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The Regulation of Herbal Medicines in Europe

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The markets for herbal medicine come under overarching laws in Europe. In the course of our work providing regulatory compliance services, UK based Avena Consultants Ltd receive many enquiries from Indian Ayurvedic manufacturers, who would like to launch products in Europe. The regulatory environment is challenging for such products and this article outlines European law in the context of Indian botanical health products.

Summary of EU Law

The EU is made up of 28 member states acting as a single trading market and as a result product law is drafted by the European Commission (EC), based in Brussels, Belgium. These directives and regulations are then transposed directly into each national states' law.

The challenge of using botanicals in products can be substantial, especially if they are non-European, ideally if they can be defined as food supplements then that is the easiest route to market. However there are also Nutrition and Health claim laws covering what you can say about a product. The second challenge is even if the herb is used as a food in India, the EU Novel food legislation stipulates that only foods that have been eaten by Europeans in a significant way pre 1997 can be deemed foods (for use in food supplements). Any food deemed novel most go through a long and complex scientific safety application which can take 2 to achieve. When we bear in mind that in the UK we only eat 33 different plant species compared to an average of 200 plant species in the Asian diet, we can see the challenge.

If the product is not defined as a food in European law the other option is to go down the traditional medicine license route. Traditional Herbal Medicinal Directive (THMPD) 2004 stipulates that only herbs that could be proved to have been on the market for 30 years (15 of which in Europe) can be licensed as traditional herbal medicines. There are only about 600 Traditional herbal products registered across the entire EU. The majority are one herb products, and of the multi-combination products, rarely do they exceed more than 3 herbs. Of these 600 products on the market only 133 different herbs are being used and the vast majority are solely European, because proving market use in Europe for 15 years is a major challenge for Ayurvedic and Traditional Chinese Medicines (TCM). Traditional Herbal Medicines are also over the counter OTC medicine only, to be used for treating minor conditions. If a traditional medicine does not fit the THMPD criteria, but is considered a medicine not a food, it would have to go through a full pharmaceutical style license process, which can be complex, timely and expensive to achieve.

Many now argue that EU laws relating to botanicals conspire to stifle innovation and prohibit the import of useful herbs and plant foods from non-European countries.

Traditional Medicine and European Approaches

In India, traditional Ayurvedic practice and over the counter (OTC) Ayurvedic medicines are extremely popular and well accepted. In Europe Ayurveda is also popular, particularly amongst the large Indian immigrant communities living in urban Europe. The challenge is that allopathic medicine is the main form of health service provision and it dominates European approaches to health. The main orthodox argument is that evidence based medicine is the only validator and that the efficacy of allopathic medicines using the gold standard double blind placebo trial method is far superior. This method suits studying the efficacy of isolated constituents on very specific conditions. However traditional approaches to medicines encompass much more holistic approaches to evaluating health and administering medicine. The allopathic approach to medicine has also been transcribed into the laws that govern both healthcare and medicines in Europe. In order to meet the requirements of these laws, traditional products and practices must follow a type of standardisation and evaluation that is often more suited to pharmaceutical drugs and allopathic treatment approaches.

The Europe the promotion of traditional medicine generally takes two approaches; the first is to argue that traditions spanning back thousands of years are valid in and of themselves and if they are evaluated, new methodology beyond that of the gold standard trial should be explored. The other approach is to attempt to validate traditional medicines and practice by meeting the regulatory and scientific expectations of the mainstream. There are organisations

in Europe promoting Ayurveda, such as the European Ayurvedic Association (EUAA) which was set up as an umbrella organisation (est. 2006) with a membership drawn from European Ayurveda Clinics, Education Institutes, Manufactures and Distributors¹. The EUAA state ‘a viable start could be an active participation in the development of EU pharmacopoeial standards for Ayurvedic plants and excipients. The quality definitions of the Ayurvedic Pharmacopoeia of India (API) for defined herbal drug substances and/or excipients could be updated to Ph. Eur. standards, thus paving the way for a commitment of the EU to accept Indian pharmacopoeial standards as equivalent to Ph. Eur. Standards’ .There are also organisations such as the Alliance for Natural Health, who robustly defend traditional medicine practices and have been very active at challenging the laws introduced to regulate herbal medicines in Europe, arguing it is the regulatory model, not traditional medicines that requires amendment^{2, 3}.

European Legal Definitions

What is a food supplement?

“Food supplement means any food the purpose of which is to supplement (taken in addition to) the normal diet and which –

- a) is a concentrated source of a vitamin or mineral or other substance with a nutritional or physiological effect, alone or in combination; and
- b) is sold in dose form”. Such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids or powders designed to be taken in measured small unit quantities”.

Food supplements must be made to the principles of food law.

What is in food supplements?

There is a wide range of nutrients and other ingredients that are allowed to be used in food supplements in Europe. There is a positive list of approved Vitamins and Minerals. The Food supplements directive describes compounds other than vitamins and minerals as ‘Other Substances’ these can include: Amino acids, essential fatty acids, enzymes, fibre, phytonutrients, various plants and herbal extracts. These ‘other substances’ are entitled to free movement throughout the EU, but often come up against obstacles at both EU and national member level, where diverging, incompatible interests and ordering systems occur. The

¹ <http://www.euroayurveda.com/index.php?id=8>

² <http://www.anh-europe.org/campaigns/protect-traditional-medicinal-cultures>

³ <http://www.saveherbalmedicine.com>

challenge is that there is no harmonised list of what plants can be used in food supplements across Europe, each member state has their own take on this. For example the herb, *Garcinia cambogia* (*Cambogia gummi-guta* L) is used traditionally in Ayurveda for bowel complaints, but is now popular as a slimming aid in Europe. In the UK the fruit is acceptable in a food supplement, but an extract of Hydroxycitric acid (HCA) from the rind is considered a medicine. Both the fruit and HCA extract are considered medicines and prohibited in food supplements in Czechoslovakia, Denmark, Estonia, Italy, Malta and Sweden, but the fruit is also acceptable in food supplements in Croatia, Germany, Romania. When we consider most formulations have multiple ingredients, then the challenge of defining the product's regulatory route in Europe is apparent.

What is a novel Food?

Regulation (EC) 258/97 placing on the market of novel foods and novel foods ingredients. Defines novel foods as edible substances not been on the EU market to a significant degree before 1997 in Europe. Such foods require a novel food application, a complex scientific dossier; on safety, metabolism, properties and safety. The dossier is submitted to the novel food division of one of the food standards agencies in the 27 EU states. They assess it and then forward it on to all 27 other food standards agencies so they can assess it to. If the assessment is favourable, then they will approve the food, but only to the company that has done the application. Other companies can then do equivalence application (e.g our product is similar) this process can take 2 years. It is there for off-putting in a commercial sense.

The EU Register of Nutrition and Health Claims

This register records authorised and non-authorised health claims assessed by European Food Standards Agency (EFSA) under the EU Nutrition and Health Claims regulations. All health claims must be authorised for use. Claims that are never permitted Include: Suggestion that health will be affected by not consuming the food, reference to recommendations of doctors, health professionals or medical type organisations. Between 2006-11 the EFSA consolidated 32,000 health claims into just 200 odd positive opinions. Botanicals are still under review by the EFSA, as their status is on hold, making commercial claims on botanical products can be difficult. It should be noted an authorised 'health claim' on a food is not the same as a medicinal claim.

What is a nutritional claim?

Any claim which states, suggests or implies that a food has particular nutritional properties due to the energy (calorific value) it provides, provides at a reduced or increased rate, or does

not provide; and/or the nutrients or other substances it contains, contains in reduced or increased proportions, or does not contain E.g. Fish is an excellent source of protein.

What is a Health Claim?

Any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health. Either by:

a) The role of a nutrient or other substance in growth, development and the functions of the body; Psychological and behavioural functions; Slimming or weight control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet ‘reduction in risk of disease’ (if authorised) claims does not overturn the food law prohibition on claims which state or infer that a food can treat, prevent or cure disease. E.g Contains plant stanols to help maintain cholesterol is ok, but saying plant stanols treat heart disease would not be ok.

What is a Medicine?

Medicine: Article 1 of Directive 2001/83/EC as amended defines a “medicinal product” as:

(a) “Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; [“the first limb”] so for example if you sold water but said it was for headaches, this would make the product a medicine, because ‘headache’ is seen as a medicinal claim.

(b) Any substance or combination of substances which may be used in, or administered to, human beings, either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis” [“the second limb”]. This means if a substance is considered medicinal in action, the product will be viewed as a drug. This often is defined by the form the substance comes in as well as accepted activity of the substance. For example Tumeric is a food, but a concentrated Tumeric extract for the treatment of cancer would definitely be viewed as a medicine.

Medicines must be licensed; in the UK companies apply for a marketing authorisation (MA) through the Medicines and Healthcare Regulatory Agency (MHRA). This requires a scientific dossier, on safety, quality of manufacture, pre-clinical and clinical studies on efficacy. Such an application can take 6 months or more to compile, 6 months or more to assess and cost between £200K-1M to achieve hence most companies work hard at formulation stage to avoid their product being a medicine in law. There is however a more simple abridged

application route for generic medicines that have been on the market for 10 years or more.

What is a traditional Herbal Medicinal Product?

This is a product that can prove the active ingredient(s) are herbs/botanicals that have been traditionally used for particular indication. E.g Echinacea (herb) for the traditional treatment of colds and flu (indication). In mainstream medicines law the product must be proven to be efficacious (it works) by way of clinical trials. For traditional products this is replaced by a requirement to demonstrate 30 years traditional use for the required indication. 15 of these years must have been in the EU. In reality very very few botanical products, especially Indian ones fit with in this legal definition. However the fees and cost of a traditional herbal registration are significantly lower than a mainstream marketing authorization (MA).

Manufacturing Standards

ALL food supplements placed on the European market must be manufactured to HACCP ISO 22000:2005 and ISO 9001:2008 Standards. HACCP focuses on hazard prevention throughout the food chain rather than relying on end product testing.

ALL herbal medicinal products, like all medicines have to be manufactured to Good manufacturing Practice (GMP) standards. Here in Europe, products must be manufactured to EU GMP Directive 2003/94/EC. This is not the same as WHO (world health organisation) GMP, which is often used in Asian countries. It is also not the same as US GMP, referred to as cGMP overseen by the FDA. All these systems have similarities, but ultimately you need the GMP certification to suit the economic area where you want to sell the products.

Conclusions

For any Indian company who wishes to market their health products in Europe. We strongly suggest engaging expert compliance consultants at the formulation stage, who can advise on key considerations such as what ingredients or formulas will work in terms of compliance as Food Supplements in Europe and what could be viable for the a Traditional Herbal Medicine license. The next step is to ensure the product is meeting manufacturing standard requirements for Europe. There are a few glimmers of hope on the horizon for example the European Commission has drafted new amendments for the novel food regulations to ensure that special provisions are also made for food which has not been marketed in the EU but which has a history of safe use in non-EU countries. This creates a more balanced system and a positive environment for trade, this will no doubt be positive for Indian health products. In

terms of a more general acceptance of traditional medicines there is a cultural shift in Europe towards self-care as the population ages and governments cannot afford allopathic end treatments for this ever more sizable group. At present the situation is difficult but not impossible in the future we think it will change and become less protectionist.

Authors Column



Chantel Henderson (Herbal Medicine BSc Hons, NIMH) is an award-winning expert in international regulatory compliance for marketing and exporting herbal medicines and health supplements. With the ten years of experience in Market Research, Regulatory and Policy advice in medical device, emerging technology and natural product industries, across multiple markets. Chantel is the Managing Director of Avena Consultants Ltd, www.avenaconsultants.com A UK Scientific, regulatory and therapeutic product compliance service. She has a passion for natural products and helping companies bring them successfully on to the market by delivering regulatory insight and strategy.

