Daniel Kraus, Tony Bunn, Michelle Mulder (Ed.)

Requirements for Access to Affordable and Efficacious Traditional Medicine(s)

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Preface

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Switzerland is home to some of the world's largest pharmaceutical companies. In addition, it has a well developed complementary and herbal medicines infrastructure and has devised regulations to harmonise these within the "western medicine" paradigm. In spite of this, while enjoying a high standard of living like other industrialized countries, Switzerland too, is suffering from the continuously rising costs of health care. In addition, there is an ever increasing burden of communicable and lifestyle diseases, coupled with the variability in efficacy of existing drugs. The growing incidence of drug resistance further raises the need for new and improved therapeutics against existing and emerging diseases and disorders. Currently, traditional medicines provide a relatively untapped source of potential new medicines to address such health issues both in Switzerland and elsewhere.

South Africa is an innovative developing country endowed with a vast biodiversity and associated traditional knowledge, which, combined, has led to a substantial collection of traditional medicines. South Africa and Switzerland have often expressed different point of views in negotiations such as those ones on access to medicines at the World Trade and the World Health Organizations. However, both countries – Switzerland as an importer of traditional knowledge and medicine and South Africa as an exporter – have a mutual and vested interest to work together in finding sustainable solutions to the question of access to affordable and efficacious medicines in both their countries. It is clear that such industrialized and developing countries need to work together if they are to find solutions in providing sustainable health care to their populations.

In the last few years, attention to the use of traditional medicines has been growing around the world. In many developing countries, traditional medicine represents an important means of providing health care to the population. According to the World Health Organization (WHO), in China, it accounts for around 40% of all health care delivered. In India, 65% of the population in the rural areas uses Ayurveda and medicinal plants to help them meet their primary health care needs. In South Africa, it is estimated that about 80% of the population regularly consults traditional healers as well as having recourse to conventional western medicines.

According to the WHO, the percentage of developed world populations that use complementary and alternative medicines (CAMs) is 46% in Australia, 49% in France and 70% in Canada. In Switzerland, a survey of 610 doctors showed that 46% of them had used some form of CAM, mainly homeopathy and acupuncture[1]. CAMs are also very popular in North America.

Several factors may explain the rise in popularity of traditional medicines. While the perceived "organic" as opposed to "chemical" nature is one factor, another is certainly that of cost. This latter factor is true not only in developing countries such as South Africa, but also in industrialized countries such as Switzerland, where the burden of cost on the State and on patients increases every year to a point that many households have difficulty paying for the basic health insurance. Traditional medicine provides a means of offering accessible healthcare to a large portion of the population in South Africa. It may also be part of the answer to the constant rise in cost of medical treatment in Switzerland. If this is shown to be the case, a series of questions need to be answered in order to foster recourse to it:

– What is considered as traditional or complementary and alternative medicines (WHO, South African and Swiss definitions)?

– What examples may be given that are successful, particularly in South Africa?

– What could be the means of encouraging its development? In particular, how could research and development of pharmaceutical products based on traditional knowledge be ensured, while respecting the rights of the owners of that knowledge?

– What is the state of legislation and of discussions at the international level (WTO/TRIPS, WIPO, CBD), in South Africa and in Switzerland?

– What then would be the conditions for commercialisation at the international and national levels? What do the World Trade Organization rules, in particular the GATT and other agreements foresee? At the national level, what are the rules, de lege lata and de lege ferenda, for authorizing marketing of these products?

– In parallel to product safety how can patients be ensured of efficacy of treatment provided by traditional, complementary or alternative healers?

1 WHO traditional Medicine Strategy 2002-2005. p. 11, available at http://whqlibdoc.who.int/hq/2002/WHO_EDM_TRM_2002.1.pdf.

– What problems have been identified in South Africa and in Switzerland? How have these been dealt with, and how can the experiences acquired in one country benefit the other?

– And finally, how is financing of treatment ensured in both countries? What problems have been identified in South Africa and in Switzerland? How have these been dealt with, and how can the experiences acquired in one country benefit the other?

The present book attempts to shed some light on those issues and is the product of an interdisciplinary seminar organized by the editors from 6 to 8 March 2007 in Cape Town, South Africa. The seminar, funded by the South African National Research Foundation and the Swiss National Science Foundation, was initiated in order to create new ties between South African and Swiss researchers specifically in the fields of law, (public) health and international trade. Not only scientific, but also practical outcomes were expected from the seminar due to the relations that both these institutes have with governmental agencies, international organizations, NGOs and public private partnerships. The present publication constitutes the second step in establishing collaboration between South Africa and Switzerland in the developing field of international public health. More seminars, more publications and hopefully practical outcomes are expected for the future.

The editors would like to express their thanks to the Swiss National Science Foundation for financing the present publication.

Special thanks also to Mrs Beatrice Stirner, Mrs Dominique Mengisen, Mrs Nicole Tscharner and Mr Jean Perrenoud for their always very friendly and efficient assistance in the publication of this book.

Traditional Medicine(s): Definitions and Terminology

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Definitions of traditional medicine(s) may vary from a State to another. This first contribution provides a compilation of definitions as developed in the WHO framework, in South Africa and in Switzerland. Although not exhaustive, it should be considered as a basis for the understanding of other contributions contained in this publication.

According to the World Health Organization (WHO), countries in Africa, Asia and Latin America use traditional medicine to meet many of their primary health care needs. In Africa, up to 80% of the population uses traditional medicine for primary health care and recourse to complementary and alternative medicine (CAM) is becoming increasingly popular in industrialized countries. WHO estimates that the percentage of the world population that has had recourse to CAM at least once, is 48% in Australia, 70% in Canada, 42% in USA, 38% in Belgium and 75% in France[1].

However, it is no easy task to define traditional medicine. What is considered as traditional in one region may be new to another, or may not be regularly used in the traditional sense.

Different words are used in different countries to describe the same products or procedures, taking into account the realities of local culture. The current contribution provides a compilation of definitions using the WHO framework and within the context of a developing and a developed country, namely South Africa and Switzerland. It is by no means meant to be exhaustive, but should rather be considered as a basis for the understanding of numerous other contributions contained in this publication.

A. World Health Organization definitions

The WHO specifies that traditional medicine may on one hand be codified, regulated, taught openly and practised widely and systematically, and benefit from thousands of years of experience. Yet on the other hand, traditional medicine may also be highly secretive, mystical and very localized, with knowledge of its practices passed on orally. While there is no precise definition of traditional medicine at the international level, the WHO recognizes the diverse and sometimes conflicting characteristics and viewpoints surrounding traditional medicine. Nevertheless, the WHO considers a working definition, which is comprehensive and inclusive, as useful; we would add that it is a necessity.

The WHO defines traditional medicine in several of its official documents. Traditional medicine is broadly described as “the sum total of the knowledge, skills, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness”. It incorporates plant, animal, and/or mineral based medicines, spiritual therapies,

1 WHO Traditional Medicine Strategy 2002-2005, p.2, available at http://whqlibdoc.who.int/hq/2002/WHO_EDM_TRM_2002.1.pdf

manual techniques and exercises applied singularly or in combination to maintain well-being, as well as to treat, diagnose or prevent illness[2].

One of the definitions given for 'African Traditional Medicine' by the WHO Centre for Health Development is the following:

"The sum total of all knowledge and practices, whether explicable or not, used in diagnosis, prevention and elimination of physical, mental, or societal imbalance, and relying exclusively on practical experience and observation handed down from generation to generation, whether verbally or in writing."

Traditional medicine systems are manifold; they may include e.g. traditional Chinese medicine, Indian ayurvedic and Arabic unani medicine. A variety of indigenous traditional medicine systems have also been developed throughout history by Asian, African, Native American, Oceanic, Central and South American and other cultures. Influenced by factors such as history, customs, traditions and philosophy, the practice may vary greatly from country to country and from region to region[3].

Traditional medicines therapies include *medication therapies* – if they involve use of herbal medicines, animal parts and/or minerals – and *non-medication therapies* – if they are carried out primarily without the use of medication, as in the case of acupuncture, manual therapies and spiritual therapies. In countries where the dominant health care system is based on allopathic medicine, or where traditional medicines has not been incorporated into the national health care system, traditional medicines is often termed "*complementary*", "*alternative*" or "*non-conventional*" medicine[4]. Biomedical literature refers to the use of traditional medicines as *phytotherapy*. Traditional medicine and traditional healers form part of a broader field of study classified by medical anthropologists as *ethnomedicine.*

1. Traditional use of herbal medicines

Traditional use of herbal medicines refers to long established use of these medicines. Herbal medicines include herbs, herbal materials, herbal preparations and finished herbal products. These contain active ingredients from plant materials.

2. Traditional procedure-based therapies

Traditional medicine also involves types of traditional procedure-based therapies. These therapeutic methods are used to provide health care using various techniques

2 Ibidem, pp. 2ff; see also WHO Executive Board Decision of 24 January 2003, doc. EB:111.R12, available at http://www.who.int/gb/ebwha/pdf_files/EB111/eeb111r12.pdf.
3 WHO Traditional Medicine Strategy 2002-2005, p.7.
4 Ibidem, p. 11.

primarily without the application of medication. They include, for example, acupuncture and related techniques, chiropractic, osteopathy, manual therapies, qigong, tai ji, yoga, naturopathy, thermal medicine, and other physical, mental, spiritual and mind-body therapies[5].

3. The Commision on Intellectual Property Rights, Innovation and Public Health definition

The Commission on Intellectual Property, Innovation and Health (CIPIH) also examined the issue of traditional medicine to determine in which way traditional medicine might best contribute to the process of discovery, development and delivery of pharmaceutical products.

In its report the Commission identified four components in which traditional medicine could be applied.

3.1. Traditional medicine as a system of treatment

This derives from the Traditional Medicine Strategy, wherein traditional medicine is considered as a system of treatment,

"sometimes with sophisticated methods of assessing health and diagnosing ill-health. These systems normally take a holistic approach […] that of viewing man in his totality within a wide ecological spectrum, and of emphasizing the view that ill health or disease is brought about by an imbalance, or disequilibrium, of man in his total ecological system and not only by the causative agent and pathogenic evolution.

Systems such as the Indian ayurveda or traditional Chinese medicine have a coherent theoretical foundation, including frameworks for classifying diseases and the medicinal plants used to treat them, and systems for classifying ill health. By contrast, modern medicine is more reductionist and direct. While many traditional remedies rely on mixtures of natural ingredients with complex compositions to cure particular conditions, modern medicine generally seeks one active ingredient to address one condition (although, as we have seen, combinations of drugs are now increasingly common e.g. in malaria, HIV/AIDS and TB)."

3.2. Traditional medicine as a source of knowledge

Secondly, and closely related to the above definition, the CIPIH defines traditional medicine as a "source of knowledge about natural remedies that are effective, and

5 Ibidem, p. 15.

are also remedies based on natural products". The fact that every Indian mother knows that turmeric has wound healing properties and that this was recorded in ancient times in a Sanskrit text is given as an example.

3.3. Traditional medicine as a source for new modern medicines

Thirdly, the CIPIH recognizes that "natural products are a rich source for discovering and isolating new modern medicines" and that "traditional medical knowledge can provide a shortcut, in that the product may already have a known impact". The question then is "how the active ingredients might be isolated or synthesized artificially, or how combinations of active ingredients that are effective might be reproduced on a commercial scale." One must also take into account how the owners of the knowledge obtain fair and equitable benefit from the use of their knowledge.

3.4. Traditional medicine as an important factor of health care systems

Fourthly, traditional medical practitioners are recognized by the CIPIH report as an important part of the health-care system in many developing countries[6].

4. Complementary medicine

The CIPIH report also specifies that, in some countries, the terms "complementary medicine" or "alternative medicine" are used inter-changeably with traditional medicine. These refer to a broad set of health care practices that are not part of that country's own tradition and are not integrated into the dominant health care systems[7].

As an example, the report mentions the traditional Chinese medicine of acupuncture therapy. Yet many European countries define it and traditional Chinese medicine in general, as complementary or alternative medicine, because they do not form part of their own health care systems. Similarly, the CIPIH report gives the example of homeopathy and chiropractic systems, developed in Europe as early as the 18th century, after the introduction of allopathic medicine; they were not categorized as traditional medicine systems nor incorporated into the dominant modes of health

6 For all these four definitions, see Commission on Intellectual Property, Innovation and Health: Public Health, Innovation and Intellectual Property Rights, 2006, pp. 160ff. http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf

7 See, generally, WHO General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine, WHO/EDM/TRM/2000.1, p. 1, available at http://whqlibdoc.who.int/hq/2000/WHO_EDM_TRM_2000.1.pdf

care in Europe. Instead, they are regarded as a form of complementary or alternative medicine[8].

B. South African definitions

In South Africa the majority of people associate traditional medicine with herbal remedies (or muti) and advice imparted by *sangomas* or *izinyangas*. Traditional healers are generally divided into two categories:

– The diviner-diagnostician (or diviner-mediums) who provides a diagnosis usually through spiritual means and,

– The herbalist who then chooses and applies relevant remedies by means of herbs.

1. Diviners: *Sangomas* – about 90% female

Diviners are the most important intermediaries between humans and the supernatural. No one can become a diviner by personal choice (unlike herbalists). Diviners (more usually women) believe that their calling originates from their deceased ancestors and they regard themselves as servants of the ancestors. Diviners concentrate on diagnosing the inexplicable.

Diviners analyse the causes of specific events and interpret the messages of the ancestors. They use divination objects and they explain the unknown by means of their particular medium powers. They often also provide medication for the specific case they have diagnosed.

2. Herbalists: *Izinyanga* – about 90% male

Herbalists are ordinary citizens who have acquired an extensive knowledge of herbal remedies and techniques. They are expected to diagnose and prescribe medicines for everyday ailments and illnesses, to prevent and to alleviate misfortune or evil, to provide protection against witchcraft and misfortune, and to bring prosperity and happiness. In the healing practices of herbalists empirical knowledge plays an important role as they are able to diagnose certain illnesses with certainty and to prescribe healing herbs for those illnesses.

8 WHO Traditional Medicine Strategy 2002-2005, p.8

3. Prophets/faith healers: *Umthandazi*

In their diagnosis and treatment of a patient, prophets/faith healers use prayer, candlelight or water. Occasionally, upon a cure, a patient automatically becomes a member of the church to which the faith healer who cured him/her belongs.

4. Traditional birth attendants: *Ababelithisi*

Traditional birth attendants (TBAs) often serve communities located in isolated and remote areas where they are consulted as a matter of necessity, due to the unavailability of "Western" health care services. However, they also render their services in urban/semi-urban communities that often still prefer TBAs.

Although information on the status of TBAs in South Africa is not readily available, they form a significant and very extensive human resource component in the traditional sector.

C. Swiss definitions

In Switzerland no standard definition of traditional medicine exists. In general, the term is used for different modalities of health care activities. The curative role of herbal remedies, mineral waters, or natural food diets is part of the Swiss culture, and has often been associated with traditional medicine. Besides this natural oriented approach the term is also employed in the country's culture to describe "newer" therapies, such as yoga, chiropractic, acupuncture or anthroposophical medicine and other methods, which are usually referred to as complementary medicine. Common ground for the diversity of understanding of traditional medicine in Switzerland is its independence from modern scientific medicine. However, this pluralism in terminology received a more concentrated direction through recent debate to integrate complementary medicine into the country's health care delivery system. A People's Initiative, launched in 2005, seeks to amend the Constitution in order to institutionalize complementary medicine into all areas of the Swiss health system, including education, research and, in particular, the social security schemes.

The following summarizes both the Swiss Federal Council's and the People's Initiative's definition of traditional or complementary medicine respectively.

1. The Swiss Federal Council definition

According to the Swiss Federal Council, complementary medicine is a collective term to describe therapies that are used to either complement biomedicine or to provide an alternative to the evidence-based conventional medicinal practices. CM refers to a wide variety of treatment modalities, including diagnosis, therapy and preventive methods. In Switzerland more than 200 different therapy forms are offered under this term[9].

Complementary medicine can be broadly divided into four major categories:

1. Whole medical systems: e.g. Homeopathy, Traditional Chinese Medicine, Ayurveda;
2. Biologically based therapies: herbal therapies, vitamins, minerals and others used as medicinal products or as dietary supplements;
3. Manipulative or body based therapies: e.g. Shiatsu, Cranial Osteopathy, Alexander technique, Feldenkrais;
4. Energy therapies: e.g. biofield therapies (Reiki, Qigong); bioelectromagnetic-based therapies.

Physicians practising forms of complementary medicine are organised under the umbrella of the Union of Associations of Swiss Physicians for complementary medicine. Therapies accepted and performed by members of the Union are for example[10]: acupuncture, antroposophic medicine, bioelectromagnetics, chiropractic, nutrition therapy, homeopathy, music therapy, neural therapy, phytotherapy, Traditional Chinese Medicine.

2. The People's Initiative for the Integration of Complementary Medicine into the dominant Swiss health care system

The Initiative's Committee provides a more comprehensive description of complementary medicines: complementary medicine comprises a broad range of treatment and diagnostic methods and products that have evolved from long cultural tradition

9 Message of the Swiss Federal Council to the People's Initiative on Complementary Medicine, August 2006, p. 7601, available at: http://www.bag.admin.ch/themen/krankenversicherung/00305/02363/index.html?lang=de

10 Message of the Swiss Federal Council to the People's Initiative on Complementary Medicine, August 2006, pp. 7603 ff, available at: http://www.bag.admin.ch/themen/krankenversicherung/00305/02363/index.html?lang=de

or, occasionally, in more recent times, in Western or non-Western cultures. They are provided by qualified medical doctors or other allied health care providers.

The term “complementary” implies that complementary medicine and biomedicine complement one another. However, when referred to as “alternative medicine” complementary methods may also be used instead of the conventional forms of medical care available.

The fundamental difference between biomedicine and complementary medicine is the philosophical approach. Conventional medicine tends to focus on the body itself, dividing it into systems and sections, measures functions and body interactions. Illnesses are diagnosed and treated as individual entities apart from the patient. The focus of conventional medicine is on the abnormalities, and therefore, to provide a cure for a specific complaint. In contrast, complementary medicine also considers energetic phenomena, not only the body’s regulative processes. The healing approach of complementary medicine concentrates on the “whole person” and the treatment of the “whole” patient, incorporating physical, mental and spiritual aspects into diagnosis and treatment. This includes the body’s inherent healing ability and self regulatory powers as well as life style and the environment of the patient. The conceptual basis of complementary medicine is, in particular, the prevention of illnesses and health promotion and well-being[11].

D. Conclusion

The above short compilation of definitions shows the differences of terminology that may be found between developing and industrialized countries, or, rather, between countries with a strong *local* history of traditional medicine and those that are more *importers* of such medicine. A unified definition from an international organization such as the World Health Organization would certainly be welcome in the future.

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Accessed July 2, 2007

International Trade in Pharmaceutical Products and the GATT 1994: The Case of Traditional Medicine

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WTO law has large implications for health policies in both industrialized and developing countries. This article provides an overview on the regulatory principles of the GATT 1994 on market access for pharmaceutical products in terms of tariffs and non-tariff barriers. These principles relevantly impact the international promotion and commercialisation of traditional medicine. The article critically assesses the legal state of the art and proposes interesting policy options.

* Many thanks go to Dr. Marion Panizzon, World Trade Institute, Berne, for her critical comments and help.

I. Introduction

Over the last few years, the use of traditional medicine has been steadily growing around the globe. WHO statistics estimate that 80 per cent of the population in Africa rely on traditional medicine for their primary health-care needs.[1] Equally, traditional medicine – or, as often used interchangeably, complementary and alternative medicine – is becoming increasingly popular in developed countries.[2] In Switzerland, approximately half of the population occasionally uses some form of medical treatment which is not based on modern science but on traditional knowledge and wisdom, mainly homeopathy and acupuncture. Furthermore, traditional medicines, which are often based on traditional knowledge, are valuable for many other reasons. Traditional knowledge forms an integral part of the conservation and further development of the world's biological resources; it is of prime importance for the livelihood of indigenous and local communities as well as for a great number of people living in subsistence economies who depend on biodiversity for their day-to-day survival.[3]

Various international agreements constitute the relevant law concerning trade in pharmaceutical products in general and traditional medicines – as a relatively new field of interest – in particular.[4] Amongst them is the WTO. Its regulatory principles on market access for goods in terms of tariffs and non-tariff barriers as well as its provisions for the protection of intellectual property rights have large implications for health policies in both developed and developing countries.[5] Entangled in a complex web of international organizations and agreements, the WTO is one of the most influential agencies in this field – yet, its likely impact on the protection of, and the enhancement of market access for, traditional medicines has not been given much attention to date. In scholarly writings, it is generally the WTO's rules on the protection of intellectual property rights which are at the forefront of debate (and criticism).[6] Pertinent questions about the safety and efficacy of traditional medicines

1 See for definitions World Health Organization, WHO Traditional Medicine Strategy 2002-2005, WHO, 2002, at 1. The first contribution in this book also provides a helpful overview on the various definitions.

2 World Health Organization (supra fn. 1), at 7.

3 Susette Biber-Klemm/Danuta Szymura Berglas, Problems and Goals, in: Susette Biber-Klemm/Thomas Cottier (eds.), Rights to Plant Genetic Resources and Traditional Knowledge: Basic Issues and Perspectives, Oxfordshire, CABI, 2006, 3-55, at 21.

4 See for an overview on the law on traditional knowledge Susette Biber-Klemm/Thomas Cottier/Philippe Cullet/Danuta Szymura Berglas, in: Susette Biber-Klemm/Thomas Cottier (eds.) (supra fn. 3), 56-111.

5 See Mike Rowson, World Trade Organisation: Implications for Health Policy, Medact, 2000, at 2.

6 See Ingo Meitinger's contribution to this book.

and hence about their international commercialisation, however, reach beyond the scope of intellectual property protection. Main obstacles to their adequate promotion are likely to result from – often only prima vista legitimate and necessary – technical barriers to trade as questions of safety and efficacy are far from resolved. Moreover, a (too) restrictive interpretation of 'like products' prevents governments from privileging traditional medicines over their conventional counterparts by, e.g., subjecting them to different internal taxation and other regulatory measures.

This paper examines the GATT 1994 regulatory framework and its relevance for trade in pharmaceutical products. It does so with a special focus on traditional medicines, aiming at identifying the main problems and at providing inputs for further research. By way of introduction, Part II deals with market access in general and turns to tariffs, being the oldest and still most common instrument at the disposition of nation states to regulate the importation, and sometimes the exportation, of goods. Moreover, the potential of privileged market access for developing and least-developed countries' products to developed countries' markets is examined. Part III turns to the basic principle of non-discrimination. In particular the scope and contours of the term 'like products', finding itself at the heart of any discussion on non-discrimination, informs national policy-makers and shapes their freedom to treat traditional medicines more favourably than conventional products. The question arises whether preferential rules can be contemplated, in terms of domestic taxation and market regulations, for traditional medicines based upon a less conservative reading of the term 'like products' than that usually applied in WTO jurisprudence. Part IV addresses technical barriers to trade and sanitary and phytosanitary measures which represent, in addition to tariffs and quantitative restrictions, the two other classical instruments applied to the importation and exportation of goods at the border. The policy of tariff reduction has given rise to this new generation of trade restrictions which are more difficult to regulate and explain why defining market access has become truly complex. Lastly, Part V provides a short outlook.

Importantly, the object of WTO law is limited to governmental measures. Rights and obligations inherently do not extend to the conduct of non-state actors, in particular private firms. They are not directly entitled and obliged under the WTO. Even if governmental barriers to trade are removed for products, private conduct may still have the potential to offset the benefits of such actions, which aim at levelling the playing field, through private anti-competitive behaviour if the involved enterprises' (combined) market power suffices to counteract governmental policies. Trade in pharmaceutical products is a prominent example in point as mergers between powerful global players or cartels (e.g., price fixing for vitamins) have frequently

demonstrated in the past.[7] At this stage, WTO law does not address domestic competition policies affecting international trade such as cross-border mergers and acquisitions and export or import cartels. This is unsatisfactory. The introduction of regulatory guidelines for members' competition policies into the WTO is a necessity if the effectiveness of the regime is to be maintained.

II. Market Access and Tariffs

The multilateral trading regime of the WTO is founded on the theory of comparative advantage according to which open markets with low tariffs, coupled with the absence of subsidies and other non-tariff barriers, lead to increased trade across national borders and bring about prosperity, growth and poverty alleviation.[8] This theory forms the conventional background against which the normative arguments for the case of liberal trade policies and the caveats of free trade are shaped. The Preamble to the WTO explicitly stipulates that its regulatory framework is based upon the idea of progressive liberalisation and the elimination of discriminatory treatment in international commerce. Hence, the GATT 1947/WTO provides a legal framework for gradually reducing tariffs and preventing or remedying circumvention of tariff cuts from indirect erosion and evasion, e.g. through the adoption of quantitative restrictions and discriminatory internal measures. Over the last fifty years, it has indeed been successful in achieving this goal.[9]

However, the WTO does not simply amount to a free trade agreement as such. It explicitly recognises the legitimacy of other policy goals and of the need to strike a proper balance between the interest of market access and that of domestic production.

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7 See Mitsuo Matsushita/Thomas J. Schoenbaum/Petros C. Mavroidis, The World Trade Organization: Law, Practice, and Policy, Oxford, Oxford University Press, 2003, at 541-45.

8 Thomas Cottier/Marion Panizzon, Enhancing Market Access, in: Susette Biber-Klemm/Thomas Cottier (eds.) (supra fn. 3), 357-91, at 361; see for an overview on economic theories in international trade Thomas Cottier/Matthias Oesch, International Trade Regulation: Law and Policy in the WTO, the European Union and Switzerland, Cases, Materials and Comments, London/Berne, Cameron May/Staempfli Publishers Ltd., 2005, at 33-43.

9 The average tariff rate in the industrial sector among developed GATT Contracting Parties amounted to 40% in 1947 and could be reduced, in several multilateral trade rounds, to 4% at the end of the *Uruguay Round* in 1995; see Cottier/Oesch (supra fn. 8), at 74.

A. Functions of Tariffs

In pursuing policy goals other than trade liberalisation, tariffs remain, in principle, the basic trade policy instruments at the disposition of governments. Unlike quantitative restrictions, which are essentially banned under Article XI of the GATT 1994, tariffs are neither excluded nor abolished under WTO law. Nor are members barred from raising tariffs if they wish to do so, though not without offering compensation above the limits set forth in their schedules of commitments pursuant to Articles II and XXVIII of the GATT 1994. WTO law clearly favours tariffs over other trade-restrictive measures. The rationale for preferring tariff protection over all other types of trade barriers imposed at the border is well known: tariffs are the trade instrument, which is most closely related to the price of a product, and thus do not distort the international allocation of resources and the mechanisms of comparative advantage.[10] Moreover, tariffs offer the advantages of legal security and predictability as potential traders can readily anticipate the costs of importation and exportation and thus of market access. Therefore, WTO law conceptually considers trade restrictions other than tariffs exceptional.

Beside of considerations of economic theory, tariffs have traditionally been relevant for another reason. For many centuries, they were and, for developing countries in particular, still are a main instrument of fiscal revenue (*fiscal tariffs*). Tariff collection at the border is simple and effective, compared to sophisticated domestic taxation. Article XXVIII^{bis}:3 of the GATT 1994 and a corresponding note explicitly recognise the needs of developing countries "to maintain tariffs for revenue purposes" and require the WTO membership to take into account their fiscal (as well as developmental, strategic and other) needs in tariff negotiations. As economies grow and domestic taxation develops, the fiscal importance of tariffs gradually diminishes and is replaced by their significance as instruments of economic policy (*protective tariffs*). In South Africa, for instance, customs and excise revenue still represented approximately 17 per cent of the total tax revenue at the end of the last decade, whereas such revenue is almost negligible for a country such as Switzerland.[11] At the same time, Switzerland strongly benefits of the protective function of tariffs as it still maintains

10 See Bernhard Hoekman/Constantine Michalopoulos/Alan L. Winters, Special and Differential Treatment for Developing Countries: Towards a New Approach in the World Trade Organization, Worldbank Policy Research Working Paper No 3107, 1 August 2004, at 17; Francis Perkins, Africa's Agricultural Trade Reform and Development Options, The South African Institute of International Affairs, Trade Policy Briefing No 1, June 2003, at 3.

11 WTO Trade Policy Review: Republic of South Africa, Report by the Secretariat of 6 April 1998, WTO Doc. WT/TPR/S/34, at 38.

an average tariff of 36.2 per cent on imports of agricultural products (compared to 2.3 per cent on non-agricultural products).[12]

B. Tariffs on Pharmaceutical Products

Tariffs on pharmaceutical products are a special case. During the *Uruguay Round* negotiations, some 22 countries agreed to completely eliminate tariffs on pharmaceutical products and on certain derivatives and chemical intermediates used in the production of pharmaceutical products.[13] The products concerned are items mainly classified in Chapter 29 (organic chemicals, tariff lines 2936, 2937, 2939 and 2941) and 30 (pharmaceutical products) of the Harmonized Commodity Description and Coding System of 1983 (HS). Moreover, the initiative applies to various 'international non-proprietary names' (INNs) which are classified in various chapters throughout the Harmonized System. At the time of writing, the EC member states, the United States, Canada, Japan, Norway, Switzerland and (at least partly) Australia participate in this sectoral initiative which has become known as the *Zero-for-Zero Initiative on Trade in Pharmaceutical Products*. It came into effect with the creation of the WTO in 1995 and effectively eliminated tariffs in the signatory countries on more than 7'000 pharmaceutical products, derivatives and chemical intermediates. Ever since, the signatories have been meeting once every three years to review the product coverage with a view to eliminating, by consensus, tariffs on additional and newly developed pharmaceutical and related products. In essence, this initiative was an efficient tool to bring about substantial tariff reductions among major trading players (prime supplying and importing countries) in the field of pharmaceutical products.[14] Of course, this plurilateral negotiating package is subject to the principle of most-favoured-nation (MFN) treatment and thus benefits all WTO members alike, without requiring reciprocity.[15] Therefore, developing countries' exports of pharmaceutical products to many developed countries do not face, with respect to tariff burdens, serious market access handicaps. As traditional medicines are in most cases considered to be pharmaceutical products under the Harmonized System, they equally profit from enhanced market access to the signatories of the plurilateral initiative. Some traditional medicines, however, might fall under HS tariff heading 2106 (food preparations), as they might be considered agricultural rather

12 WTO Trade Policy Review: Switzerland and Liechtenstein, Report by the Secretariat of 17 November 2004, WTO Doc. WT/TPR/S/141, at 46 (the maximum rate being 1'705 per cent for out-of-quota imports of edible bovine offal).

13 GATT Doc. L/7430; see Anwarul Hoda, Tariff Negotiations and Renegotiations under the GATT and the WTO, Cambridge, Cambridge University Press, 2001, at 81-2.

14 Besides pharmaceutical products, plurilateral negotiations during the Uruguay Round resulted in substantial reductions in tariffs on chemical products, medical equipment and information technology products.

15 See for the principle of MFN treatment below III.A.

than pharmaceutical products, and thus face high levels of tariff protection still maintained by many developed countries in the field of agricultural products.[16]

Parallel to the successful plurilateral negotiations, tariffs are equally decreasing for pharmaceutical products among those WTO members which have not signed the *Zero-for-Zero-Initiative*.[17] Average tariffs on pharmaceutical products are generally low or moderate in the developing world, with the exception of only a few (but economically attractive) countries such as India, Brazil and Tunisia (applied tariffs of approximately 12.5-15 per cent, 12-14 per cent and 20-43 per cent, respectively).[18] The same holds true for active ingredients that go into the manufacture of pharmaceuticals, as some developing countries have average tariffs in the range of 20 to 30 per cent for such products (e.g., Burkina Faso, Pakistan, Tanzania, India, Kenya and Tunisia).[19] At least some developing countries allow a limited number of essential drugs to enter duty free. Overall, there appears to be some scope for further lowering tariffs on health-related products. For instance, WHO statistics on barriers to trade in anti-malaria supplies show that tariffs on mosquito nets and insecticides in sub-Saharan African countries add 20 to 40 per cent to their prices.[20] South Africa has in practice eliminated almost all tariffs on pharmaceutical products and applies a zero tariff for most products falling under HS chapter 30, without having formally acceded to the *Zero-to-Zero Initiative*.[21]

C. S&D Treatment for Developing Countries

As traditional medicines are typically – although by no means exclusively – developed and used in developing countries, they might profit from WTO rules specifically drafted for their benefit. In fact, market access rights and tariff rates are not in all circumstances uniformly defined for developed and developing countries alike. Dispersed among the various agreements under the WTO umbrella are provisions providing for more favourable treatment to small and low-income countries. These provisions make up the concept known under the term of Special and Differential

16 The average EC tariff for agricultural products amounts to 16.5%, that of Switzerland to 36.2%.

17 See Pietro Fontana, Ergebnisse der Uruguay Runde: Zollsenkungen, Zollbindungen und Tarifizierungen, in: Daniel Thürer/Stephan Kux (eds.), GATT 94 und die Welthandelsorganisation: Herausforderung für die Schweiz und Europa, Zürich, Schulthess Polygraphischer Verlag AG, 1996, 227-253, at 249.

18 See online service at www.osec.ch/internet/zolltarife_weltweit; see also WTO Agreements & Public Health, A Joint Study by the WHO and the WTO Secretariat, 2002, para. 167.

19 WTO Agreements & Public Health (supra fn. 18), para. 167.

20 WTO Agreements & Public Health (supra fn. 18), para. 168. Uganda, for instance, eliminated taxes and import tariffs on mosquito nets and insecticides used to fight malaria in 2000 completely, thus responding to the pledge made by African Heads of State at the African Malaria Summit in April 2000.

21 See online service at www.osec.ch/internet/zolltarife_weltweit.

(S&D) Treatment. Originally set up in the *Tokyo Round* in 1979 and induced by the UN Conference on Trade and Development (UNCTAD), S&D rules have in the meantime become an integral "part of the WTO's legal *acquis*".[22] S&D provisions are designed to accomplish mainly two objectives, namely to enhance market access conditions for the beneficiary countries and to exempt them from certain multilateral trade disciplines, thus giving them some flexibility in the use of trade and trade-related measures. Broadly speaking, they are intended to further the developing and least-developed countries' integration into the multilateral trading system. In addition to granting more leniency in procedural matters (such as, for instance, longer transitional periods), some rules expressly provide for materially different treatment. With respect to traditional medicines, however, the GATT 1994 framework does not foresee specific provisions to this effect.[23]

The *Generalised System of Preferences* (GSP), which permits to grant developing countries preferential market access, is one of the cornerstones of the concept of S&D treatment accorded to developing countries in the WTO. Since 1971, most OECD countries implemented GSP schemes according to a specifically drafted waiver. In the 1980ies, the waiver was superseded by the 'Enabling Clause' which is still valid today.[24] As of the date of writing, Australia, Canada, Japan, New Zealand, Norway, the United States, the European Communities and Switzerland accord preferences under the GSP to developing and least-developed countries. However, the effectiveness of current GSP schemes is increasingly doubted, as the privileges often remain without real practical impact and may be, from an economic viewpoint, even counterproductive. Four deficiencies are commonly identified. First, the WTO does not provide for a multilateral system of preferences. The current schemes are set up by each developed member on its own and do not follow common rules or guidelines. By arbitrarily granting and withholding preferences, developed countries can exert undue political leverage on developing countries. Second, rules of origin are often a prime suspect with regard to the under-utilisation of trade preferences. Beneficiaries under GSP schemes need to fulfil the requirements of the donor country's own system of rules of origin. Third, some developed countries have

22 Peter Sutherland et al., The Future of the WTO: Addressing Institutional Challenges in the New Millennium, Report by the Consultative Board to the Director General Supachai Panitchpakdi, WTO, 2005, para. 89; see for an overview on S&D treatment Cottier/Oesch (supra fn. 8), at 552-74; Peter Gallagher, Guide to the WTO and Developing Countries, London, Kluwer, 2000; Will Martin/Alan L. Winters (eds.), The Uruguay Round and the Developing Economies, Cambridge, Cambridge University Press, 1995; with a particular view to traditional knowledge Thomas Cottier/Marion Panizzon (supra fn. 8), at 364-74.

23 See with respect to Article 12 of the TBT Agreement below IV.A.

24 Decision of the Contracting Parties of 28 November 1979, GATT Doc. L/4903, BISD 26S/203 (1978-1979).

begun to link their GSP schemes to the furtherance of social and other policy goals and to make the availability of preferences conditional upon the fulfilment of policy goals such as environmental standards and labour rights. Fourth, it is argued that the GSP schemes in use do not adequately address those trade concerns which are most essential to developing counties such as agricultural products and textiles. With respect to pharmaceutical products (and hence also traditional medicines), the effect of tariff preferences is, in any way, reduced as tariffs are quite low in general and have been completely eliminated among the signatories to the *Zero-for-Zero Initiative*. Particular advantages and incentives to use tariff preferences are virtually lost, whereas the GSP might still provide an attractive platform to enhance market access for traditional knowledge-based products originating in developing countries as far as such products otherwise face high tariff burdens abroad.[25]

Moreover, the GSP idea is not limited to North-South relations. The *Global System of Trade Preferences* (GSTP) permits developing and least-developed countries to maintain trade preferences with each other (South-to-South, so to speak). This scheme was, similarly to the GSP, introduced and authorised by the Enabling Clause. Upon intensive negotiations among the then-Group of 77 developing and least-developed countries, the Agreement on the Global System of Trade Preferences among Developing Countries entered into force in 1989. At the time of writing, however, only 44 countries have ratified the agreement which provides for most-favoured-nation (MFN) treatment among the signatories. With a view to the still rather high tariffs on pharmaceutical products in some parts of the developing world, the GSTP could potentially play a more significant role in granting trade preferences in this sector. Thus, the GSTP could also be an important port of entry for special rules relating to trade in traditional medicines among developing countries. In an effort to encourage trading activities, it might be possible to define traditional medicines either in terms of substance and quality or in terms of their process and production methods based upon the use of traditional knowledge or upon their impact on the conservation of biological diversity and environmental sustainability.[26]

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25 This applies, in particular, to agricultural products, see supra fn. 16.

26 Contrary to PPMs under the GATT 1994 in general (see below III.C.), the granting of trade preferences under the GSP/GSTP *conditional* upon the fulfilment of other policy goals not directly linked with the physical characteristics of a product is commonly considered to be consistent with WTO law, see *EC – Conditions for the Granting of Tariff Preferences to Developing Countries*, Report of the Appellate Body, 7 April 2004, WT/DS246/AB/R.

III. Basic Principle of Non-Discrimination

The basic principle of non-discrimination amounts to a constitutional cornerstone in the WTO legal framework. It forms, together with the protection of other legitimate policy goals (traditionally but inadequately dealt with under the heading of exceptions), an indispensable and constitutive element of the treaty-based multilateral trading system – and is equally relevant for any discussion of the proper treatment of traditional medicines vis-à-vis their conventional counterparts.

A. Most-Favoured-Nation and National Treatment

The two prime non-discrimination principles are that of most-favoured-nation (MFN) treatment and of national treatment (NT). They are of paramount importance and apply, in principle, across the board in WTO law.[27] Article I of the GATT 1994 obliges a WTO member to accord unconditionally and immediately all privileges granted to a product originating in one member state to like products originating in any other member state. Article III of the GATT 1994 applies the principle in relation to the treatment of domestic products. Upon customs clearance, all foreign products are entitled to obtain treatment no less favourable than domestic like products. Both principles are expressions, and variations, of the idea of equality and equal treatment. Economically, they seek to bring about level playing fields and fair conditions of competition for products, which have different origins, and, to some extent, even for foreign people. They serve the purpose of reducing differential treatment and discrimination which are inherent to the system of nation states and their political economy, as the identity of states and its citizens, its producers and consumers is often defined in terms of according special rights and privileges which are not extended to foreigners and foreign products.

Under general international law, states are essentially free to treat others as they deem best and to enter into any agreement of any kind and content. The sovereignty and equality of nation states entails the power to choose one partner and to discriminate the other. There are only very few limitations beyond those found in the UN Charter. Norms relating to *ius cogens* hardly affect trade relations, except for the prohibition of slavery in its different forms or policies supporting racial segregation. The principle of *pacta tertiis nec nocent nec prosunt* (a treaty must neither benefit nor impair a third party) equally is of limited effect. Short of specific treaty provisions, it certainly

27 See for these principles Thomas Cottier/Petros C. Mavroidis (eds.), Regulatory Barriers and the Principle of Non-Discrimination in World Trade Law: Past, Present, and Future, Ann Arbor, The University of Michigan Press, 2000; WTO Secretariat, The Fundamental WTO Principles of National Treatment, Most-Favoured-Nation Treatment and Transparency, 14 April 1999, WTO Doc. WT/WGTCP/W/114.

does not limit the conclusion of preferential and discriminatory trade agreements, having the potentially distorting effect of trade diversion. Non-existent in customary international law, non-discrimination principles therefore need to be positively agreed upon among trading partners. MFN and national treatment essentially stem from the traditions of bilateral trade agreements. They can be found in agreements as early as in the 12th century and throughout trade and investment agreements of the 19th and early 20th century.[28] In the GATT 1947 framework, these principles were multilateralised, putting an end to policies based on bilateral reciprocity.

B. 'Like Products'

Given the radical impact of equal treatment obligations on nation states, it is apparent that they are often not given full but merely limited effect. Such limitations are inherent to the different forms and variations of equality. It all boils down to the question as to which products need in fact be treated alike. The scope and practical relevance of Articles I and III of the GATT 1994 depend to a large extent on the reading of the term 'like products'. Its definition essentially sets the benchmark for national regulatory freedom to treat imported products differently from domestically produced as well as to differentiate between products of different foreign origin. Not astonishingly, the matter is at the heart of WTO law and policy, and much attention has been paid to it in jurisprudence and literature. In 1970, the Border Tax Adjustment Working Party provided the starting point for the analysis of likeness when it established the relevant criteria in order to define permissible internal tax adjustments applicable to like products crossing national borders.[29] Since then, the so-called Border Tax Adjustment criteria have consistently been used in determining likeness pursuant to Articles I and III of the GATT. In addition to the three criteria of i) physical characteristics; ii) consumers' tastes and habits; and iii) the product's end-uses in a given market, tariff classification has additionally been established as the fourth criterion over the years.[30] These criteria are relevant for determining likeness across the board in WTO law, as the term 'like products' appears in various provisions and agreements. Read in context, however, the term's exact meaning might slightly vary from one provision to the other – a phenomenon which has become known as

28 Cottier/Oesch (supra fn. 8), at 346-47.

29 Border Tax Adjustments, Report of the Working Party, adopted 2 December 1970, BISD 18S/97 (1972), para. 18.

30 See for the relevant case law and scholarly reception Cottier/Oesch (supra fn. 8), at 390-407.

the Appellate Body's 'accordion approach', widening and narrowing the scope of likeness as different provisions apply.[31]

With respect to pharmaceutical products, the classical Border Tax Adjustment approach means that traditional medicines and conventional, modern health-care products are basically considered 'like' as far as they share common physical characteristics. Granting privileges to traditional medicines vis-à-vis their conventional counterparts in terms of tariff and non-tariff treatment seems in particular possible if consumer preferences can be clearly distinguished.[32] WTO jurisprudence to date indicates that health concerns can well translate into diverging consumer preferences.[33] Thus, they may allow different regulatory approaches to traditional and modern medicines. Furthermore, it might be conceivable that not only health but also other non-trade concerns such as the protection of biodiversity and the environment, sustainability in agriculture and the conservation of traditional knowledge result in different consumer preferences and decisively shape the determination of likeness under the Border Tax Adjustment criteria, thus opening a potential gap length for different regulatory approaches to traditional and conventional medicines.

Persistent reliance by WTO panels and the Appellate Body on the Border Tax Adjustment criteria for determining 'likeness' has not remained undisputed. Strict dependence on those criteria in general, and the physical characteristics of a product in particular, amounts to high levels of intrusiveness and considerably limits the scope of governments to undertake product differentiations, even domestically, in the pursuit of non-trade policy goals. As the objective of the GATT 1994 is to ban protectionism, and not to limit the pursuit of legitimate policy objectives, a school of thought has begun to question the Border Tax Adjustment criteria and to develop an alternative test seeking to target protectionist product distinctions more precisely and to leave governments more leeway in regulating legitimate non-trade concerns. Accordingly, a definition of 'likeness' should take into account whether a measure

31 *Japan – Taxes on Alcoholic Beverages*, Report of the Appellate Body, 4 October 1996, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, at 21: "The concept of 'likeness' is a relative one that evokes the image of an accordion. The accordion of 'likeness' stretches and squeezes in different places as different provisions of the WTO Agreement are applied. The width of the accordion in any one of those places must be determined by the particular provision in which the term 'like' is encountered as well as by the context and the circumstances that prevail in any given case to which that provision may apply."

32 Cottier/Panizzon (supra fn. 8), at 383, with respect to traditional knowledge.

33 *EC – Measures Affecting Asbestos and Asbestos-Containing Products*, Report of the Appellate Body, 12 March 2001, WT/DS135/AB/R; see Matthias Oesch, Commentary on EC – Asbestos, International Trade Law Reports, London, Cameron May, 2003, 441-65, at 459-60.

has the aim and/or effect of protecting domestic production.[34] The Appellate Body, however, appeared to reject such an 'aims-and-effect' test in its report on *Japan – Alcoholic Beverages*.[35] At least, the current state of law and practice recognises implicitly what the 'aims-and-effect' test seeks to achieve expressly, namely to enlarge the governments' leeway of manoeuvre in the pursuit of legitimate, non-protectionist policy goals.

C. Process and Production Methods

Moreover, products might not only be defined by their physical properties, their end-uses in a given market and consumers' tastes and habits. They can also be characterised and distinguished by way of how they have been produced, i.e., on the basis of process and production methods (PPMs). In such a case, an isolated comparison of the end-products does not reveal any (physical) differences; it is the 'history' of the product that distinguishes it from other (physically similar) products. The recognition of PPMs implies that it is explicitly allowed to pursue non-trade policy concerns and, based on their legitimacy, to accordingly differentiate between physically similar products. PPMs are particularly important, and discussed in academic writings, in relation to environmental concerns and human or labour rights. However, they might be of equal relevance in the field of pharmaceutical products. Granting privileges to traditional medicines vis-à-vis modern types of medical treatment might be legitimate with a view to the policy goals of, *inter alia*, protecting biodiversity by conserving the sources of herbal medicines in a sufficient quantity, of furthering local, 'decentralized' and low-cost health systems and of supporting the continual passing down of necessary traditional knowledge on which traditional medicines are based.[36]

The issue as to whether Articles I and III of the GATT 1994 allow different regulatory approaches to products, which are physically similar but processed or produced

34 The 'aims-and-effect' test was first applied in *US – Measures Affecting Alcoholic and Malt Beverages*, Report of the Panel, adopted 19 June 1992, DS23/R, BISD 39S/206 (1993), and further developed in *US – Taxes on Automobiles*, Report of the Panel, 11 October 1994 (not adopted), DS31/R, 33 I.L.M. 1397 (1994); see for an account William J. Davey/Joost Pauwelyn, MFN-Unconditionality: A Legal Analysis of the Concept in View of its Evolution in the GATT/WTO Jurisprudence with Particular Reference to the Issue of 'Like Product', in: Thomas Cottier/Petros C. Mavroidis (eds.) (supra fn. 27), 13-50, at 38-40.

35 *Japan – Alcoholic Beverages* (supra fn. 31), at 19-21.

36 See for such elements of basic health care and traditional medicines Susette Biber-Klemm/Danuta Szymura Berglas (supra fn. 3), at 50.

differently, is highly controversial.[37] A very early GATT 1947 panel report, *Belgium Family Allowances*, is often interpreted, and cited as an important precedence, to the effect that discrimination on the basis of how (physically similar) products are produced or processed is prohibited under the GATT.[38] The subsequent case law is inconsistent; mostly, PPMs have been rejected.[39] In particular, they are commonly opposed by developing countries which consider PPMs a (too) forceful tool in the hands of developed countries to impair developing countries' market access rights (e.g., in the form of high environmental or labour standards). Moreover, the debate on PPMs is closely related to the systemic value and relevance of the exceptions provided for in Article XX of the GATT 1994 and to the issue of extraterritorial application of trade-related measures by WTO members.[40] It is argued that admitting measures under the GATT 1994 on the basis of extraterritorial criteria would mean that economically powerful WTO members could try to impose their own perceptions of appropriate environmental policies or other non-trade concerns upon other members.

The current state of the art appears to be that PPMs are not permitted under the GATT 1994. A different regulatory approach to traditional medicines vis-à-vis conventional pharmaceutical products solely based upon the different product and production methods would most likely be considered unjustifiably protectionist. At this stage, PPMs would not meet the classical Border Tax Adjustment test of likeness which renders considerations of equity and ecological policy goals, of course, more difficult. Still, the near future might bring a change of attitude towards PPMs. Two reasons stand in favour of such optimism: First, the matter is at the heart of interfacing trade regulation with other policy concerns, in particular the environment, biodiversity, human rights and culture. Thomas Cottier and Marion Panizzon convincingly

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37 See Cottier/Oesch (supra fn. 8), at 412-18; Robert Howse/Donald Regan, The Product/Process Distinction – An Illusory Basis for Disciplining 'Unilateralism' in Trade Policy, in: European Journal of International Law 2000, 249-89; Matsushita/Schoenbaum/Mavroidis (supra fn. 7), at 461-69; Ronald Steenblik, Liberalising Trade in 'Environmental Goods': Some Practical Considerations, OECD Trade and Environment Working Paper No 2005-05, 16 December 2005, at 11-2; with respect to traditional knowledge Cottier/Panizzon (supra fn. 8), at 385-86.

38 *Belgian Family Allowances (Allocations Familiales)*, Report of the Panel, adopted on 7 November 1952, BISD 1S/59 (1955).

39 An important precedent being *US – Restrictions on Imports of Tuna (Tuna I)*, Report of the Panel, 16 August 1991 (not adopted), DS21/R, BISD 39S/27 (1993).

40 See for extraterritorial application *US – Import Prohibition of Certain Shrimp and Shrimp Products*, Report of the Appellate Body, 12 October 1998, WT/DS58/AB/R, paras. 133; for an analysis Matthias Oesch, *US – Shrimp Case*, in: Rüdiger Wolfrum (ed.), Max Planck Encyclopedia of Public International Law, Oxford, Oxford University Press, forthcoming 2007, para. 9; Lorand Bartels, Article XX of GATT and the Problem of Extraterritorial Jurisdiction: The Case of Trade Measures for the Protection of Human Rights, in: Journal of World Trade 2002(2), 353-403.

argue that product differentiation on the basis of PPMs will become a necessity in bringing about more coherence in treaty interpretation as many existing multilateral agreements already recognise the environmental, social and cultural implications of the process and production methods leading to a finished product.[41] This holds true, in particular, for international conventions aiming at the protection of the environment (multilateral environmental agreements, MEAs).[42] These agreements indicate that there has been an evolution in public international law towards an appropriate consideration of environmental, social and cultural concerns in the course of the production of a product. Thomas Cottier and Marion Panizzon conclude that the "PPMs in MEAs" discussion functions as a strong reasoning for why the WTO should allow to integrate PPMs in the like product definition for purposes of non-discrimination within Articles I and III of the GATT 1994.[43] Second, developing countries might begin critically to review their systemic rejection of PPMs. With respect to products such as traditional medicines and others based on traditional knowledge, developing countries might well be interested in legitimately protecting their own traditionally made products and in gaining enhanced market access for such products abroad.[44] Hence, developing countries might actively support the inclusion of PPMs into the GATT 1994 acquis. Under the current legal framework *de lege lata*, it will be up to the WTO dispute settlement organs to reassess the current state of law and practice and to bring PPMs back in. At the moment, it is not realistic to expect too much from the deadlocked *Doha round* negotiations in this respect. This is regrettable. Eventually, only multilateral negotiations would allow placing the issue of PPMs in the broader context of technology transfer and financial support in bringing about state of the art process and production methods, as developing countries would, from an economic viewpoint, still be disadvantaged by many PPMs in the field of environmental and labour standards.

D. General Exceptions

Irrespective of whether a conservative or progressive interpretation of 'likeness' is applied, the GATT 1994 might offer an additional justification for a different treatment between traditional and conventional medicines, thus promoting the sustainable use and adequate commercialisation of the former over the latter. The basic principle of

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41 Cottier/Panizzon (supra fn. 8), at 386-87.

42 See for an illustrative list of MEAs potentially influencing international trade under the auspices of the WTO online at www.wto.org (click the link to environment/MEA database: Matrix on Trade Measures Pursuant to Selected MEAs).

43 Cottier/Panizzon (supra fn. 8), at 386; see also Robert Howse, Adjudicative Legitimacy and Treaty Interpretation in International Trade Law: The Early Years of WTO Jurisprudence, in: J.H.H. Weiler (ed.), The EU, the WTO, and the NAFTA: Towards a Common Law of International Trade?, Oxford, Oxford University Press, 2000, 35-69, at 56.

44 See Cottier/Panizzon (supra fn. 8), at 387.

non-discrimination is further balanced by a number of important exceptions for the protection of non-economic goals and ends of states. The principles of MFN and national treatment need to be read in conjunction with such non-trade concerns contained in key provisions of the GATT 1994. What the principles essentially seek to avoid is *illegitimate* protectionism and rent-seeking, based on privileges accorded in national law and policies. Validating traditional medicines demonstrates that the furtherance of policy concerns other than pure short-term, economically-driven motivations does not necessarily result in unsolvable tensions with the principle of non-discrimination.

In the context of trade in pharmaceutical products, Article XX of the GATT 1994 is of prime interest (termed 'General Exceptions'). It stipulates the relevant guidelines for the delicate balancing act between equal treatment, trade liberalisation and the pursuit of other legitimate policy goals. This provision justifies deviations from other rules, in particular, but not exclusively, from the principles of MFN and national treatment and from the prohibition of quantitative restrictions. It is composed of two distinct parts: First, Article XX of the GATT 1994 consists of an enumeration of specific motives and conditions for restricting trade, listed in paragraphs (a) through (j). Not all of them are of equal practical importance. The critical provisions which are frequently invoked in practice – as WTO members have become increasingly concerned with environmental and human health issues as well as with the protection of intellectual property rights – refer to measures necessary to protect human, animal or plant life and health (paragraph b), to measures necessary to secure compliance with laws relating to the protection of patents, trademarks and copyrights and to the prevention of deceptive practices (paragraph d), and to measures relating to the conservation of exhaustible natural resources (paragraph g). Paragraph (d) was, in the GATT 1947-years, the only provision explicitly dealing with intellectual property rights – hence being relevant for trade in pharmaceutical products – and was several times invoked in dispute settlement proceedings.[45] It has kept its relevance also after the coming into force of the WTO and its third pillar, the TRIPs Agreement. For instance, paragraph (d) provides, under the GATT 1994, the basis for combating the counterfeiting of drugs and for restricting parallel imports of essential drugs made available to developing countries.[46] Paragraph (g) might be invoked, for instance, if a WTO member applies specific measures to protect traditional medicines which

45 See for an overview Cottier/Oesch (supra fn. 8), at 447-51; Michael J. Trebilcock/Robert Howse, The Regulation of International Trade, London, Routledge, 3rd ed. 2005, at 402; panels confirmed several times that Article XX(d) is to be interpreted *narrowly*, placing the burden of justifying its use on the party invoking the exception, see *US – Section 337 of the Tariff Act*, Report of the Panel, adopted 7 November 1989, L/6439, 36S/345 (1990); *US – Measures Affecting Alcoholic and Malt Beverages*, Report of the Panel, adopted on 19 June 1992, DS23/R.

46 Cottier/Oesch (supra fn. 8), at 448.

are considered to constitute non-renewable resources. Based on such rationale, it is conceivable that a WTO member adopts a system of differential taxation for traditional medicines and conventional pharmaceutical products, provided that the privileges do not amount to disguised protectionism.[47] The Appellate Body's rather generous interpretation of Article XX(g) in the *US – Shrimp* case seems to support such a reading.[48]

Second, all exceptions listed in the paragraphs of Article XX are further qualified by the so-called *chapeau*. It applies in addition to the specific motives and is intended to prevent the abuse of the limited and conditional exceptions under which a contested measure might be preliminarily justified. The *chapeau* is a balancing principle to mediate between the right of a member to invoke an exception and its obligation to respect the rights of other members. It is, as the Appellate Body famously held, "but one expression of the principle of good faith."[49] As the exceptions set forth in the respective paragraphs have been consistently interpreted generously since the dawn of the WTO, the chapeau has gained in operational importance. The fulfilment of its requirements has in many cases become a difficult task to be accomplished by the members invoking Article XX of the GATT 1994.

IV. Technical Barriers to Trade

WTO rules which govern technical barriers to trade applied for the protection of human health and other policy goals are covered either by the Agreement on Technical Barriers to Trade (TBT Agreement) or by the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). Under both agreements, various policy concerns other than trade liberalisation are considered perfectly legitimate objectives for restricting trade.

A. TBT Agreement

The TBT Agreement was first developed in the *Tokyo Round* (then also called 'Standards Code') and was further improved in the *Uruguay Round*, with a view to strengthening the basic disciplines enshrined in Article XX of the GATT 1994.[50] The TBT Agreement was largely inspired by the work undertaken within the EC

47 Cf. Cottier/Panizzon (supra fn. 8), at 385.

48 *US – Shrimp* (supra fn. 40), paras. 128-30; see Oesch (supra fn. 40), para. 5.

49 *US – Shrimp* (supra fn. 40), para. 158.

50 See for an overview on the TBT Agreement Carlos M. Correa, Implementing National Public Health Policies in the Framework of WTO Agreements, in: Journal of World Trade 2000(5), 89-121, at 103-5; Cottier/Oesch (supra fn. 8), at 750-64; Matsushita/Schoenbaum/Mavroidis (supra fn. 7), at 510-13; WTO Agreements & Public Health (supra fn. 18), paras. 26-33.

and the EFTA and responds to two broad policy considerations. On the one hand, (mandatory) technical regulations and (voluntary) product standards, including packaging, marketing and labelling requirements, as well as procedures for testing and certifying compliance with these regulations and standards potentially serve the purpose of limiting market access for competing products. Since regulations and standards largely vary among different countries, they may be excessively strict and may be upheld artificially. Therefore, the TBT Agreement provides that technical regulations and standards shall not create unnecessary obstacles to international trade. On the other hand, members should be able to adequately pursue legitimate policy objectives such as the protection of national security, the prevention of deceptive practices and the protection of human, animal and plant life and health. Equally, labelling requirements are commonly considered legitimate in order to achieve adequate consumer information. The agreement is designed according to these two underpinnings which are explicitly referred to in the preamble. In order to do so, Article 2:4 of the TBT Agreement encourages members to base TBT measures on international standards where they exist (such as the *International Organization for Standardization* [ISO] and the *Codex Alimentarius Commission*, a joint body of the WHO and the FAO, focusing mainly on food safety). In the case of pharmaceutical products, the WHO is assigned a leading role in the area of standard setting for their quality, efficacy and safety through, *inter alia*, the *International Pharmacopoeia* and the *WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce*.[51] Systemically, international standards are becoming a decisive benchmark for determining the WTO-consistency of national technical regulations, and the legitimacy of the standard setting organisation's decision-making process is watched with increasing attention and concern. In the absence of international standards (or in the case of deliberate deviation therefrom), members are obliged to prove the legitimacy and proportionality of regulations and standards.[52]

With respect to traditional medicines, the major difficulty of adopting adequate technical regulations and standards is twofold: First, the quantity and quality of safety and efficacy data on traditional medicines are often insufficient and do not meet common criteria in order to support its use worldwide.[53] Scientific evidence from randomised clinical trials is only strong for some uses of acupuncture, some herbal medicines and manual therapies.[54] The lack of adequate research data results,

51 See Colette Kinnon, WTO: What's in it for WHO?, WHO Task Force on Health Economics, Geneva, 1995.

52 Cottier/Oesch (supra fn. 8), at 760-61.

53 World Health Organization (supra fn. 1), at 21.

54 World Health Organisation, Traditional Medicine: Fact Sheet No. 134, May 2003, online at www.who.int/mediacentre (click the link to fact sheets).

according to the WHO, not only from inadequate health care policies but also from a shortage of adequate or accepted research methodology for evaluating traditional medicines.[55] Therefore, it is highly recommended that further research in safety and efficacy be promoted, not only for health reasons as such but also for ensuring market access of traditional medicines under the TBT Agreement. Furthermore, the failure to undertake serious research in this area has not allowed the international community to develop international standards on safety, efficacy and quality control of traditional medicines.[56] Second, developing countries' products may simply not satisfy safety regulations and standards as commonly defined with production in industrialised countries in mind.[57] The TBT Agreement does not expressly address regulations and standards with a particular view to the needs and capabilities of developing countries. Their products have, in principle, to comply with the general substantive rights and obligations set out in the TBT Agreement. Special and differential (S&D) treatment only exists with respect to regulations and standards adopted by developing countries taking effect in their own jurisdiction. Traditional technology may be exempted from international standards pursuant to Article 12:4 of the TBT Agreement which permits developing country members to "adopt certain technical regulations, standards or conformity assessment procedures aimed at preserving indigenous technology and production methods and processes compatible with their development needs." While this regulatory approach clearly promotes the use by developing countries of indigenous technical barriers to trade, it does not require industrialised countries to open up their own markets for such products.[58] Therefore, this provision is not drafted in a way to facilitate the international commercialisation of products such as traditional medicines which do not *per se* meet safety standards acknowledged in the developed world.

Moreover, the debate on the legality of PPMs for regulatory purposes is also relevant in the context of the TBT Agreement. They have been dealt with supra under Articles I and III of the GATT 1994.[59] The TBT Agreement adds an additional perspective to the controversial issue. Its Annex 1 defines "technical regulation" as a "document which lays down product characteristics or their related processes and production methods …" This definition is not entirely clear. On the one hand, it indicates that the TBT Agreement applies not to all PPMs but only to those which are in some

55 See World Health Organization, General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine, Geneva, 2000.

56 See World Health Organization (supra fn. 1), at 22, in particular referring to herbal medicines.

57 Cottier/Panizzon (supra fn. 8), at 375.

58 Cottier/Panizzon (supra fn. 8), at 375; they conclude that developing countries should aim at amending the TBT Agreement accordingly; see also Correa (supra fn. 50), at 104.

59 See supra III.C.

way or other connected with the characteristics of the end product. They need to have a distinguishable effect on the product characteristics such as its quality or performance. If PPMs do not translate into the product, they should not be able to justify trade restrictions under the TBT Agreement.[60] On the other hand, it is difficult to see why the TBT Agreement should not extend to disciplining all existing PPMs and hence rendering them subject to the principle of proportionality.[61] In fact, various members have notified to the WTO Committee on Technical Barriers to Trade (TBT Committee) regulations and standards which are based upon PPMs and thus affect the way in which the product at issue is processed and produced abroad.[62] Again, this issue will most likely be raised, at some point or other, in formal dispute resolution proceedings, and the Appellate Body will have to clarify it.

B. SPS Agreement

The SPS Agreement was negotiated during the *Uruguay Round* as the disciplines of the GATT 1947 and the TBT Agreement were considered to be too general and lenient for assessing food standards. The SPS Agreement, being *lex specialis* to Article XX(b) of the GATT 1994 and to the TBT Agreement, contains detailed rules on the enactment of measures intended to protect human, animal and plant life or health from risks arising from additives, pests, contaminants or other disease-causing organisms.[63] According to Articles 3 and 5 of the SPS Agreement, trade-restrictive measures strictly need to be scientifically justified. The requirement to conducting a proper risk assessment in all SPS matters is central to the functioning of the Agreement. Article 2:2 of the TBT Agreement, in contrast, only requires that available scientific information may be one of the relevant elements of consideration in assessing risk, besides the motivation to standardise products, to ensure quality or to avoid consumer deception.[64] While the new SPS Agreement did not attract much attention during the negotiations, it quickly moved to the centre of major trade

60 See Cottier/Panizzon (supra fn. 8), at 377.

61 Cottier/Oesch (supra fn. 8), at 762.

62 The Netherlands, for instance, made a notification with respect to "animals and plants belonging to protected indigenous and non-indigenous animal and plant species and products of these animals and plants", see Notification to the TBT Committee, 7 August 2000, WTO Doc. G/TBT/Notif.00/344.

63 See for an overview on the SPS Agreement Correa (supra fn. 50), at 97-103; Cottier/Oesch (supra fn. 8), at 778-99; Henrik Horn/Petros C. Mavroidis, National Health Regulations and the SPS Agreement: The WTO Case Law of the Early Years, in: Thomas Cottier/Petros C. Mavroidis (eds.), The Role of the Judge in International Trade Regulation: Experience and Lessons for the WTO, Ann Arbor, The University of Michigan Press, 2003, 255-84; Matsushita/Schoenbaum/Mavroidis (supra fn. 7), at 494-510; WTO Agreements & Public Health (supra fn. 18), paras. 34-43; with respect to traditional knowledge Cottier/Panizzon (supra fn. 8), at 377-79.

64 See WTO Agreements & Public Health (supra fn. 18), para. 39; Correa (supra fn. 50), at 104.

disputes after its coming into force at the end of the *Uruguay Round*. Questions regarding risk assessment and risk management, the proper balance of government discretion and adequate judicial review of member state determinations have extensively been tried and debated in this context. Moreover, the SPS Agreement finds itself at the heart of the debate on market access and trade restrictions for biotech products.[65]

Technical regulations and standards on pharmaceutical products such as measures relating to the quality and other conditions for their approval and commercialisation usually do not constitute SPS measures (even though they are motivated, in essence, by health considerations).[66] They fall under the GATT 1994 and the TBT Agreement and need to satisfy the (more relaxed) disciplines set forth in those agreements.

V. Epilogue

This paper demonstrates that the GATT 1994 relevantly impacts the promotion and protection of traditional medicines. Whereas many developed countries have, by virtue of the *Zero-for-Zero Initiative*, eliminated their tariffs on pharmaceutical products (and hence also on traditional medicines), there is still some scope for further lowering tariffs on health-related products in developing countries. In those cases in which traditional medicines are considered agricultural products under the Harmonized System, they still face, however, high levels of tariff protection maintained by many developed countries. Furthermore, a change of paradigm with respect to the interpretation of 'likeness' under Articles I and III of the GATT 1994 would allow to differentiate between traditional medicines and their conventional counterparts and to adopt different internal taxation and other regulatory measures in order to foster traditional medicines. Such an approach would offer interesting policy options in both developing and developed countries. Yet, WTO panels and the Appellate Body have not acknowledged such a reading of 'likeness' to date.

Besides, the main obstacles to traditional medicines are likely to result from TBT measures. While the protection of human health by requiring adequate safety standards is imperative, enhanced involvement of developing countries and co-

65 See *EC – Measures Affecting the Approval and Marketing of Biotech Products*, Report of the Panel, adopted on 21 November 2006, WT/DS291/R, WT/DS292/R, WT/DS293/R; for an analysis Matthias Oesch, The Jurisprudence of WTO Dispute Resolution (2006), in: Schweizerische Zeitschrift für Internationales und Europäisches Recht 2006, 501-23, at 514-23.

66 Correa (supra fn. 50), at 98; Hans-Georg Kamann, Übereinkommen über die Anwendung gesundheitspolizeilicher und pflanzenschutzrechtlicher Massnahmen, in: Hans-Joachim Priess/Georg M. Berrisch (eds.), WTO-Handbuch, München, Verlag C.H. Beck, 2003, para. 29.

operation between all stakeholders in standard-setting operations may relevantly assist in avoiding overly protectionist standards and in adequately acknowledging the various non-trade policy concerns for traditional medicines.[67] Such concerns are obvious, and their legitimacy is confirmed in a growing number of international agreements and conventions. Therefore, the pledge to better interface WTO law and other areas of public international law stands at the forefront. Two levels need to be distinguished. First, it is a matter of seeking coherence in a number of international negotiations, taking place in different and often quite isolated fora. Countries all over the globe, being developed or less developed, need to realise that they have, in essence, a mutual interest in finding sustainable and efficacious solutions as to the protection and promotion of traditional medicines. It essentially boils down to the process of defining standards for their quality, efficacy and safety. Such standards have not yet been satisfactorily defined, as standardising activities with respect to traditional medicines within, and outside of, the WHO are only in their infancies. The WTO needs to acknowledge that the WHO is assigned the leading role in this process. An important – but only first – step to this effect is the participation of the WHO as an observer in the WTO Committee on Technical Barriers to Trade (TBT Committee). In the current *Doha Round*, the quest for coherence and interactivity between the WTO and the WHO is not officially acknowledged. At least, the need to further clarify the relationship between the rules of the WTO and of other international legal sources has been affirmed for multilateral environmental agreements (MEAs). In the Doha Ministerial Declaration, it is explicitly agreed to negotiate rules "with a view to enhancing mutual supportiveness of trade and environment."[68] The Convention on Biological Diversity with its policy goal of protecting and promoting biodiversity and equity comes to mind; it represents an example in point of the unresolved and (at least partly) controversial relationship of the WTO legal framework to the wider body of public international law. Only well-balanced and mutually acceptable procedures of co-operation and interaction ultimately assist in overcoming traditional rivalries between different international organisations as well as domestic government agencies.[69] Second, the relationship is equally addressed in WTO dispute settlement. The interfacing of different international regimes and agreements can in many cases readily be achieved under the rules of the Vienna Convention on the Law of Treaties, in particular its Article 31:3(c).[70] Pursuant to this provision, international legal instruments other than the WTO agreements can

67 See Cottier/Panizzon (supra fn. 8), at 387, with respect to traditional knowledge in general.

68 WTO Doc. WT/MIN(01)/DEC/1, adopted on 14 November 2001, para. 31.

69 See Cottier/Panizzon (supra fn. 8), at 380.

70 Article 31 sets out the general methods of interpretation; its paragraph 3(c) reads as follows: "There shall be taken into account, together with the context: (…) any relevant rules of international law applicable in the relations between the parties."

relevantly inform the correct interpretation of WTO rules. This holds also true for trade in pharmaceutical products and the special case of traditional medicines. Most likely, WTO panels and the Appellate Body will be called upon, in some case or other, to give adequate consideration to the WHO and its active delivery of scientific and other evidence where public health concerns and access to traditional medicines are at issue.[71] By doing so, panels and the Appellate Body could help to develop a 'traditional medicine perspective' through their daily dispute resolution work.

71 See for a precedent in which the WHO, upon the request of the panel, delivered factual evidence as to health effects of cigarette consumption *Thailand – Restrictions on Importation of and Internal Taxes on Cigarettes*, Report of the Panel of 7 November 1990, DS10/R, 37S/200; Correa (supra fn. 50), at 113.

Promotion and Protection of Traditional Medicines through International Intellectual Property Rules

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This constribution first examines the role of intellectual property protection titles for the protection and promotion of traditional medicines. Thereafter, it gives an overview of the relevance of existing protection titles and examines the question whether a sui generis intellectual property protection for the protection of traditional medicines is necessary and what its underlying policy objectives should be.

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Introduction

The aim of this contribution is to give an overview of the role intellectual property protection can play in the context of the protection and the promotion of traditional medicines. This encompasses two aspects: On the one side, it relates to the issue of the so called positive protection of traditional medicines by intellectual property protection titles, on the other side, it relates to the protection of traditional medicines and its underlying knowledge and information against misappropriation and monopolization by others, the so-called negative protection. The relationship between traditional knowledge, including traditional medicine and intellectual property protection as a whole has never had as much relevance as today. According to the World Health Organization (WHO), the use of "traditional medicine has maintained its popularity in all regions of the developing world and its use is rapidly spreading in industrialized countries" and "25% of modern medicines are made from plants first used traditionally"[1]. Biotechnology and genetic engineering will further ad to an increase of this quota[2].

In its first part, this contribution takes stock of the role of intellectual property rights provided for by existing intellectual property laws and treaties with regard to traditional medicine. After that, a non-conclusive overview of the current international debate about the relationship between intellectual property protection and traditional knowledge in general is given. Further, the contribution briefly touches upon the issue of a sui generis protection of traditional medicine.

Until today, no internationally binding definition of traditional medicines exists. However, the WHO has proposed a definition, which today is used by most governmental bodies and academics and which shall also form the basis of this contribution:

> Traditional medicine refers to health practices, approaches, knowledge and beliefs incorporating plant, animal and mineral based medicines, spiritual therapies, manual techniques and exercises, applied singularly or in combination to treat, diagnose and prevent illnesses or maintain well-being.[3]

The aim of the WHO definition is to cover all disciplines and aspects of traditional medicines, this is why it follows a rather broad approach[4]. What is important for the

1 WHO Fact sheet No. 134, "Traditional Medicine", May 2003, available at: www.who.int/mediacentre/factsheets/fs134/en/.
2 See also Hoering (2004), p. 15.
3 See supra (FN 1).
4 WHO (2002), p. 5 and 7.

discussion of protection of traditional medicines by intellectual property is that the medicine does not necessarily have to be old in order to fit under the definition[5]. What is „traditional“ about traditional medicines is the way they are acquired, used and transferred over time[6].

The Role of Intellectual Property Protection in the Context of Traditional Medicine

In general, the role of intellectual property protection is to provide incentives to individuals (or a group) to behave a certain way. The underlying aim of intellectual property protection is to enhance inventiveness, creativity and quality, which, in the end should lead to the advancement of human mankind in the direction of a better and more agreeable life. Thus, the primary role of intellectual property protection is not to provide individuals with monetary advantages, but to try to influence them to use their creativity and innovative abilities for the social benefit of all. In this regard, intellectual property protection has an important role to play.

Indirectly, intellectual property protection can influence people to protect the environment and by this biodiversity through, e.g. incentives to innovate environmentally sound technologies and to develop knowledge on sustainable agriculture and forestry. In addition, it can motivate people to preserve cultural diversity and continue to practice folklore. This will also be to the benefit of the preservation of traditional medicine.

The direct role of intellectual property on the other side is the actual protection of traditional medicine in the broad sense of the WHO definition. Here, IPRs play an important role in the whole product cycle of traditional medicines: They provide for an incentive (i) to develop traditional medicines, (ii) to disseminate and share their underlying knowledge and (iii) to distribute the product. Below, these aspects of the direct role of intellectual property protection will be further analyzed.

The Relevance of existing Intellectual Property Titles for Protection of Traditional Medicine

The existing intellectual property titles are generally applicable to any object that meets the relevant requirements. In the following, it will be examined how far traditional medicine can meet these requirements by its nature[7]. The examination

5 See Hansen/Van Fleet (2003), p. 3 and for traditional knowledge in general: Graber/Girsberger (2006), p. 4.
6 See Ng'etich (2005), p. 5/6.
7 For further analysis of the relevance of existing intellectual property protection titles see,

shall be illustrated by some examples how the protection titles have been successfully or unsuccessfully used in the past.

Patents

For an invention to be eligible for patent protection, three main conditions must be met: (1) the invention must be new, (2) involve an inventive step and (3) it must be capable of industrial application. The novelty criterion may be met in case of traditional medicine if the knowledge has been successfully kept secret and is therefore unknown by more than some individuals that are under a strict non-disclosure obligation. Tentatively, this will less be the case if the traditional medicine is very old. However, even in that case, if we think of the information on a medical treatment which has been passed over generations within close family lines such as father and son, the novelty requirement may still be fulfilled.

The “inventive step” of traditional medicine will usually be the knowledge about healing effects of plants and about the form and dosage they are to be given to patients. The industrial application will be given as soon as the medicine could be used on several patients and not only for one specific patient. It is highly important that the requirements for patent protection of an invention, especially the novelty requirement, are strictly applied also with regard to traditional medicine. If not, there is a great risk that others acquire the knowledge about the medicine and patent it under their own name and by this, obtain a tool to even exclude the real inventor or his descendants from using the medicine[8]. One example of successfully patented traditional medicines is that of traditional Chinese medicine, on which China has granted more than 3300 patents[9]. However, these patents, because of the novelty criterion, do not encompass the traditional core of the medicine.

Apart from the requirements of protection, an important obstacle of acquisition of a patent is the high costs and the highly technical application procedure. This leads to the important question, whether it is really worthwhile for traditional healers or communities to apply for this protection, primarily designed for inventions that are intended for large scale marketing and sale[10]. However, it is clear that the originators of the traditional knowledge must have a stake in the health sector in order to be interested and willing to share their important knowledge with others and allow for an overall advancement of medicine and human well being. In this regard, it would

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among others, Hansen/Van Fleet (2003), p. 9-23, WIPO (2003), p. 16-20.

8 See infra, p. 60

9 WIPO (2003), p. 18, see also Qian Jia, p. 40-43.

10 See also, Patwardhan (2005), 91.

be important to provide holders of knowledge of traditional medicine with an effective tool of protection.

Plant Varieties

Many countries provide for a specific right for protection of plant varieties in compliance or in accordance with the International Convention for the Protection of New Varieties of Plants (UPOV Convention)[11] instead of protecting plant breeders under patent law[12]. The protected subject matter under this right are plants which are (1) new, which means that they have not been sold or marketed earlier than 4 years before the filing for protection, (2) distinct from other commonly known varieties, (3) uniform and (4) stable. As we can see, the novelty requirement with regard to plant variety protection is somewhat less strict than for patenting of inventions. If a healer has used a plant strictly for his own healing practice and has not marketed or sold the plant, novelty might be fulfilled even after a relatively long time of using the plant.

The main disadvantage of plant variety protection is that it can never be used as protection for traditional medicine as such but only to protect the plant itself. In many cases of important application for healing, such plants will not necessarily be a result of specific breeding of plants by humans, but simply plants growing wildly in a certain region. Thus, the requirement of distinctiveness from existing plants will often not be met.

Confidentiality and Trade Secrets

According to the internationally prevailing conditions to legal protection as a trade secret, information must (a) be secret, (b) have commercial value and (c) have been protected against disclosure[13]. For information to be considered secret, it suffices that it is secret as a whole. It is not necessary that all parts of it are unknown. It even suffices if only the assembly of the components of the information is secret. That means that, e.g., a plant may be generally known, but not its healing effect or how the healing effect is best triggered. To be considered secret, information may not be generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question. These conditions

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11 On November 24, 2006, 63 countries, among others, South Africa and Switzerland, were members to the UPOV Convention (http://www.upov.org/en/about/members/pdf/pub423.pdf).

12 For a detailed description and comment of the significance of this area of intellectual property law for traditional medicines see the contribution by David Cochrane in this publication.

13 For detailed description of the conditions for trade secret protection, see: Meitinger (2003), Correa (2002).

do not require an absolute secrecy. The requirement that the information may not be generally known refers to the relationship of persons that know the information and persons that do not know the information. As soon as the number of knowing persons exceeds a certain quota of the interested circles, the information is not considered secret anymore. It follows from this provision that the secret may be disclosed to third parties, without it being considered as generally known, as long as the number of these third parties is small enough that their observation of the secrecy obligation can be monitored. It is therefore possible, that a whole community knows and keeps a secret in the legal sense. The required commercial value of the information means that there must be an objective (commercial) interest to keep the secrecy. The commercial value of the secrecy will usually consist of an advantage over competitors that would be lost if competitors obtained the information, which would cause commercial damages to the proprietor of the information. The required amount of the commercial value of the information may not be too high. It should suffice if the information is useful for an entity in its professional activity, e.g. in the way that it enhances efficacy of that activity. It is not required that the knowledge of the secret results in a direct rise of the benefits of the company. As opposed to other intellectual property titles, trade secrets do not enjoy an absolute protection. The proprietor of a secret must take reasonable steps under the circumstances to keep the information secret. Obviously, the law can only protect secrets that are also protected by their proprietor. When judging the protection measures taken, the reasonability of the different possibilities of protection, as well as of the relation of the value of the secret and the costs of protection has to be taken into account.

Trade secret protection can be an option to protect traditional medicines if e.g. a recipe or a ritual has been kept secret in the past. Generally, the legal requirements for protection of information as a trade secret are not difficult to meet. However, as easy it is to fulfill these requirements, as limited is the strength of this title: Analysis and reinvention of the product by third parties is legal and loss of secrecy by leaks of information can easily put the protection to an end.

Nevertheless, trade secret protection in fact is probably the intellectual property title which has been mostly used to protect knowledge of traditional medicine and healing practices. Customary laws of communities often require that certain knowledge be disclosed only to certain recipients. Courts have awarded remedies for breach of confidence when such customary laws were violated. In one example from Australia, the publication of sacred-secret materials in a book written by an anthropologist had been successfully prevented by using a breach of confidence action. The plaintiffs successfully argued that the book contained information that could only have been supplied and exposed in confidence to the anthropologist and that the “revelation of the secrets contained in the book to their women, children

and uninitiated men may undermine the social and religious stability of their hard-pressed community"[14].

Geographical Indications

As a geographical indication can be protected the name of a region or locality, used to identify a product as originating from that region or locality, where a given quality, reputation or other characteristics of the good is essentially due to the geographical origin. Generally, this right can be used to identify a healing product. However, protection of geographical indications do not provide for protection against others producing the same thing under a different name. Although the quality, reputation or other characteristics of the good play a role for the acquisition of this protection title, these factors are only protected indirectly. The protection itself is limited to the geographical designation of products. Therefore, geographical indication protection in the area of traditional medicines can only be relevant if, e.g. a healing plant only grows in a specific area of the world or if it only develops its healing effects if grown in a specific place. An example would be the South African roibosh tea[15].

Copyright

Copyright protects works made by human beings that contain a certain level of creativity or originality. Typical works that are protected are written texts, songs, performances, sculptures etc. Copyright and copyright like concepts play an important role for protection of traditional knowledge in general and of folklore[16]. However, the use of copyright for the protection of traditional medicine is rather limited, because again, the protected subject matter is not the contents of the work but only its form. This means that copyright of a booklet containing healing recipes would only protect the form of the text of that booklet, but not the actual recipes. Therefore, protection through copyright could only be envisaged regarding procedures and rituals applied by healers as part of their traditional or spiritual healing methods.

Trademarks and Designs

Trademarks and Designs also have a rather minor significance for protection of traditional medicine. A trademark can protect the name of a medicine, but it cannot prevent others from producing and selling the same product under a different name[17]. Regarding designs, the protected subject matter of protection is the aesthetic aspect

14 WIPO (2003), p. 20.
15 See, among many other information sites: www.theherbspiral.com/supps/herbpages/Rooibos.htm and www.raysahelian.com/rooibos.html.
16 Lucas-Schloetter (2004), pp. 259-284.
17 For a detailed presentation on this see Kur/Knaak (2004), pp. 224-237.

or the shape of an object. Therefore, this title will be also of marginal importance for the protection of traditional medicines.

Conclusion

It has been shown in this chapter that existing intellectual property protection titles do not fit very well to protection of traditional medicine. The reason for this is that these titles have been created and developed parallel to and for the enhancement of industrialization. Except in the area of geographical indications, rural and traditional aspects have never been in the focus of intellectual property law development. In order to protect traditional medicines and their flanking aspects a specific, sui generis protection title would be necessary.

The Case for a Sui Generis Title

Possibility to create a new Protection Title?

The literature on intellectual property rights often refers to the numerous clausus, i.e. the conclusive list, of existing intellectual property titles. This view has also been taken by some delegations in the negotiation of the WTO Agreement on Trade-related Aspects of Intellectual Property Rights (WTO/TRIPS Agreement) during the Uruguay Round[18]. However, the WIPO Convention, which has been ratified by 184 countries and serves as the legal foundation for all international treaties on intellectual property administered by WIPO, contains a very open definition of intellectual property rights by referring in its Article 2 Paragraph 8 to all rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields. In other words, intellectual property is a broad concept and can include productions and matter not forming part of the existing categories of intellectual property[19]. Under this definition, it is clear that the existing list of intellectual property titles is non conclusive and sui generis protection titles can be created and implemented. In fact, in their discussion of the international protection of traditional knowledge, several international bodies have touched, or even gone into, the issue of a sui generis intellectual property right.

18 See Meitinger (2005), 124 and GATT Doc. MTN.GNG/NG11/W/37, 10 July 1989, Para. 46.

19 WIPO (2001), 24.

The International Debate on Intellectual Property Protection of Traditional Knowledge, Genetic Resources and Folklore

As mentioned above, the international discussion of protection of traditional medicine by intellectual property rights is part of the larger discussion of protection and treatment of traditional knowledge, genetic resources and traditional cultural expressions or expressions of folklore. Efforts to find solutions have mainly focused on the aspect of regulating access to genetic resources and traditional knowledge and the fair and equitable sharing of the benefits arising out of their utilization. This discussion takes place in various fora, in particular, the "Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore" of the World Intellectual Property Organization (WIPO-IGC), as well as other bodies of that organization, the World Health Organization (WHO), the bodies administering the Convention on Biological Diversity (CBD); the Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS Council) of the World Trade Organization (WTO) and the Food and Agriculture Organization (FAO).

WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (WIPO-IGC)

The WIPO-IGC was established in 2000. Since then it has broadly discussed both policy and practical linkages between the intellectual property system and the needs and interests of holders of traditional knowledge. The work of the WIPO-IGC started based on the results of extensive studies undertaken by the WIPO in the forefront. Currently, the WIPO-IGC is moving towards an international understanding of the shared objectives and basic principles of protection of traditional knowledge[20]. In comparison to other fora, the WIPO-IGC has no mandate to take binding decisions on the protection of traditional knowledge. This has the disadvantage that some countries are of the opinion that the WIPO-IGC is not a useful forum to get concrete results. However, this more consultative role of WIPO-IGC leads to the advantage that issues can be discussed more freely. In addition, the WIPO-IGC can deal with all questions that arise and it is not limited to the possibilities and issues under specific existing treaties. The limits of the WIPO-IGC of course are determined by the fact that it cannot extend the discussion to issues outside the area of intellectual property protection.

20 For all the documents produced by WIPO and the participating countries see: www.wipo.int/tk/en/tk/index.html.

World Health Organization

The World Health Organization (WHO), in 1978, albeit hesitantly, recognized the relevance of traditional medicine as a source of health care in its Primary Health Care Declaration of Alma Ata. Later on, the Organization started to address the topic systematically and in 2002, it implemented the WHO Traditional Medicine Strategy 2002-2005[21]. In its 111th Session, the Executive Board of the WHO adopted a resolution on traditional medicine[22], in which Members, among many other issues, Member States are urged

> "to take measures to protect and preserve traditional medical knowledge and medical plant resources for sustainable development of traditional medicine, including the intellectual property rights of traditional medicine practitioners, as provided for under national legislation consistent with international obligations"[23].

and requested the Director-General of WHO

> "to collaborate with other organizations of the United Nations system and non-governmental organizations in various areas related to traditional medicine, including research, protection of traditional medical knowledge and conservation of medicinal plants resources"[24].

Significant research on the various issues in the context of traditional medicine has been done by the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH), which was created in May 2003 at the 56th World Health Assembly through the adoption of Resolution WHA56.27 on Intellectual Property Rights, Innovation and Public Health[25]. This resolution requested the WHO to establish a time-limited body to collect data and proposals from the different stake holders involved and to produce an analysis of intellectual property rights, innovation, and public health. The CIPIH submitted its final report to the 59th World Health Assembly in 2006[26]. The report ends with an extensive catalogue of recommendations in order to improve public health. Among others and similar to the Executive Board in 2003, the report recommends:

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21 WHO Doc. WHO/EDM/TRM/2002.1, available at: http://whqlibdoc.who.int/hq/2002/WHO_EDM_TRM_2002.1.pdf.

22 WHO Doc. EB112.R12 of 24 January 2003, available at: www.who.int/gb/ebwha/pdf_files/EB111/eeb111r12.pdf.

23 See FN 2, Paragraph 2(6).

24 See FN 2, Paragraph 3(4).

25 Available at: www.who.int/gb/ebwha/pdf_files/WHA56/ea56r27.pdf.

26 The full final report is available at: http://www.who.int/entity/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf.

> "WHO, WIPO and other concerned organizations should work together to strengthen education and training on the management of intellectual property in the biomedical field, fully taking into account the needs of recipient countries and their public health policies."[27]

However, the CIPIH does not make any suggestions regarding the international negotiation or the national implementation of amendments of intellectual property right protection or of a sui generis protection title for traditional medicine.

WTO Council for Trade-related Aspects of Intellectual Property Rights

Another forum, where the relationship between intellectual property protection and traditional knowledge has been debated for several years, is the Council for Trade-related Aspects of Intellectual Property Rights of the WTO. Its mandate to deal with this issue evolved over the years after the establishment of the WTO in 1994: In section 5, the TRIPS Agreement lays down the minimal standards of patent protection (Articles 27 through 34). In its first paragraph, Article 27 defines the patentable subject matter. Paragraphs 2 and 3 allow WTO Members to make certain exceptions from patentability in their national legislation. Article 27.3(b) prescribes a review of this very provision, respectively, of the optional exceptions to patentability. This review should take place four years after the WTO Agreement came into force, that is, in 1999. The corresponding work had begun with the collection of information from Members (at first only from industrialized countries) regarding the implementation of this provision in their national legislation. The discussion became more vivid when in 2001 at the WTO Ministerial Meeting of Doha in Paragraph 19 of their Declaration, the Ministers of the WTO Members instructed

> "the Council for TRIPS, in pursuing its work program including under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of this Declaration, to examine, inter alia, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by Members pursuant to Article 71.1."[28]

27 CIPIH (2006), p. 183, paragraph 5.3.

28 WTO Ministerial Conference 2001, Ministerial Declaration, adopted 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 20 November 2001.

What started with a review if and how WTO Members provide for patent protection, has turned to a discussion that is dealing today exclusively with the relationship of patent protection and traditional knowledge, genetic resources and folklore. After turning in circles for quite some time, the discussion came to a standstill after the suspension of the whole Doha round negotiations in summer 2006 and was only continued in February 2007, when Ministers had decided to continue the negotiations in order to conclude the round as soon as possible. However, since then, as many of the trade topics, the discussion of traditional knowledge and intellectual property continued to be a treadmill as before the brake.

WIPO Working Group on Reform of the Patent Cooperation Treaty- Swiss proposal enable introduction of requirement of declaration of source

In 2003, Switzerland proposed to explicitly enable the national patent legislation to require the declaration of the source of genetic resources and traditional knowledge in patent applications. More specifically, it proposed to amend the Regulations under the Patent Cooperation Treaty (PCT) to explicitly allow the Contracting Parties of the PCT to require patent applicants, upon or after entry of the international application into the national phase of the PCT procedure, to declare the source of genetic resources and/or traditional knowledge, if an invention is directly based on such resource or knowledge. Furthermore, Switzerland proposed to afford applicants the possibility of satisfying this requirement at the time of filing an international patent application or later during the international phase. In case an international patent application does not contain the required declaration, national law may foresee that in the national phase the application is not processed any further until the patent applicant has furnished the required declaration. The proposals were intended to enhance the cooperation between the international fora and the mutual supportiveness of the applicable international agreements. By reference, the proposed amendment to the PCT would also apply to the Patent Law Treaty (PLT). Accordingly, the Contracting Parties of the PLT would be able to require in their national patent laws that patent applicants declare the source of genetic resources and/or traditional knowledge in national patent applications. Based on the PLT, national law may foresee that the validity of granted patents is affected by a lacking or incorrect declaration of the source, if this is due to fraudulent intention.

In the view of Switzerland, the proposed amendments to the PCT-Regulations presented one simple and practical solution to the issues arising in the context of access to genetic resources and traditional knowledge and the fair and equitable sharing of the benefits arising out of their utilization. The advantages of these amendments are seen in their possible introduction in a timely manner and that

they do not require extensive changes to the provisions of relevant international agreements. However, the proposal so far has not obtained the support of a larger part of the WIPO Membership. For some delegations it goes too far, for many others, it is not going far enough.

Convention on Biological Diversity (CBD)

The objectives of the Convention on Biological Diversity, which was adopted in 1992 and entered into force on December 29, 1993[29], are the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits arising from the commercial and other utilization of genetic resources. Regarding traditional medicine, this convention plays a role as far as plants or animals are involved in traditional healing. Regarding the protection of genetic resources, the CBD primarily takes care of the problem of misappropriation and monopolization of these resources by imposing obligations on their users to declare from which source they were obtained and to prove that the acquisition of the resources was done with the informed consent of the providers of them prior to such use and by regulating access to those resources and the fair and equitable sharing of the benefits arising out of their utilization[30]. At its seventh meeting, taking place in 2004, the Conference of the Parties of the CBD, mandated its Ad Hoc Open-ended Working Group on Access and Benefit Sharing to further

> "elaborate and negotiate an international regime on access to genetic resoureces and benefit-sharing with the aim of adopting an instrument/instruments to effectively implement the provisions in Article 15 and Article 8(j) of the Convention and the three objectives of the Convention"[31].

This international regime shall also include "traditional knowledge, innovations and practices in accordance with Article 8(j)."[32] Parallel to this Working Group, the Conference of the Parties formed a Working Group on Article 8(j), which is mandated to address, among other issues, *sui generis* systems for the protection of traditional knowledge. The working group proposed put considerable thinking in the development of elements of a *sui generis* system for the protection of traditional knowledge, innovations and practices[33]. The elements looked at here, however,

29 For the text of the CBD see: www.biodiv.org/doc/legal/cbd-en.pdf.
30 See for a condensed summary, Graber/Girsberger (2006), p. 13/14.
31 See CBD-COP7 (2004), Section D, para. 1, available at: www.biodiv.org/doc/meeting.aspx?mtg=COP-07.
32 See supra (FN 3), Annex, para. (c)(ii).
33 See CBD-Working Group on Article 8(j), 2003. See generally <www.biodiv.org/doc/meeting.aspx?mtg=WG8J-03> and <www.iisd.ca/biodiv/wg8j-3/>.

relate primarily on the protection of traditional knowledge against misappropriation by third parties[34].

How to Shape a Sui Generis Intellectual Property Protection for Traditional Knowledge?

Several questions have to be answered when trying to create a sui generis protection title for traditional knowledge. Much work has been done on this in international fora, in particular, by the WIPO-IGC, which in its decisions of the Tenth Session of the Committee[35] has agreed on a list of questions and issues to be resolved for the protection of traditional knowledge and on another one for protection of expressions of folklore[36]. The list, which is relevant in the context of traditional medicine, is the one on traditional knowledge. The questions therein concern the definition of traditional knowledge, the beneficiaries of the protection, the underlying objectives of the protection, the infringing acts, the duration and limitations of protection, the sanctions and penalties for infringement and the international aspects of the protection. The most important of these questions is certainly the one about the policy objectives underlying such a protection title, which shall be treated more in depth than the other questions, where this contribution is limited to raising some of the relevant issues non-conclusively.

Objectives of a Sui Generis Protection Title of Traditional Knowledge?

Intellectual Property Rights as Interference in the Free Market Economy – Requirement to Limit the Scope of Protection

Intellectual property rights are economic rights that interfere in the free market by limiting access to information and/or know-how. Therefore, granting such a right must result in a socio-economic benefit[37]. Looking at the existing protection titles, these benefits are the following:

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34 For the latest stage of the work of the Working Group see the Report of the fourth meeting of the Ad Hoc Open-Ended Inter-Sessional Working Group on Article 8(J) and Related Provisions of the Convention on Biological diversity, p. 17 and 39, available at: http://www.biodiv.org/doc/meetings/cop/cop-08/official/cop-08-07-en.doc.

35 WIPO-IGC, Decisions of the Tenth Session of the Committee, 8 December 2006, available at: http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_10/wipo_grtkf_ic_10_decisions.doc.

36 See supra (FN 2), Annex.

37 Generally regarding necessary justifying reasons for intellectual property protection see also Gehl Sampath (2003), 15-22.

For patents, it is the accelerated advancement of innovation through the provision of limited exclusive rights as an incentive to invest in research and development. Furthermore, there is the dissemination of technical knowledge through the obligatory publication of the invention. Thanks to this requirement, the knowledge behind an invention becomes generally available and everybody can built on it and further develop and improve an invention. This is – besides registration fees – the prize the inventor has to pay in order to obtain a limited period of exclusivity. In the area of copyrights, the socio economic benefit is the enriched culture and the advancement of sciences, as a result of the motivation to creativity by the grant of exclusivity rights in a work. Regarding trademarks and geographical indications, it is the quality of products and services provided under a certain name. The incentive to invest in a name is triggered by the attribution of this name through trademark and geographical indication protection to an individual or collective right holder.

Summarizing, it can be said that intellectual property rights generally aim at the enhancement of human mankind through the provision of incentives to private sector entities to invest in development, research, creativity or quality[38]. This has to be kept in mind when creating protection titles for traditional medicine and in particular when the scope of such a title is defined. Only as far as they assist to realize such socio-economically beneficial policy objectives, the creation of a sui generis right in traditional medicine is justified. Financial gains of right holders alone may never be the aim of the right but only a side effect.

Therefore, the first and most important issue when shaping a sui generis right in traditional medicine is the clarification of the policy objectives that shall be achieved by this right. Here, the following objectives can be envisaged: (i) Distribution of knowledge about traditional medicine, (ii) continued practice and development of traditional medicine, (iii) prevention of monopolization by third parties of knowledge which is in public domain or has been protected as a secret by its originators, (iv) preservation and continuation of practice of traditional knowledge and live styles, (v) sharing of information and benefits and collaboration of all stake holders[39]. What should be the very aim of the protection of traditional knowledge by intellectual property right is said, in my view, in a very convincing manner by the CBD in its Article 8(j):

> Each Contracting Party shall, as far as possible and as appropriate:

38 On objectives of intellectual property protection, see also WIPO (2001), 32.

39 See also Cotter/Panizzon (2006), 204, referring to the importance to adapt the classical intellectual property protection system in order to give custodians of traditional knowledge an appropriate incentive and reward for creating and taking care of this knowledge on which much of westernized industry builds on.

> (j) Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising.

This wording could very well be used as the overarching goal of intellectual property protection of traditional medicines. Traditional and allopathic medicine should go hand in hand. Here, intellectual property should contribute by providing incentives of fair use of information on traditional medicine and of the development of medicine as a whole.

Protectable Subject Matter

Definition of Protection of Traditional Medicine

A sui generis protection title should not be limited to traditional medicine but extend to all categories traditional knowledge. Here, the WIPO-IGC uses as a working definition of traditional knowledge that encompasses:

> "the content or substance of traditional know-how, innovation, information, practices, skills and learning, rather than to the form of its expression"[40].

If we relate this definition with the WHO definition of traditional medicine[41], the protected subject matter of the traditional medicine aspect of sui generis protection would be *the content or substance of traditional health practices, approaches, knowledge and beliefs incorporating plant, animal and mineral based medicines, spiritual therapies, manual techniques and exercises, applied singularly or in combination to treat, diagnose and prevent illnesses or maintain well-being.*

Preconditions of Protection

An important precondition to provide for intellectual property protection is the involvement of an intellectual activity in the specific traditional medicine. If such an activity is lacking, no intellectual property protection can be attributed to the medicine[42]. As a formal requirement, WIPO-IGC has also considered necessary that

40 See WIPO-IGC (2004), para. 31.
41 See above p. 45.
42 See WIPO-IGC (2002), para. 25; Cottier/Panizzon (2006), p. 223.

the information is recognized or documented in a codified knowledge system[43]. It would have to be examined further whether such a publication requirement is really necessary or if it should rather be foreseen as a consequence of protection.

Beneficiaries of the Protection

The sui generis right, in most of the cases, will not be attributable to one individual right holder. Usually, there will be a small group or even a whole community that has been developing and using certain treatments. This fact is often considered as one of the challenges of the shaping of the sui generis right. However, there are examples where collective ownership of intellectual property rights has existed for a long time[44]. One is the collective trademark, where upon compliance with certain preconditions (usually membership in an association of a certain business sector) the trademark may be used by anybody. The other example is the protection of geographical indications: Everybody who fulfills the requirements contained in the product specifications of a geographical indication may use it and defend it against illegitimate use by others. Protection of traditional knowledge should have the same approach and provide for an inclusive, rather than an exclusive character of the right[45]. Some authors even suggest that such rights should never be attributed to one individual, according to them, in case that individuals add value to traditional knowledge, they should be referred to existing intellectual property titles[46]. However, it seems that such a division of titles in traditional knowledge could lead to a highly confusing legal situation. On the other hand, if a protection title, which includes later improvements of the knowledge, would be provided for, this would have other downsides in the sense that it risks to make protection unlimited in time, which would not stand the benchmark with other protection titles for inventions.

Rights Conferred

The normal scope of any intellectual property right is predominantly to prevent third parties from using the intellectual property without the consent of the right holder. Typically, this right extends to the prevention of making, using, offering for sale, selling and importing[47] products containing the protected subject matter and to the prevention of using the protected subject matter in services. Rights in traditional knowledge or medicine may encompass to the same powers.

43 See WIPO-IGC (2004), para. 32.
44 As Cottier/Panizzon (2006) state correctly, collective ownership today is also common for patents and trademarks.
45 See also Cottier/Panizzon (2006), p. 222.
46 See supra (FN 3).
47 Sometimes the right extends even to export and transfer of products.

However, the international debate and large parts of academics concentrate at first hand on defensive rights against appropriation and monopolization of traditional knowledge by third parties, providing primarily for a right of recognition and compensation of the holder of the traditional knowledge[48]. Although it is questionable if this will be enough in order to achieve the policy objectives mentioned above, it might be right that this issue is the one where a solution is most needed and that hence pragmatism requires taking care of this issue first[49]. In addition to that, as indicated above, limitations of rights granted are important. It can be asked, e.g., whether it is really desirable to prevent multinational companies from using and exploiting traditional knowledge, if they do not prevent others from using that knowledge. Is the use by others of knowledge on traditional medicine, which is in the public domain against the underlying policy objectives of protection of traditional knowledge? It could be argued that what should be prevented is simply the monopolization of knowledge, since the use alone of the knowledge by third parties like pharmaceutical companies does usually not harm the individuals or groups the knowledge comes from, since the two are not in a competitive relationship. The use by others, to the contrary, makes available traditional treatment to patients that otherwise would not have the chance to benefit from it. Monopolization can be prevented by limiting relevant intellectual property rights, in particular patent rights acquired by third parties. The options here are a system of declaration of source of the traditional knowledge or the genetic resources in patent applications that could be combined and complemented with a requirement of prior informed consent of the holder of the knowledge to the use of the knowledge in a patent application and of general access and benefit sharing regime[50].

Furthermore, it can be argued that if those that generated the knowledge or received it from their ancestors can obtain a (sui generis) right in traditional medicine, limitations must apply. Because, like in the area of allopathic medicine patents may limit access to pharmaceuticals by the public, in the area of traditional medicine a sui generis right protection could become a hurdle for access to this medicine for vast parts of the world population[51]. This danger would be avoided if the right would be limited to compensation and recognition, whereas at the same time fairness would be preserved, which apart from prevention of monopolization is of paramount importance if a good and sustainable collaboration and cooperation between traditional and allopathic medicine shall be established. However, the downside of such a limited scope of protection is that developing countries and in particular their

48 See WIPO-IGC (2006), WTO Secretariat (2006), in particular at paras. 33-40, Cottier/Panizzon (2006), p. 226, qualifying this as a unfair competition protection.
49 See Correa (2004), p. 14, confirming this view: Patwardhan (2005), p. 89.
50 See on this Graber/Girsberger (2006), p. 12.
51 See also Correa (2004), p. 6.

indigenous peoples remain dependent on developed countries and their companies, whereas if they would be empowered by fully fletched protection titles, they would have a much stronger position, which would contribute, in the long run, to their enhanced development and independence[52]. Nevertheless, what is important is that the public good character of the knowledge or information is also respected with regard to traditional medicine and traditional knowledge and, therefore, as in any other area of intellectual property, not each and every step of traditional medicine can and should be protected. Experiences traditional healers gain through their practice might not be protected.

Enforcement of Rights and International Aspects of Protection

Generally, enforcement measures of a sui generis right in traditional knowledge would be similar than for any other intellectual property right. However, there are two factors regarding enforcement of the sui generis right, which need further thought. First it is the fact that indigenous peoples in most cases, because of limited financial resources and because of the lack of integration in the legal system, have only limited access to the legal system of a country, so specific schemes might be necessary in order to implement and enforce these rights. Second, many of the cases of infringement will be international disputes or at least have an international aspect.

How can Indigenous Communities Defend their Rights in Traditional Medicine?

Access to the legal system for indigenous communities is a general challenge for the countries in which such communities live, so a solution to enable this access should be sought not only for the enforcement of sui generis rights in traditional knowledge, but also for all other rights of indigenous people[53]. To overcome financial hurdles to enforce the rights, Switzerland and many other countries foresee in their jurisdictions a system of qualified assigned (free of charge) counsels who defend the rights of people with insufficient financial means in court and/or vis-à-vis the administration. This approach could very well be taken to enforce sui generis rights in traditional knowledge. Another possibility would be to promote pro bono programs of law firms, by underlining the image value of such an activity. If one would like to

52 See also Cottier/Panizzon (2006), p. 227.

53 See, e.g., the obligations under Article 2 of the Indigenous and Tribal Peoples Convention, 1989 (No. 169) and under Article 4 of the Declaration on the Rights of Persons Belonging to National or Ethnic, Religious and Linguistic Minorities Adopted by General Assembly resolution 47/135 of 18 December 1992 (both texts are available at: http://www.ohchr.org/english/law/).

go further in providing incentives for such work, tax reductions could be granted to law firms providing for pro bono services in favor of indigenous people. As an example, in the United States, intellectual property firms have allied in a pro bono initiative, the Public Interest Intellectual Property Advisors (PIIPA), which administers a network of intellectual property professionals which are willing to provide groups or individuals from developing countries with free of charge legal advise on intellectual property[54].

Apart from the financial burden, indigenous people often face logistical difficulties to access the national legal system. Part of this challenge might be solved by free of charge or pro bono attorneys who, once mandated, would also act as interface between the indigenous right holder and the infringer and the legal institutions. However, in order to even get in touch with such an attorney could be difficult. Here, indigenous people's organizations could play a role to bring the right holder and the attorney together.

For the International Scale: Register for Traditional Medicines to Destroy Bona Fide

International enforcement of intellectual property is a difficult challenge. Even in developed countries, not only individual right holders but also multinational companies often struggle a lot in order to have their rights respected. This is even more the case for rural indigenous communities and their individuals. How can they monitor the world market to detect possible right infringements? How can they, even if they would discover such an infringement, take the necessary steps to prevent that infringement? Here, a register of traditional knowledge might be of assistance[55]. It would at least allow those companies who want to avoid biopiracy to do so. In addition, a register could have the side effect that, like in patent law, its contents could be a useful source of information that could be used upon a license-like fee or after individual agreement with the proprietor of traditional knowledge. Furthermore, a register would be an important tool to preserve traditional knowledge for the future[56]. Those participants in a certain economic sector, who try to misappropriate the knowledge, would be charged with the burden of proof to satisfyingly explain how they had legitimately acquired the information. In fact, there have been several national and international initiatives to establish such registers of traditional knowledge and or genetic resources[57].

54 See Gollin (2005), in particular on pp. 199-201 and www.piipa.org.
55 For a comprehensive overview of the discussion on this, see: Cottier/Panizzon (2006), 228-231.
56 See Balick (2003), 3.
57 See, e.g., the China Traditional Chinese Medicine Patents Database (http://211.152.13.119/

Conclusion

It has been seen in this contribution that existing intellectual property titles do not entirely fit for protection of traditional medicine. A sui generis protection title would be necessary. In a first step, this protection title might be limited to defensive rights against misappropriation and monopolization of the knowledge by third parties. However, to allow indigenous holders of traditional knowledge to overcome the dependence of developed countries' companies, it would be important to fully empower them by a fully fletched protection title, also encompassing positive rights. One of the results of this contribution is that almost every idea about possible solutions on how to protect and promote traditional medicine by intellectual property rights has been said and described. Hence, the time is ripe to implement these ideas and proposals into international and national law, giving the system a try in practice. Discussions alone will not bring the case of traditional medicine and traditional knowledge in general any further.

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Protection of indigenous knowledge and traditional medicine in south africa

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Developing nations although endowed with significant biogenetic resources and traditional knowledge associated with use thereof, suffer from extreme poverty, ill-health, unemployment, a lack of understanding of how to protect and benefit from their resources and associated indigenous knowledge, and find themselves in a weak position in respect of defending themselves against bio-piracy. The protection of traditional medicine and indigenous knowledge, in as far as it is related to traditional medicine in South Africa, is discussed. It is submitted that traditional intellectual property systems find application in such protection, albeit with a number of challenges owing to characteristics of indigenous knowledge. Protection under the South African National Environmental Management: Biodiversity Act no 10 of 2004 is also briefly discussed.

Introduction

In today's knowledge driven economy, not only has the rate of generation of knowledge become important, but also the protection of such knowledge. In recent years, there has been an increase in debate in the international arena about the appropriateness of conventional intellectual property systems in respect of the protection of indigenous knowledge systems and biogenetic resources. This debate is not that surprising if one considers that most developing nations endowed with significant biogenetic resources and traditional or indigenous knowledge associated with use thereof, still suffer from extreme poverty, ill-health, and unemployment. Furthermore, these countries lack an understanding of how to protect and benefit from their resources and associated indigenous knowledge, and find themselves in a weak position in respect of defending themselves against bio-piracy. In recent years the developing nations have questioned the potential benefits of international intellectual property arrangements, including the adequacy of the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS).

Legislative Framework in South Africa for the Protection of Indigenous Knowledge and Traditional Medicine

Intellectual property rights generally refers to a bundle of rights aimed at protecting a variety of creations of the human intellect, and includes patents, copyright, trademarks, designs, plant variety protection (PVP), undisclosed confidential information (trade secrets). In this paper, attention is placed on the protection that can be afforded to indigenous knowledge and traditional medicine, in as afar as there is a relationship between them, within the South African context.

Indigenous knowledge can be defined as a body of knowledge built by a group of people, essentially communities, through generations living in close contact with nature, and includes the know-how, skills, innovations, and practices[1] [2]. From this definition, it is apparent that this body of knowledge can be differentiated from other knowledge systems, typically protectable by conventional intellectual property systems by its characteristics. Typically, indigenous knowledge is not always recorded, but often is passed, often orally, from one generation to another. In certain cases, it is learned and developed through observations and experience. Furthermore, indigenous knowledge is rooted in a social context rather than individualistic context

1 Graham Dutfield, Intellectual Property, Biogenetic Resources and Traditional Knowledge, Earthscan, 2004.

2 Indigenous Knowledge Systems (IKS) Policy for South Africa, Department of Science and Technology (www.dst.gov.za).

typical of intellectual property systems[3]. Thus, the question arises, as to how one affords protection to a body of knowledge that is often not recorded, is transmitted orally, is intuitively practiced by communities that possess such knowledge, and is often misappropriated by other parties.

The conventional intellectual property regime as we know it can be adapted to include protection of indigenous knowledge systems. If one considers for example, folklore, copyright laws can be used for the protection and enforcement of indigenous knowledge embedded in folklore. Although there are certain challenges in respect of identifying the author of works based on indigenous knowledge systems, the copyright laws can be adapted to deal with this challenge.

In November 2004, the Cabinet of the Government of the Republic of South Africa adopted The Indigenous Knowledge Systems (IKS) Policy[4], in an effort to "*recognize, affirm, develop, promote and protect indigenous knowledge systems in South Africa*". Although the Policy is not law as such, its principles are consistent with those of the Convention on Biodiversity (CBD) which came into force in 1993, and have to some extent been incorporated in the South African National Environmental Management: Biodiversity Act No 10 of 2004 (Biodiversity Act)[5]. The Biodiversity Act provides protection for indigenous biological resources, including any living or dead animal, plant or other organism of an indigenous species, and any derivatives thereof.

There is limited protection for indigenous knowledge under common law in South Africa, only to the extent that there is a delict. The need for mechanisms to strengthen such limited common law protection of indigenous systems has been heightened with increased incidences of misappropriation of such indigenous knowledge systems in the form of bio-prospecting.

Another mechanism of protecting indigenous knowledge and traditional medicine is based on trade secrets. Under the TRIPS Agreement, all member states are required to provide measures to recognize trade secret protection. South Africa, being a signatory to the TRIPS Agreement, recognises trade secret protection, notwithstanding the fact that there is no statute per se that deals with trade secrets. The protection is under common law, being based on the law of delict. For trade secret protection to subsist, the indigenous knowledge must be undisclosed confidential

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3 Macdonald Netshitenze and Natalie Sunker, Interfacing Protection and Commercialisation of Traditional Knowledge Systems with the existing intellectual property system, Department of Trade and Industry, South Africa, 2005.

4 Indigenous Knowledge Systems (IKS) Policy for South Africa, Department of Science and Technology (www.dst.gov.za).

5 South African National Environmental Management: Biodiversity, Act No 10 of 2004.

information which derives independent economic value, actual or potential, from not being generally known. In addition, there must be reasonable efforts in relation to the value and under the circumstances, to maintain the information secret. Trade secret protection has unlimited duration of protection, subject to the trade secret becoming part of the public domain whether through the actions or otherwise of the proprietor. It is thus evident that this form of protection is synergistic with the principles of indigenous knowledge, in which the knowledge is transmitted from one generation to another, either in codified or uncodified form, with the benefits being enjoyed by each generation. The limitation of this form of protection is that where the information no longer meets the requirements for trade secret protection to subsist, it is difficult for a proprietor, and indeed communities to enforce their rights to indigenous knowledge where this information has been made available to the public. It is this limited protection that the Biodiversity Act seeks to address. It is submitted that the Biodiversity Act will not *per se* provide protection in the form of negative right typical of intellectual property statutory mechanisms such as patents and copyright, but will provide protection to the extent of ensuring that community rights are recognised and their consent requested prior to dealing in indigenous knowledge. Furthermore, the communities' rights to be entitled to benefits in the exploitation of any endeavours that make use of their indigenous knowledge, is established.

It is submitted that trade secret protection finds application in traditional medicine, as some herbal compositions are informed by sacred practices.

In today's knowledge economy, the patent system is recognised as probably one of the strongest forms of protection of knowledge. According to the South African Patents Act 57 of 1978 ("the Patents Act")[6] in order for an invention to be patentable, it must (i) be new or novel, (ii) non-obvious or comprise an inventive step, (iii) be capable of use in trade, industry, or agriculture; and (iv) not consist of subject matter excluded from patentability in terms of s25(2) of the Patents Act.

Thus, the first issue that arises in respect of protection of indigenous knowledge and traditional medicine in particular, within the context of the minimum patentability standards is that of novelty. For the most part, indigenous knowledge by virtue of being transmitted from generation to generation is regarded as having been disclosed to the public. Furthermore, certain disclosures have been made by third parties who have obtained such knowledge directly from the indigenous communities, without the communities' prior-consent to such disclosure. Thus, when one considers the requirement for novelty in respect of patentability, indigenous knowledge, particularly as applied to traditional medicines, may be deemed to be absent, as some of the

6 South African Patents Act, Act no 57 of 1978.

medicinal properties of herbs / plants have been known to indigenous communities for some time. However, in some of the abovementioned cases, although there has been some disclosure in part, there are certain components of that body of knowledge which remains undisclosed, which can be classified as falling within what one would regard as trade secrets. The patent system provides inadequate protection for sacred components of traditional knowledge and medicine.

The South African patent system now gives recognition to the importance of indigenous knowledge in as a far as it informs the subject matter of a patentable invention. The recent amendments introduced into the Patents Act by the Patents Amendments Act of 2005[7] requires that an applicant for a patent which makes use of indigenous knowledge in the form of indigenous biological resource or genetic resource and is based on traditional knowledge or traditional use, comply with the following requirements for an ensuing patent to be valid: (i) disclosure in prescribed form of source of origin (ii) prior-informed consent of use of the traditional or indigenous knowledge and (iii) declaration that applicant has entered into a benefit sharing arrangement with the community / source, in respect of commercial outputs of the patent. Thus, protection for indigenous knowledge is strengthened, although this requires changes to the administrative procedures at the patent office to ensure compliance with these requirements, which should pose some interesting challenges for a country with a non-examining system.

Failure to comply with the provisions of the Patents Act[8] gives the Registrar of Patents the power to revoke the relevant patent.

Although the provisions of the Patents Act strengthen protection to indigenous communities where there has been no prior informed consent and no agreement on benefit sharing, may be laudable, in that the patent is revoked, the downside however is that any indigenous knowledge disclosed without prior-informed consent which was “sacred” or comprised trade secret, becomes part of the public domain. Thus, although the affected communities will be entitled to recourse under common law or in delict, it is not certain that such recourse will compensate such communities for the damage caused by the indigenous knowledge becoming part of the public domain.

More recently, with increased use of traditional medicines, questions have been asked whether or not a patent can be filed for a traditional medicine. We are of the view that there is nothing in the Patents Act, *per se*, that specifically precludes a traditional medicine from being the subject of a patent application or a patent,

7 South African Patents Amendment Act 2005.
8 South African Patents Amendment Act 2005.

provided that the minimum patentability requirements set out above have been complied with. Support for this position has also been found through a search through the Patent Co-operation Treaty („PCT“) database which revealed amongst other patent applications, a patent application on use of Chinese traditional medicine to reduce blood published under WO2004052382A1, whose abstract provides as follows:

> The invention relates to a drug treating hyperipodemia, especially relates to a Chinese traditional medicine preparation, which can nourish Yin to clear away liver-fire, and promote blood circulation and stimulate the menstrual flow, especially can treat hyperlipodemia due to Yin-deficiency of liver and kidney and blood stasis. The preparation of the invention can be prepared by mixing and extracting five Chinese herbs which are Sickle senna seed (Semen Cassiae), fruit of Chinese wolfberry (Fructus Hoveniae), White mulberry fruit (Fructus Mori), fruit of hawthorn (Fructus Crataegi) and Safflower (Flos Carthami).

One of the challenges, however, is that the patent system requires that an inventor, i.e. an individual or group of individuals be identified as inventors of the invention covered by the patent application. The characteristic of ownership of indigenous knowledge is that it does not vest in an individual since it has been passed down from one generation to the next and innovated on by each generation with the result that the communities *per se* are not owners of the indigenous knowledge but merely custodians. Notwithstanding this characteristic, we are of the view that in the case where a traditional healer puts together a new composition or remedy which complies with the patentability requirements, such traditional healer is the inventor. However, often there is the case where the traditional healer says that the composition came to them in a dream or some other sacred way, with the result that on the question of protection, there is often an element of resistance or difficulties in clearly articulating what the inventive step is.

In the case where a novel active ingredient is isolated from a traditional medicine, patent protection can be afforded to the active ingredient, with the inventor being the person who isolated the active compound, provided that there has been compliance with the requirements of the Patents Amendment Act in respect of traditional knowledge. In addition, where the medicinal properties of the herb(s) used in the traditional medicine were informed by indigenous or traditional knowledge, there is a need to include individuals such as traditional healers, who might have made an inventive input in respect of the medicinal properties. In the case of traditional healers that have made inventive input, the traditional healer is the inventor, only to the extent of the inventive input. Typically, it is impossible or difficult to determine the

inventor, in the case of traditional medicine and/or in case of biogenetic resources whose medicinal properties are informed by traditional or indigenous knowledge, except for the cases where a previously unknown active compound has been isolated.

In terms of the South African Patents Act, "*an invention of a method of treatment of the human or animal body by surgery or therapy or of diagnosis practiced on the human or animal body shall be deemed not to be capable of being used or applied in trade or industry or agriculture*". However, a product consisting of a substance or composition for use in a method of treatment of the human or animal body can be patented and in this regard, one should seek to obtain patent protection for the substance or composition, a process for producing the substance or composition and also use of the substance or composition in the manufacture of a medicament. It should be noted that in other jurisdictions, such as the USA, a method of treatment of the human or animal body by surgery or therapy or of diagnosis is patentable. Thus, should the invention have potential for exploitation in countries where patent protection for methods of treatment are possible, then the claims must include claims directed to such methods of treatment. From the practices emerging in countries such as India and China, it is hereby submitted that traditional medicine can be protected as traditional medicine, as such, to the extent that it still complies with the novelty and inventiveness requirements, as the utility requirement is for the most cases fulfilled. Further, there is possible and potential protection of the isolated active compounds. It is this latter part that has necessitated the need to find a system of protection that can be used to protect the interests of the indigenous communities, particularly against unauthorised appropriation of indigenous knowledge or bio-piracy. Notwithstanding, it is further submitted that protection can be afforded to herbal composition containing particular extract(s), together with processes for preparation of the extracts or the composition comprising the extracts.

The amendments to the Patents Act are in line with the principles of the Convention for Biological Diversity (CBD) and also the Biodiversity Act (in particular Chapter 6, which regulates bio-prospecting). Chapter 6 requires permits and compliance in the case of commercial intent. The regulations which will give effect to Chapter 6 have been published recently[9], and they make provision for various permits, including research, bio-prospecting and export permits (if indigenous biological resources are being exported for purposes of bio-prospecting), in addition to guidelines in respect of material transfer and benefit-sharing agreements.

9 National Environmental Management: Biodiversity Act, 2004: Regulations and Bio-prospecting, access and benefit-sharing; Notice 329 of 2007, Government Gazette No 29711, 16 March 2007.

Notwithstanding the merits of the patent system, it is important to bear in mind that this is a foreign system to indigenous communities, and as such, its use is still not that prevalent. Further, this system is still not accessible to the bulk of the indigenous communities that are likely to make use thereof, owing to costs of legal counsel. As a decision to patent is often driven by the benefits one is likely to derive from protection when compared to the costs of patenting, most traditional healers are hesitant to commit substantial funds to obtain a patent. However, with an increase in trade in traditional medicine and also as more and more traditional healers are approached by bio-prospectors, there has been an increase in the number of trade mark applications for traditional medicine remedies under the Trade Marks Act 194 of 1993[10]. Naturally, the value of these marks will be in as far as they are distinguishing the products, i.e. traditional medicines to which they relate, in comparison to other traditional medicines in the market place.

Copyright per se is not a feasible mechanism for protecting traditional medicines and/or derivatives thereof, as the requirements are that the knowledge must be (ii) new (iii) reduced to a material embodiment and (iii) the protection is against reproduction or copying of the material embodiment. However, as stated earlier, some forms of indigenous knowledge can be protected in terms of the Copyright Act 98 of 1978[11], provided they meet the criteria.

Conclusion

Indigenous knowledge and traditional medicine are protected in South Africa under the law of delict. Further protection of traditional medicines is possible under the Patents Act, and also the *sui generic* measures, which will include the Patents Act as amended by the Patents Amendment Act 2005, with appropriate disclosures and benefit sharing arrangements. Other protection is possible in terms of the National Environmental Management: Biodiversity Act 10 of 2004 and accompanying regulations in the case of bio-prospecting which makes use of indigenous biological resources and knowledge.

Traditional medicine protection under the Patents Act can extend to herbal compositions, extracts, and also protection of the derivatives thereof, in both cases, with the originators benefiting, in addition to methods of extraction and preparation, provided they meet the patentability requirements.

Trade mark protection is also possible for the names under which traditional medicine is sold or traded, under classes 5 of the Trade Marks Act.

10 South African Trade Marks Act, Act no 194 of 1993.
11 South African Copyright Act, Act no 98 of 1978.

Trade Secret is available for “sacred“ components of indigenous knowledge and traditional medicines, with this form of protection being more difficult as one typically is dealing with knowledge which may be passed from communities to communities, and hence the challenge of maintaining the knowledge ‘confidential’.

Plant Breeders' Rights and Biodiversity as applied to Traditional Medicine in South Africa

David Cochrane

Spoor and Fisher

This paper discusses the international and South African regimes for the protection of plant varieties. It explores in more detail the South Africa Plant Breeders' Rights Act 15 of 1976, with relevant examples. In particular, the paper explores the possibility of using the Act to protect plant varieties used as traditional medicines.

I. Introduction

South Africa has been a member of the World Trade Organisation (WTO) since 1st January 1995 and is a signatory to the agreement on Trade-Related Intellectual Property Rights (the TRIPs Agreement).

The TRIPS Agreement enjoins member countries to make available protection for certain Intellectual Property Rights. Article 27 of the TRIPS Agreement deals with the types of technology that patents should be available for, as well as technologies which may be excluded from patent protection. One such exculsion found in Article 27(3) is that member countries may exclude from patentability plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, member countries must provide for the protection of plant varieties either by patents or by an effective *sui generis system* or by any combination thereof.

South Africa's intellectual property laws are by and large in compliance with the TRIPS Agreement and while Section 25(4)(b) of the *South African Patents Act 57 of 1978* provides that a patent shall not be granted for any variety of animal or plant or any essentially biological process for the production of animals or plants not being a microbiological process or the product of such a process, there is a *sui generis system* (i.e. a system of its own kind) for the protection of plant varieties, namely *The South Africa Plant Breeders' Rights Act 15 of 1976*[1].

II. Plant Breeders' Rights in South Africa

In this paper I will refer to Plant Breeders' Rights as PBRs.

South Africa is a member of the International Union for the Protection of New Varieties of Plants (UPOV), being a signatory to the 1978 UPOV Act. The South African PBR Act is largely in line with the 1978 UPOV Act, and has provisions which are in line with the updated 1991 UPOV Act.

In the South African PBR Act, provision is made for the protection of plant varieties. A plant *variety* is a plant grouping within a single botanical taxon of the lowest known classification which can be defined by the expression of characteristics resulting

1 http://www.nda.agric.za/docs/plant_breeders_act/default.htm. Although plants produced by cross-breeding cannot be protected by way of a patent in South Africa, it is believed that genetically modified plants, which are the product of a microbiological process, can be.

from a given genome type or combination of genome types; distinguished from any other plant grouping by the expression of at least one of the said characteristics; and considered as a unit with regard to its suitability for being propagated unchanged.

A PBR must be applied for by a *breeder*, who is the person who bred, or discovered and developed the new plant variety, or the person or company who has derived ownership from such person.

For a breeder to apply for a PBR and for the plant variety to qualify for PBR protection, the variety must be:

a) *new*;

b) *distinct*;

c) *uniform*; and

d) *stable*.

To be *new* the propagating material or harvested material thereof has not been sold or otherwise disposed of by, or with the consent of, the breeder for purposes of exploitation of the variety -

i) in South Africa for more than one year; and

ii) in a UPOV country or an agreement country in the case of:

varieties of vines and trees, for more than six years; or other

varieties for more than four years, prior to the date of filing of the application for a plant breeders' right.

To be *distinct*, a variety must be clearly distinguishable from any other variety of the same kind of plant of which the existence on the date is a matter of common knowledge. Although the South African PBR Act and Regulations no longer define what material would be regarded as "common knowledge", a reference collection open to the public, a publication, and, I submit, the knowledge of an indigenous community should be regarded as common knowledge.

To be *uniform*, a plant variety must be sufficiently uniform with regard to the characteristics of the variety in question, subject to the variation that may be expected from the particular features of the propagation thereof.

To be *stable*, the characteristics of the variety must remain unchanged after repeated propagation or, in the case of a particular cycle of propagation, at the end of such cycle.

Once a PBR is granted, the right extends to varieties which are *essentially derived* from the protected variety, which are not distinguishable from the protected variety and the production of which requires the repeated use of the protected variety.

Provision is however made in the South African PBR Act for "*Farmers Rights*". A farmer who has procured propagating material of a variety of plant protected by a PBR and grows the variety on a particular piece of land is entitled to use harvested material for the purposes of re-planting, but only on that piece of land.

III. Examples

1. Canna–Phasion

Although this variety is not an indigenous variety in South Africa and although (as far as I am aware) this plant is not used in Traditional Medicines, the PBR for the "Phasion" variety of canna, which was revoked by the South Africa Supreme Court of Appeal in the matter between *Weltevrede Nursery (Pty) Ltd and Keith Kirsten's (Pty) Ltd* on 23 November 2003, makes an interesting case-study on the possibility of obtaining PBRs for plant varieties discovered in South Africa (http://www.supremecourtofappeal.gov.za/judgments/sca_judg/sca_2003/515_02.htm).

Canna Phasion is a variety of Canna which has rich burgundy leaves with red, pink, yellow and green stripes which distinguishes it from other varieties of canna.

On 25 July 1994 Morgenzon Estates (the trading name for Sapokoe (Pty) Ltd) applied for a PBR for a variety of canna called "Phasion". It stated that the discoverer of the plant was Keith Kirsten and that Keith Kirsten had transferred his rights in the variety to Morgenzon Estates.

As it turns out however, Keith Kirsten was not the discoverer of the variety. He saw it in the garden of a nurseryman in Bethal (a Mr Kruger) who was aware of the existence of the variety. It also appeared that Kruger had obtained the plant from someone else years before. It was therefore found that Keith Kirsten was not the "breeder" of the variety and was not entitled to apply for the right.

It was also held that, even though Kirsten had multiplied and tested the variety, this did not qualify as "developing" the variety as is required by the PBR Act.

Evidence was also presented which showed that people in South Africa had known about this variety and had it in their gardens since the 1960's and that the plant had "come to the knowledge of the public" and that the variety lacked the distinctiveness requirement.

It was therefore held that the right should be revoked on the basis that the person applying was not the breeder and the variety was not distinct.

2. Sweet Piquante Peppers– Peppadew™

A Mr Johan Steenkamp “discovered“ in the garden of his holiday home in the Eastern Cape an unusual-looking bush with small bright red fruit which looked like something between miniature red peppers and cherry tomatoes. He applied for and was granted a PBR for this variety of plant. There has been quite a lot of controversy over this PBR because, apparently, the plant was already known and had been used for making food items in the North of Gauteng and Southern Zimbabwe. According to the SA Department of Agriculture, this PBR has been revoked but the revocation has been appealed.

IV. The South African PBR Act and Traditional Medicine in South Africa

1. Is it possible to protect plant varieties used as Traditional Medicines by way of a PBR in South Africa?

Traditional Medicine in South Africa is based on natural substances, most of which are part of, or derived from, indigenous varieties of plants in South Africa.

A question that arises is whether or not benefit can be derived from indigenous varieties of plants which are used, or are capable of being used, as, or to produce, Traditional Medicines through the South African PBR Act?

Firstly, the person or entity applying for the right must qualify as the *breeder* of the variety. The other requirements are that the variety must be *new, distinct, uniform* and *stable*.

At this stage the users of Traditional Medicine, Traditional Healers, for the most part do not cultivate the plants that they use but gather them from the wild. In such circumstances, the Traditional Healer could not qualify as a *breeder* of the variety. A Healer who has “discovered“ in the wild and who has not taken the next step of developing the variety cannot be regarded as a breeder of the variety. It is also questionable as to whether at this stage the Healer will have discovered the variety because the discovery would often have been made generations before.

The next requirement is that the variety must be *new*, i.e. not sold or otherwise disposed of in South Africa for more than one year prior to the filing date of the PBR.

Indigenous varieties that have been used and sold for generations as traditional medicines would fall foul of this requirement.

The existence of an indigenous variety that has been used for generations, and which has probably also been catalogued would, I submit, be regarded as being of "common knowledge" and will fall foul of the requirement of being *distinct*. Furthermore, many plant varieties have already been discovered and catalogued by scientists and would not be regarded as common knowledge.

Without a Healer planting and cultivating a variety, it is further unlikely that the requirements of *stability* and *uniformity* would be met.

It is hence unlikely that an indigenous variety of plant used by a Traditional Healer as a Traditional Medicine will be capable of being protected under the South African PBR Act.

2. Examples of commercial successes

An example of a plant from Southern Africa which was known as a traditional medicine and which has become a commercial success is Hoodia Gordonii.

As far as I know, no PBR right has been granted in South Africa for this variety because it would not comply with the requirements of the South African PBR Act.

This does not however mean that it is not possible to obtain a PBR in South Africa for an indigenous plant. PBRs have been validly granted for indigenous plants for new plants that have been bred in breeding programmes and which have different characteristics to wild varieties which were "common knowledge".

3. Examples of new varieties of indigenous plants that have been granted PBRs

Examples of new varieties of indigenous plants that have been granted PBRs are new varieties of:

Leucadendron	a genus of about 80 species of flowering plants in the Protea family, endemic to South Africa.
Leucospermum (Pincushion Protea)	a genus of about 50 species of flowering plants in the Protea famly, native to Zimbabwe and South Africa.
Erica	small shrubs from 0.2-1.5 m high, the great majority of the species are endemic in South Africa, and are often called the Cape Heaths.

Plectranthus a genus of warm-climate plants, sometimes known as the spurflowers. Several species are grown as ornamental plants, as leaf vegetables, or as root vegetables for their edible tubers.

V. Should the South African PBR Act be amended to provide protection for indigenous varieties of plants that have been used as Traditional Medicines in South Africa?

India's Protection of Plant Varieties and Farmers' Right Act of 2001[2] allows protection for four types of varieties:

1) New variety

2) Extant variety

3) Essentially derived variety

4) Farmer's variety.

The South African PBR Act provides protection for new varieties and essentially derived varieties of plants. Protection for *extant varieties* and *farmer's varieties* are new forms of protection which are not found in the South African PBR Act.

The provisions in India's legislation relating to extant varieties are to protect existing varieties, in particular farmer's varieties, varieties already in the public domain, and varieties that are common knowledge. The provisions relating to farmers' varieties protect existing varieties that have been traditionally cultivated and evolved by farmers. These provisions do not require the variety to be "new", but still require the variety to be "distinct". There is not clarity on what "distinct" means, because, according to the Act, this will be decided by Regulations laid down by the "Authority".

South Africa could study India's Protection of Plant Varieties and Farmers' Right Act to ascetain:

a) whether or not such provisions could be applied to the protection of plants used for Traditional medicines in South Africa;

b) whether the Indian legislation has been successful; and

c) whether such legislation would be for the good of South Africa.

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2 http://agricoop.nic.in/seeds/farmersact2001.htm

In an EPTD Discussion Paper No. 96 2003, Anitha Ramanna discusses India's Plant Variety and Farmers' Rights Legislation and the potential impact on Stakeholder Access to Genetic Resources[3]. Ramanna cautions against the "tragedy of the anticommons". The tragedy of the anti-commons occurs refers to underuse of resources arising from multiple ownership or rights to exclude others from use. It occurs when governments grant too many people rights over a resource with no one having an effective privilige of use.

South Africa should hence review the experiences of other countries, and in particular India, to ascertain whether it is in the interests of all stakeholders to amend the PBR Act to provide protection for indigenous varieties of plants that have been used as Traditional Medicines in South Africa.

3 http://www.ifpri.org/divs/eptd/dp/papers/eptdp96.pdf

Community Involvement in the Commercialization of Plant-based Traditional Medicines in South Africa

Case Study: The Ilanga-Lomso Community Project for the cultivation of Medicinal Plant *Silybum marianum*

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This paper describes a case study on the involvement of communities in the commercialization of plant-based traditional medicines in South Africa, specifically the commercial cultivation of the medicinal plant Silybrum marianum by the Ilanga-Lomso community in Hofmeyr, for job creation and poverty alleviation.

1 Abstract

Ilanga-Lomso Project is a community-owned project, established in 2004 in the Tsolwana Municipality in the Eastern Cape. The project is located in the remote town of Hofmeyr about 130 km North West of Queenstown.

Ilanga-Lomso Project involves the commercial cultivation of the medicinal plant *Silybrum marianum*, also known as milk thistle. This project is striving towards creating jobs and alleviating poverty within the community of Hofmeyr. The project comprises of 15 beneficiaries of whom 10 are females. These beneficiaries have been trained extensively on entrepreneurship by the Indigenous Knowledge Systems (IKS) [Health] Lead Programme of the Medical Research Council (MRC), Cape Town, to create capacity and a sense of self-confidence, in order to promote economic development and growth of the project. Currently, the beneficiaries are involved in maintaining the general performance of the project in terms of ploughing of the land for cultivation of the medicinal plant, drying of the plant, harvesting and processing of the seed, and finally packaging for transport and export to the market. The Ilanga-Lomso Community project is currently in the early stage of implementation.

2 Motivation for the project

Medicinal plants are an essential part of the health care system, especially for poor local communities in developing countries. In South Africa, it is estimated that around 80% of the population is dependent on medicinal plants for the treatment of a variety of diseases, including life-threatening diseases such as malaria, tuberculosis, and HIV/AIDS. Medicinal plants are also important sources for the development of pharmaceutical medicines available on the market today. Around 25% of conventional pharmaceutical medicines have been derived from medicinal plants, and many other synthetic medicines have been produced from prototype compounds derived from these plants.

Furthermore, medicinal plants are playing an increasingly important role in the subsistence economy of poor rural communities. South Africa is rich in biodiversity of medicinal plants coupled with remarkable traditional knowledge. Despite the presence of this enormous biodiversity, relatively few of these plants are economically utilized to benefit the social needs of local communities, as well as the economy of the country. It is documented that around 200 000 tonnes of medicinal plants are harvested in the wilderness annually by community members from remote areas to trade in the informal sector, generating an estimated annual income of R270 million. Many opportunities exist to improve rural livelihoods by helping small-scale farmers organize to profitably produce medicinal plants on marginal lands

in an environmentally sustainable manner, while maintaining the biodiversity of these natural products. Hence, enterprises based on medicinal plant cultivation, with appropriate innovative technologies to increase productivity, may lead to new employment opportunities and capacity development to uplift the livelihood of poor local communities, while fuelling economic growth in the country.

It is within this background that the Department of Science and Technology (DST) of South Africa undertook the Poverty-reduction Programme to support bioprospecting projects that are aimed at commercial cultivation of medicinal plants to uplift the socio-economic status of local communities in terms of job creation, income generation and poverty alleviation. The IKS [Health] Lead Programme of the MRC is the implementing agency of the Poverty-reduction Programme on behalf of the DST, and has established an enterprise known as Ilanga-Lomso Community Project in the town Hofmeyr in the Eastern Cape, South Africa. The community in this town is extremely poor and faces many challenges relating to improvement of their socio-economic status to create jobs and alleviate poverty. The case study focuses on involving communities in the cultivation of medicinal plant *Silybrum marianum* and the improvement of entrepreneurial and business skills to increase market opportunities and facilitate commercialization of the medicinal plant.

3 Background

3.1 Social and environmental considerations

Local communities collect medicinal plants from the bush for traditional and cultural purposes, including health care, as well as providing them as raw material to the market[1,2]. Due to the high incidence of disease, including Tuberculosis and HIV/AIDS, in the country, demand for some medicinal plants is outstripping the natural production of these plants, resulting in the loss of biodiversity and environmental degradation. The labour-intensive cultivation of these medicinal plants is suited to the rural poor because the production and handling requirements for these plants match their available land and labour resources. Consequently, systematic production and processing of medicinal plants offers promising new income and employment opportunities, as well as poverty alleviation to improve the livelihoods of the rural poor in an environmentally sustainable manner.

1 Singh, K.M. & Swanson, B.E. (2004). Development of supply chain for medicinal plants: A case study involving the production of Vinca Rosa by small farmers in the Patna district of Bihar India.

2 Donald, A.P. & Cocks, M.L. (2002). Research paper: The trade in medicinal plants in the Eastern Cape Province, South Africa. South African Journal of Science 98: 589-597.

The demand for high quality, safe and registered plant-based TMs has created an unsustainable harvesting of medicinal plants (TMs). The commercial production of plant-based TMs has filled the market by providing eco-friendly and alternative natural products from plants for both domestic and industrial uses[3,4].

A number of medicinal plants can be grown under poor agricultural conditions such as poor soil profiles, low rainfall and poor moisture content of the soil, thereby assisting in the natural regeneration of these plants. The majority of the species of medicinal plants are shade tolerant, while others are climbers, trees and shrubs that can be grown in different land-use and cropping systems[5]. The entry of medicinal plants into the food and drug market as environmentally friendly products is emerging as an important new opportunity for the small-enterprise community.

3.2 The interest in plant-based TMs

Plant-based TMs are locally known as *muthi* in Zulu and *ditlhare* in Sesotho. These remedies are widely used in the health-care system of South Africa, particularly by the African population. There are up to 100 million users of plant-based TMs in southern Africa, and as many as 500,000 traditional healers[6]. Up to 700,000 tonnes of medicinal plants are consumed each year, with an estimated value of as much as US $150 million. Medicinal plants provide basic requirements for the treatment of certain conditions, irrespective of education and income level[7]. The use of plant-base TM is not confined to rural, low-income groups, but also prevails in urban areas, where access to conventional medicines is affordable.

It is believed that the trade in plant-based TMs forms part of a multimillion-Rand hidden economy in South Africa[8]. At a national level, it is estimated that around

3 Bordeker, G. (2002). Medicinal plants: towards sustainability and security; IDRC Medicinal plants global network sponsored discussion paper for WOCMAP III, Chiang Mai, Thailand.

4 Temptesa, M.S. & King, S. (1994). Tropical plants as a source of new pharmaceuticals. In: Barnacal, P.S. (editor) Pharmaceutical manufacturing international: The International review of Pharmaceutical technology research and development. Sterling Publications Ltd, London.

5 Singh, K.M. & Swanson, B.E. (2004). Development of supply chain for medicinal plants: A case study involving the production of Vinca Rosa by small farmers in the Patna district of Bihar India.

6 Mander, M. & Le Breton, G. (2005). Plants for therapeutic use. In: Mander, M. & McKenzie, M. (editors). Southern African trade director of indigenous natural products. Commercial products from the wild group, Stellenbosch University , Matieland, 3-8

7 Cocks, M. & Donald, A. (2000). The role of African chemists in the health care system of the Eastern Cape province of South Africa. Social Science and Medicine 51: 1505-1515.

8 Cunningham. A.B. (1989). Herbal medicines trade: a hidden economy. Indicator South Africa 6: 51-54.

20,000 tonnes of medicinal plants, harvested annually from over 1000 plant species, are traded in the informal market for primary health care, with an approximate value of R270 million[9]. This demand for medicinal plants has the potential to create a large increase in the number of rural jobs, as well as to reduce poverty in a number of regions in South Africa[10].

3.3 Expanding domestic and international markets

The demand for plant-based TMs in South Africa to meet domestic and exports markets is expected to increase in the coming years. This is due to South Africa's rich biodiversity, coupled with traditional knowledge, which are seen as a potential source for the provision of a diverse range of economic opportunities through enterprise development, technology transfer and intellectual property management. The realization of socio-economic benefits is currently becoming more and more achievable as market trends continue to favour the expansion of domestic and international natural product markets. The trends regarding the use of plant-based TMs, which are resulting to expansion of domestic and international markets include:

– Increased health consciousness and interest in alternative healthcare practices, which has led to increased demand for natural products from plants that have been proven to enhance well-being and prevent diseases.

– Novel natural products from plants are often seen as different and unique, which enhances their appeal among some consumers.

– Increased socially responsible spending by consumers is motivated by the perception that buying indigenous natural products from developing countries is more likely to ensure the social upliftment of local producers.

– Local is lekker – consumer patriotism continues to motivate some purchases.

3.4 Domestication and cultivation

Traditional healers in different regions of South Africa have a tradition of practicing farming systems for various medicinal plants. Therefore, the cultivation of medicinal plants, which usually takes place in the back yard of traditional healers, applying

9 Mander, M. (2004). An overview of the medicinal plant market in South Africa. In: Lawes, M.L., Eeley, H.A.C., Shackleton, C.M., et al. (editors), pp. 440-445. Indigenous forests and woodlands in South Africa: policy, people and practice. University of KwaZulu-Natal Press, Scottsville.

10 Wiersum, K.F., Dold, A.P., Husselman, M. & Cocks, M. (2006). Cultivation of medicinal plants as a tool for biodiversity conservation and poverty alleviation in the Amatola region, South Africa. In: Bogers, R.J., Cracker, L.E. & Lange, D. (editors), pp. 43-57. Medicinal and aromatic plants. Wageningen University, The Netherlands.

organic farming concepts, has considerable scope in different regions of South Africa. The advantages of cultivating medicinal plants include the ease of their incorporation into existing cropping systems, due to the availability of a large number of species, and the ability to choose plant types based on their suitability for growth under different eco-physical conditions. However, this requires an improved input and service delivery system, including marketing and post-harvest technologies. Cultivation needs to be performed on a business platform by a chain of small and micro-enterprise-based groups and individuals. In order to achieve economies of scale and desired impact, it may be necessary to intensify production of specific medicinal plants within selected production areas and as a cluster of micro-enterprises.

3.5 New Government regulations for medicinal plants have created new market opportunities

As a result of the growing demand for medicinal plants and the impending loss of biodiversity for many of these plants, the South African government has introduced an Indigenous Knowledge Systems (IKS) policy, Biodiversity Act 2004 and Patent Amendment Bill 2005. These regulations now require all parties wishing to undertake bioprospecting in South Africa to obtain prior informed consent and to agree on benefit-sharing before gaining access to genetic resources. This new regulatory environment has opened up new market opportunities for small-scale farmers, if they can acquire the necessary production technologies to successfully produce medicinal plants to market specifications.

3.6 The commercial potential for medicinal plants

The market for medicinal plants in South Africa is one of the sectors that has been hugely neglected, yet has enormous commercial prospects. This is due to a lack of public and private sector investment and limited resources for the development of this opportunity into enterprises to benefit communities of South Africa and the country's economic growth. Significant resources are required to address this challenge.

4. The market information

According to a recent survey of the market for medicinal plants in Southern Africa[11]:

11 Medicinal plant market has massive commercial potential (2006). Volume 1 Izimpane

– *The informal market*: The market system is not regulated and focuses exclusively on crude and untested plant-based TMs. This market comprises of 50 – 100 million users, who depend on these medicines for primary health care. The market is dominated by around 400 000 – 500 000 traditional health practitioners, who dispense around 35 000 – 70 000 tonnes of crude plant-based TMs to consumers annually. More than 1000 species of medicinal plants are actively traded, with an estimated value of R270 million per annum. Hence, people involved in this industry earn their primary income from selling these medicines.

– *The formal market*: The market system is regulated and comprises usually of tested medicines produced from plant materials such as complementary medicines, pharmaceutical formulations, nutraceuticals and cosmeceuticals. The annual trade of these medicines is estimated at around US$ 150 million per annum. Between 5000 – 10 000 tonnes of processed raw material of medicinal plants are exported from the South African market into global markets, especially Europe.

5. The *Silybum marianum* case study

Silybum marianum is also known as milk thistle and belongs to the Asteraceae family[12]. Morphologically, *Silybum marianum* is characterized by a typical thistle with red to purple flowers and shiny pale green leaves with white veins. *Silybum marianum* is a native plant of Southern Europe through to Asia, and is currently found in abundance almost everywhere, especially in the United States, Africa, India, China, Australia and South America. The medicinal properties of the plant are found in the extract of ripe seeds.

Though many varieties of this plant are found locally, and almost everywhere, the variety with purple coloured flowers is in greater demand by the pharmaceutical industry. The extract of the ripe seeds of milk thistle with purple coloured flowers is known for its high content of the compound silymarin and its active constituent, silybin, which have been rigorously demonstrated in preclinical and clinical trial investigations to have antioxidant properties in patients with acute and chronic liver diseases, as well as pharmacological effects against prostate cancer[13,14].

12 http://en.wikipedia.org/wiki/Silybum_marianum, downloaded on 6 February 2007 at 13:45

13 Flora, K., Hahn, M., Rosen, H. & Benner, K. (1998). Milk thistle (Silybum marianum) for the therapy of liver diseases.

14 Sing, P.S. & Agarwal, R. (2004). A cancer chemopreventive agent silibinin, target mitogenic and survival signaling in prostate cancer. Mutation Research 555: 21-32.

Unfortunately, accurate information pertaining to the market for milk thistle is currently not available.

5.1 Setting the scene: Tsolwana Municipality

Tsolwana Municipality is the home of the Ilanga-Lomso community-based poverty alleviation project, which is situated in the town of Hofmeyr, about 130 km North West of Queenstown in the Eastern Cape Province. The area is located within a climatic transition zone between the temperate south coast and the subtropical north coast. In winter, maximum temperatures can range from 22^{O}C – 24^{O}C. In summer on the other hand, the maximum temperature may range from 24^{O}C – 28^{O}C. Rain falls mainly in summer (October – April) with an annual rainfall of between 500mm – 700mm. Evaporation is approximately 1 700mm per annum, which complicates crop cultivation in the area, as it requires moisture conservation for dryland cropping and sophisticated irrigation systems.

Agriculture is the dominant form of land-use in the area. Cultivation is largely restricted to the summer months when the rainfall is highest. The local community depends primarily on a traditional subsistence economy, based on garden cultivation of vegetables as a dominant livelihood strategy, despite the influence of a modern cash economy. Like many subsistence-based societies, the local Xhosa-speaking people have a spiritual and utilitarian relationship with their environment.

Unemployment in the Tsolwana Municipality is among the highest in the Eastern Cape Province, as well as in the country. Around 83% of the households earn less that R1 200 per month, with up to 10% of the households in the area having no source of formal income[15]. More than 70% of households are below the poverty line, and more than 50% are regarded as ultra-poor. Most households rely on a combination of government pensions and remittance from family members that have been able to find employment in the urban areas of South Africa. The sanitation situation is worse than the water situation. Very few rural and informal settlements have access to clean water.

Considering the low socio-economic standing of the rural population in the Tsolwana Municipality, natural resources play an extremely important role in people's lives. The community relies heavily on traditional methods of health care, as well as job creation.

15 Palmer, R., Timmermans, H. & Fay, D. (2002). From Conflict to Negotiation: Nature-based development on South Africa's Wild Coast, chap.3, pp. 334. Human Sciences Research Council, Pretoria.

This case study outlines the steps followed by the MRC's IKS [Health] Lead Programme to start the business of cultivating *Silybum marianum* in the Tsolwana Municipality. It should be noted that many of these activities needed to be carried out more or less at the same time; therefore requiring good coordination across the different organizations that were providing services to the farmer groups.

5.2 Getting started in the business

In order to identify what marketable medicinal plant might successfully be introduced into a poverty-reduction programme, feasibility studies were conducted to assess local conditions using various participatory rural appraisal techniques. Because of national and international demand, and the regulatory environment in South Africa, making it compulsory for companies to meet their raw material requirements through cultivated sources, the cultivation of medicinal plants quickly emerged as one of the most viable options.

5.2.1 Planning phase

During the participatory rural appraisal excise, different medicinal plants were found growing wild in Hofmeyr, some potentially carrying a very high market value. However, the local community was unaware of the commercial importance of these medicinal plants, making it necessary to conduct extension activities, such as exposure visits, to create farmer awareness about the potential economic and poverty alleviation opportunities. In addition, the local community was informed both about the need to conserve the biodiversity of the medicinal plant, as well as the growing demand for this medicinal plant by pharmaceutical companies.

In the process, the local community was informed about the economic importance of this medicinal plant as a viable alternative immune modulator for HIV/AIDS, as demonstrated in various preclinical and clinical studies around the world. This medicinal plant is known for its protective effect on the liver, particularly its role in protecting against liver damage in people on antiretroviral treatment. As a result of these activities, the local community became receptive to the idea of cultivating the medicinal plant.

Finally, after long discussion among the team of the MRC's IKS [Health] Lead Programme and with the selected community of Hofmeyr, it was agreed that this community could successfully engage in the commercial cultivation of the medicinal plant, and become the major beneficiaries of the project. As a result of this assessment, the decision was taken by the MRC's IKS [Health] Lead Programme and the Poverty-reduction Programme of the DST to give priority to the development

of the medicinal plant as an initiative to alleviate poverty and create employment for the local community of Hofmeyr.

Next, the long and extensive negotiations took place between the MRC's IKS [Health] Lead Programme and the Tsolwana Municipality, followed by presentations to the Municipality management, Municipality executive committee and ward councilors by the MRC's IKS [Health] Lead Programme to obtain their full institutional support for the project and to make sure that these essential stakeholders understood the anticipated objectives of the project. The purpose of the negotiations and the presentations was to get buy-in from politicians in the area, municipality support in order to obtain the land for the cultivation of the medicinal plant, infrastructure, community mobilization and administrative assistance. The Municipality provided a building, which was renovated into a pre-processing factory, and a 50 hectare farm.

Presentations were also delivered to the private companies specializing in the production of herbal medicines in order to gain their support and investment for the project. The long process of negotiations and presentations was followed by drafting of the required agreements with the assistance of the legal office of the MRC to obligate and govern the relationship of the parties involved in the project. An agreement was signed between the private sector, Municipality and local community, as well as parties involved in the scientific investigation of the medicinal plants, including clinical trials. The agreement includes confidentiality clauses and stipulates the sharing of the intellectual property rights and benefits. The project is currently in the implementation phase.

5.2.2 Training of the Municipality officials

The training programme on entrepreneurship for the municipality officials (local economic development) from Tsolwana Municipality was oriented to promote economic growth, job creation, poverty alleviation, implementation, and sustainable development of the project. The training programme was offered by MRC's IKS [Health] Lead Programme consultant, who has vast knowledge and experience in entrepreneurship and economic development, and designed a training programme suitable for the development of Ilanga-Lomso Community project based on the commercial cultivation of medicinal plants. The relevant aspects, which formed the basis of the training programme, were level of theoretical knowledge, understanding of the context of project implementation in South Africa, different theories that related to development methodologies, the theory of business management, industry and market analysis and the role of institutions in promoting economic development.

The technical publications of the training programme were prepared in English, and explained the activities of the programme, evaluation of the concepts, reading materials, practical examples and application of concepts (field visit) and individual evaluation of the entire training programme. The comprehensive report of the training programme was compiled for the MRC's IKS [Health] Lead Programme.

5.2.3 The implementation phase

The MRC's IKS [Health] Lead Programme believes that the sustainable viability of the poverty-reduction project based on medicinal plant cultivation will not only depend on technical expertise and secured markets, but also on entrepreneurial attitude displayed by, especially, municipality officials and the local community. The strategic approach for the implementation of the Ilanga-Lomso Community project into a sustainable business with viable and secured markets is shown in Fig.1.

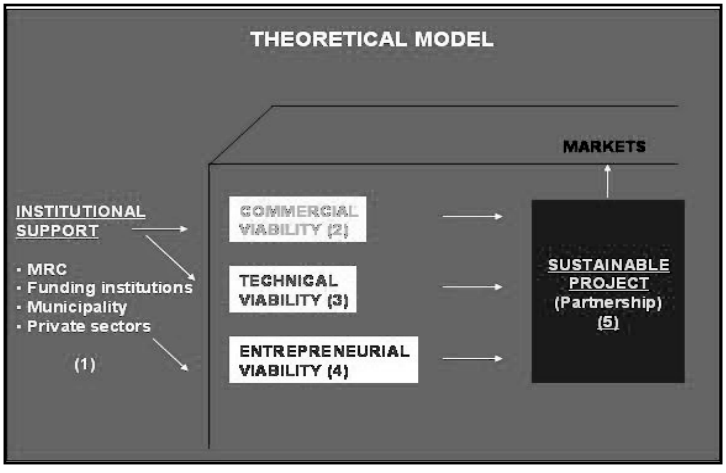

Fig. 1: The strategic approach for the implementation of the Ilanga-Lomso Community project

Technical viability

The project is at its early stage of understanding and conceptualizing how an agricultural oriented project should work or what the main variables involved in agricultural production and propagation are. To get an overview and understanding of this aspect, the project was visited by MRC's IKS [Health] Lead Programme officials and the project partner from the Technology Transfer for Social Impact office of the CSIR, which is tasked with the agricultural aspects of the project, to assess the general performance of the project. It was deduced among these parties that the project was experiencing difficulties in terms of good agricultural practices for the

commercial cultivation of milk thistle. The following recommendations were made in order to overcome this difficulty:

– Good farming practice under commercial conditions to establish 10 ha milk thistle from seed by April 2007 is required. This aspect will need to be investigated by a person experienced in commercial farming. Exact size of available land must be measured; exact amount of borehole water for irrigation must be determined; and an audit of available farming implements and the need for purchase of additional items must be conducted/ determined.

– Structural integrity of existing nursery requires inspection, possible strengthening of lateral beams may be required. Gate to nursery is an unacceptable hazard (head can be injured).

– Availability of change rooms, eating area and ablution facilities to be investigated.

– Soil properties including chemical analysis must be determined. At the moment the soil properties of the land appear unusual for the commercial cultivation of milk thistle. Technical advice is needed on a soil improvement strategy if required (organic).

– Selection of irrigation system that considers both the scarcity of water and the difficulty of moving drag line between thorny plants.

– Planting of seed under controlled conditions to ensure even spacing of plants thereby facilitating production forecasts.

– Implementation of a weed control programme.

– Establishment of system of recording crop records, as well as records of all herbicides and fertilizers on site or in immediate area.

The development of vegetable gardens represents a good example of commercial oriented activities that can be developed in the meanwhile and serve as an extra income and food security source once the challenges facing the project have been tackled and solved, and the objectives of the project in terms of its operation are fulfilled.

Entrepreneurial viability

As mentioned, the MRC's IKS [Health] Lead Programme believes that the sustainability of the project will not only depend on the technical aspects of the project, as well as secure and viable markets, but also on the entrepreneurial attitude and spirit displayed, especially at community level. Entrepreneurial attitude can be developed through practical training on entrepreneurship involving the following variables:

– Change in proactiveness
– Mind set change in terms of self responsibility
– Ideas and dreams contextualization
– Use of business language and terminology
– Ownership of the project
– Questioning and information request

In terms of these variables, a more proactive attitude was found, although different aspects can be noted. The degree of responsibility and entrepreneurial attitude is evident as well as the amount of questions and request for information. These aspects were evident in and projected by the project leader (Mr Thobile Takane).

There is a strong cohesive group that is benefiting from the degree of implementation that is being observed. The use of the nursery for vegetable production, as well as the request for information regarding planting and propagation activities and the future of the project, provides an indication of the entrepreneurial attitude that is currently being developed.

Another important aspect is represented by the change in the leadership of the project. During the field visit, a strong degree of leadership was presented by the members of the community. Emerging leaders among the members are promising. These leaders would represent a good example of a more business oriented mind set and entrepreneurial attitude. The degree of involvement by the members of the community in the day by day operations of the project would lead to satisfactory results.

5.3 Major developments

During February and August 2006, the following major developments were achieved by Ilanga-Lomso Community Project:

Between February and March 2006 milk thistle was cultivated on 2 hectares of land and resulted in 400kg of harvested seed

– Between March and April an additional 15 hectares of land was ploughed for commercial cultivation of Milk thistle – 2 hectares of this land has been cultivated thus far
– From April to May 2006, two brand new boreholes were installed for irrigation of the land
– Electricity within the project area had be installed

– Two brand new irrigation electric pumps were installed
– The processing machines are currently available, and are in operation
– Vegetables were harvested and sold to the community of Hofmeyr and earned an income of R4000

5.4 The challenges

The project is currently facing major challenges with regard to agricultural aspects to increase its commercial and entrepreneurial viability. These challenges are being tackled at the moment by the Office of Technology Transfer and Social Impact of the CSIR and will hopefully form the discussion of the next meeting.

Overview of traditional medicine usage and challenges in Switzerland

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Plant preparations related to Traditional Medicine occupy a unique and peculiar position in the Swiss health system as they are issue rather from an acquired local – sometimes imported – knowledge than from a well described and standardized pharmaceutical research and development process. In this respect, a specific drug registration procedure has recently been introduced. This paper deals with the specificities of traditional herbal medicines and the way their efficacy, safety and quality is addressed from a Swiss regulatory point of view. Relevant figures, examples and a list of the major challenges related to the use of these medicines in Switzerland have been included.

A. Introduction

According to WHO definitions[1,2], Traditional Medicine refers to traditional systems used to prevent diseases or/and cure them. Such systems include prophylactic medicine, medication therapies (herbal medicines, animal parts and minerals) and non-medication therapies. In this latter category, treatments are carried out primarily without the use of medication as in the case of acupuncture, manual therapies and spiritual therapies and also refer to "complementary", "alternative" or "non-conventional" medicine, usually named Complementary Alternative Medicines in contrast to allopathic medicine. Complementary Alternative Medicines also implies that these therapies are used as a substitute for conventional treatments. While this may be the case for some of them, the vast majority of consumers embrace both types of treatment[3]. The terms Traditional Medicine and Complementary Alternative Medicines are also used to define traditional ways to deal with diseases depending whether one considers the Western world or developing countries, respectively. Traditional Medicine is indeed generally not integrated or only partially recognized in the national health systems of countries strongly based on allopathic medicine.

This latter situation is true for Switzerland, the home of some of the major pharmaceutical industries, which has tailored its health care system and drug legislation on the development and use of new active single chemical entities. Switzerland has, however, a long history of oral as well as written Traditional Medicine mostly dedicated to herbal remedies–the Swiss flora has around 2600 plant species vs. 25000 for South Africa–as can be witnessed from the related monographs of the Swiss and European Pharmacopeias. The monographs of the European Pharmacopeia are recognized in Switzerland and most of them were already part of past editions of the Swiss Pharmacopeia. To date, a total of 144 monographs have been integrated into the European Pharmacopeia[4] while 14 are specific to the Swiss Pharmacopeia[5]. Several non-indigenous plants are also part of these monographs. Though these drugs enter the preparations of different medicines, the previous figures remain quite small when compared to to the 7,890 drugs registered by the Swiss drug authorities (Swissmedic) in 2001, of which only

1 WHO Traditional Medicine Strategy 2002-2005.

2 Zollman, C. and Vickers, A. J. (2000). ABC of Complementary Medicine. London, BMJ Books, (reprinted from a series of articles that appeared in the British Medical Journal during 1999).

3 Murray, J. and Shepherd, S. (1993). Alternative or additional medicine? An exploratory study in general practice, Social Science and Medicine, 37: 983–8.

4 European Pharmacopeia, 2007, 5th Edition, http://online.pheur.org.

5 Pharmacopoeia Helvetica, 10th Edition, for more information www.swissmedic.ch/fr/industrie/overall.asp?lang=3&theme=0.00105.00004&theme_id=522 (not available in English).

971 (12.3%) are herbal drugs[6]. By comparison, a recent survey showed that around 35% of the pure chemical entities contained in the prescribed drugs approved by the Food and Drug Administration (the US drug authorities) during the last two decades are of natural origin[7] while more than half of the 20 best-selling drugs are based on natural products.

Traditional Medicine and more especially preparations based on plants are for many people worldwide the only method of treatment, as plant remedies are not only available and accessible, but also affordable and sometimes more acceptable than Western medicine. For instance 80% of the African population and 65% of the rural population in India use only traditional medicine to treat as well as prevent diseases. In China, Traditional Medicine represents around 40% of all delivered health care while Malaysia annually spends US$ 500 millions on Traditional Medicine–especially Jamu–whereas only US$ 300 mio are allocated to allopathic medicine. In Western countries, Complementary and Alternative Medicines represent 40-70% of drug sales and have been increasing during the last few years. Around 75% of them are distributed between France and Germany 1. In Europe 30-50% of Over-The-Counter (OTC) sales are herbal preparations accounting for a total amount of 7 billion euros. The use of alternative therapies is estimated at 40% in Switzerland[8]. According to the case definitions previously mentioned for Complementary Alternative Medicines and Traditional Medicine, these latter figures of course do not only involve traditional plant treatments. Such figures have however been perceived as an indicator of the renewed interest of Western population for Traditional Medicine.

B. Traditional Medicine and challenges in Switzerland

The Swiss Government has recently decided to withdrawn complementary and alternative medicines from the treatments reimbursed by the basic healthcare insurance. Such treatments can however be covered by additional health arrangements (also locally called complementary health insurance) provided they are prescribed by officially recognized practitioners. Several types of medicines are involved in this process (homeopathy, naturopathy, osteopathy and anthroposophy) but this study will be limited to those herbal preparations that are issued from

6 Brunella, S. and Grogg, N. (2003). Herbal medicines in Europe – regulation and registration, www.pharmabiz.com/article/detnews.asp?articleid=17339&sectionid=50&z=y .

7 Newman, D. J., Cragg, G. M. and Snader, K. M. (2003). Natural products as a source of new drugs over the period 1981-2002. *Journal of Natural Products*, 66: 1002-1037.

8 Vickers, A. Complementary therapies surge, challenge conventional wisdom. (2001). *Global Health and Environment Monitor*, 1.

traditional knowledge and used for the treatment or the prophylaxis of diseases. An overview of the specificities of the aforementioned plant preparations will be given including some important associated background pieces of information regarding regulatory issues. The different requirements that have to be addressed in order to obtain a market authorization for these particular preparations in Switzerland will also be covered. This will include some general features related to the requirements mentioned above; some examples taken from the Swiss market illustrate specific issues related to these kinds of medicines as well as some of the challenges linked to these requirements. A list of additional challenges will also be proposed for discussion.

B.1. Specificities of plant preparations from Traditional Medicine

– Plant preparations issued from Traditional Medicine may not refer to the same understanding of what national drug regulatory authorities mean by “diseases”, “treatment” and “protection/prevention” in allopathic medicine.

– Plant preparations can be used as raw collected materials or after processing which includes different techniques such as grinding, extraction with a liquid (tea decoctions for instance) or distillation. This process refers to knowledge that is often orally transmitted though some traditional health systems are also based on written recipes. These preparations usually contain a complex mixture of chemicals of known or unknown identity: some of them have been well described from a chemical point of view, whereas others have only been partially – or sometimes never – studied. A similar observation can be applied to the pharmacological effects traditionally claimed for these medicines: in some cases the activity of the traditional remedy has been demonstrated in an evidence-based assay (i.e. clinical trials, pre-clinical assays,…) while ambiguous or no scientific proof of evidence has been obtained for other therapies related to Traditional Medicine. Most Traditional Medicine preparations have not been studied in terms of their pharmacological and clinical effects.

– Plant preparations are subjected to batch variation, meaning that their chemical content and – as a consequence – their pharmacological and clinical efficacies can slightly/greatly differ according to various criteria. Among the parameters that may be responsible for such variations are the period and location of plant collection, the process used to prepare the traditional remedy as well as the conditions of storage of the raw and processed materials. This is however not an exhaustive list.

– Plant preparations can be subject to adulteration (botanical confusion, careless collection, substitution by other plants material) and contamination (i.e. heavy metals, pesticides in the case of cultivated plant, microorganisms etc.). This relates to quality control issues.

– Traditional Medicine is closely linked to Intellectual Property rights as well as to biodiversity issues.

B.2. Regulatory issues related to plant preparations used in Traditional Medicine

Medicines – either as new chemical entities or as other kinds of preparations including Traditional Medicine plant preparations – that aim to be used to treat/ prevent human diseases have to be approved by Swissmedic in order to be granted a market authorization in Switzerland. Different categories of authorization (A-E) can be granted, depending on various criteria that have to be included in the registration dossier. The quality and quantity of requirements to be fulfilled are related to the targeted category and mainly focus on the pharmacological effect, toxicity, indication, adverse effects, type of medical diagnosis and surveillance and potential of addiction of the investigated preparation. The A category poses the most stringent conditions, while E is the least restrictive category. The A-E list also determines the distribution channel of the medication. Further information related to the way of obtaining a market authorization for drugs in Switzerland, associated legal documents and the aforementioned categories of authorization is available from the Swissmedic website (www.swissmedic.ch, in French, German and Italian).

Following a recent directive of the European Community regarding traditional plant preparations (2004/24/CE,[9]), a simplified dossier can be submitted to Swissmedic provided that:

– Traditional use exists for at least 30 years (at least 15 years in Western Europe)

– Efficacy and safety can be well studied and documented

– At least 30 years of use for the same indication, same dosage and route of administration (15 years in Western Europe)

– only “non severe“ diseases (symptoms should be easily identified by patient)

9 Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004 as regards traditional herbal medicinal products http://ec.europa.eu/enterprise/pharmaceuticals/review/doc/final_publ/dir_2004_24_20040430_en.pdf.

– only one single indication is claimed
– only active principles of list D-E
– ways of administration: only oral, topic or inhalation are allowed
– not more than 5 active principles included

According to Swissmedic, plant-based medicines (phytomedicines) are defined as medicines that contain only vegetable material but are neither chemically pure substances, nor synthetic or semi-synthetic compounds, nor medicines that are part of special therapies that have to undergo a specific process of production such as homeopathy, naturopathy, aromatherapy, anthroposophy (defined as Complementary Alternative Medicines). Vegetable substances such as plants, lichens, mushrooms, algae are accepted as plant-based medicines and the term vegetable preparations is used to described products obtained after processing. A fundamental distinction is made in the registration process according to whether a market authorization is requested for a known or a new active principle. This distinction refers to the existing list of active principles which have already been granted a market authorization by Swissmedic (the list is available from the Swissmedic website). It has to be noted that any modification in terms of indication, process of production, association can turn a known active principle into a new one. Swissmedic has also built up a list of vegetable substances and preparations that:

– are registered as active principles
– are considered as fruit/vegetables
– are considered as spices, teas, aromas or food supplements.

Depending on the part of the plant, the type of preparation and the amount of a specific active ingredient (some chemicals have been given limiting values), a vegetable substance/preparation can be shifted from one of the categories mentioned above to another or can possibly be considered as toxic. Also, if a specific ingredient/ mixture of ingredients (enriched extract for instance) is obtained from one of these vegetable substances, its safety profile has to be assessed as if it were a new preparation.

B.3. Efficacy-Safety-Quality

The 3 main criteria widely recognized to assess any medicinal preparation are its efficacy, its safety and its quality.

Efficacy

As mentioned above, plant substances/preparations issued from Traditional Medicine and aiming to be registered in Switzerland with a therapeutic/prophylactic indication are considered as active principles by the Swiss regulatory authorities and have to undergo a simplified/full registration process depending upon whether they fulfill/ do not fulfill the criteria previously mentioned (see B.2 Regulatory issues related to Traditional Medicine plant preparations). Only a few substances or preparations used in Traditional Medicine have been well assessed from a clinical point of view and even fewer have led to significant therapeutic/prophylactic outcomes. Among these are, for instance, Gingko (*Gingko biloba L.*) and St John's wort (*Hypericum perforatum L.*), which are among the best-selling plant preparations in Switzerland. However, most clinical studies run on Traditional Medicine plant preparations still involve small numbers of patients as well as methodologies of poor quality. More recently published systematic reviews provide an increasingly reliable basis for making healthcare decisions, especially the Cochrane Library listing, which includes over 4000 randomised trials. For instance, a Cochrane review of St. John's wort (*Hypericum perforatum*) for mild to moderate depression polled 27 trials with a total of more than 2000 patients. Though not fully tested for safety, St. John's wort was found to be superior to placebo and equivalent to tricyclic antidepressants, with fewer adverse effects[10] [10]. In Switzerland, most clinical trials based on plant products are funded by the private sector due to their relatively high cost. The types of documentation needed to assess the clinical efficacy of a plant preparation will depend on several criteria including mainly its safety, the claimed medical indication (traditional indication versus evidence-based indication) and the presence of closely related preparations on the Swiss market. Associations of active principles have to be considered as separate entities even if one or all of the substances/preparations is (are) already registered separately on the Swiss market. One has indeed to assess whether the addition of a new/known active principle may lead to a change in the efficacy/safety profile of the whole preparation. The proof of pharmaceutical equivalence between 2 different plant preparations (i.e. between one already registered on the Swiss market and another one that is not) can be demonstrated either by clinical trials but also by showing that their contents are identical or similar (identical vegetable substances, similar processes of production, identical indications, similar formulations, standardization using a known pharmacologically active chemical or another ingredient,…).

10 Swerdlow, J. L. (2001). Complementary therapies surge, challenge conventional wisdom. Global Health and Environment Monitor, 1-2.

Safety

Safety plays a central role in the registration of traditional phytomedicines in Switzerland. By way of introduction, it should be noted that there is no difference in terms of activity/toxicity between chemicals isolated from nature or obtained through synthesis. One living organism (plants, microorganisms, lichens,…) can contain up to 10'000 different chemicals and some are of those natural products active/toxic at very low doses such as botulinic toxin, atropine, aconitine and colchicine. Numerous cases of intoxication by mushrooms and plants are, for instance, reported every year in Switzerland by the Toxcentrum (the Swiss Center for Toxicological Information) and plants have been shown to be responsible for roughly 10% of all notified cases of intoxication.

The use of phytomedicines based on traditional knowledge makes the assumption that the safety of the substances/preparations has been proven over a long period of time by local populations. It has to be said in the first place that – as in the case of allopathic treatments – only very few drugs have no or mild adverse effects and that as a matter of fact most traditional preparations are likely to have some. Several factors can contribute to induce/worsen the toxicity of a vegetable substance/ preparation such as batch variation (change of the amount of the possible toxic ingredient in the collected or processed plant), changes in the mode of preparation and administration, age and health status of the patient, possible interactions will other treatments, length of treatment (chronic toxicity), concomitant ingestion of food, genetic factors (i.e. slow vs. fast metabolizers). The geographic extension of a locally used traditional treatment should therefore carefully consider the aforementioned factors (not an exhaustive list) and rule out these risks by presenting a well documented report or by performing appropriate pre-clinical/clinical studies.

Quality

The quality of all medicinal preparations has to be ensured. The quality of vegetable substances/preparations is closely related to their efficacy/safety profile and deals with different issues such as identity of the starting material (botanical identification to rule out adulteration), intermediate and final products, absence of residues/ contaminants (pesticides, heavy metals, microorganisms), percent of the active ingredient(s) if known, stability of intermediate and final products and other process associated issues.

Monographs of closely-related plants can be used to assess the quality of a new active vegetable principle. The standardization of a known active (or inactive) ingredient constitutes a way to ensure the quality of vegetable substances/preparations (pharmaceutical equivalence and quality control for batch consistency).

The quality of vegetable substances/preparations is determined by reference to the different chemical, analytical and pharmaceutical assays described in the relevant plant monographs of the Swiss and European Pharmacopeias, if they exist. These assays involve different techniques such as microscopy, dissolution profile, chemical tests, chromatographic techniques, desiccation, and titration of active ingredients using appropriate analytical methods.

B.4. The challenges

The following challenges have to be addressed in order to incorporate plant preparations issued from Traditional Medicine more efficiently into the Swiss health system. The list is certainly not exhaustive and is proposed for discussion.

– Ensure recognition of Traditional Medicine as a public good (public funding, priority on political agenda)

– Develop an appropriate research methodology for clinical assessment of Traditional Medicine

– Move from basic academic research to clinical evaluation (i.e. improve public sector-private sector collaboration)

– Improve communication between regulatory authorities and public/private sectors

– Improve notification of adverse effects (pharmacovigilance)

– Clarification of the status of borderline phytomedicines (fuzzy border between drugs, food supplements, food)

– Address in an appropriate and quick way the safety issues due to Traditional Medicine plant preparations commercialized by new channels or new types of preparations (i.e. Asian preparations with/without indication)

– Fight substandard, fake Traditional Medicine preparations (e.i. through public awareness)

– Improve quality control of phytomedicines (ensure standardized protocols of production and quality control, external controls)

– Ensure cost-effectiveness of treatment (vs existing allopathic treatment)

– Avoid competition with allopathic medicine

– Ensure sustainability/reproducibility of supply (collection vs production, endangered species)

– Address intellectual property issues in an satisfying way for all parties

– Ensure rational use of phytomedicines (i.e. information systems, coordination with allopathic treatments)

The Registration of Drugs Under Health Law and Under Social Insurance Law, with Particular Consideration of Drugs Used in Complementary Medicine, Especially of Phytopharmaceutics

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Medicinal drugs are an important part of health treatment. The present contribution presents the requisites that must be complied with for the registration of medicines. Aspects of insurance law are also considered. Natural medicines, for which further questions and problems arise, are at the centre of the contribution.

List of abbreviations

BGE	Bundesgerichtsentscheid	Decision of the Swiss Federal Court
EVG	Eidgenössisches Versicherungsgericht	Swiss Federal Insurance Court
HMG	Bundesgesetz über Arzneimittel und Medizinprodukte (HMG, Heilmittelgesetz, vom 15. Dezember 2000, SR 812.21)	Swiss Federal law on drugs and medical products (law on therapeutic products, of December 15, 2000)
HMI	Schweizerisches Heilmittelinstitut, Swissmedic	Swiss Agency for Therapeutic Products, Swissmedic
KLV	Verordnung des EDI über Leistungen in der obligatorischen Krankenpflegeversicherung (Krankenpflege-Leistungsverordnung, KLV, vom 29. September 1995, SR 832.112.31)	Ordinance of the Swiss Ministry of the Interior on benefits to be paid by the obligatory basic health insurance scheme (ordinance on basic health insurance benefits, of September 29, 1995)
KPAV	Verordnung des Schweizerischen Heilmittelinstituts über die vereinfachte Zulassung von Komplementär- und Phytoarzneimitteln (Komplementär- und Phytoarzneimittelverordnung, vom 22. Juni 2006, SR 812.212.24)	Ordinance of Swissmedic on simplified registration of complementary-medical and herbal drugs (ordinance on complementary-medical and herbal drugs, of June 22, 2006)
LMG	Bundesgesetz über Lebensmittel und Gebrauchsgegenstände (Lebensmittelgesetz, vom 9. Oktober 1992, SR 817.0)	Swiss federal law on food and utensils (food law, of October 9,1992)
VAM	Verordnung über Arzneimittel (Arzneimittelverordnung, vom 17. Oktober 2001, SR 812.212.21)	Ordinance on drugs (drug ordinance, of October 17, 2001)
VAZV	Verordnung des Schweizerischen Heilmittelinstituts über die vereinfachte Zulassung von Arzneimitteln und die Zulassung von Arzneimitteln im Meldeverfahren (vom 22. Juni 2006, SR 812.212.23)	Ordinance of Swissmedic on simplified registration of drugs and registration of drugs by means of a notification procedure (of June 22, 2006)

I. The Registration of Drugs as a Cross-Sectional Problem

The question whether a drug has to be registered and – if so – what corresponding price is to be listed represents a cross-sectional issue with juridical and economic aspects. In addition, different legal domains are concerned. In the first place, health and insurance law aspects are of relevance. But apart from these there are also issues regarding patent law and liability law. At present, the specific design of the registration procedure under health law (especially with regard to complementary-medical drugs) and the financial impacts of drug registration are particularly controversial.

In this contribution, I will discuss issues relating to health law and to social insurance law and examine them with a particular focus on complementary-medical drugs. This will allow me to discuss the relations between the mentioned two legal domains and to draw conclusions regarding some topical questions.

II. The Notion of Drugs, and in Particular of Complementary-Medical and Herbal Drugs

1. Description According to Art. 4 Par. 1 lit. a HMG

Art. 4 par. 1 lit. a HMG has the margin title “Notions” and defines a drug as a product of chemical or biological origin that is meant for or recommended as acting medically on the human or animal organism. Drugs have to be distinguished from medical products, which include such objects as instruments or apparatuses (e.g. one-way syringes, artificial cardiac valves). Drugs and medical products taken together are denoted as therapeutic products – at least in the Swiss legal sphere.

2. The Notion of a Complementary-Medical Drug, in Particular of a Herbal Drug

Complementary medicine is not characterized by a homogeneous medical concept and is thus hard to define. The Swiss basic health insurance scheme had temporarily acknowledged five areas of complementary medicine as eligible for obligatory benefits. Today, however, only acupuncture is covered by the basic health insurance scheme. Related controversies focus in particular on the issue of evidence-based therapeutic efficacy.

In analogy to the wide range of complementary-medical therapies, there is also a wide range of complementary-medical drugs, including, in particular, herbal drugs and homeopathic drugs.

Herbal drugs are also called phytopharmaceutics. Examples of phytopharmaceutics are valerian (valeriana officinalis), ginkgo, ginseng (panax quinquefolium), St. John's wort (hypericum perforatum), ginger root (zingiberis officinalis radix), garlic (allium sativum), butterbur (petasites vulgaris), purple coneflower (echinacea angustifolia), greater celandine (chelidonium majus), liquorice (liquiritia officinalis), or black cohosh (cimicifuga racemosa). Such drugs contain only herbal agents. These agents are characterized by being natural multicomponent mixtures with efficacy-determining or at least partly efficacy-determining constituents and concomitant substances. In the Swiss pharmaceutics market, herbal drugs are of considerable relevance.

III. Registration of Complementary-Medical Drugs under the Law on Therapeutic Products

1. The Issue

With the law on therapeutic products, the legislator has given a wide definition of the notion of drugs and has created the system of a registration under health law. This also affects complementary-medical drugs. They are usually meant to act on the human organism, including the possibility to treat a disease, an injury, or a disability. Often, side-effects of phytotherapeutics can be observed. In view of these facts and with respect to the protection of public health, the question arises whether registration of such drugs is to be regulated, and if so, how this is to be done.

2. Registration Under the Law on Therapeutic Products

The law on therapeutic products is part of the administrative law and has the purpose of regulating a certain sector of economic activity (for which basically the right of economic freedom holds) as far as this is required by control interests – in particular the interest of safeguarding public health – as well as by the interest of consumer protection. To the same end, by the way, the World Health Organization (WHO) has issued guidelines, particularly regarding natural drugs, which stipulate that alternative drugs and food supplements are to be controlled.

The definition of a consistent and centralized registration procedure is one major objective of the law on therapeutic products. It is to be established in view of the protection of human and animal health, ensuring that only safe and effective drugs of high quality standard are sold or distributed. Accordingly, a regular registration procedure (which, in some cases, is to be performed in an accelerated way) and,

apart from it, a simplified procedure were defined. By this latter procedure, the law on therapeutic products takes the principle of proportionality into account and, for certain drugs, permits a registration procedure which is simpler in several respects. Besides, some drugs have not to be registered at all but only to be notified – which holds for drugs that would have to be registered by means of a simplified procedure but for which this procedure is not expedient either. Finally, certain drugs are not liable to any registration or notification.

As to the registration of complementary-medical drugs, at first there had been a "concise" regulation at the level of an ordinance. After extended preliminary work, this regulation was substituted by the ordinance on complementary-medical and herbal drugs, which has been in force since October 1, 2006. In legal respect, the latter is particularly based on art. 14 par. 1 lit. b HMG, which decrees that for complementary-medical drugs a simplified registration procedure is to be performed, a principle which is adopted by art. 5 KPAV. The ordinance relates to homeopathic and anthroposophic as well as to Asian drugs. An extended appendix specifies the requirements regarding the simplified procedure. In its elaboration of the ordinance, the Swiss Agency for Therapeutic Products (Swissmedic) oriented itself by Directive 2004/24/EC concerning amendments of the European Directive 2001/83/EC regarding traditional herbal drugs, and it did so in particular with respect to the definition of terms. At the level of implementation, the ordinance is complemented by the guideline for submission of an application for the registration of human-medical herbal drugs.

It is thus clear that complementary-medical and herbal drugs are basically registered according to the simplified procedure defined in art. 14 par. 1 lit. b HMG. The choice of the registration procedure to be applied is hence not subject to a discretionary decision of the registration authority, there is rather the legal right to registration according to the simplified procedure if the respective preconditions are given.

3. Cases Where No Registration Is Required

With art. 9 par. 1 HMG, the principle has been formulated that all drugs ready for use need to be registered by Swissmedic if they are to be made available. In comparison to former law, this means a major development, in particular with respect to complementary-medical drugs. Since homeopathic, anthroposophic, and Asian products, too, are meant to medically act on the body or are recommended for that purpose, they are seen as drugs. Nevertheless, it cannot be overlooked that evidently, not any complementary-medical or herbal product is necessarily a drug. A respective key criterion for distinction is the issue of medical action on the body. This criterion is concretized in law by referring to the terms of disease, injury, and disability. The distinction hence refers to states of absent or incomplete health,

where there is an interaction between the product and the human organism or metabolism. A respective definition is difficult in particular with regard to food, since certain complementary-medical products are marketed as food supplements.

Therefore, it has to be clarified in each individual case whether the complementary-medical or herbal product is a drug (in which case a registration under health law is necessary) or not (in which case other legal directives, e.g. of food quality control, are to be observed). Mixed forms do not occur.

4. Conclusion

Complementary-medical products are seen as drugs if they are designed for or recommended as acting on the human body. There is hence no particular definition of this term, and in that respect, the new law on therapeutic products means an aggravation. On the other hand, in its registration procedure, the legislator provides for the situation that for complementary-medical drugs, in view of the principle of proportionality, the regular registration procedure does not always appear to be necessary. This decision has probably been influenced by the fact that such drugs have been known and used for long and are regarded as “safe” products. A respective simplification of the procedure refers in particular to the provision of evidence regarding therapeutic efficacy and safety. Such evidence can be provided, for example, by means of a documentation listing the related literature. Nevertheless, the simplified registration procedure in its actual form turns out to be very demanding, and it is assumed that a great number of products used so far will not be registered as complementary-medical drugs.

IV. Complementary-Medical Drugs and Health Insurance

1. The Notion of Illness

Obligatory basic health insurance covers the incidence of illness. A person is ill if his/her physical, mental, or emotional health is impaired in a way that medical assessment or treatment is necessary or an inability to work results. This description does not cover all criteria that are of relevance in the context of the registration of drugs under health law. Art. 4 par. 1 lit. a HMG refers to medical action and understands the term in a very wide sense. For instance, medical action also includes the act of addressing a medically stable health state, as it may exist for example with a disability. Apart from that, the term also includes those actions that are of medical character but take place without a previous medical assessment or treatment.

The following table classifies the constellations to be considered, starting from the product and describing what consequences the relevant criteria will have under the law on therapeutic products and under the law on health insurance. In that way, the significance of the differentiation between medical action (= drug) and medical assessment or treatment (= disease) is to be highlighted.

Example	Medical action (=criterion according to art. 4 par. 1 lit. a HMG)?	Medical assessment or treatment (criterion according to art. 3 ATSG)?	Consequences under the law on therapeutic products	Consequences under the law on basic health insurance
example: Antra	Yes	yes	acknowledged as officinal drug	reimbursement of drug costs
example: cough lozenge	Yes	no	acknowledged as officinal drug	no reimbursement of drug costs
example: tranquillizing tea to remedy insomnia	No	yes	not acknowledged as officinal drug	no reimbursement of drug costs, but reimbursement of the costs of medical assessment or treatment
example: peppermint tea for relaxation	No	no	not acknowledged as officinal drug	no reimbursement of drug costs

2. Preconditions for Coverage by Health Insurance

The precondition for coverage by health insurance is the efficacy, expedience, and economic efficiency of a measure (a medicament or a medical service). Efficacy is assumed if, in an objective perspective, the measure can be expected to achieve its therapeutic goal – the remedying of the health impairment – as completely as possible. With drugs, for instance, it is essentially considered what medical success they are to achieve. Expedience is evaluated by considering the diagnostic and therapeutic purpose in a concrete application of a measure, with also considering the related risks. Finally, economic efficiency refers to the relation between costs and benefits of a measure, which is of relevance if in a concrete case different (effective and expedient) forms of measures or different methods are available.

These basic preconditions for the payment of benefits also hold for alternative treatment methods or for complementary-medical measures. In this respect, it is of relevance that in art. 32 par. 1 KVG – in contrast to former law – no longer the “scientific recognition” of a measure is required but that, instead, it is presupposed

that the efficacy of the measure has to have been proved by means of scientific methods. This stipulation was designed to ensure that the field of complementary medicine was not excluded from coverage in the framework of the obligatory basic health insurance scheme. In addition, it is of importance that the term “scientific” is not to be understood as restricted to natural sciences – efficacy can also be proved by means of statistics, for instance. The legislator wanted to extend the liability for reimbursement of measures to methods of complementary medicine as well, while at the same time ensuring, however, – by requiring evidence of efficacy by means of scientific methods – that “the risk of misuse, which is suspected particularly in the field of complementary-medical measures” is counteracted.

3. The List Principle for Preparations

What measures are covered or reimbursed by a social insurance can be determined according to different criteria. In individual branches of the Swiss social insurance (e.g. in the military insurance) the measures covered are defined in form of a general clause. In other sectors, the measures covered can be defined by means of a respective list. This is for instance the case with the accident insurance, although the Swiss federal government has not yet made use of its respective competence so far.

For the obligatory basic health insurance, the law defines a basic list of measures to be reimbursed. That is, art. 34 par. 1 KVG stipulates that only measures “according to articles 25 – 33” are to be reimbursed. This, however, is not yet an actual implementation of the list system. Rather, in wide areas it is still left to the respective insurance to define what measures will be reimbursed. In practice, however, it is the list contained in appendix 1 of the ordinance on basic health insurance benefits which is of importance. This list determines, for instance, what measures of complementary medicine are to be reimbursed.

For pharmaceutical specialties and ready-for-use drugs, there is a list, too, which has to be produced by the Swiss Federal Office of Public Health. A concretizing regulation is specified in the implementation ordinance. The specialty list is published in electronic form and, in addition, at least once every year in print. It also comprises complementary-medical drugs. Under sequence number 70, homeopathic and anthroposophic drugs are listed. Specific forms are available to apply for inclusion of a complementary-medical drug into this list.

V. Inclusion of a Drug into the Specialty List in the Context of Health Insurance

1. The Function of the Specialty List

The specialty list has a double function. On the one hand, it lists the drugs the costs of which have to be reimbursed by health insurances. On the other hand, it lists the prices that will be reimbursed.

As to drugs not included in the specialty list, health insurances are not liable for reimbursement. There are cases, however, where in spite of non-inclusion of a drug into the specialty list, the liability for reimbursement of its costs has been affirmed by a court judgment, with reference to the so-called “treatment complex”. Furthermore, there is a judicial hint that liability for reimbursement could be examined if, with a specific ailment, it is clear that no other drug is included in the specialty list that would allow effective and expedient treatment.

As to other measures, the second function – the fixing of prices – is achieved in another way. Regarding, e.g. a doctor’s services, there is the instrument of the tariff contract. This tariff contract is concluded by means of individual contracts between insurers and persons providing medical services. It is the result of negotiations and does not contain own legal regulations. Accordingly, jurisdiction starts from the assumption that a respective fixation of prices must not restrict the insured person’s legal claim to services. As to drugs, on the other hand, their price is fixed with their inclusion into the specialty list. This fixation is done by means of a decree of the Swiss Federal Office of Public Health, which can be subjected to a judicial examination. The specialty list does hence not represent a tariff (and therefore can be judicially examined).

2. Inclusion of a Drug into the Specialty List

2.1 Authorization for Application

Art. 52 par. 2 lit. b KVG stipulates that the specialty list is produced by the Swiss Federal Office of Public Health, and does not explicitly define whether this has to be done as a regular official task or in response to applications considered. The issue is not regulated in the implementation regulations either, only marginally, the “owner” (of a registration) is referred to. In practice, however, only such drugs are included into the list for which an application for inclusion is submitted by the producer. Nevertheless, it cannot be excluded that, in view of the protection of public health, a drug might be included into the specialty list without respective application by the

producer. This reflects the fact that regarding the specialty list, the authority has the task to achieve the “objective goal” of ensuring a qualitatively high and expedient health care, as cost-effective as possible.

2.2 Registration Under the Law on Therapeutic Products

In the context of health insurance, the primary precondition for admitting a drug to the specialty list is its valid registration by Swissmedic. Insofar, the official registration based on the regulations of the law on therapeutic products plays a pivotal role with regard to a reimbursement of the drug costs under social insurance law, since this registration defines the frame for an examination of the drug with respect to the criteria of efficacy and expedience.

It has to be mentioned, though, that jurisdiction admits exceptions from this precondition of registration if there is a so-called treatment complex or if, due to lacking therapeutic alternatives, no other effective treatment method is available for a disease that may be fatal for the insured person or result in severe and chronic health problems. With such exceptions, however, the drug has to be of high therapeutic benefit (so-called off-label use). The linking to an indication registered under the law on therapeutic products as well as to an approved dosage may be dropped in those cases.

2.3 Efficacy and Expedience in Particular

With inclusion of a drug into the specialty list, its efficacy and expedience are evaluated on the basis of the documents that were relevant for its registration by Swissmedic. But this registration under the law on therapeutic products is not per se already a sufficient precondition for an affirmation of the efficacy under health insurance law. In this latter evaluation, the chosen perspective must not be restricted to that of the natural sciences, and efficacy has to have been sufficiently proved already (i.e., no longer be in the stage of clarification).

In this respect, inclusion of complementary-medical drugs into the specialty list under health insurance law has hardly ever been controversial. Anyhow, there is a court judgment stating that the authority in charge of producing the specialty list did not on principle refuse the admission of complementary-medical drugs, but that instead, in the concrete case, the difficulty was the lack of meaningful scientific studies. Accordingly, in spite of an observed health improvement (= efficacy) and good tolerability (= expedience), no liability for reimbursement on the part of the health insurance was assumed. Insofar as a drug has been included into the specialty list with limitations, there is no liability for reimbursement if these limitations are not observed.

2.4 Economic Efficiency in Particular

Controversies about the inclusion of drugs into the specialty list usually refer to the criterion of economic efficiency. This criterion is meant to promote realization of the legal goal that health care is to be provided in a most cost-effective way. Thus, with inclusion of a drug into the specialty list under health insurance law – in contrast to its registration under the law on therapeutic products – also a socio-political and a financial criterion are considered. Accordingly, the specialty list contains an enumeration of admitted drugs together with their defined prices.

Evaluation regarding the criterion of economic efficiency is done by comparison with other ready-for-use drugs and with prices in other countries. There are hence different relevant comparison criteria, but they do not obligatorily have to be considered in a cumulative way. Instead, it is also possible to base a decision (only) on the element of the lowest price.

In the examination for economic efficiency, the comparison with prices in foreign countries is of particular relevance, since prices ex factory in foreign countries are named as the first criterion. This criterion allows an external benchmarking, the relevance of which as a regulation system, however, is not right away obvious. In particular, it is of significance in this respect that the group of comparison countries defined according to Swiss law comprises countries with rather high drug prices. But after all, the comparison with foreign prices cannot be used to justify a price increase, since the regulations are designed to ensure the use of the drug which is most cost-effective. Besides, an evaluation based on the comparison with foreign prices must not relate to an individual country. Instead, the mean price regarding all countries considered has to be referred to.

3. Conclusion Regarding Complementary-Medical Drugs

Health insurance law does not on principle ignore the importance of complementary-medical drugs. It has to be admitted, though, that in administrative practice of former years the inclusion of these drugs into the specialty list was faced with high barriers, since evidence of scientific approval could hardly be provided. With the new health insurance law that has come into effect on January 1, 1995, a significant change took place in this respect, since now it has to be examined whether efficacy has been proved by means of scientific methods (which are not restricted to the perspectives of the natural sciences or of classical medicine). Another important development is the simplified registration of complementary-medical drugs under the law on therapeutic products. In this context it has not to be ignored, though, that in its actual form, this registration procedure means high barriers.

With inclusion into the specialty list under health insurance law, the criteria of efficacy and expedience are examined on the basis of the documents that were relevant for registration under the law on therapeutic products. But this registration under the law on therapeutic products is not a sufficient precondition for inclusion into the specialty list under health insurance law. At least, however, it is of importance that with complementary-medical drugs – in contrast to allopathic drugs – clinically controlled studies are not obligatorily required.

There is hence a two-step examination for inclusion of a drug into the specialty list. As a first step, the registration under the law on therapeutic products is presupposed, and then, in addition, the specific inclusion procedure under health insurance law is performed, in the course of which the criteria of efficacy and expedience are examined anew, and economic efficiency is considered as a further criterion.

To sum up, specific preconditions hold for complementary-medical drugs, insofar as the presupposed registration under the law on therapeutic products is performed in form of a simplified procedure, the examination of efficacy under health insurance law is not exclusively performed according to methods of the natural sciences or of classical medicine, and clinically controlled studies do not necessarily have to exist.

VI. Natural Remedies and Supplementary Insurance

In the context of the basic health insurance scheme, supplementary insurances are of considerable relevance. In this respect, it has to be taken into account, though, that supplementary insurances can only reimburse measures that are “true supplementary measures”. As to drugs, this means that for a preparation included in the specialty list no benefits can be paid by a supplementary insurance. Respective drug costs are reimbursed by the basic health insurance, to the extent of the price determined in the specialty list, and because of tariff protection there is no potential further reimbursement by a supplementary insurance.

Insofar, supplementary insurance benefits are of relevance mainly with respect to those drugs that are not included in the specialty list.

VII. Summary

Swiss law does not acknowledge complementary-medical drugs as a basically particular group of drugs. Nevertheless, consequences of the particular position of these drugs can be seen in individual areas.

With respect to the law on therapeutic products, i.e. in consideration of health protection, the registration of a complementary-medical drug is not performed in a basically specific way. At least, however, such drugs are registered in a simplified procedure. As the reason for this, the principle of proportionality is put forward. But this argument seems to be invalid insofar as the respective principle, if applicable, should not result in a procedural simplification but should make an official registration unnecessary at all.

In the context of the basic health insurance scheme, costs for certain complementary-medical drugs are reimbursed by the health insurance. This presupposes registration of the drug under the law on therapeutic products, and in addition, consideration of the principle of economic efficiency. The criteria of efficacy and expedience are examined anew. What complementary-medical drugs are eligible for reimbursement can be seen from a list – the specialty list.

The application for inclusion of a drug into the specialty list in the context of the obligatory basic health insurance scheme is usually submitted by the producer. It cannot be excluded, though, that inclusion of a drug into the list is induced by the authority in charge.

In the context of supplementary insurances, reimbursement is possible for the costs of such complementary-medical drugs that are not included in the specialty list.

Regulation of practitioners in Switzerland (Traditional medicine)

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This contribution highlights the authorization process for the exercise of professions in the field of traditional medicine in Switzerland. It shows that the cantons are responsible therefore. The cantons have chosen different models, some liberal, some strongly regulated.

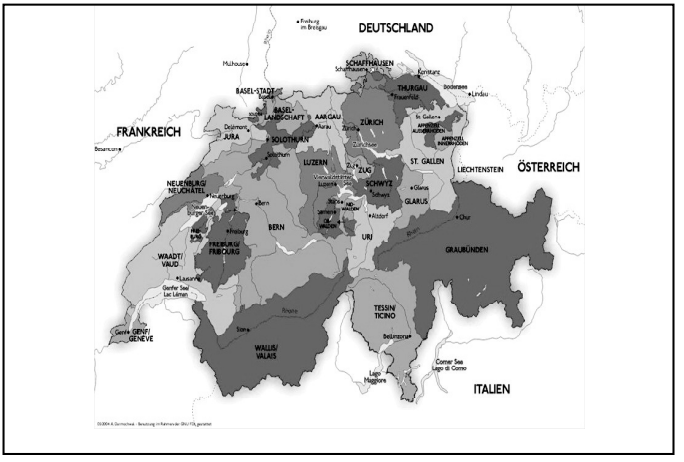
1 Swiss legislation – an overview

The Swiss professional medical care regulatory system consists of two parts, namely the Federation and the Cantons (States). Currently, the Cantons are in charge of public health and have their own regulations for the sector. The Cantons are free to regulate medical practice, including opening or restricting it; however, the physicians having a recognized university degree and a title as a common practitioner or specialist are allowed to practice anywhere in Switzerland.

The new federal legislation will have some effects on the separation of allopathic and non-allopathic medical services. The new Federal law on medical professions (Medizinalberufegesetz, MedBG, 23rd June 2006) will become effective on 1st October 2007. The MedBG defines the educational aspects and deals only with the European-style, “scientific” type of medicine, which is a part of the traditional university education. This type of education concerns only allopathic medicine, although it touches occasionally on traditional medicine. The MedBG provides for a certification system that is linked to university education and degrees, combined with professional continuing education. Certified allopathic physicians are free to practise medicine on a self-employed basis all over Switzerland. The Cantons are not allowed to demand further professional qualifications.

The Cantons will, however, still be free to regulate activities beyond the field of allopathic medicine and the activities of employed physicians. Traditional medicine will remain under cantonal legislation, including the regulation of licensing to practice non allopathic medicine (traditional medicine). It is likely that the new legislation will lead to a new separation between allopathic medicine and traditional medicine, especially in Cantons that have a tolerant system, as both the exercise of allopathic medicine and areas of the allopathic system (the healing) will be strictly reserved for university certified physicians. Therefore it is probable that traditional practitioners will be restricted to non-healing activities, such as well-being.

Switzerland: one small country – 27 health system regulations



2 Use of traditional medicine in Switzerland[1]

Users of complementary/alternative medicine who are ill report that they use complementary/ alternative medicine because the therapies do not involve treatment with drugs or chemicals, there are no side effects, and allopathic medicine was unsuccessful in treating their illness. Users of complementary/alternative medicine who are not ill report that they use complementary/alternative medicine to improve their well-being and to keep from falling ill.

A 1992–1993 study showed that the use of complementary/alternative medicine within the previous 12 months was closely related to whether or not a patient had complementary/ alternative health insurance:

Of those surveyed that had insurance covering complementary/alternative medicine, 20.7% did not use complementary/alternative medicine; 18.9% used one form of complementary/alternative medicine; 21.5% two forms; and 39.0% three or more forms.

– Of those without insurance covering complementary/alternative medicine, 56.4% did not use complementary/alternative medicine; 20.5% used one form of complementary/alternative medicine; 13.4% two forms; and 9.7% three or more forms.

1 Legal Status of Traditional Medicine and Complementary/Alternative Medicine: A Worldwide Review, WHO, Geneva 2001, 129.

Persons living in the German- and French-speaking parts of the country used complementary/ alternative medicine more extensively than those living in the Italian-speaking region. Women and persons with higher levels of formal education were more likely to consult a complementary/alternative medical practitioner than were men and persons with lower levels of formal education. The most commonly consulted forms of complementary/alternative medicine are shown in the chart below.

Medicine	Consulted Patients with insurance coverage	Patients without insurance coverage
Homeopathy	63%	26%
Alternative massage therapies	41%	19%
Phytotherapy	27%	14%
Nutrition therapy	22%	9%
Acupuncture	18%	4%
Anthroposophic medicine	13%	3%
Magnetotherapy	8%	3%

3. Definition of medical professions

The MedBG does not define the profession of a physician, it only mentions that it deals with university linked medical professions (i.e. doctor, dentist, veterinarian and pharmacist). The university curriculum is defined in the MedBG and gives a more precise definition of the area of the physician's activities. Medical education is based on natural sciences, while medical "non-science-professions" are not a part of the MedBG. The cantons are free to regulate all medical activities not ruled by the MedBG.

4. Definition of medical activities

The Federal Court has had to deal with the question of whether or not acupuncture is a medical activity. In Canton Zurich, a traditional practitioner bearing a "Master of Acupuncture", issued by the Institute of Chinese Medicine in Santa Fe (USA), and a Certificate of the US-National Commission for the Certification of Acupuncturists was not allowed to practice as a self-employed acupuncturist. The cantonal health department put forward the argument that acupuncture is an activity reserved strictly for physicians with a (Swiss) state medical certificate, held only by academic medical persons. This restriction was questioned, and the Federal Court denied the need for a monopolistic system for acupuncture (Bundesgericht, 7th June 1999, BGE 125 I 335, www.bundesgericht.ch). The main reasons were that acupuncture

is a profession with its own professional profile (education, exams, standards) and that this profession can be separated from allopathic medicine on the basis of its lower health risks.

Furthermore, the Federal Court considered that acupuncture as therapy (not as a diagnostic) cannot cause more harm than other medical activities being practiced by paramedical staff. Nevertheless the Federal Court accepted the requirement for proof of education. Foreign diplomas have to be recognized by a domestic professional association (e.g. Swiss Professional Organization for Traditional Chinese Medicine).

Contrary to this liberal decision, the Federal Court decided eighteen years ago that homoeopathy should be reserved for allopathic practioners (Bundesgericht, 12th May 1989).

There is no guarantee of free movement and no guarantee of freedom to exercise a cantonal acknowledged profession of a traditional practitioner all over Switzerland. If the profession is (legally) forbidden in other cantons then it cannot be practiced in these cantons.

5. System of regulation of practitioners

5.1 Overview

There are three systems known to describe the legal status of traditional medicine in Europe: the monopolistic system, the mixed system and the tolerant system. The distinction between the systems can sometimes be difficult.

Monopolistic system
Only the practice of scientific medicine by professionals is recognised as lawful, to the exclusion of, and with sanctions against, all other forms of healing.

Mixed System
Only health care professionals are allowed to perform specific medicals acts and violation of this limited monopoly is an offence. For the remaining medical acts, persons who are not qualified as physicians are tolerated.

Tolerant system
Only the practice of scientific medicine by professionals is recognised as lawful, although, to some extent, the law tolerates some practitioners of various forms of traditional medicine.

Three step-system

I prefer a description more adapted to the Swiss health care system. It can be described as a three step-system:

– First of all one has to analyze the separation line between medical and non medical treatments, as found in the federal and cantonal legislation, being aware of the jurisdiction of the Federal Court;

– Medical treatments need a state authorization;

– Non medical treatments need a special (cantonal) licence or are totally free.

5.2 Acceptance of traditional medicine by the Swiss health insurance system

Traditional medicine is widely used and accepted in Switzerland, although the term traditional medicine is not well known. Instead the terms complementary or alternative medicines are used, with complementary medicine being the more modern and appropriate term. 10% of the treatments administered by physicians make use of traditional medicine and 58–78% of the population (depending on the survey used) request greater inclusion of traditional medicine in the national health system and the health insurance system.

Since July 1999, six commonly used complementary/alternative therapies, namely acupuncture, homeopathy, Chinese medicine (TCM), anthroposophic medicine, neural therapy, and phytotherapy, have been reimbursed by compulsory social insurance when they were provided by an allopathic physician with a postgraduate education recognized by the Swiss Medical Association (FMH), while treatments provided by non-allopathic physicians have not been reimbursed. With the exception of acupuncture, in order for these therapies to continue to be reimbursable after 2005, their efficacy and cost-effectiveness had to be proven by that year. After that experimental period of 6 years, anthroposophic medicine, homeopathy, TCM, neural therapy and phytotherapy were excluded. Only acupuncture remains a part of the Swiss health insurance system, but only if administered by, or under the supervision of, a physician carrying the FMH-title of speciality in acupuncture (FMH = Swiss professional organisation of physicians). All other traditional medicine disciplines have to be paid out of pocket or through private insurance.

The complementary/alternative medicine policies of private insurance companies were influenced by the Swiss Government's decision to cover the most commonly used therapies. Private insurance companies generally offer complementary/ alternative health care policies covering, apart from the cancelled four therapies, acupuncture, acupressure, Alexander technique, anthroposophy (when provided

by a physician), audiopsychophonology, auriculotherapy, lymphatic drainage, etiopathy, curative eurythmy, eutony, homeopathy, postural integration, iridology, colonic irrigation, Kneipp therapy, kinesiology, anthroposophic medicine, mesotherapy, naturopathy, osteopathy, polarity, energetic balancing, reflexology, relaxation, breathing techniques, shiatsu, sophrology, and sympathicotherapy. The supplementary fee for complementary/alternative policies varies, for example between 10 and 20 Swiss francs per month. Reimbursement varies between 30 and 100 Swiss francs per consultation, with three to 10 consultations covered per year. Helsana, the major Swiss health insurance company, offers, for 5 Swiss francs per month, insurance for the 5 therapies that are no longer being reimbursed by the compulsory social insurance.

5.3 Licensing to practice[2]

The licensing of traditional practitioners is often described as either a monopolistic or a tolerant system, descriptions that can be misleading, as even the tolerant system has its own rules to protect the consumer/patient, often requiring a license to practise.

According to the rules of the MedBG, scientifically approved medicine is reserved for specially qualified allopathic physicians (university degree and the title of a general practitioner or specialist). The Cantons, on the other hand, are free to regulate the non-university field of medicine.

The degree programmes and professions, such as allopathic physicians or chiropractors, are recognized throughout the country, and the titles of some professions, including “Medical Doctor” and “Chiropractor,” are protected.

The cantons allowing only allopathic physicians to practice medicine are Appenzell internal Rhodes, Jura, Nidwalden, Uri, and, with the provisions noted, the following:

Aargau: a licence is not required to provide care to healthy persons (when treating nervousness, stress, sleeplessness, or phobias, for example).

– Basel Stadt: authorized physiotherapists and masseurs are permitted to use reflexology.

– Bern: the practice of acupuncture by non-allopathic practitioners is tolerated when provided under the orders of an allopathic physician.

2 This chapter is mostly based on Maddalena, 161 ff. and the WHO-Report, 129 ff.

– Fribourg: the Department of Health may issue licences to practise complementary/alternative medicine on condition that practitioners do not use methods and techniques restricted to authorized health care professionals.

– Geneva: recently, the authorities have been relatively tolerant of non-allopathic practitioners.

– Glarus: reflexology, acupressure, and other similar forms of massage may be freely provided.

– Schwyz: non-physicians may obtain a licence to practise acupuncture.

– Solothurn: the practice of complementary/alternative medicine as a self-employed profession with proof of education is allowed.

– Vaud: recently, the authorities have been relatively tolerant of non-allopathic practitioners.

– Zug: under the supervision of the health authority, reflexology, sport massage, acupressure, and health advising may be freely provided. Persons who have completed three years of training, including comprehensive theoretical and practical courses, and who have passed a cantonal exam may provide acupuncture.

– Zurich: magnetism is not considered a form of medicine and, therefore, its practice does not require official authorization.

Although the law in these cantons is typically monopolistic, the authorities are relatively tolerant with regard to non-allopathic practitioners. In order to be allowed to practice in German-speaking cantons (Appenzell external Rhodes, Basel Landschaft, Graubünden, Luzern, Obwalden, St. Gallen, Shaffhausen, and Thurgau), non-allopathic providers must pass the State exam and obtain a licence from State authorities. In most German-speaking cantons, there are specific medical acts that are reserved for physicians.

In non-German-speaking cantons, the situation is slightly different. In the canton of Neuchâtel, since the introduction of a 1995 law, non-allopathic practitioners are permitted to provide non-dangerous complementary/alternative therapies. While a licence to practice is not required, complementary/alternative medical providers may not advertise their services. In Valais, the same restrictions apply, with two additional requirements: complementary/alternative providers must clearly inform their patients that they do not have any allopathic education and they must have a licence from the health department. In the canton of Ticino, non-allopathic practitioners may practise medicine without a licence; however, they must clearly inform their patients that they do not have an allopathic education. In addition, they are not permitted to advertise,

use optical, mechanical, electrical, or ionizing equipment, or prescribe medications or drugs. Homeopathy is among the most frequently practised complementary/ alternative therapies in Switzerland. All persons legally providing health care may apply homeopathy according to the standards of good medical practice. In some cantons, those not medically qualified may also practice homeopathy.

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Financing of traditional medicine in Switzerland

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In Switzerland, traditional medicines – usually referred to as "complementary medicines" – belong to the social insurance schemes benefits. However, major differences exist between the different schemes. Five complementary medicines were excluded from the compulsory heath insurance in 2005. A popular initiative called "Yes to complementary medicines" asks for an amendment to the Constitution. People will have to vote on this much debated question of traditional medicines and their full integration into the social security schemes, training programs, research and therapeutic products.

In Switzerland, traditional medicines are supported and financed by three social security schemes: health insurance, accident insurance and invalidity insurance. Besides, private insurances may offer special coverage of traditional medicines.

Social security schemes

1. Health Insurance

Health insurance is a compulsory system of protection against illness, maternity, accidents (subsidiary) and congenital disability (subsidiary). The Health Insurance Law[1] was adopted on March 18th 1994 and entered into force on January 1st 1996.

Health insurance is operated by non-profit organizations (health insurance funds) which must be recognized as such by the Federal Department of Home Affairs.

Each person has to pay a premium individually ("capitation premium") which is not dependent on the income. Premiums do vary from one health insurance fund to another and from canton to canton. Individuals with a low income are entitled to reduced health insurance premiums (subsidies fixed up by the canton). As far as cost-sharing is concerned, the system is based on:

– a standard deductible (CHF 300 per year). Children and adolescents up to 18 years do not have to pay the deductible;

– a retention fee of 10% of the remaining invoiced amount (up to a maximum of CHF 700 per year). Children and adolescents up to years pay a limited amount (up to a maximum of CHF 350 per year).

1.1 Health care professionals

Authorized health care providers are mentioned in the Health Insurance Law[2]: physicians, pharmacists, chiropractors, midwives and health care professionals who are entitled to practice at a doctor's request. The list of these health care professionals is included in the Ordinance on Health Insurance[3]: physiotherapists, occupational therapists, nurses, speech therapists, dietitians. The Federal Council has chosen the system of a "locked list". No other health care professional may provide treatment and claim reimbursement from the health insurance.

1 Loi fédérale sur l'assurance-maladie (LAMal), RS 832.10: http://www.admin.ch/ch/f/rs/8/832.10.fr.pdf
2 Art. 35, al. 2 LAMal.
3 Ordonnance sur l'assurance-maladie (OAMal), RS 832.102: http://www.admin.ch/ch/f/rs/c832_102.html

1.2 Services and benefits

Services provided by a physician, examinations (analyses, x-rays e.g.), nursing care at home or in a nursing home, stays in and treatment provided in general wards at hospitals (on special lists kept by the canton) and medicines which appear on the List of Pharmaceutical Specialties are among the benefits which are covered by the health insurance funds. Besides, the revised Health Insurance Law has included new services and benefits such as medical transport and rescue (limited amount)[4], preventive healthcare (according to a specific list)[5], dental treatments (in connection with a severe generalized disorder)[6], medical aids and devices (according to a specific list)[7]. However, no legal provision has been adopted by the Parliament as far as traditional medicine ("complementary medicine") is concerned. In the preliminary works of the law revision, requests were made to include "healers" in the list of registered practitioners whose treatments would be covered by the compulsory health insurance. The Federal Council argued that an exhaustive list of health care providers and treatments would not be appropriate to handle the rapid developments in this field. However, the Federal Council clearly approved the recognition of alternative treatments and the principle of their coverage by the compulsory (basic) health insurance.

According to the legal system, the Federal Council has to determine to what extent "new and controversial medical measures" should be covered by the compulsory health system, as long as their "efficiency, cost-effectiveness and appropriateness" are questionable and submitted to evaluations[8]. Following political discussions, the Federal Department of Home Affairs decided to introduce five methods of complementary medicine to the benefit catalogue of the compulsory health insurance on a temporary basis: homeopathy, anthroposophical medicine, neural therapy, traditional Chinese medicine, herbal therapy (phytotherapy). On this occasion, acupuncture was included on a permanent basis. The new provision entered into force on July 1st 1999[9]. For a reimbursement by the basic health insurance, treatments had to be performed by physicians with an appropriate training approved by the Swiss Medical Association. Complementary medicine treatments carried out by registered health care providers at a doctor's request were not covered by the compulsory health insurance.

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4 Art. 25, al. 2 let. g LAMal.
5 Art. 26 LAMal.
6 Art. 31 LAMal.
7 Art. 25, al. 2 let. b LAMal.
8 Art. 33, al. 3 LAMal, art. 33, let. c OAMal.
9 Ordonnance sur les prestations de l'assurance des soins (OPAS), Annexe 1, ch. 10, RS 832.112.31: http://www.admin.ch/ch/f/rs/8/832.112.31.fr.pdf

The interim arrangement was limited to the end of June 2005. On June 3rd, 2005, the Department of Home Affairs notified its decision to exclude the five methods of complementary medicine from the benefit catalogue. The decision, which was to become effective on July 1st 2005, was based on several studies that were conducted in a nationwide evaluation program[10]. According to the Department, there were "insufficient elements to prove that the five methods would fulfill the fundamental criteria of cost-effectiveness, and mainly of efficiency and appropriateness"[11]. It clearly stressed that this decision was in no way to be considered as a "value judgment" on traditional medicine, but as a restriction of health insurance providers' obligations. Furthermore, the Department assumed that top-up insurances were already offering appropriate coverage of traditional medicine and would provide for the integration of the five methods which were excluded from the compulsory health insurance. The decision gave rise to public criticism. Some comments focused on the danger of initiating a "two-speed" medicine.

1.3 People's initiative

In the Swiss system which is characterized by direct democracy[12], citizens may seek an amendment to the Constitution[13]. On October 4th 2005, an initiative called "Yes to complementary medicines" was handed over to the Chancellery[14]. The text reads as follows:

"Within the limits of their powers, the Confederation and the Cantons shall take complementary medicines fully into account".

For their authors, the initiative means:

– free choice of the therapy for the patients;

– free choice of therapeutic methods for the physicians and non-physicians;

– integration of complementary medicines into the curricula (basic education, advanced and continuing training) and into the research;

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10 Final report and other documents: http://www.bag.admin.ch/themen/krankenversicherung/00305/02363/index.html?lang=fr

11 Federal Office of Public Health, Press release, June 3rd 2005: http://www.bag.admin.ch/dokumentation/medieninformationen/01148/01215/index.html?lang=fr&msg-id=3740

12 Swiss Confederation a brief guide: http://www.bk.admin.ch/dokumentation/02070/index.html?lang=en

13 For such an initiative to take place, the signatures of 100'0000 voters must be collected within 18 months.

14 The initiative was signed by 138'724 voters: http://www.admin.ch/ch/f/ff/2005/5631.pdf

– taking complementary medicines into account in the field of therapeutic products, as well as in the social security schemes (for treatments carried out by physicians).

On August 30th 2006, the Federal Council released its "Message"[15] about the initiative. It requires the Parliament to submit the initiative to the vote and recommends to reject it, because "complementary medicines are not essential in a quality public health system"[16]. For the Federal Council, the catalogue of the compulsory health insurance system is regarded as adequate. A great majority of people do have – or are ready to have – a private insurance for traditional medicine. On January 26th 2007, the Committee for Social Security and Health of the National Council (CSSH-N) invited the plenum to reject the initiative and decided not to follow a proposal to reintegrate traditional medicines into the catalogue of the compulsory health insurance. The matter has been referred to the plenum of the National Council. After discussion and vote in this Council, the initiative will be examined by the National Council of States.

2. Accident Insurance

According to the Accident Insurance Law[17] which entered into force on January1st 1984, the accident insurance is a compulsory scheme for all employees. It intends to cover the damage to health and occupation due to an occupational accident or an occupational disease. For employees who work more than 8 hours per week, the insurance also covers the non-occupational accident. Self-employed persons may be insured on a voluntary basis. Persons who are not engaged in a gainful employment are not entitled to this social security protection. They have to take out accident insurance with their health insurance.

Accident insurance is handled by the Swiss Accident and Insurance Fund[18] (SUVA) and other registered accident insurance providers (private insurers, health insurance funds). The insurance relationship with SUVA is determined by law and depends on the type of business.

Premiums for occupational accidents and diseases are paid by the employer. Premiums for non-occupational accidents are paid by the employees (deduction

15 Message relatif à l'initiative populaire "Oui aux médecines complémentaires", du 30 août 2006, FF 2006 p. 7191ss: http://www.admin.ch/ch/f/ff/2006/7191.pdf
16 Ibidem, p. 7193.
17 Loi fédérale sur l'assurance-accidents (LAA), RS 832.20: http://www.admin.ch/ch/f/rs/8/832.20.fr.pdf
18 Schweizerische Unfallversicherungsanstalt (SUVA).

from the employee's salary). Contrary to the health insurance system, there is no cost-sharing in the accident insurance.

2.1 Health care providers

According to the Accident Insurance Law, the policy holder is entitled to "appropriate medical treatments" carried out by physicians, dentists, chiropractors and health care professionals who practice at a doctor's request[19]. In opposition to the health insurance scheme, the Ordinance on Accident Insurance[20] has no specific provision concerning the list of those professionals. The Ordinance simply refers to the topic provisions of the Ordinance on Health Insurance and indicates that the Department of Home Affairs may appoint other health care professionals whose treatments would be reimbursed by the accident insurance. So far, the Department has made no use of this competence.

2.2 Services and benefits

Services, care benefits and expenses which are reimbursed by the accident insurance are similar to the above mentioned benefits in the health insurance scheme. However, the extent of the protection is more favorable to the insured persons. For example, the accident insurance provides for a full coverage of medical transport and rescue, dental treatments, follow-up and spa therapy.

In this social security scheme, complementary medicines have no special mention in the legal provisions. However, medical treatments and medical drugs provided by traditional medicine might be part of the accident's scheme benefits. In order to guarantee an equal application of the legislative provisions by the different insurance providers, a "Commission ad hoc" was implemented in 1984. "Recommendations"[21] were adopted and published in agreement with the Federal Office of Public Health. Although they have no binding force, the Recommendations play an important role in the application of the law, as stated by the Federal Insurance Court[22]. According to Recommendation No 01/1999 (as amended on March 29, 2005), "the insurance provider should decide in each particular case if a traditional medical treatment is appropriate or not". Besides, these treatments must meet the legal requirements mentioned in the Health Insurance Law: efficiency and cost-effectiveness. The accident insurance scheme covers traditional medicines either as such or as a

19 Art. 10 LAA.
20 Ordonnance sur l'assurance-accidents (OLAA), RS 832.202: http://www.admin.ch/ch/f/rs/8/832.202.fr.pdf
21 http://www.svv.ch/index.cfm?id=6471
22 ATF 114 V 315.

complement to conventional medicine. In this latter case, traditional medicines must set up favorable conditions for a more efficient and rapid effect of conventional medicine (i.e. combination of a craniosacral therapy with physiotherapy or kinesiology with physiotherapy).

In order to assure equality of treatment, the Recommendations make a distinction between three treatments' groups:

– treatments which are covered by the accident insurance scheme (i.e. osteopathy, kinesiology, lymphatic drainage);

– treatments which are covered once approved by the insurance internal services (i.e. bioresonance therapy, laser therapy, psychology – in particular psychological support, autogenic training, music therapy, etc.);

– treatments which are excluded from the accident insurance (i.e. Bach's flowers; lithotherapy, shiatsu, etc.).

Despite a more open approach to traditional medicines, the accident insurance scheme does not reimburse complementary medicines which have been excluded from the catalogue in the health insurance (homeopathy, anthroposophical medicine, neural therapy, traditional Chinese medicine, herbal therapy-phytotherapy).

The Recommandation, which was amended on March 12th 2007, has been recently published. All details concerning the abovementioned therapies have been cancelled. The importance of alternative medicines is recognized and the insurer may decide freely what treatment e is ready to reimburse.

3. Invalidity Insurance

Invalidity insurance is a compulsory system of protection against "disability". According to the Federal law on the general part of social insurance law, which entered into force on January 1st 2003, disability is defined as "a continuing full or partial loss of ability to take up employment in the relevant job market due to impaired health in spite of reasonable treatment and rehabilitation"[23].

The Federal Law on Invalidity Insurance was adopted on June 19th 1959 and entered into force on January 1st 1960.

The invalidity insurance is run by cantonal offices under the supervision of the federal authorities (Federal Social Insurance Office) and together with other bodies

23 Loi fédérale sur la partie générale du droit des assurances sociales (LPGA), Art. 8, RS 830.1: http://www.admin.ch/ch/f/rs/8/830.1.fr.pdf

(compensation funds, medical and occupational observation centers, regional medical services).

The invalidity insurance is financed through the contributions paid by insured persons and their employers. Besides, the Confederation and the cantons cover around 50% of outgoings.

3.1 Health care providers

According to the Federal Law on Invalidity Insurance, the insured persons have a free choice of health care professionals among physicians, dentists and pharmacists who hold a federal diploma[24] or a special authorization delivered by the cantonal authority[25].

The same free choice is recognized for health care professionals who practice at a doctor's request and meet the cantonal prescriptions and the insurance requirements.

3.2 Services and benefits

Invalidity insurance provides benefits in the form of rehabilitation measures, supply of appliances, cash benefits, helplessness allowances and collective benefits. According to the Federal Law on Invalidity Insurance, medical measures belong to the benefits aimed at the rehabilitation of the disabled. They are reimbursed as long as they treat:

– a congenital disability[26] (until the age of 20);

– a more or less stabilized medical condition, insofar as they contribute to a permanent or real improvement in the earning capacity.

Services provided by physicians, examinations, nursing care at home, stays in and treatment provided in general wards at hospital are among benefits which are covered by the invalidity insurance scheme. According to the Ordinance on Invalidity Insurance[27], physiotherapy and psychotherapy are covered by the insurance insofar as these methods are appropriate with regard to the actual state of medical knowledge and allow a simple and adequate rehabilitation process[28].

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24 Art. 26, al. 1 LAI.
25 Art. 26, al. 2 LAI.
26 Ordonnance concernant les infirmités congénitales (OIC), RS 831.232.21: http://www.admin.ch/ch/f/rs/8/831.232.21.fr.pdf
27 Règlement sur l'assurance-invalidité (RAI), RS 831.201: http://www.admin.ch/ch/f/rs/8/831.201.fr.pdf
28 Art. 2 RAI.

None of these texts make references to traditional medicines. As is the case of the accident insurance, the invalidity insurance does not reimburse the complementary medicines which have been excluded from the catalogue in the health insurance (homeopathy, anthroposophical medicine, neural therapy, traditional Chinese medicine, herbal therapy–phytotherapy)[29].

However, some complementary medicines (treatments) are recognized and reimbursed by the invalidity insurance. According to the "Administrative Circular on medical rehabilitation measures" which was adopted by the Federal Social Insurance Office[30], hippo-therapy and botulic toxin treatments are among the numerous medical measures which are covered. On the other hand, invalidity insurance grants no coverage of: "foodstuffs, tonic wines and elixirs, spirituous liquors, mineral waters, fresh yeast preparation, cosmetics and similar products..", even if prescribed by a physician ![31]

In a recent judgment[32], the Federal Insurance Court had the opportunity to clarify the notion of "health care professionals" in the invalidity insurance. The case concerned a 12-year old girl who suffered from cystic fibrosis (genetic disease) and had to undergo treatments (osteopathy). The cantonal office (invalidity insurance) refused to reimburse her medical expenses on the grounds that osteopaths do not belong to the health professionals who are entitled to carry out treatments covered by the invalidity insurance. The Federal Insurance Court pointed out that:

– osteopathy belongs to the methods developed by traditional medicines;
– as far as professionals are concerned, the invalidity insurance scheme has no "close list" system;
– the Federal Council did not use its competence to establish such a list;
– the Federal Social Insurance Office is not entitled to exclude osteopaths in its Administrative Circular;
– the invalidity insurance system relies on the free choice of care professionals.

Nevertheless, in that particular case, the right to reimbursement was denied because no medical prescription had been established before the beginning of the treatment.

29 Circulaire, ch. 1209.
30 Circulaire concernant les mesures médicales de réadaptation de l'AI (CMRM): http://www.sozialversicherungen.admin.ch/storage/documents/275/275_1_fr.pdf
31 Circulaire, ch. 1207.
32 Judgment dated December 28th 2004, I 174/03.

The interest of the case lies in the clear distinction between invalidity insurance and health insurance. The latter is based on an exhaustive benefit catalogue. In this case the federal judges could not have declared that osteopaths are entitled to carry out treatments and claim for insurance benefits.

II. Private insurances

Insurers may decide freely on the type and the extension of the coverage they are willing to offer. Premiums may be based on the "risk" that the individual represents. The insurer may refuse to insure certain persons or attach special conditions to the insurance policy in consideration of the state of health.

Most of the insurers rely on a register called "Register of Empiric Medicines"[33]. This list of registered therapists is regularly updated. Each insurer chooses freely the therapists and/or the methods that will be part of the benefits offered by the insurance policy. Changes are frequent. They are synonymous to insecurity for the insured. At the beginning of this year, a major insurance fund decided to exclude eleven registered methods and required additional training and certification for naturopaths. Another insurer banned eight therapeutic methods (e.g. reflexology, lymphatic drainage). The last one introduced a high standard deductible (CHF 600.-) on alternative treatments.

In these circumstances, no global comprehensive picture may be provided as far as the effective coverage of traditional medicines in private health insurances is concerned.

III. Conclusion

In the actual social security systems, major differences exist between the different schemes. The most restrictive legislation is the Health Insurance Law. Accident insurance and invalidity insurance provide a broader protection by including alternative health care providers and/or alternative treatments in their benefits catalogue.

For the patients, these differences have major economic consequences related not only to the payment of the treatment but also to cost-sharing, which is a legal obligation in the health insurance scheme only.

The decision to exclude five complementary medicines from the compulsory health insurance in 2005, and, moreover, the procedure that lead to the decision were

33 Registre des Médecines Empiriques (REM): http://www.emr.ch/index.htm

heavily criticized. The gap between the political decision and the popular will has been documented. In a survey made by Polyquest in March 2005, 87% of Swiss citizens “wished that complementary medicines be reimbursed by the compulsory health insurance system on a permanent basis“[34]. 138’724 signatures[35] were collected within 13 months[36] for the people’s initiative called “Yes to complementary medicines“: a great success. Despite the clear position of the Federal Council against the text of the initiative, the discussion continues. People will have to vote on this much debated question of traditional medicines and their integration into the social security schemes.

34 Communiqué de presse de l’Union des sociétés suisses de médecine complémentaire, du 21 avril 2005: http://www.svkh.ch/index.php?id=33&L=1&tx_ttnews[pS]=1163533201&tx_ttnews[pointer]=1&tx_ttnews[tt_news]=23&tx_ttnews[backPid]=8&cHash=e1ba01a1ee

35 100'000 signatures are required.

36 6 months before the deadline.

Joint Swiss/SA Seminar on Requirements for Access to Affordable and Efficacious Traditional Medicine(s)

Report by the Medical Research Council of South Africa and the Institut de droit de la santé, University of Neuchâtel, Switzerland

Introduction

The South African Medical Research Council (MRC) has a strong involvement in the field of traditional medicines, both from a research and commercialization point of view, through its South African Traditional Medicine's Research Unit, Indigenous Knowledge Systems (IKS) Lead Programme and Innovation Centre (IC). The University of Neuchâtel's Institut de Droit de la Santé (IDS), on the other hand, is the first academic centre specializing in health law in Switzerland. Although academically independent, the Institute is very well introduced in all Swiss government agencies involved with health issues, in particular traditional medicine, as well as international organizations dealing with health issues and international trade. This includes the Swiss Federal Office of Public Health (BAG), the Swiss Agency for Development and Cooperation (SDC), the Swiss Federal Institute of Intellectual Property, the Swiss Agency for therapeutic products (Swissmedic), the World Health Organization (WHO, including its Commission on Intellectual Property Rights, Innovation and Public Health-CIPIH), the World trade organization (WTO), other organizations of the UN system, and other NGOs and public-private partnerships based in Geneva.

In November 2005, the MRC Innovation Centre and the University of Neuchâtel's IDS jointly applied for funding to the Swiss National Science Foundation and the South African National Research Foundation for a seminar aimed at bringing together the collective expertise of the units and other relevant bodies to discuss and debate issues surrounding the research, commercialization and implementation of traditional medicines in South Africa and Switzerland. The objectives of the seminar were 6-fold, namely:

– To foster exchange of knowledge between Switzerland and South Africa, as representatives of "the North" and "the South", in the common field of interest of traditional medicine

– To foster interdisciplinary research, in particular in the field of traditional medicine

– To identify the main problems linked with traditional medicine in South Africa and in Switzerland

– To foster practical solutions to the identified problems

– To ensure sustainability of the new collaboration

– To produce a concrete outcome

In summary, the interdisciplinary seminar was intended to create new ties between South African and Swiss researchers, in particular in fields such as law, (public) health

and international trade; to exchange information and experiences between the two countries; to identify common fields of interest for future research on chosen aspects of traditional medicines; and to begin to identify practical solutions to the many issues and challenges relating to traditional medicine research, commercialization and usage.

Seminar Content and Discussions

The planned seminar took place from 6 - 8 March 2007 at the Monkey Valley Resort in Cape Town, South Africa. It included participants from a variety of different organizations, backgrounds and disciplines, including medical science, pharmacology, economics, policy, and law (see Appendix A for delegate list), and covered a broad range of issues related to traditional medicine from both the South African and Swiss perspectives. The topics covered and issues discussed are summarized below. Copies of the presentations and associated papers are available on request. These will be included in a publication on the seminar and are not covered in detail in this report.

The seminar was opened by Prof. Tony Mbewu, President of the MRC. Prof. Mbewu provided an overview of traditional medicines and some of the key issues faced, highlighting the wealth of biodiversity and human genetic diversity present in South Africa.

Prof. Tony Bunn (MRC Innovation Centre) and Dr. Daniel Kraus (Institut de droit de la Santé, University of Neuchâtel) provided an introduction to the seminar, including an overview of the history, the objectives and the programme. The programme comprised of the following broad sessions and presentations:

Session 1: Traditional Medicines and their usage in Switzerland and South Africa

– Clarification of the terminology (Prof. Tony Bunn, MRC Innovation Centre and Dr. Daniel Kraus, Institut de droit de la Santé, University of Neuchâtel)

– Overview of traditional medicine usage and challenges in Switzerland (Dr. Jean-Robert Ioset, Laboratoire de Pharmacognosie et Phytochimie, University of Geneva)

– Overview of traditional medicine usage and challenges in South Africa (Dr. Gilbert Matsabisa, IKS Lead Programme, Medical Research Council)

– Clinical trials on traditional medicines in South Africa (Prof. Quinton Johnson, South African Herbal Science and Medicine Institute, University of the Western Cape)

Session 2: International trade related aspects of traditional medicine

– Trade in pharmaceutical products under the GATT, and sanitary and phytosanitary rules of the World Trade Organization (Dr. Matthias Oesch, Faculty of Law, University of Berne)

– Marketing authorizations/Regulatory issues related to traditional medicines in South Africa (Prof Peter Eagles, Medicines Control Council, SA)

– Marketing authorizations/Regulatory issues related to traditional medicines in Switzerland (Privatdozent Dr. Ueli Kieser, Faculty of Law, University of Berne – delivered by Prof. Dr. Tomas Poledna, University of Zurich)

Session 3: Protection and commercialization of traditional medicines

– Promotion and protection of traditional medicine through international intellectual property rules (Dr. Ingo Meitinger, Swiss Federal Institute of Intellectual Property)

– Protection of indigenous knowledge and traditional medicine in South Africa (Mr. McLean Sibanda, Innovation Fund, National Research Foundation)

– Plant Breeders Rights and Biodiversity as applied to traditional medicine in South Africa (Mr. David Cochrane, Spoor and Fisher)

– Commercialization of natural medicines in South Africa – past experiences (Prof. Petro Terblanche, Medical Research Council)

– Community involvement in the commercialization of traditional medicines in South Africa (Dr. Sechaba Bareetseng, IKS Lead Programme, Medical Research Council)

– Valuation of indigenous knowledge and benefit sharing (Mr. Rabogajane Busang, MRC Innovation Centre)

Session 4: Regulation of practitioners and financing of traditional medicine(s)

– Regulation of practitioners in Switzerland (Prof. Dr. Tomas Poledna, University of Zurich)

– Regulation of traditional practitioners in South Africa (Mr. Isaac Mayeng, Directorate of Traditional Medicine, Department of Health SA)

– Managing medicinal knowledge: the future of databases and IKS centres (Dr. Otsile Ntsoane, National IKS Office, Department of Science & Technology SA)

– Financing of traditional medicine in Switzerland (Prof Beatrice Despland, Institut de droit de la Santé, University of Neuchâtel)

Day 3 of the seminar included a tour of Cape Point to witness first-hand a sample of South Africa's vast biodiversity, followed by a site visit to the MRC's IKS Lead Programme facility at Delft. This included a tour of the traditional medicine manufacturing facility and medicinal plant garden. The visit coincided with the graduation ceremony of around 150 traditional healers who had participated in the MRC's traditional healer training programmes. Thus, the seminar participants had the opportunity to meet and interact with practising African traditional healers.

The seminar concluded with a meeting at the MRC's Head office in Parow at which the discussions from the seminar were summarized and a way forward devised (see below).

Summary of Issues Raised

The following issues were raised and discussed at the seminar in relation to the presentations delivered:

– Difference in definitions: It was clear from the first presentation that the definitions of traditional medicine differ between SA and Switzerland. In SA, traditional medicine refers to the healing system used by indigenous communities, which is strongly linked to African tradition and culture (African traditional medicines), while, in Switzerland, traditional medicine refers to complementary or alternative medicine. Although some of the issues relevant to these areas of medicine differ, it was agreed that issues common to both could be covered by referring to "plant-based medicines".

– Scientific validation of traditional medicines: A key issue discussed throughout the seminar was the question of the degree of scientific and clinical validation that should be required for the registration and use of traditional medicines. It was noted that Switzerland has registered a number of traditional medicines; the criteria used could potentially be used as a guideline for the development of systems for registration of traditional and complementary medicines in SA. Another issue raised in this context was the fact that traditional medicines produced in the laboratory or under defined conditions may differ from those

produced by the traditional healers. There is also the issue of spirituality, which forms an important part of African traditional medicine.

– Inadequacies in the current legal and policy frameworks, particularly in South Africa: Although this is currently under development, the lack of a clear regulatory framework for the registration of complementary and African traditional medicines was raised as a significant barrier to the development and commercialization of safe, efficacious medicines in South Africa. The Chair of the Medicines Control Council acknowledged the difficulty in balancing the need to establish a system that recognizes the prior knowledge that comes with traditional medicines and eases the regulatory (and cost) burden of getting products onto the market with the need to protect the health and safety of the consumer. On the policy side, it was clear that the various government departments, including the Departments of Health, Environmental Affairs and Tourism, and Science and Technology, are actively developing policies, legislation and strategies to address various issues surrounding traditional medicines in the country; however, there is a need to communicate these to stakeholders, to coordinate the efforts of the different departments, and to ensure effective implementation.

– Lack of appropriate legal systems for the protection of traditional knowledge and traditional medicines: An overview of current Intellectual Property (IP) regimes (SA and international) revealed that, for various reasons, none of them are appropriate for the protection of traditional knowledge and traditional medicines. This issue needs to be dealt with on an international basis.

– Dearth of available information and case studies on the commercialization of traditional medicines: Discussions on the Hoodia case highlighted some of the complex issues involved in the commercialization of traditional medicines. It was noted that such case studies need to be publicized in order to provide best practise guidelines for issues such as suitable business/commercialization models, scientific and clinical studies, IP protection strategies, models for engaging and benefit sharing with the relevant indigenous communities, and models for community involvement in commercialization and entrepreneurship aimed at poverty alleviation and job creation.

– Documentation of traditional knowledge: There was some debate over the benefits of establishing a database of indigenous knowledge in SA and what sort of model should be applied in terms of access to and use of the information.

– Regulation of practitioners and financing of traditional medicines: Regulation of practitioners and financing issues proved to be challenging both in South

Africa and in Switzerland, where historical and/or institutional aspects come into play. As regards financing of complementary medicine in Switzerland, it was observed that the current legal framework for reimbursement reflects the fragmentation of the social security system.

Outcomes and Way Forward

The seminar was extremely informative and valuable to those working in the field of traditional medicines and allowed for extensive networking and exchange. There is no doubt that the seminar achieved its primary objective, which was to facilitate networking and collaboration between Swiss and SA groups. Other objectives met include identification of the main problems linked with traditional medicine in South Africa and in Switzerland; the development of practical suggestions towards solving some of the identified problems; and the exchange of knowledge between Switzerland and South Africa. A key aspect of the seminar was the identification of areas of commonality, and opportunities for collaboration on interdisciplinary research. Potential future opportunities for collaboration were identified as follows:

– Produce a common set of definitions
– Publicize best practices (commercialization, benefit sharing, prior informed consent etc.)
– Investigate models for governmental support of traditional medicine
– Investigate appropriate systems for protection of IP associated with traditional medicine and traditional knowledge, including databases
– Investigate issues around the regulation of traditional and complementary medicines
– Investigate models for scientific and clinical evaluation of traditional and complementary medicines
– Identify a potential case study for SA and Switzerland to cooperate on

The results of the seminar will be published as a book in Switzerland, and will be made available in SA. This will include an introduction, the papers contributed by the various speakers, and a discussion of the issues raised. A summary of the proceedings will also be published in SA (medium to be identified). The intention is to hold a follow up conference in Switzerland in 2008 to explore the above-mentioned issues further.

Acknowledgements

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Appendix A: DELEGATE LIST

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