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# The position of drugs used in traditional medicine within the Indian healthcare system

This article is the third part in a series of texts entitled:

“The current problems in drug management in countries of the Indian subcontinent”

**Key words:** Ayurveda, Unani, Siddha, Homeopathy, tribal medicines, traditional medicines, India, Europe

## ■ Introduction

India is the only country in the globe with officially recognized multiple systems of medicine, namely Allopathy; Ayurveda; Yoga and Naturopathy; Unani; Siddha; and Homoeopathy [1]. The traditional medicine came into the limelight because of the politicization of the traditional medicine agenda. India adopted a parallel model within the national health care system through the Indian Medicine Central Council Act in 1970. The modern and traditional medicines are separate within this [2]. The National Health Policy of 1983 also focuses on the Indian Systems of Medicines and Homeopathy. The Department of Indian Systems of Medicines and Homoeopathy (ISM and H) was established under the Ministry of Health and Family Welfare in 1995. This was renamed as the Department of Ayurveda; Yoga and Naturopathy; Unani; Siddha; and Homoeopathy (AYUSH) in 2003.

The origin of Ayurveda goes back to 5.000 B.C. in India. It has been written in Sanskrit language. Unani originated in Greece around 980 A.D. and was introduced in India by the Arabs. The literature available is in Arabic and Persian language. Siddha originated in the southern part of India and the literature available is in Tamil language (AYUSH, 2007). After a brief description of the scope of the traditional medicines (Ayurveda, Unani, Siddha and some tribal drugs) in India, the issues related to their research, standardization and Trade Related Aspects of Intellectual Property Systems (TRIPS) is documented in this article.

## ■ Scope of traditional medicines in India

The Indian Pharmacopoeia 2007 (IP) includes 26 medicinal plants [3]. The essential drug list for dispensaries and hospitals include 340 Ayurvedic drugs and 206 Unani drugs [4]. The Government of India has added ten Ayurvedic and Unani medicines into its family welfare

programme. They are used for anaemia; oedema during pregnancy; postpartum problems such as pain, uterine and abdominal complications; difficulties with lactation; nutritional deficiencies; and childhood diarrhoea [5].

The traditional medicines are used in chronic and debilitating disorders such as heart disease, cancer, diabetes and mental disorders. These drugs improve the quality of life and help to avoid iatrogenic problems [6]. In case of less serious ailments, one third of people in India prefer the Indian System of Medicines and Homeopathy. Moreover, one fifth of them prefer the Ayurvedic medicines. However, in case of serious diseases, only 18% prefer these medicines. About 14% of sick persons availed these medicines because of less adverse-effects, affordability, effectiveness and accessibility. The reasons for not availing these medicines were: less than expected effectiveness, unavailability of practitioners, no faith and unavailability of medicines. In rural and urban India, 40% and 30% of households visit the traditional healers, respectively. People prefer traditional treatment for ailments such as fractures, animal bites, jaundice, sciatica and measles. The preference of people to avail traditional medicines increases with the increase in income and literacy level [7]. The prescribing habits of the practitioners vary significantly according to the geographical location, practitioner's background and pharmaceutical advertisements [1]. Therefore a drug-utilization survey of the traditional medicine teaching hospitals and practitioners should be performed in order to evaluate the usage frequency of these drugs.

## ■ Contemporary issues of traditional drug use in India

In India, traditional medicines are followed under two streams, namely Local Health Tradition, such as tribal medicines and Organized System of Medicines, such as Ayurveda. The first one is based on the oral traditions in which many plants were selected on the basis

on trial and error in order to treat ailments confronted. The latter one is based on the codified written systems of medicine with their own theoretical and philosophical explanations. The research in the latter stream is better than the former one. The respect, preservation, maintenance and validation of drugs associated within the Local Health Tradition are seriously lacking. The research councils have documented over 10.000 of such folk medicines but the level of documentation in this area is still incomplete [2]. Therefore, there is an immediate need to promote, safeguard and involve such Local Health Tradition medicines. The tribal communities involved in the Local Health Tradition should receive enough funds and expertise to codify and preserve their drugs.

The Ayurvedic, Unani and Siddha drugs manufacturing and related matters are covered under the Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945. In July 2000, new regulations were laid down in relation to the standardization of traditional drugs. The requirements for infrastructure; manpower; quality control and authenticity of raw materials; and absence of contamination have been mentioned in the regulations. There are 9.000 licensed traditional medicine manufacturers. Those who satisfy the requirements can seek certification for good manufacturing practice (GMP). Those who cannot satisfy the requirements have two years to comply with and to seek the certification. Ten new traditional drug testing laboratories have been established by the Government of India. Moreover, the government is upgrading the existing laboratories so that high quality evidence can be provided to licensing authorities on the safety and quality of traditional medicines. This has substituted an informal system of testing that was considered unreliable and, thus would provide the basis for their international licensure as medicines rather than simply as food supplements [8]. Pharmexcil was established under the Ministry of Commerce and Industry for export promotion of pharmaceutical products including traditional medicines. Most of the traditional medicine exporters are in the medium and small scale sectors that needs assistance and guidance. The committee under the Pharmexcil provides guidance on heavy metal contamination and acceptable level for the same in the traditional drugs. Now, every drug should first fulfill the pharmacopoeial specifications before the drug is marketed due to the growing demand and trade of traditional drugs throughout the world [9]. However, quality control, rational usage, safety and efficacy of traditional medicines have not been completely assured till date. The enforcement mechanism has been documented in the Act, and is also in place in most of the States of India; however the implementation of the enforcement laws remains questionable. The good manufacturing practices are not followed by most of the drug manufacturers. The preparation of formularies and pharmacopoeial standards are on the move but it is not yet completed. There is no assurance whatsoever that formularies and pharmacopoeial standards are being followed by the drug manufacturers [6]. The adulteration and substitution of traditional drugs is a major problem in India. Sometimes people sell raw

herbs in an open market without any regulation. Moreover, raw herbs are dried in an unhygienic way prior to its processing in many pharmaceutical companies. People purchase unregulated medicines from the unlicensed vendors leading to irrational use of traditional drugs [10]. Therefore, the standardization of traditional drugs and enforcement of related laws should be emphasized more, both for domestic consumption and for export.

The pharmaceutical companies are not following the exact procedures of drug manufacturing as mentioned in Ayurveda and therefore the expected results are not achieved. Ayurveda addresses the issues of raw herb collection for the purpose of drug manufacturing. For instance, *Phyllanthus emblica* fruits should be collected during the months of March and April from the Himalayan and sub-Himalayan region as per Ayurveda in order to obtain the maximum amount of required constituents [10]. Thus, the pharmaceutical industries should follow the accurate procedure of drug manufacturing as per Ayurveda.

The clinical research on traditional medicine differs from conventional medicine. The economic evaluation of traditional medicines compared to conventional medicines is still lacking. The World Health Organization has provided guidelines for clinical research in the field of traditional medicine. Accordingly, it is ethical to proceed directly from basic animal toxicity studies to Phase III clinical trials in case of a traditional medicine drug with an established history of use [11]. However, ethical problems come while evaluating traditional drugs. For instance, while evaluating an anti-malarial traditional drug, the ethics may require the standard conventional drug to be given to all subjects which leads to evaluation of traditional drug in conjunction with conventional drug [2]. Therefore, some alternative models should be developed in order to evaluate traditional medicines within the clinical research. Moreover, the economic evaluation of traditional medicines, comparing them with conventional medicines should be started. This would help the health experts in making informed choices about the selection of medicines to be incorporated into the integrated healthcare programmes.

The Indian Council of Medical Research is conducting randomized controlled trials on traditional drugs which are monitored by the Scientific Advisory Groups. These groups consist of experts on the traditional and allopathic medicines; pharmacognosy; toxicology; pharmacology; clinical pharmacology; and standardization and quality control. Moreover, these studies are conducted in 20 allopathic clinical trial centers so that traditional medicines can be integrated into the usage system of allopathic hospitals. For example, *Picrorhazia kurroa* and *Pterocarpus marsupium* are found to be effective herbs in hepatitis and diabetes, respectively [12]. However, the research has never been reoriented and prioritized and thus, has not kept pace with the time [6]. Moreover, some pure traditional practitioners oppose this type of „modernization” especially when carried out by modern scientists in order to bring authenticity to Ayurveda by the amalgamation of modern research for further deve-

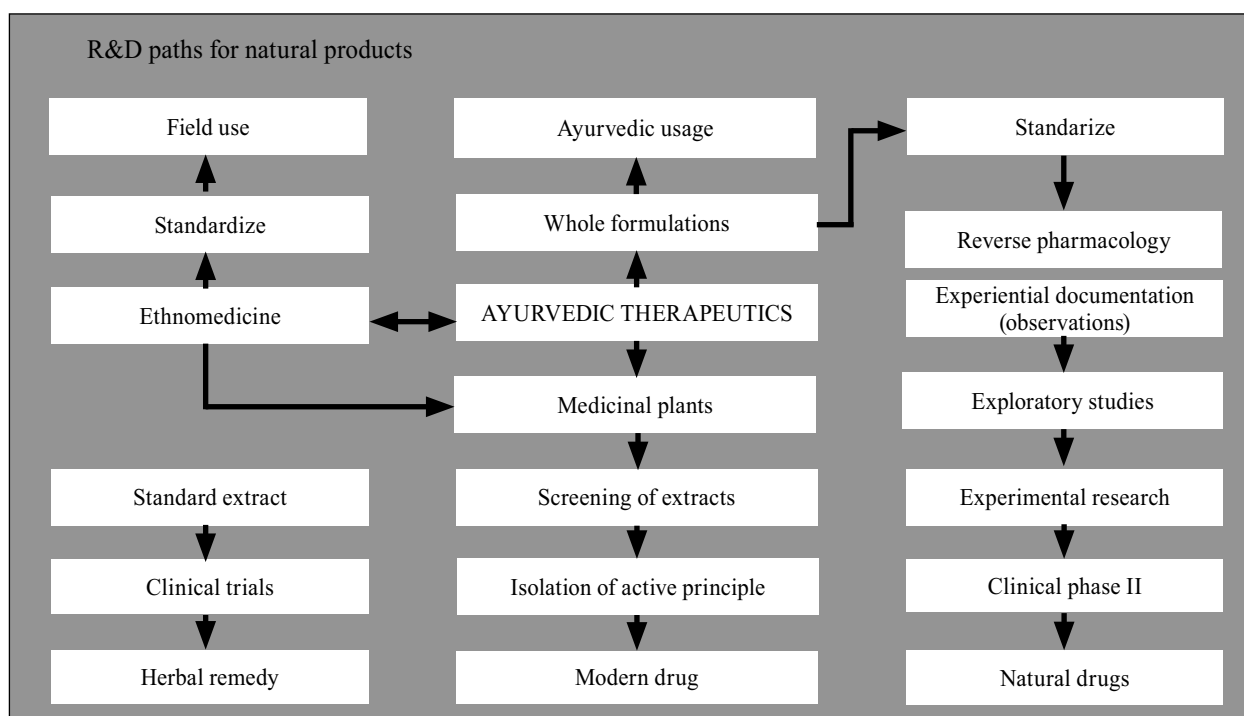
lopment. They agree to comply with modern concepts, such as conducting randomized controlled trails but advocate that not all traditional medicines need to undergo these rigorous trials as these medicines have been already in use for ages. Furthermore, the randomized controlled trial does not consider the philosophical concepts behind the traditional medicines, such as the body constitutions (prakriti in Ayurveda or Mijaj in Unani) of the individual which determines the specific medicine to be used [10]. Therefore, the research areas should be re-oriented and prioritized according to the strengths of the systems and contemporary relevance. Secondly, clinical trails should incorporate the philosophical concepts behind these drugs.

Most of the traditional medicines contain a number of ingredients. The research becomes more difficult to perform than that of single synthetic compounds, due to the presence of a large number of active constituents. Proper quality control evaluation systems are employed with the help of technological advances in the field of analytical chemistry. In order to properly identify the medicinal plants at the genetic, species, cultivar or variety level, there should be proper markers for quality control of the

plants themselves. The biological and genomic markers as tools for quality assurance can be used in addition to chemo-profiling. The move towards molecular and system level can be achieved with the help of institutes such as the Central Drug Research Institute (CDRI) and the National Botanical Research Institute (NBRI). The NBRI is presently engaged in examining the medicinal plants through either reverse pharmacology or ethnopharmacological approach. The Pharmacognosy and Ethnopharmacology division of the NBRI has been recognized as a drug testing center for traditional medicines and more than 160 single herbal drugs and a number of herbal formulations have been standardized by this laboratory [10]. Reverse pharmacology or observational therapeutics, emerging at the edge of modern and traditional medicine has been actively encouraged with utilization projects and centres for excellence, and research at all tiers of healthcare. The world may be convinced about the evidence-based traditional medicine by this approach. Many leads for drugs have been obtained by astute clinical observations in the field. The list of drugs obtained by the reverse pharmacology path is shown in the **Figure 1**, which could be an economical and effec-

#### Drugs obtained by the reverse pharmacology path

Indian		Other	
Medicinal plant	Disease	Medicinal plant	Disease
Rauwolfia serpentina	Hypertension	Catharanthus roseus	Cancer
Commiphora wightii	Hyperlipidaemia	Cinchona officinalis	Malaria
Mucuna pruriens	Parkinson disease	Digitalis purpuea	Heart failure
Picrorrhiza kurroa	Hepatitis	Salix alba	Fever
Curcuma longa	Oral cancer	Ephedra sinensis	Asthma



**Figure 1.** The reverse pharmacology path of obtaining traditional medicines (Source: Vaidya, 2005 [1]).

tive drug development path among diverse resource and development paths for traditional medicines [1].

The formulation of traditional medicines and medicinal plants has been mentioned in the ancient texts and treatises. This has attracted many foreign interests and unfortunately, a large number of such medicinal uses have been patented by the foreign entities, claiming them as „innovations” in spite of the fact that they are already available in the public domain and so cannot be patented under the Intellectual Property Rights (IPR). Unfortunately, the ancient texts and treatises are available in not easily accessible form and their language is different from the one which is generally used by the foreign patent examiners. For instance, Ayurveda has been written in Sanskrit which is tough to understand by the foreign patent examiners. The procedures for reclamation and competing patents are very costly and time consuming which ultimately hampers the India’s national interest [6]. The Trade Related Aspects of Intellectual Property Systems (TRIPS) of the World Trade Organization made no reference in order to safeguard traditional knowledge. Moreover, it had not acknowledged or distinguished the indigenous, community based knowledge, and that of the industry. The Convention on Biological Diversity contested recently with the TRIPS. The World Trade Organization in 2002 started harmonizing TRIPS and the Convention on Biological Diversity in order to protect indigenous intellectual and cultural property rights. Now the researchers who evaluate traditional medicines should be aware of the country of origin of the traditional drug under the IPR. Prior informed consent and just benefit sharing with the country of origin should be established in case patent is sought by a non indigenous group [2]. Now, the participating countries under the TRIPS have the freedom to select the intellectual property protection of plant varieties, either under a patent regime or a *sui generis* system or a combination of the two. In the *sui generis* system, an incentive is provided to the grass root innovator of the plant based knowledge in order to disclose knowledge. In India, a digital library for each system of medicine is under development in order to protect India’s traditional medicinal knowledge. It will eventually be performed for the uncodified knowledge leading to innovation and good health outcomes [6]. On the other hand, the research and policy on traditional medicines give more focus on the clinical and experimental medicine (safety, efficacy and mechanism of action) and also on the regulatory and supply-oriented issues. They lack the wider public health dimensions, such as social, cultural, political and economic, in order to enhance the contribution of the traditional medicine to the healthcare systems. The ethnicity, culture, familiarity and religion play a vital role in the usage of traditional medicine. The research on safety, efficacy and mechanism of action has received more importance from the funders than the public health research; because of the response the funders received from the biomedical community and not from the public health research community [2]. Therefore, in order to enhance the contribu-

tion of traditional medicine to healthcare systems, public health dimensions should be added to the research and policy. Moreover, political and scientific intents should focus on this issue.

The inter-sectoral cooperation with other Ministries and Departments, such as of Culture and Tourism, promote and propagate the traditional medicines by providing these medicines or reimbursing their costs [6]. People are paying huge amount of out-of-pocket expenses for traditional medicines which are mostly not covered under the available health insurances [2].

## ■ Use of alternative medicines in Europe

Apart from India, European countries also have many popular medicines. These medicines originated even many centuries before the era of contemporary modern pharmacology. They are often referred to as alternative medicines, which imply that these therapies are currently being used as a substitute to the conventional therapies. Other terms which are used for this kind of medicines are as follows: complementary, unconventional, unorthodox, related to irregular or integrative medicine. Some of them are more popular than others, depending on the country. The four groups of alternative medicines are particularly popular in different countries of Europe: homeopathic, herbal (phytotherapy), essential oils and flower remedies [13].

Homeopathic drugs which are currently used both in India and Europe, originated from the theories propagated by the German scientist Samuel Hahnemann in the XIX-th century. The homeopathic medicines are based on the principle of „like cures like”. Interestingly, these drugs have retained more popularity in India compared to most of the European countries. The phytotherapy is based on the remedies derived from plants and plant extracts, and it relies on principles which are shared with well-grounded modern science of pharmacology. The variety of currently used herbal products in Europe comes not only from this continent (e.g. traditionally used folk remedies) but also from far distant locations such as China or India. This includes herbs like *aloe vera*, *echinacea*, *garlic*, *ginkgo*, *ginseng*, *kava*, *feverfew*, *saw palmetto*, *St John’s wort* and *valerian*. The position of essential oils in the alternative medicine is much weaker in Europe, and the quite popular form of application of essential oils is referred to as aromatherapy. The health effects of essential oils are supposed to be both psychological and physiological. Moreover, these oils also work at the cellular level. In the present Europe, the foundation of flower remedies as a form of alternative medicine was laid down in the beginning of the XX-th century. The mechanism of action of these flower remedies is supposed to be through their „energy” and is not related to the scientifically grounded pharmacology. Therefore, some similarities of this therapy with the homeopathy can be found.

The formal status of availability of alternative medicines to patients is differentiated, ranging from pharma-

cies to the direct sale. They usually belong to the OTC (over the counter, i.e. available without prescription) category of drugs. Herbal medicines are more popular in Germany (30% of the OTC market) and France (28% of the OTC market) [14]. They are also quite popular in Poland and the Polish market of herbal products is on the second rank within the European countries (after Germany). The production of herbal products in Poland accounted for 4% of their global production. In 2003, the value of global market of herbal products was reported to be €20,000,000,000, out of which €7,500,000,000 accounted for Europe itself. At the same time, the value of Asian market was assessed to be €5,700,000,000 and the value of North American market was about €3,800,000,000 [15].

In some European countries, many herbal or even homeopathic products were used to be financed by the health insurance, especially until the late 90-s of the XX-th century. The reason for withdrawing many of these products from the reimbursement systems (such as in Germany) was the struggle to reduce the growing pharmaceutical public expenditures. There are some interesting historic justifications for inclusion of certain traditional therapies into the reimbursement systems. For example, when the NHS was created in the UK in 1948, all alternative medicines were excluded from the coverage of public funds, except homeopathic products due to the strong royal patronage [13].

The market of the alternative medicines within the European Union is growing, and the majority of expenses for these medicines are paid out-of-pocket by the patients. The WHO has issued the same recommendations for other countries (including the European ones) as in case of India, which relates to building of national policies and regulations on traditional (complementary and alternative) medicines. This would support the proper use of traditional medicines; integrating them into the national health systems; building or strengthening the pharmacovigilance systems to monitor herbal medicines use; and promoting sound use of these medicines by consumers and providers [16].

## Conclusions

The traditional medicine plays a vital role in both the Indian and European health care systems and needs more research and development with due consideration to the philosophical concepts behind them. The research should focus more on public health dimensions along with clinical research, reverse pharmacology and economic evaluation. The standardization of drugs, enforcement of related laws and TRIPS should be strictly followed. It would be interesting to see what kind of light will be put on a particular traditional medicine by the currently popular scientific approaches such as the Evidence Based Medicine or the Health Technology Assessment. This would provide more arguments in answering the question, if and which of the many traditional medicines or therapies should be covered by the national health insurance systems.

## Streszczenie:

### Miejsce leków pochodzących z medycyny tradycyjnej w indyjskim systemie opieki zdrowotnej

**Słowa kluczowe:** Ayurveda, Unani, Siddha, homeopatia, leki tradycyjne, Indie, Europa

Indie są jedynym krajem, który oficjalnie uznaje różnorodność systemów medycznych, w tym takich jak: allopatia, Ayurveda, Yoga i naturopatia, Unani, Siddha i homeopatia. Wielu Hindusów preferuje tradycyjne sposoby leczenia niektórych schorzeń, przy czym te preferencje nasilają się wraz ze stopniem zamożności i wykształcenia. Znaczna liczba tradycyjnych metod leczniczych została opatentowana przez podmioty zagraniczne, które następnie utrzymywały, że metody te stanowią „innowacje”, pomimo że były one już wcześniej publicznie dostępne. W ostatnich latach podjęte zostały w Indiach kroki zmierzające do ochrony praw własności intelektualnej i kulturowej, przystępujących rdzennej ludności. Także w krajach europejskich stosowane są tradycyjne leki homeopatyczne, ziołowe, olejki eteryczne czy środki oparte na kwiatach. Badania kliniczne leków tradycyjnych różnią się od badań innych leków, stosowanych badań farmakoeconomicznych zaś wciąż brakuje. Postępy w naukach medycznych powinny dostarczyć argumentów pomocnych w udzieleniu odpowiedzi na pytania, czy i które spośród leków tradycyjnych powinny być finansowane z publicznych środków finansowych.

## References:

1. Vaidya A.D.B., *Effective Integration of Indian Systems of Medicine in Health Care Delivery: People's Participation, Access and Choice in a Pluralistic Democracy*, Section II, „Financing and Delivery of Health Care Services in India” 2005, National Commission on Macroeconomics and Health, Ministry of Health and Family Welfare, Government of India, New Delhi, p. 77–87.
2. Bodeker G., Kronenberg F. *A Public Health Agenda for Traditional, Complementary, and Alternative Medicine*, „American Journal of Public Health” 2002, 92 (10): 1582–1591.
3. IPC, *Indian Pharmacopoeia Commission*, 26 Herbal Monographs to be Appear in IP 2007 (<http://ipc.nic.in/newsdetails.asp?nid=37>) Accessed it on 16<sup>th</sup> December 2007.
4. AYUSH, *Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy*, Ministry of Health and Family Welfare, Government of India (<http://indianmedicine.nic.in/index.asp>). Accessed it on 15<sup>th</sup> December 2008.
5. Kumar S., *India's Government Promotes Traditional Healing Practices*, „Lancet” 2000, 335: 1252.
6. WHO India, *National Policy on Indian Systems of Medicine and Homoeopathy: 2002*, World Health Organization 2002 ([http://www.whoindia.org/LinkFiles/Policy\\_ISM-homeopathy.pdf](http://www.whoindia.org/LinkFiles/Policy_ISM-homeopathy.pdf)) Accessed it on 4<sup>th</sup> October 2006.
7. Singh P., Yadav R.J., Pandey A., *Utilization of Indigenous Systems of Medicine and Homoeopathy in India*, „Indian Journal of Medical Research” 2005, 122: 137–142.
8. Bodeker G., *Lessons on Integration from the Developing World's Experience*, „British Medical Journal” 2001; 322: 164–167.
9. Pharmexcil, *No Ban on Ayurvedic Drugs in Canada or U.K.*, Pharmaceuticals Export Promotion Council, Ministry of Commerce and Industry, Government of India 2005, ([http://www.pharmexcil.com/v1/docs/PressReleases/no\\_ban.pdf](http://www.pharmexcil.com/v1/docs/PressReleases/no_ban.pdf)), Accessed it on 4<sup>th</sup> October 2006.

10. Gauniyal A.K., Rawat A.K.S., Pushpangadan P., *Interactive Meeting for Evidenced-Based Complementary and Alternative Medicines: A Report*, „Evidenced-Based Complementary and Alternative Medicine” 2005; 2(2): 249–252.
11. Chaudhury R.R., *Herbal Medicine for Human Health*, World Health Organization, Regional Office for Southeast Asia, New Delhi, India 1992.
12. Chaudhury R.R., *Commentary: Challenges in Using Traditional Systems of Medicine*, „British Medical Journal” 2001; 322: 167
13. Edzard E., Dixon A. *Alternative medicines in Europe*, in: Mossialos E., Mrazek M.e, Walley T. (eds), *Regulating pharmaceuticals in Europe: striving for efficiency, equity and quality*, Open University Press, Berkshire, England 2004
14. Mintel International Group, *Complementary medicines*, Mintel International Group Ltd, London 1997.
15. Guttman G., *Ziola pod kontrola*, Apteki Dbam o Zdrowie – Portal Zdrowia, 2008. ([http://www.doz.pl/czytelnia/a1041-Ziola\\_pod\\_kontrola](http://www.doz.pl/czytelnia/a1041-Ziola_pod_kontrola)) Accessed it on 15th of April 2008.
16. WHO, *WHO Traditional Medicine Strategy 2002–2005*, WHO, Geneva 2002.

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