Introduction

Over the last twenty years, many people in the developed countries, whose health care modality had so far been satisfied by the orthodox medicine, began to look to complementary medicines in ever increasing numbers. The popularity of the complementary medicines has been phenomenal by any stretch of imagination.

One medical professional association amended its perception of the level of interest in the complementary medicines from a “passing fashion” to recognition of their existence and called for improved training and education for those who practice them (BMA 1986, 1993).

The Directive

The Directive is on the traditional herbal medicinal products. It aims to develop a Europe wide legal framework to manage the herbal medicinal markets to assure public safety.

The underpinning philosophy is to give recognition to those herbal medicinal products if they have been used for at least 30 years, by licensing them as traditional herbal medicines.

These products will not need to undergo the full procedures of clinical trials to prove their efficacy. Instead, the Directive proposes to license these products based on evidence of safe traditional use.

However, the Directive does expect the products to have undergone similar quality and safety processes and control as other medicinal products. The thirty-year rule includes 15 years of continuous use within the EU for the non-EU products.

Both the practitioners and the suppliers of all ethnic herbal medicines should welcome this development. In addition to vigilant and facilitative efforts of UK’s medicines control agency (MCA), the Chinese Medicine Association of Suppliers (CMAS) has long lobbied for a clearer and stronger control to give them a level playing field against the suitcase importers and to give them the confidence to invest effectively and efficiently in this very competitive field.

The Directive focuses on the herbal products exclusively. The combined herbal medicinal products such as patent medicines that may contain minerals and animals appear to have been left out for some unknown reason.

It is also not aimed at the homeopathic products. The proposed Directive appears to create as many issues as it
Traditional Chinese Medicinal Herbs in the UK

In the UK, traditional Chinese medicine (TCM) is increasingly popular. Many sufferers enjoy an improved quality of life as they obtain relief from using TCM for their chronic conditions.

Three universities offer full-time undergraduate programs in TCM with many thriving private schools. On average, there is at least one inquiry per week seeking information on setting up a TCM import or export business or setting up clinics.

These inquiries come from the TCM manufacturers, the health companies and individuals. As this article is being written, a major international company has just set up a TCM business in the UK with different focus from the traditional formula of setting up a TCM clinic business.

The TCM herbs along with other medicinal herbs have so far been exempt from licensing requirements under the Medicines Act 1968 sections 12.1, 12.2, 51.1 and 51.2 which states that:

a) the remedy is manufactured or assembled on premises of which the person carrying on the business is the occupier and which he is able to close so as to exclude the public, and;

b) the person carrying on the business sells or supplies the remedy for administration to a particular person after being requested by or on behalf of that person and in that person’s presence to use his own judgement as to the treatment required.

Section 12.2 exemption applies to the “over-the-counter sale of herbal remedies stating that the licensing requirements “do not apply to the sale, supply, manufacture or assembly of any herbal remedy where the process to which the plant or plants are subjected consist of drying, crushing or comminuting, with or without any subsequent process of tableting, pill-making, compressing or diluting with water, but not any other process.”

Section 51.2 states that “The restrictions do not apply to the sale or supply of a herbal remedy sells or supplies it for administration to particular person after being requested by or on behalf of that person or in that person’s presence to use his own judgement as to the treatment required”.

The exemption is only for the dried herbs and mixing them with minerals and animal parts is not permitted. Similarly, these herbs cannot be called medicines as they are not licensed and in the UK, they are referred to as “herbal tea”.

There is an element of cat and mouse play. The public know that these herbs prescribed by the TCM practitioners have medicinal properties and are therefore, medicines whilst referring them as “herbal teas”. The public is the willing collaborator to this duality. As already alluded, the lack of adequate control poses serious problems to both the MCA and the suppliers.

It is also true that as a result of mis-authentication of the herbs in the herbal slimming products, many thousands people were taking Aristolochia fangchi instead of Stephania tetrandra.

Consequently, many have developed end-stage renal failure (WHO, 2000). This happened in Europe. In the UK, two patients also suffered end stage of renal failure following intake of TCM herbs that included the mistaken specie Aristolochia fangchi.

Traditional Medicines — A WHO Perspective

According to WHO, traditional medicines (TMs) include a diversity of health practices, approaches, knowledge and beliefs incorporating plant, animal, and/or mineral based medicines…. to maintain well-being, as well as to treat, diagnose or prevent illness (WHO, 2001). TCM falls within this broad definition.
WHO also exhorts countries, in particular the underdeveloped countries, “to identify safe and effective remedies and practices for use in public and private health services” (WHO, 2001) with the following objectives to:

- “facilitate integration of traditional medicine into the national health care system by assisting Member States to develop their own national policies on traditional medicine;
- promote the proper use of traditional medicine by developing and providing international standards, technical guidelines and methodologies;
- act as a clearing-house to facilitate information exchange in the field of traditional medicine”.

The underlying message is also an appeal to both protect and preserve TM knowledge “to ensure access to traditional forms of health care and respect for those who hold TM knowledge”.

**Impact of Proposed EU Directive on TCM**

First and foremost, the Directive excludes TCM herbs and herbal products because “only medicinal use within the community is relevant since it is very difficult to verify whether information on use outside the community provides a reliable basis to conclude on the efficacy and especially the safety of the product” and because the Directive does not address combined patent products which include minerals and/or animals which apply to many TCM products.

It is not apparent whether the exclusion of TCM is an acknowledgment that most of the latter products are monographed in Chinese. The required expert reports will be very difficult and resource intensive to prepare because all the existing literature will need to be translated unless they are conversant with Chinese language.

The Directive also has restrictive articles to which TCM cannot conform by the time the Directive is implemented. Thus:

- Article 11(4) requires a summary of product characteristics such as “pharmacological properties, and in so far as this information is useful for therapeutic purposes, pharmacokinetic particulars”. This will be difficult for both single ingredient and combination products. To-date, very limited TCM herbs have identified “active” ingredients.
- Article 16c2 defines “corresponding medicinal product” as having the same active ingredients. Can it be assumed that plant products with similar ingredients or markers will be considered as “corresponding medicinal product”? Should this be the case, will *Panax quinquefolium* L. be considered the corresponding medicinal product of *Panax ginseng* C.A Mey, both of which are used for different conditions in TCM?
- Article 16g1 requires article 51 be applied. The latter requires that medicinal products coming from the third countries, that each production batch has undergone in the importing Member State a full qualitative analysis. A quantitative analysis of at least all the active constituents etc. to meet the requirements of the marketing authorization. Again, TCM herbs have no identifiable active constituents or markers. Therefore, what analysis will apply to TCM products? Exemption may be obtained in article 51(2) only if the community has arrangement with the exporting country. Is there such an arrangement? Is this information in the public domain?

In seeking to harmonize the herbal medicinal market across Europe, the Directive appears to undermine its own political inclusiveness and the core philosophy of WHO’s strategy for traditional medicines as highlighted above. It is also not proportionate. It is also perceived that the proposed exclusion:

- promotes and focuses ethnic segregation and devalues their traditional medicines;
- will deprive a large proportion of its own population who have been seeking non-allopathic medicines for their chronic conditions for which the allopathic medicines have been so far ineffective;
- will destroy all the goodwill in cooperating with MCA to assure public safety;
- will endanger any clinical researches which have been painstakingly nurtured and this will be a disastrous retrograde step;
- will drive the affected ethnic medicines into back street activities thus nullifying all the efforts the MCA has invested in promoting dialogues and cooperation;
- will jeopardize public safety more should these
medicines be relegated to the back street operation because the Directive prevents the public from accessing TCM in the open without fear of the law;

- will curtail the rights of the individual to choose what is best for them;
- TCM will be perceived to have been slapped a “ban”;
- will permanently exclude TCM should the next review date happens beyond the transitional period for section 12(1) which has a predetermined shelf life;
- will not address the safety problems the Directive is purported to achieve.

Political inclusiveness should extend to the socio-economic, socio-cultural and legal levels. This harmonious interdependence is best achieved with facilitative policies and regulations to enable concerns over safety and quality to be effectively and transparently addressed and managed.

The solution to the issue of public safety cannot be achieved through exclusion of TCM and other traditional ethnic herbal medicines. Rather, they must be embraced and be made to conform to the safety and quality levels demanded of.

The proposed Expert Committee must include relevant and appropriate TM experts to support and encourage these ethnic medicines industries to cooperate to assure safe, quality and CITES compliant products. Being experts in TCM does not necessarily mean experts in translation and vice versa.

An expert is a practitioner who has undertaken full-time study for an appropriate length of time and who has a long history of practice. This expert appointed must inspire confidence and trust among the practitioners and TCM industry. WHO would be the best advisor. In the absence of monographs and the TCM herbs in the national pharmacopoeia, the Directive must in the initial stage accept the Chinese pharmacopoeia.

In the long term, a Directive that is inclusive and proportionate not only supports the WHO strategy and also benefits the developing countries from the experiences and knowledge thus gained.

Another area the Directive may wish to include is education of the suppliers/importers to achieve closer collaboration and supervision. CMAS will support more stringent and more enforcement power to control TCM products in a Directive that is inclusive and fair.

The Directive must also reflect WHO’s definition of TM which “includes a diversity of health practices, approaches, knowledge and beliefs incorporating plant, animal, and/or mineral based medicines applied singularly or in combination to maintain well-being, as well as to treat, diagnose or prevent disease”.

Conclusion

The principles of the Directives are welcomed and are necessary. The means and the scope to achieve the ends, i.e., harmonization, are not proportionate politically, culturally, socially and economically.

In excluding non-EU TMs, the Directive is more likely to enhance the harm to the public safety as these TMs are pushed to the back streets.

There is still time to write your views to the EU Commissioner, Enterprise Directorate-General, Rue de la Loi 200, B-1049 Bruxelles, Belgium. Fax: (+32-2) 2961520

References