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Traditional Chinese medicine and Ayurvedic medicine products: a possible cause for concern – the Polish perspective

Abstract

Introduction. The demand for Traditional Chinese Medicine (TCM) and Ayurveda have been increasing and there is great potential for complementary medicine development nowadays. However, there are some safety concerns in relation to these products and they hardly ever meet the European Union (EU) requirements for medicines. Moreover, there is no EU-wide legislation governing the regulation of complementary medicine practitioners.

Aim. This study aimed to evaluate health risks of the Polish, as part of the European, society associated with the use of TCM and Ayurvedic products.

Material and methods. The number of web pages related to TCM and Ayurveda was assessed using popular Internet search engine Google. A questionnaire consisting of 8 close-ended questions was sent to the Polish pharmaceutical and sanitary structures. Chief Sanitary Inspectorate (CSI) in Poland, as well as EU Rapid Alert System for Food and Feed (RASFF) databases, were analysed.

Results. There are thousands of web pages offering TCM and Ayurvedic medicines on the Internet. However, only a few such products are registered for the Polish market, thus only a few are supervised. Between 2007 (Jan) and 2018 (Feb) only 0.8% and 0.4% of all food supplement notifications in Poland were related to products from China and India, respectively. Not supervised illegal TCM and Ayurvedic medicines are in 90% adulterated with undeclared substances.

Conclusions. TCM and Ayurvedic product irregularities may pose serious health risks to Polish consumers.

Keywords: Traditional Chinese Medicine (TCM), Ayurveda, regulation, quality, safety.

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INTRODUCTION

The European research network for complementary and alternative medicine (CAM) suggests that more than 100 million of the European Union (EU) citizens are regular users of complementary medicine [1]. The use of CAM has increased considerably in Western countries over the last 25 years, with consequent epidemiological, economic and political importance for public health. With an increasing multiculturalism, traditional medicine of other cultural heritages, particularly traditional Chinese medicine (TCM) and Ayurvedic medicine, have become much more common. It has been reported that 90% of the EU population would accept TCM treatment for managing their health and disease [2]. Main reasons for that include patient dissatisfaction with conventional medicine, side-effects associated with taking medication, preference for natural treatments, and a better therapeutic relationship with the complementary medicine provider, offering a more personal service [3]. More frequently there are females and patients with chronic diseases who are mostly resistant to conventional therapies and tend to choose CAM [4]. The EU citizens perceive CAM products as 'natural' and

therefore, safer than conventional treatment [5]. Moreover, 44% of TCM users believe that TCM products are regulated and that there has been some formal assessment of TCM for the conditions for which it is promoted [6].

With the European Traditional Herbal Medicinal Products Directive 2004/24/EC having taken full effect on 30th April 2011, it is now illegal for companies to sell herbal medicines within Europe without the appropriate licence, i.e. a Marketing Authorization (MA) or a Traditional Herbal Registration (THR) [7]. However, only two TCM products have met the registration requirements: Diao Xin Xue Kang capsules (Netherlands) for headache and muscular pains and Phynova Joint and Muscle Relief tablets (UK). Most of the TCM products from China as well as Ayurvedic ones from India are registered as foods or food supplements to be exported to Europe. Additionally, unlicensed products are sold illegally, due to the lack of statutory regulation for herbal medicine practitioners, and also via the Internet [6].

There is no EU-wide legislation governing the regulation of herbal medicine practitioners. This results in a range of approaches being applied across Europe. A review of the European legislation found that each EU Member State used different

structures of legislation to regulate complementary medicines [8]. This ranged from one extreme in some countries, where anyone can practise CAM without any education or training, to the other extreme, where only medical doctors with a specialisation in the relevant CAM discipline are allowed to practise. This situation raises serious concerns with regard to the predictability, quality and safety of healthcare provided to the European citizens. In Poland, there are no specific regulations on Ayurvedic medicine or TCM. Only medical doctors and dentists are allowed to treat patients. Consequently, only medically qualified professionals may provide CAM treatment [9].

The Committee of Experts on Quality and Safety Standards in Pharmaceutical Practices and Pharmaceutical Care has noted important regulatory gaps as concerns TCM, such as a lack of reliable information addressing the risks to health brought about by this medicinal system, usage of unlicensed products by complementary medicine providers, lack of standardised curricula for health professionals and absence of specific reporting systems for undesirable effects caused by the TCM, including unlicensed products [10].

Studies examining CAM products have highlighted the risk of inadequate quality control, including deliberate or accidental substitution of species, contamination with toxic or prescription ingredients, and mismatches between labelled and actual contents. Recent examination of legally purchased products revealed undeclared presence of toxic plant species (*Asarum*, *Ephedra* and *Apocynum* genus); synthetic compounds (analgesic, antibiotic, stimulant and antihistamine drugs) and high levels of toxic metals (lead, cadmium, arsenic; even with a level above 10 times higher than the acceptable limit) in 24 out of 26 TCMs [11]. Therefore, in view of the growing interest in complementary medicine, the aim of this study was to evaluate health risks to the Polish society, as a part of the European community, associated with the use of TCM and Ayurvedic products.

MATERIAL AND METHODS

In order to assess the number of web pages related to TCM and Ayurveda, the popular Internet search engine Google was used. The following key terms were searched: “Traditional Chinese Medicine”, “Traditional Chinese Medicine products”, “Ayurveda”, “Ayurvedic medicine products”.

A questionnaire, consisting of 8 close-ended questions (with a possibility of an additional comment) was prepared. The questionnaire was then sent to the Polish Pharmaceutical and Sanitary Inspection structures, Office for Registration of Medicinal Products as well as to Medicine and Food Control Laboratories in the total number of 27. The number of 11 (41%) responses were received (1 and 7 from Pharmaceutical and Sanitary Inspection, respectively, and 3 from different Departments of the Medicines Control Laboratory). Answers are presented in Table 1.

The Chief Sanitary Inspectorate (CSI) in Poland, as well as EU Rapid Alert System for Food and Feed (RASFF) databases, were analysed. CSI database includes information about products (mainly food supplements) covered by the notification of first placing on the Polish market. The period of CSI database assessment was settled from January 2007 until February 2018. EU RASFF database includes information about food safety risks with division into the product category, hazard type and countries involved. The category ‘dietetic

foods, food supplements and fortified foods’ was evaluated. The period of assessment was settled from 2015 until 2017. Data analysis was performed with Excel 2016.

RESULTS AND DISCUSSION

Terms “Traditional Chinese Medicine” and “Ayurveda” retrieve approx. 20 and 51 million results, respectively, what reveals a great interest in that kind of therapy systems. These web pages can be divided into three main categories: therapeutic cabinets with the direct contact with the therapist, courses and training, as well as educational sites with frequent redirection to the shops of natural medicine products. Typing in the search engine terms directly related to products: “Traditional Chinese Medicine products” and “Ayurvedic medicine products” retrieve approx. 200,000 and 27,000 results, respectively. Thus, the opportunity to buy such products is virtually unlimited. While rates of herbal medicine purchased online are not known, it is estimated that 8.5% of people in EU countries buy prescription medications online [8].

However, it is important to bear in mind that the relevant EU regulations (Directive 2001/83/EC, relating to medicinal products for human use, and Directive 2004/24/EC, regarding traditional herbal medicinal products) covering marketing authorization and registration of herbal medicinal products in the EU also apply to Traditional Chinese Medicine and Ayurvedic medicine products. There are no separate rules for TCM or Ayurveda [12].

Under the Polish law (in compliance with Directive 2001/83/EC), Pharmaceutical Inspection supervises only authorised medicinal products. Since most of the TCM and Ayurvedic products are registered as foods or food supplements in order to be exported to Europe, and because there are no registered medicines in Poland originating from China and India, the Pharmaceutical Inspection does not deal with those.

TABLE 1. Answers from the Sanitary Inspection Structures and Medicine Control Laboratory in the field of the TCM and Ayurveda product research.

Question about:	Sanitary Inspection Structures	Medicine Control Laboratory
type of the tested products	food (therefore food supplements)	food supplements and products with unknown status
reasons for the check	official control or consumer complaint	suspected irregularities, non-compliance with the declared composition, drug adulterations
sources of the products	pharmacies, shops, warehouses	Internet, postal service, border crossings, natural medicine clinics
legality of the products	legal	illegal
type of the research	chemical and microbiological contaminants	qualitative composition
compatibility with the composition declared	not tested	90% of the tested products had undeclared substances
detected substances	heavy metals, mycotoxins	sibutramine, sildenafil and analogues
language of the information on the packaging/leaflet	Polish	partly Polish, English or language of the country of origin

In the individual EU Member States, the food market (therefore food supplements market) is controlled by national sanitary structures. Sanitary Inspection supervises products approved for marketing in a given country. The main directions of research within the framework of official controls or consumer complaints is the presence of chemical and microbiological contaminants, including pesticides, heavy metals (cadmium, lead, mercury) and mycotoxins (Table 1).

In general, authorised products meet requirements, only occasionally exceeding the permissible standards. However, there are not many products from China and India legally placed on the market. Since 2007, when the Chief Sanitary Inspectorate (CSI) in Poland started keeping a register of the products – mainly food supplements – covered by the notification of first marketing in the Polish territory, the number of food supplements has grown by over 350%. Until February 2018 there were 59,620 notifications. At the same time, the number of registered products from China and India remained relatively small, 452 (0.8%) and 247 (0.4%) respectively (CSI 2007-2018) [13].

This may be surprising considering that the European Federation of Complementary and Alternative Medicine suggests that there are 360,000 CAM practitioners across Europe and that China alone exports 240,000 tonnes of medicines annually [14]. Therefore, taking the demand for complementary medicine into account, there is a high probability that a part of the products sold in Poland has not been reported to be included in the register, and they are thus not supervised by the Sanitary Inspection. Such products can be bought mainly on the Internet or in natural medicine clinics and in the case of suspected irregularities, they are examined by the Medicines Control Laboratory, an official public research entity dealing with illegal products from China and India. It is estimated that 9 out of 10 tested products contain undeclared synthetic substances, mainly sildenafil (erectile dysfunction medicine, contraindicated in heart conditions and potentially fatal if taken with nitrates) and sibutramine (slimming agent, withdrawn from the EU market in 2010 due to the risk of serious cardiovascular events). Moreover, the information on the packaging of such products is difficult to verify, often written in the language of the country of origin (Table 1).

An important place in the supervision of food (food supplements) safety in Europe is held by a platform known as the Rapid Alert System for Food and Feed (RASFF). The reports from Polish Sanitary Inspection and Medicines Control Laboratory concerning substances detected in products originating in China and India are in line with RASFF notifications, in which the most commonly indicated incidents include, but are not limited to, the presence of sildenafil and its analogues, sibutramine, heavy metals and mycotoxins (Table 2) (RASFF 2015-2017) [15].

These undeclared ingredients, adulterants and other notified irregularities of TCM and Ayurvedic products may pose serious health risks to Polish consumers. Especially, regarding the fact that many consumers do not share information about using herbal medicines with medical doctors. Moreover, since there is no standardised level of pharmacological knowledge that CAM practitioners should possess, these complementary medicine providers might not have enough knowledge to advise consumers safely about adverse effects and interactions with conventional medicines.

TABLE 2. Type of RASFF notifications related to dietetic foods, food supplements and fortified foods from China and India between 2015 and 2017.

Type of notification	China	India
Unauthorised substances	sildenafil, thiosildenafil, tadalafil, sibutramine, phenolphthalein, magnesium aspartate, 5-hydroxytryptophan (5-htp), isoprothiolane, high content of vitamin E, D3	progesterone, androstenedione
Prohibited substances		chloramphenicol
Unauthorised placing on the market	maca root – <i>Lepidium meyenii</i>	<i>Solanum nigrum</i> , <i>Sida cordifolia</i> , <i>Operculina turpethum</i> , <i>Nepeta hindostana</i>
Unauthorised novel food ingredient	agmatine sulphate, <i>Epimedium</i> , <i>Bauhinia purpurea</i> , <i>Cirsium oligophyllum</i> , <i>Polygonum multiflorum</i> , <i>Rauwolfia canescens</i> , <i>Viscum coloratum</i> , Stevia leaves	
Heavy metals	mercury, lead	mercury, lead
Industrial contaminants	benzo(a)pyrene, polycyclic aromatic hydrocarbons (PAH)	
Pathogenic micro-organisms	Salmonella	Salmonella, shigatoxin-producing <i>Escherichia coli</i>
Mycotoxins	citrinin	
Allergens	too high content of gluten	
Food additives and flavourings	too high content of colours	

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