IMPACT ASSESSMENT OF THMPD ON TRADE OF AYURVEDA PRODUCTS * *

By
Praful Patel, General Secretary
International Ayurveda Foundation

The western appeal towards India's natural wealth is perhaps as old as the history of Indian civilization. The colonists, travellers, traders and students from around the globe targeted India as a rich treasury of natural wealth and profound traditional knowledge. The travelogues of early years of the last millennium have described in detail about the art and science of healing prevailed in India in those days. The British Pharmacoepia has many drugs of Indian origin. Trade of spices, natural herbs and other agricultural products brought immense wealth to this country of ancient wisdom. A resurgence of the herbal trade in global arena was noted in the last two decades due to the popularity gained by Ayurveda, as natural wellness medicine.

Today, Ayurveda is fast catching the attention of the global community. Its holistic approach, its natural and mostly safe methods, its potential for taking care of global health needs are all recognized globally. Mainly the people from Europe and America have emerged as strong supporters of this age-old Indian wisdom.

Herbal Medicines Regulation in Europe, a preview

By early nineties, the practise of Ayurveda and other traditional medicines had advanced considerably and most of the medicines were sold as food supplements, cosmetics and health promoters, without any medicinal claims. In many countries of the EU, Ayurveda gained popularity as a wellness system that uses natural medicines and yogic exercises for healing and for promoting positive health. In countries like UK and Germany it developed fast and gained good clientele for minor ailments and for general well being. UK was one EU country where Ayurveda flourished well.

In the European Union, there had been an agreement that all countries would have their herbal industries and products under identical medicines controls by the end of year 1992. The only major country to achieve tight control was UK in the course of which most of the efficacious herbal products ceased to exist. Germany, France, Italy and Spain all had different degrees of light control and their product ranges actually grew. No unified market existed in January 1993 and no progress has been made towards it in the last decade.

An important product test case in Europe for a foodstuff "Cassis de Dijon" took place sometime in the late 1970s. The direction of the European Court was that any product legally sold in one country of the Union must be freely sold in all the others. However there was a proviso "as long as the product was safe and did not harm consumers". Most of the countries used this proviso to bar the products from other countries since their own authorities (experts) doubted the safety standards of such products. This created chaos among the public as to how a product can possibly be safe for the people of one country and not for the consumers of another country. This created a situation where the consumers of some country can sue their Government for permitting unsafe products to be sold and vice versa.

The THMPD is supposed to address these problems – unfortunately, the Directive which has been thus created still does not serve the purpose of a better regulation of traditional medicine sector, and will, in effect, prevent authentic traditional medicine from other countries to be available to the European population – which means that they will be deprived of availing the health care of their choice.

Of all EU countries, UK leads in the matter of legislative control for Herbal Medicines.

Since the introduction of the Medicines Act 1968, Herbal Medicines (Manufactured) are all supposed to be Licensed as Medicines but Herbal Medicines made of pure herbs and prepared by a Herbalist for patients are exempted under Section 12 of the act. This situation led to confusion, dating from 1975, and many manufactured products were and are being sold under section 12 exemption. The MCA of UK was unable to stop this from happening. When they tried to stop it in the early 1990s, there was an outcry from consumers and Medical Practitioners and the practice was allowed to continue under Section 12 (2) provided no claims were made for these anomalous products. Holders of Official Authorisations for Herbal Products objected and have been fighting the 12(2) exemption ever since. They want the Directive to clear the anomalous products from the market.

After the introduction of Medicines Law in 1968, thousands of herbal products went off the UK market during the 1970s and 1980s. They were driven off not because of their inherent dangers or lack of efficacy but because manufacturers could not afford to provide all the documentary proofs required to maintain the products on the market. Maintaining the products in the market needed huge financial resources, which the herbalist sector could mostly not afford. It was not just a question of producing one set of documents per product but maintaining their validity on five-year review when extra data was always needed. Same purity criteria were imposed on Herbal medicines as for the synthetic (allopathic) drugs. Hence, by 1992 the UK market showed a marked decline with regard to the Herbal medicines.

Traditional Herbal Medicinal Products Directive (Directive 2004/27/EC, amending Directive 2001/83/EC)

What is THMPD?

The Traditional Herbal Medicine product Directive (THMPD) is an amendment made to the EU Directive regarding medicinal products, the Directive 2001/83/EC, Directive of the European Parliament and of the Council, to include a new provision for traditional herbal medicinal products. It claims to offer a “simplified registration” for “Traditional Herbal Medicine Products” which are in use in the EU Countries, without going through the complex marketing authorisation process under the Community law. According to this amendment, those “Traditional Herbal Medicine Products” would receive a traditional use registration, if the applicant could provide the necessary evidence of traditional use for the specified time, and prescribed quality.

This is actually a sub-Directive, being part of the Human Medicines (Pharmaceuticals) Directive. It is intended only for those herbal products that are considered as “medicinal” and which have a history of traditional use. It came into force in Member States in October 2005, although provides a transition period up to 2011 before it is fully implemented. Products regulated by this Directive benefit from a fast-track drugs regime where the need to supply costly safety studies can be

avoided if it can be demonstrated that the product in question has been used safely over a period of 30 years, of which 15 must be in an EU Member State.

The key difficulty here is that many products from non-EU countries have yet to be used in the European Union and would thereby be excluded. They would then only be permitted if they were able to successfully pass through a full drugs regime, likely to be prohibitively expensive for most non-pharmaceutical manufacturers or suppliers. There is also a risk that herbal products, which should rightly be considered as food supplements will be considered by competent authorities in individual Member States as "herbal medicinal products." Particular combinations of herbal products may be disallowed and complex mixtures with significant levels of nutrients will be prohibited. Combinations with vitamins and minerals will only be allowed if the action of the nutrients is considered "ancillary" to that of the herbal ingredients. Significant compliance costs will apply, which will need to be passed on to consumers.

The legal route for Ayurveda drugs to the European Markets:

Once the Directive is implemented, there are two legal routes left for Ayurveda drugs to reach European consumer.

1. The Manufactured Ayurveda products may be supplied under medicines law:

- As licensed medicines. This requires proof of efficacy, quality and safety. Their supply may be as Prescription Only Medicine (POM) or Pharmacy (P) or OTC.

- As medicines exempt from licensing: until April 2011, when the Traditional Use Directive (2004/24) disallows it, products may be sold as medicines without a licence provided they make no claims at all and that they are named only by one or more of their ingredients. The ingredients must be herbal or not less inert than water.

- As medicines with a Traditional Use Registration: From October 2005, under directive 2004/24, it will be possible to obtain a traditional use registration for products that have been in medicinal use for more than 30 years of which more than 15 years must have been in the EU.

2. Non-manufactured products may be supplied as medicines:

- By a practitioner to a customer after a one-to-one consultation. These medicines may contain any ingredient other than those confined to licensed medicines. The section 12 (1) of the Medicines Law permits a practitioner to make and supply those herbal medicines, which are not prohibited or potent. This should be made by the practitioner in his premises and not to be placed on the market.

- As per the section 12(2), Practitioners may also request a manufacturer to supply products to the practitioner's specifications. Interestingly, the legislation does not define what qualifications a practitioner must have. The Dept. of Health proposes that registered herbalists, including Ayurveda practitioners, may be allowed access to some of the restricted herbs from 2006.

Traditional Use Registrations (TUR):

Any Traditional Herbal Medicine, which can be sold without the intervention of a practitioner, can apply for this, if it can provide the required data for quality and of traditional use history for a total of 30 years of which 15 years should be within the EU boundaries. The purpose of the Directive is to give a fast track registration to TM. But, the cost of obtaining a TUR in effect will be exorbitant. The estimated fee for registration of one product with four ingredients could cost as much as £75,000-100,000. With the market for these products being small at present, will not be registered and may go out of the market. Much of this high cost is due to excessive and inappropriate quality control requirements The suppliers of multi-ingredient products in EU - Ayurveda, Chinese and Western - consider that the regulatory requirements are excessive. The high costs will only be born by large companies with simple products and a large customer base. None of the Indian Ayurveda Companies can at present afford to bear this huge expense.

Impact of the Directive on Trade of Ayurveda

The unfortunate part of the Directive as far as Ayurveda is concerned is that Ayurveda drugs are considered within the ambit of this Directive, which is exclusively designed for regulating Herbal medicines, which are sold as OTC products.

The directive says, “The medicine applying for traditional medicine exemption should have indications appropriate for traditional herbal medicine products that are designed to be used without the intervention of a medical practitioner for diagnosis, treatment or monitoring purpose.” A vast majority of Ayurveda products uses raw materials other than herbs as active ingredients. Hence, they cannot be called herbal. By being classified herbal, many of the popular Ayurveda drugs will be prohibited from being sold as Traditional Drugs without authorisation. They will not be considered for traditional Use Registration either since they are not purely herbal.

The scope and limit of Ayurveda system of medicine cannot be restricted to a few trivial indications which the authorities find ‘appropriate’ for traditional medicine’. The recent researches and advancements in the system should be offered for public welfare irrespective of their geographic origin. Further only very few Ayurveda products can be safely dispensed as OTC products, especially among a public who is uninformed regarding the indications, actions and reactions and antidotes in case of ADRs. In short, this clause excludes the whole range of Ayurveda products that are required for a proper Ayurveda treatment by an Ayurveda Practitioner. It denies the European public the freedom of choice for Ayurveda medicines for their treatment purposes and poses threat to the existence of many small-scale Ayurveda drug companies in India, who are exporting these drugs to EU.

The major set backs for Ayurveda drugs due to the Directive against relevant recommendations are tabled below.

	RECOMMENDATION	IMPACT
1.	Role of an Ayurveda practitioner: The medicine applying for traditional medicine exemption should have indications appropriate for traditional herbal medicine products that are designed to be used without the intervention of a medical practitioner for diagnosis, treatment or monitoring purpose.	This will cover only those Purely Herbal OTC products. All Ayurveda essentially need the presence of a qualified Ayurveda practitioner to supervise and monitor the various physiological and pathological changes in the patient during various stages of therapeutic action of the concerned drug or therapy. In short, this clause excludes the whole range of Ayurveda products that are required for a proper Ayurvedic treatment by an Ayurveda Practitioner. It denies the European public the freedom of choice for Ayurveda medicines for their medical purposes.
2.	Route of administration: The directive excludes medicines that take any other route for administration other than oral, external application or inhalation.	All medicines that should be used for treatments like Vasthi (Medication through anal route), Utharavasthi (Medication through urethral and vaginal routes) are excluded and denied entry into the EU.
3.	Scope of the Directive: The directive only binds "herbal products" and the inclusion of other non-herbal biological and non-biological active ingredients are not covered.	The Directive would not allow for products that are combinations of otherwise legal ingredients (for example, biological products like honey, milk, ghee, other animal products etc.). This would leave many of the Ayurveda products like Chyavanaprasham, most lehas, all ghrithas, asavarishtas, gutikas etc. apart from many internally used oils like Dhanwantharam (101), all rasa preparations etc. which use other than herbal ingredients in a regulatory vacuum. The word ancillary in the directive is quite confusing, since there is nothing like an ancillary action for a medicine. Even though the therapeutic action of a drug is the combined effect of the total ingredients, Ayurveda identifies many drugs that have a supportive role in enhancing the action of other drugs in the specific combination. They may not have a direct pharmacological action, still their presence is very important in catalysing the therapeutic action of the drug. In such cases, the term ancillary may not suit even such ingredients since they are as important or even more.

4.	On efficacy: The directive insists that the OTC product licensed under THMPD should be labelled as "*the efficacy of the product has not been clinically proven, but relies exclusively on long term use and experience."*	This questions the scientific nature of the system of medicine that the product belongs to. Ayurveda products are mostly clinically proven within Ayurveda parameters by qualified Ayurveda practitioners in the Indian subcontinent for several decades. This clause will adversely affect the reputation of the science of concerned tradition, in our case Ayurveda.
5.	On safety: The applicant needs to present Bibliographic review of safety data, together with an expert report. There is a provision for the authorities to ask for "more data" to prove safety.	It is not justifiable asking for a safety data to be provided when the system itself is not defined or recognised in EU. Without defining who is qualified to be called as an expert in case of Ayurveda medicine, the experts can be a western herbalist who is not qualified for certifying Ayurveda medicine or an under qualified Ayurveda practitioner in UK/EU.
6.	On quality: The applicant should furnish all the quality requirements applicable to licensed medicines in EU.GMP requirements would be required of manufacturers, importers and licensing for the manufacturers, importers and distributors will be compulsory.	It will be difficult for most of the products to comply with the quality requirements laid down in the GMP. It is unfair that Traditional herbal medicines should undergo same quality requirements as other synthetic medicines while speaking of a simplified registration. Separate quality requirements should be defined for TM keeping in view its proximity to Nature and the positive effects it brings to an individual as a whole.
7.	About the positive list: The directive proposes a positive list of herbal substances with therapeutic indications, specified strength, route of administration and relevant safety information. This list should be prepared by a Committee for Herbal Medicinal Products that would be established by the Directive. The applicant can get the exemption from licensing without any traditional use data or safety data if the concerned herbal substance is in the list, but just providing a quality data.	A sample list circulated by MHRA contains about 200+ herbs and many of them will not be there in the positive list due to the lack of traditional use data. A very few number of Ayurveda products only will get through this list and the fate of most others will be in dark. Ayurveda uses more than 600 herbs in its medicines. The detailed bibliography is available in the Ayurveda Pharmacopoeia of India. To ensure safe and effective practice and trade of Ayurveda, the whole range of products enlisted in Ayurveda Formulary of India and Ayurvedic Pharmacopoeia of India should be granted a TUR accepting Traditional use evidence from India.

8.	Traditional use evidences: This is the most harmful clause in the Directive, which wipes off any chances of justice to non-European traditions. It demands that for a product to apply for traditional use registration, it should provide the sufficient data to prove that it has been in use for a minimum period of 30 years of which 15 years should be within the European Community.	This will exclude all the Ayurveda products, which do not have a documented usage history for 15 years in EU. Most of the purely herbal Ayurveda medicines that were used by practitioners for their treatments also will not meet this requirement due to • Those with history of 15 years use in EU also lack documented data since most of them are not labeled as medicinal products and are covered under Food Supplements or Cosmetics. Due to the restrictions for the legalized practice of the medicines with "medicinal actions" practitioners cannot claim for their medicinal action for a traditional use registration. • Due to less duration of usage in EU. • Besides, no new products could be brought to market even if they had been available for many years in another non-EU country with a good safety record. • Even those, which are in use for EU for over 15 years, would need to produce bibliographic and expert evidence of Traditional use. In the case of Ayurveda products since there was no statutory regulation for the practice, this evidences are either difficult to be collected from reliable sources or cannot be reliable as to their loyalty to the Science of Ayurveda.

The key issues briefly can be summarized as below:

a. Bans on the use of traditional 'combinations' that have been safely used for thousands of years in Ayurveda.

b. Bans on animal products used in traditional medicines that have been safely used for thousands of years in Ayurveda.

c. Forcing Ayurveda products into a medicinal regime owing to a perception of toxicity of ingredients, without consideration of dosages used.

The smallest companies will be the hardest hit and all may go out of business, causing reduction of consumer choice, and the eclipse of the holistic values of Ayurveda and the adoption of an ideal system of medicine. The high cost of

compliance will increase the tendency for avoiding open market and promoting Internet marketing. Thus, the potential safety benefits that the regulation intends to offer the consumer will be lost. The inherent dangers of conventional medicines, which justify detailed and expensive regulation, is blinding the regulators to the long and generally safe history of the use of natural traditional remedies for which such detailed regulation is inappropriate. Lack of proper regulations has since time long encouraged the traders of Herbal medicines to market any product in the name of Ayurveda. The only solution to effectively check this misbranding is to enforce a suitable regulation for controlling the manufacture, trade and dispensing of Ayurveda and similar TSMs But it is a challenging task in itself to visualize proper regulations for Ayurveda medicines. This can only be possible by a well-organised bilateral initiative between the EU Authorities and Indian Government, with substantial input from the Indian Ayurveda think tanks. Without authoritative technical assistance from Indian Ayurveda Community, it is impossible to accomplish this task ever in future as well.

At this time when WHO is actively promoting the development of traditional and complementary medicine as a valid way of combating ill health throughout the world, and particularly in developing countries, it is imperative that the European regulators also give due consideration to traditional medical knowledge systems like Ayurveda and not weigh them on the same scales as western medicine. The directive is not adhering to the issue of proportionality, which is one of the main mottos of Good Regulation. It will limit trade between the EU and other countries by making the standards too high to meet for the majority of manufacturers.

We believe that the MHRA who was given the task of drafting the directive was not able to do sufficient justice to Ayurveda and other such systems. The public consultations made were not wide enough to fulfil such a Herculean task. Active involvement from Indian Ayurveda Experts were never sought officially. The pleas for inclusion of traditional medicines other than herbal ones were repeatedly turned down, without even a proper hearing.

The MHRA published a summary of all responses to MLX 318 with own comments on the different issues raised by various parties. Disappointingly, the Agency rejected the many valid points and suggestions made by those who participated in the consultation and bluntly stated: “Having considered the comments made in response to MLX 318, the Ministers have decided to make no further changes in response to this latest consultation”.

With reference to the suggested change of title for the committee for Herbal Medicine Products to include the major systems of Traditional Medicines like Ayurveda and Traditional Chinese Medicine, the MHRA stated: “There is no current policy intention to set up distinctive regulatory arrangements designed specifically to cover the overall range of medicinal products used in traditional medicinal systems, whether in traditional medicines as a whole or for individual medicine systems such as Ayurveda or traditional Chinese medicines.” They also shut the door to further negotiation by saying,“….we think it would be unhelpful to risk creating an expectation that there will be separate regulatory arrangements set up for the full range of medicinal products used across whole traditional medicines systems.”

However, the EU and the UK Government impact assessment of this legislation falls short of two more impact assessments that need to be done thoroughly: 1) whether this legislation is in accordance with the WTO rules and Traditional Knowledge protocol; 2) whether they have given adequate consideration to study race and human rights impact of this legislation. WTO/WHO defines Traditional Knowledge Medicine as "Traditional medicine includes diverse health practices, approaches, and knowledge and beliefs incorporating plant, animal and/or mineral based medicines, spiritual therapies, manual techniques and exercises, applied singularly or in combination to maintain well-being, as well as to treat, diagnose or prevent illness." Traditional knowledge should be recognized in the form and concepts of the traditional medicine system of a particular country, and not necessarily on a western model.

The present scenario seems to be very dark for Ayurveda in EU. This will increase black marketing and Internet sales, which are more harmful for the public. At the same time, the reputation of the Traditional Systems like Ayurveda will be at stake, and getting an official recognition at that stage will be infinitely remote! It is a now or never situation for the providers and consumers of Ayurveda in EU.

Once the THMPD is enacted, three kinds of herbal medicinal products will be there in the EU market.

1. The products with Product Licences and full Marketing Authorisation under the 1968 Medicines Act.

2. Products with established traditional use under the THMPD.

3. Products that are not considered Medicinal by function and have no labelling or promotional medicinal claims to bring them into the medicinal category.

The first two categories will be legally authorised but the third will remain on sale without a legal classification as medicines. This means that most products will continue to be sold freely as now avoiding the Law. The proviso being that no overt claims are made for them and they are not considered medicinal by function. Since the authorities think most Herbals ineffective, they will be reluctant to make them medicinal by function since that means that they acknowledge their effectiveness. If a company registers a product under the THMPD, that apparently does not preclude others from selling the same item without claims and thus without authorisation. This questions the whole purpose of the regulation.

There is only one permanent solution to this critical issue. A separate Directive has to be designed for Traditional Systems of Medicines. Individual systems should have recognised statutes under this Directive for regulation of the practise of their medicines. Separate clauses should be designed for various categories of ingredients considering the specifications of various Traditions. This is the need of the time.

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