability testing*
- *Allergenic reaction testing*
- *Potential ocular irritancy testing*
- *Functional testing*
- *Toxicity/toxicological testing*
- *Carcinogenic and/or repro-toxic testing*
- *Efficacy of the active substances testing*
- *Nanomaterials*
- *Glycolic esters*
- *Heavy metal residues*
- *Formol or formol liberating substances*
- *Sulfates*
- *INCI composition (with CAS and EINECS numbers)*
- *REACH registration*

CHAPTER EIGHT

8.1 Testing services: support and services needed

DPR being the lead and scientific authority on plant resources, should dynamically work in forefront for the promotion of MAPs sector in Nepal. NPRL, the testing and analysis wing of DPR should maintain basic analytical instruments and develop the workforce for analysis of MAPs and their derivatives and also create the own reference chemicals for native plants.

The following points highlight the support and services required for NPRL in order to strengthen the existing laboratory facilities:

1. NPRL needs financial support to furnish the laboratory rooms and maintain chemical storage and documentation rooms so as to comply with the minimum criteria for the laboratory accreditation.
2. NPRL requires coordinated effort from DPR for the electrification of 3-phase electricity power at NPRL and 24 hours power supply in the laboratory.
3. NPRL is in need of support to generate funds for purchasing analytical instruments such as Spectroscopy, Mass Spectrometry, HPLC and standard reference/reference chemicals (both explored and unexplored compounds) which are much expensive to purchase from the allocated annual budget.
4. Combined lobbying with Ministry of Forests and Soil Conservation from NPRL, private sector, and support organization is necessary to established NPRL as an autonomous body. However, at present there is urgent need to fulfill the vacant positions at NPRL with analytical and natural products chemists and allocate risk allowance for analytical chemists as an incentive.
5. NPRL is looking for support for advance trainings on operation of instruments and updated methods of tests and analysis parameters for MAPs and its products. Natural products laboratory at Nepal Academy of Science and Technology (NAST) is the potential scientific body that can provide such trainings to NPRL quality control laboratory staffs.
6. NPRL needs consultant's service for documentation procedure such as quality manual and standard operating procedures (SOP) to comply with the standards of accreditation body prior moving ahead for accreditation.

8.2 Way forward

Quality issues in MAPs sector is ever raised concern in Nepal. Therefore, in order to address the quality issues of MAPs sector in Nepal, there should be a combined effort from the government sector, private sector and support/funding organizations in the following ways:

a. Trainings, guidelines preparation and implementation

Trainings should be conducted on GAP, GACP and GMP to the lead farmers, collectors and traders, processors and traders/exporters respectively. Trainings should be replicated to other farmers, collectors and concerned staffs of traders/exporters.

DPR should prepare guidelines on GAP, GACP and GMP as per WHO guidelines and/ or standards. Furthermore, DPR should encourage and assist the concerns parties for

the implementation of guidelines for the quality assurance in each step of value chain of MAPs.

b. Collective warehouse/storage house in major trading centers

The collective storage house- with controlled storage conditions, should be established in major trading centers such as Kakarvitta, Biratnagar, Birgunj, Nepalgunj and Attariya. Proper storage of MAPs helps maintaining the quality to some extent.

c. Strengthen the existing government laboratories

NPRL should be well equipped with required analytical instruments and equipment for the testing and analysis of MAPs and products. Existing equipment needs to be calibrated. Required human resources should be hired and existing manpower should be trained to operate the instruments.

d. Accreditation of NPRL

MAPs and its derivatives' testing and analysis parameters should be accredited at NPRL. Certificate of analysis is required to approach buyers/markets and in few occasions for the customs clearance at the destination countries.

e. Decentralization of testing laboratories and testing services

It is necessary to operate the MAPs testing laboratory at JABAN (in Nepalgunj) and also establish analysis laboratories in other major trading centers of MAPs such as Kakarvitta and Birgunj. These laboratories should be authorized for certification of MAPs and its products for export.

f. Preparation of pest database for traded MAPs

DPR is responsible to carry out pest risk assessment (PRA) of MAPs that are mostly exported in raw form. Both DPR and National Plant Quarantine Program (NPQP) lack the national pest database for MAPs which is a first step towards PRA. Survey surveillance of commodities for pests and diseases identifications is necessary to prepare the pest database.

On the other hand, the regulation of importing countries requires pest database and also PRA assessment report of species. Plant Quarantine Office has been issuing Phytosanitary certificate (PC) for the export of MAPs on the basis of visual observation. Whereas, PC is an assurance that the exporting commodity is not associated with plant quarantine objects that is in trade.

g. Focus on R&D in collaboration with private sector

DPR, NAST, RECAST and other research and/or academic institutions should collaborate with private sectors for R&D on MAPs and its products (essential oils, extracts, vegetal oils, active ingredients, etc.) which are not in trade. R&D is essential for the commercialization of such MAPs and products.

h. Monographs and herbal pharmacopoeia

Nepal government should initiate the publication of monographs of selected traded MAPs in compliance with WHO guidelines and/or standards and ultimately the publication of "*Nepal Herbal Pharmacopoeia*".

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