IMPACT OF THE TRADITIONAL HERBAL MEDICINAL PRODUCTS DIRECTIVE (THMPD), THE NEW CHALLENGE FOR GLOBAL AYURVEDA

BY DR. VIDHI BAPNA
ON BEHALF OF INTERNATIONAL AYURVEDA FOUNDATION, UK, INDIA AND SWITZERLAND

My salutations to all my Ayurvedic friends who are present here in this glorious stage where tradition meets the latest trends in the quest of the greatest wealth for humanity; A healthy life!

I stand before you on behalf of Mr. Praful Patel, the General Secretary of the IAF, who is an Ayurvedic activist – that is how he likes to associate himself to this ancient science of life - for whom Ayurveda is not a profession, but a passion. His profession is doing service to Goddess Laxmi, who provide us with wealth but my passion lies with Dhanwantari, her brother, without whose blessings there is no use in having her with you!). Mr. Praful Patel is supported by many scientists and Ayurveda experts on the Board of Directors in London, Bombay and Geneva. I have been asked to convey warm greetings from Dr. Vishal Gulati and Dr. A.J. Baxi, Chairmen of IAF respectively in London and Bombay.

I am deputing on behalf of Praful Patel, who could not come due to previous commitments, to present some of IAF thoughts on the impact of the THMPD and the new challenges for Global Ayurveda.

IAF has been seeing many of you in many similar platforms for the past over 5 years in connection with this mission we have begun in 2003 in service of Ayurveda. I entered the arena about a year ago as a stalwart soldier of the great fight to gain Ayurveda its due recognition among the Scientific Medical systems of the globe which serve humanity helping them to maintain and promote health and to prevent and cure illness. Way back in 2003 when we formed IAF, the picture seemed to be much colorful and atmosphere so very pleasant with many of our Ayurveda friends and the Government of India authorities being more proactive and contributive. As the time passed by, the enthusiasm in Ayurvedists unfortunately, was getting died, and for us personally it was an army of many professional scientists, academicians, well known physicians and others. Lord Dhanwantari did test our endurance and perseverance with a couple of major health jolts that Mr Praful Patel experienced in the last 2 years. Here I am like a phoenix, standing in front of you with the same

appeal for your co-operation, your active participation in this battle for our own self esteem, and preservation of our heritage.

Some History:

The story has been old by now, but its impacts and fatality hits our age old science in new avatars every day! The assault began officially in June 2002 when the MHRA on behalf of European Union issued a consultation letter MLX 283, with a deadline ending on July 25th 2002 regarding the implementation of THMPD. We managed to respond in time and followed up extensively with the help of many renowned Ayurveda experts from all walks of Ayurveda trade and practice. The rest is history, and presently I am glad that the GOI and many other NGOs within and outside India and EU showed interest in understanding the issues and the gravity of the situation, I feel our efforts paid off if we the entire Ayurveda community of the globe stand up now, it is late, but not lost; and tell the anti Ayurveda elements in no uncertain terms that we are not going to take this anymore and we will fight our way out to the recognition due for the world's oldest system of medicines which have been helping ailing humanity for over 30 centuries, and many more to come!

Since the introduction of the UK's 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.

What is THMPD?

The Traditional Herbal Medicinal 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.

By the end of the transition period in 2011, any Ayurveda medicine, if need to be made available in EU market, it has to go through either a marketing authorisation, which is prohibitively expensive due to the extensive dossier requirement for safety, efficacy and quality in the lines of the synthetic drugs. The only other route is to obtain a Traditional Use Registration or TUR, showing the evidence that the product is safe, is of prescribed quality and has been in EU market for the last 15 years and in total the drug has been in use for 30 years in some part of the world or other! This sounds to be simple, but the various intricacies of getting a TUR is as good and cost prohibitive as getting a Market Authorisation as a drug like any other synthetic drug!

Our mission today is to briefly highlight the most crucial threats the Directive poses to Ayurveda. The allotted time is too little to get into the details of the Directive and its after effects, but I am just trying to highlight a few important points which may be fatal to the trade of Ayurveda drugs in the EU in future. A document titled "Impact of THMPD on Trade of Ayurveda Products", which was commissioned by the Government of India and presented to the European Union is being distributed at the conference, if you like to pick up a copy.

Traditional Use Registration (TUR) - what it is and how it is given:

Before getting into that let me throw a little light into TUR the so called fast track registration. 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 basic and most relevant issue we have against this Directive is that they have included Ayurveda which is a system of medicine, using a wide variety of raw materials of herbal, mineral, animal and marine origin within the ambit of a Directive meant to regulate the trade of purely Herbal medicines, which are to be “sold” (remember the difference between medicines prescribed and sold) OTC without the intervention of a medical person! 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 authorization. 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. We all know that 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. (An Ayurveda friend of mine keeps quoting from time to time that a drug which is used improperly by a person who does not have thorough knowledge of it is as good as a poison, and even poison used by a person who has thorough knowledge of it can save life as an ambrosia!!- you all know it better!!)

The Directive through its restricted scope for OTC products 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. Classification of drugs as OTC products will give room to many more Robert Saper and his group of so-called experts at the Boston Medical School to randomly pick up samples from General stores and tell us that they contain heavy metals!!

The other high lights of the directive and their impacts are summarized as below:

1. **The Directive closes the door for all new Ayurveda products in the EU market, unless we obtain a Market Authorisation, which is absolutely impossible due to cost factors.**
2. **The dossier requirements to obtain the Traditional Use Registration are very stringent in terms of safety and quality which are drafted primarily for synthetic drugs. (The directive shares the relevant clauses with the mother Pharmaceutical Directive). Most of the Indian manufacturers will find it prohibitive to even apply for the TUR.**
3. **The Committee for Herbal Medicine Product has the power to relax the Traditional use time limit, but for that the data requirement is again not rational to be asked from the products**

which are currently not sold as medicines or under any kind of pharmaco vigilance. The dubious products which misutilized the loopholes and were using the label of Ayurveda products should be distinguished well and the current EU system does not have the technical strength for this duty.

4. **The proposal for a positive list is a small silver line seemingly, but again the EU is not technically equipped with man power for accomplishing this task and there are no Ayurveda experts in this Committee, they solely rely on the many Ayurveda practitioners in the UK and EU whose expertise and experience cannot be relied on due to the situation prevailing in Europe till date.**
5. **The 15 year rule is very discriminative to all non EU traditions including Ayurveda and Traditional Chinese Medicine, the two most popular Traditional Medicines in the world. To put it bluntly, it's a huge joke.**

We at the IAF have been campaigning widely since 2002 July to give a wake call to the sleeping Ayurveda Trade and Commerce Industry as well as the Practitioners! The peace loving followers of Dhanwantari however invariably go back to their peaceful life for "roti-kapda-makan" - leaving us alone to do all the fight! UK government has been trying to woo the mutually fighting Ayurveda groups in EU to get support for the Directive. Luckily there are some organizations who have been using all the ways of diplomacy and one off protests to get the message through even though not with much of a hope! Recently we have heard that our partners Alliance for Natural Health, whose representatives are here and may throw more light on the current situation, have been campaigning for an amendment to THMPD. Government has tried to paint the directive white by incomplete Impact Assessments. However, the EU and the UK Government's 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 authorized 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 authorization. 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. This is what we are pursuing relentlessly with the EU authorities.

What needs to be done?

1. We are considering to launch a legal battle in the lines of violation of our basic human rights to choose and avail the system of medicine of our choice. Thousands of people across EU are denied the drugs of their choice!

2. Discrimination against non EU traditions should be condemned and GOI should be persuaded to raise the issue in world forums like Commonwealth, WHO etc.

   Issues of trade between India and EU and issues related to WTO rules and Traditional Knowledge protocol should be looked into by a suitable committee which needs to be set up with experts by GOI.

3. Strong campaigning and protests by friends of Ayurveda round the globe. Each drop counts in the making of any ocean. All of us have to pledge to give our best to gain our traditional treasure its due respect and recognition and save our trade and professional interests as well by demanding for a proper regulative mechanism suitable to the specifications of Ayurveda.

Mr. Praful Patel has a strong message for this conference. He strongly feels that this is a second battle against the British and European Union Authorities for self esteem and for guarding our culture and heritage. His slogan for this conference is “Jaagte Raho India!!” The last nail in the coffin may be stroked in anytime!!

Thank you for patiently listening to me. If you wish to join as an Associate of IAF, you are most welcome to fill up the form, which I will gladly provide you with.

Note:The research for this paper/speech and the presentation as follows was done by Praful Patel and Dr. Hemalatha Potti.