

# The Regulation of Complementary and Alternative Medicine (CAM) in the EU

Michael McIntyre MA, MRCHM, FNIMH, DU  
Visiting Professor Middlesex University, UK

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### Section 1. – What is CAM? Definition and Usage

Complementary and Alternative Medicine (CAM) is a general term used to describe a number of non-conventional treatments<sup>1</sup> and natural products (e.g. herbal and homeopathic medicines) widely used throughout the EU.

There have been several attempts to define the heterogeneous practices generally considered as CAM.

**The CAMbrella Project** (2013)<sup>2</sup>, charged by the European Commission to survey the use of CAM in Europe, proposed the following definition: *“CAM, as utilised by European citizens, represents a variety of different medical systems and therapies based on the knowledge, skills and practices derived from theories, philosophies and experiences used to maintain and improve health, as well as to prevent, diagnose, relieve or treat physical and mental illnesses. CAM therapies are mainly used outside conventional health care, but in many countries some therapies are being adopted or adapted by conventional healthcare.”*<sup>3</sup>

**The British Medical Association** (BMA) adopted a working definition in 1993 of CAM as *“those forms of treatment which are not widely used by the orthodox health-care professions, and the skills of which are not taught as part of the undergraduate curriculum of orthodox and paramedical health-care courses.”*<sup>4</sup>

**WHO** has a somewhat different description of CAM declaring that *“The terms “complementary medicine” or “alternative medicine” are used interchangeably with traditional medicine in some countries. They refer to a broad set of health care practices that*

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<sup>1</sup> E.g. acupuncture, Ayurveda, chiropractic, osteopathy, naturopathy, herbal medicine (phytotherapy), acupuncture, reflexology, shiatsu, massage, aromatherapy, Alexander technique.

<sup>2</sup> The findings of the CAMbrella Project under the 7<sup>th</sup> Framework Programme of the European Commission, were published on line in April 2013. <http://www.cambrella.eu/home.php?il=203&l=deu>.

<sup>3</sup> Von Ammon K et al (2012). Health Technology Assessment (HTA) and a map of CAM provision in the EU. Final Report of CAMbrella Work Package 5. Available at <https://phaidra.univie.ac.at/view/o:300096>. Accessed 12/1/17.

<sup>4</sup> BMA Complementary Medicine, *New Approaches to Good Practice*, OUP 1993, p.7.

are not part of that country's own tradition and are not integrated into the dominant health care system." For this reason WHO prefers to use the abbreviation T&CM (Traditional and Complementary Medicine)<sup>5</sup> describing traditional medicine as "the sum total of the knowledge, skills, and practice based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness."<sup>6</sup>

### **Complementary and/or alternative**

The BMA made a distinction between complementary and alternative forms of CAM: "Complementary therapies are those which can work alongside and in conjunction with orthodox medical treatment. Within this category there is clearly a wide diversity of types of practice, which would include self-help therapies... such as yoga; re-educational therapies such as the Alexander Technique; relatively non-invasive therapies such as healing and massage; and all interventive therapies such as acupuncture, osteopathy, and chiropractic....In this role the therapies are an additional and complementary form of treatment. ...By contrast, 'alternative therapies' could be seen as those which are given in place of orthodox treatment... - there are some therapies which, by their very nature, aim to replace orthodox medicine. Examples of such therapies might include herbal medicines, which are often given in place of orthodox medication..."<sup>7</sup>

### **Integrated and integrative**

More recently there has been a move in the European sphere to replace the term CAM with the epithet "Integrated Medicine"<sup>8</sup> while in the USA the term "Integrative Medicine" is generally used<sup>9</sup> signalling a similar shift in emphasis since both descriptors highlight the trend that in some countries aspects of CAM therapies are now being adopted or adapted by conventional healthcare.

### **CAM usage**

The extraordinary upsurge in the use of CAM has for the most part been driven by public demand, as citizens seek to integrate a variety of CAM therapies and products into their own healthcare regime. CAM is now used by one out of two EU citizens<sup>10</sup> and there are more than 180,000 registered and certified non-medical CAM practitioners in Europe. This amounts to 65 CAM providers per 100,000 inhabitants, as compared to the EU figures of 95 general medical practitioners per 100,000 inhabitants.<sup>11</sup> However, regulation of and education in

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<sup>5</sup> WHO Traditional Medicine Strategy 2014-2023.

[http://www.who.int/medicines/publications/traditional/trm\\_strategy14\\_23/en/](http://www.who.int/medicines/publications/traditional/trm_strategy14_23/en/).

<sup>6</sup> <http://who.int/medicines/areas/traditional/en/>.

<sup>7</sup> BMA. Op cit.

<sup>8</sup> For example, the Royal London Homeopathic Hospital in London is now rebranded as The Royal London Hospital for Integrated Medicine.

<sup>9</sup> <https://nccih.nih.gov/health/integrative-health>.

<sup>10</sup> [www.cordis.europa.eu/news/rcn/35388\\_en.html](http://www.cordis.europa.eu/news/rcn/35388_en.html).

<sup>11</sup> Ibid.

CAM is different in each of the European countries.<sup>12</sup> The fragmentary and piecemeal state of CAM regulation in the EU and its Member States is explored in this Report.

### **Significant and Contradictory trends**

These remarkable statistics highlight two trends: Firstly, they demonstrate that instead of relying solely on conventional medicine, EU citizens are increasingly seeking holistic CAM methods of healing which emphasise a patient-centred model of care. Secondly, in the absence of coherent regulation of CAM or its products across the EU, it is apparent that EU regulators are failing to utilise this potentially vast untapped resource or, for that matter, to safeguard the public from poor or unsafe practice or products.

In 2013, Health Commissioner Borg stated that health systems across Europe are under significant pressure to meet increasing demands and suggested that CAM could have a role to play in responding to this challenge. Specifically with regard to CAM, he said, “*Any treatment which demonstrates better outcomes at lower costs is a step forward on the path towards more sustainable health systems.*”<sup>13</sup> However, without resources for research into CAM modalities or appropriate legislation to enable CAM to develop and integrate with conventional healthcare systems, the potential benefit of CAM is unlikely to be realised.

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<sup>12</sup> Ibid.

<sup>13</sup> Commissioner Borg. Address June 2013. Available at <http://ehpta.eu/>.

## Section 2. CAM regulation by the European Union

CAM medicines and practice are regulated separately. The EU has declared that while medicines legislation is ultimately set by EU medicines law, the determination of health policy and the regulation of the healthcare force is the responsibility of each individual Member State. This principle was confirmed in the Lisbon Treaty.<sup>14</sup>

Although this treaty apparently leaves regulation firmly within the remit of individual Member States, two EU Directives have the potential to impact on the regulation of CAM practitioners. The first of these is “Directive 2005/36/EC of 7 September 2005 on the Recognition of Professional Qualifications”<sup>15</sup> which gives *“mutual recognition of the evidence of formal qualifications of doctors, nurses responsible for general care, dental practitioners, veterinary surgeons, midwives, pharmacists and architects should be based on the fundamental principle of automatic recognition of the evidence of formal qualifications on the basis of coordinated minimum conditions for training.”*

Comment [MM1]: Add this

### CEN and European Standards

It is desirable in time, especially from the point of view of patients, that various CAM specialities will also receive cross-border recognition. Indeed, this process is seemingly underway as in 2012 the European Committee for Standardisation (CEN) was empowered to set standards for services across the EU.

This procedure is complex and expensive, requiring sponsorship of a therapy by an Individual Member State and over 70% of Member States to vote in favour.<sup>16</sup> Nevertheless, once agreed, a European Standard is automatically transposed into National Standards of Member States and any conflicting National Standards must be withdrawn.

This process is only suitable for a CAM therapy which is widely established across the EU like osteopathy. In the case of naturopathy, phytotherapy (herbal medicine), Chinese herbal medicine, Ayurveda and Tibetan medicine, the practice of which is restricted to medical doctors in several EU Member States, CEN standardisation for non-doctor practitioners is not a viable option at this time.

In July 2015, CEN published a European Standard on Osteopathic Healthcare Provision. The Standard requires osteopaths to complete relevant education and training to a specified level, as well as following continuing professional development. In addition, the European Standard sets out that evidence-informed practice is an important part of an osteopath’s approach to patient treatment and case management.<sup>17</sup> By September 2016 all conflicting national standards were required to be withdrawn. In October 2016, CEN also set a European Standard (EN 16872:2016) specifying the minimum requirements for medical doctors with additional qualification in homeopathy and their services.

<sup>14</sup> TITLE XIV Public Health Article 168 number 7(4): 7. <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3Aai0033>.

<sup>15</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32005L0036>.

<sup>16</sup> Information provided in a presentation to EUROCAM by CEN 3/12/14.

<sup>17</sup> <https://www.cen.eu/news/brief-news/Pages/News-2016-008.aspx>.

### **Patients' Rights Directive**

A second EU Directive with a potential impact in time on the regulation and provision of CAM practitioners and services is the "Patients' Rights Directive" 2011/24/EU of 9 March 2011, on the application of patients' rights in cross-border healthcare.<sup>18</sup> This sets out the conditions under which a patient may travel to another EU country to receive safe and high quality medical care and have the cost reimbursed by their own health insurance scheme. It also encourages cooperation between national healthcare systems. In time this Directive may well influence the delivery of CAM whether the specific treatment or practitioner is registered as conventional or non-conventional in the Member State concerned.

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<sup>18</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=URISERV%3Aasp0002>.

### Section 3. The regulation of CAM practitioners and CAM practises

CAM practice is currently regulated by various EU States and members of the European Free Trade Association (EFTA). This subject is covered in depth in the Final report of CAMbrella.<sup>19</sup> There is no reason here to replicate CAMbrella's excellent review of 39 European Countries and their specific regulation of various CAM modalities. Instead, this Report surveys a sample of 9 EU and EFTA countries (updating data from the time of publication of the CAMbrella Report) comparing the way that CAM practice is regulated, demonstrating the bewildering variation in the regulation of CAM currently in force through Europe.

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#### The benefit of regulation of CAM professionals

In the absence of EU wide legislation, there appears to be a clear public benefit in Member States introducing regulation of CAM modalities that ensure high standards of training and practice together with research programmes to measure treatment outcomes and safety.

The practice of CAM should *not* be limited to medical doctors but to any practitioner that undertakes training to the required level in a CAM speciality. Such measures are being taken in Switzerland and Portugal for example. In the absence of these measures, and given the evident popularity of CAM, treatments will continue to be sought out and practised without adequate regulation. Lack of regulation is clearly not in the interests of the many millions of citizens who regularly access CAM treatments. It poses health hazards and may severely limit patient choice.

Comment [MM3]: Spelling correction

On the other hand, regulation that gives equivalence with other authorised health professionals (particularly for the main CAM modalities using herbal medicines, homeopathy, osteopathy, chiropractic, naturopathy and acupuncture) provides a structure that enables clinical efficacy to be measured. Lastly, there will almost certainly be economic benefit in regulating and assimilating CAM into healthcare provision since its treatments are generally low tech, employing relatively inexpensive procedures and natural medicines with a good safety profile.

Such integration is in line with the WHO recommendation (*The WHO Traditional Medicine Strategy 2014-2023*) wherein WHO Director General, Dr Margaret Chan, observed:

*“Much has changed since the previous global strategy was published in 2002. More countries have gradually come to accept the contribution that T&CM (traditional and complementary medicine) can make to the health and well-being of individuals and to the comprehensiveness of their health-care systems. Governments and consumers are interested in more than herbal medicines, and are*

<sup>19</sup> see <http://www.cambrella.eu/home.php?il=203&l=deu>

*now beginning to consider aspects of T&CM practices and practitioners and whether they should be integrated into health service delivery... The strategy has two key goals: to support Member States in harnessing the potential contribution of T&CM to health, wellness and people centred health care, and to promote the safe and effective use of T&CM through the regulation of products, practices and practitioners.*"<sup>20</sup>

While the regulation of CAM products (herbal, homeopathic and food supplements) is now largely centralised via the EU Regulations and Directives, the regulation of CAM practice and CAM practitioners is remarkably diverse. Each Member State seemingly has its own unique set of rules and laws that apply to the practice of CAM. Patients crossing borders and requiring CAM treatment encounter significant differences in the training and regulation of seemingly identical practitioners who work under different sets of rules and regulations as well as reimbursement systems. These variables make meaningful research into CAM treatments difficult to undertake.

The EU Commission, European Parliament and national politicians should give serious consideration to EU-wide harmonisation of CAM practice to benefit the health of EU citizens. Calls for such reform have been made in resolutions by the Parliamentary Assembly of the Council of Europe (Resolution 1206(1999) and by the European Parliament (see the Lannoye Report below).

### **The Lannoye Report**

In the early 1990s, variations of approach by various Member States towards CAM and the widespread use of CAM therapies encouraged the MEP Paul Lannoye to try and advance the resources and legal status of CAM within the EU.

As a member of the Committee of the Environment, Public Health and Consumer Protection, in 1994 he published a report on the status of complementary medicine (in subsequent versions termed non-conventional medicine), which made several far-reaching proposals for ratification by the European Parliament.<sup>21</sup> The Lannoye Report sought to open the way to EU recognition of non-traditional forms of medicine (chiropractic, osteopathy, homeopathy, anthroposophic medicine, phytotherapy /herbal medicine, traditional Chinese medicine, shiatsu and naturopathy). Amongst the Report's extensive proposals were provisions for recognition and harmonisation of CAM qualifications and training throughout the EU.

**Comment [MM4]:** I think this is now the preferred form

In addition it called for the inclusion of certain alternative medical disciplines in the teaching of conventional medicine and the inclusion in the *European Pharmacopoeia* of the full range of supplements and herbal products used as non-conventional medicines so as to guarantee the quality and safety of such products. Lannoye also petitioned the Commission to fund a full research programme into the efficacy of CAM treatments and to draft a Directive to

<sup>20</sup> [http://www.who.int/medicines/publications/traditional/trm\\_strategy14\\_23/en/](http://www.who.int/medicines/publications/traditional/trm_strategy14_23/en/)

<sup>21</sup> The Lannoye Report (DOC-EN\RR\251\251535PE208.336/fin went through several stages. The first version was published 26 April 1994. A further version (DOC-EN\PR\289\289543 PE216-066) was published 18 April 1996. A still later version PE216.0666/fin was published 3 March 1997.

guarantee CAM practitioners the freedom to provide their services throughout the EU and access the therapeutic products they need in the exercise of their profession.

Although the first report was adopted by the Committee on the Environment, Public Health and Consumer Protection it ran out of time when it was debated in the European Parliament. A second report in 1996 reached the European Parliament where it was submitted to many amendments that so reduced its scope that Lannoye requested his name be removed from the final version. In effect all that remained of the original Report, ratified by the European Parliament as the "Collins resolution" in 1997 (A4-0075/97), was its call on the Commission to research the "non-conventional medicine" sector and develop research programmes in the field of non-conventional medicines.<sup>22</sup> This has not been achieved and harmonisation of CAM practice across the EU, a fundamental aim of the Lannoye Report/Collins Resolution, appears no nearer attainment than it was when this report was mooted twenty years ago.

This experience highlights a significant difficulty regarding the integration of CAM. Since CAM is not backed by powerful pharmaceutical lobby or, for that matter, supported by and large by the medical establishment, there appears no incentive on the part of "the powers that be" to provide a more coherent legislative basis for its practice, or fund research that may demonstrate its health benefits. Progress is painfully slow.

### **Doctors practising CAM**

Doctors and other authorised health professionals are able to practise CAM but should have undertaken requisite and appropriate training in the modality being employed. They are free to use CAM medicinal products under Article 3 of Directive 2001/83/EC ("magistral formula") or Article 5 of this Directive ("special needs").

### **Napoleonic Code v common law**

Historical legislative variation within the EU appears to have influenced the way CAM has developed in various Member States. Napoleonic Code, instigated by Napoleon in 1804 to determine the civil law of the French Empire, has been adapted for use by several EU Member States (France, Holland, Belgium, Italy, Portugal and Spain). The Scandinavian countries, UK and Ireland did not adopt the Code. A ramification of Napoleonic Code, which in contrast to UK and Irish common law is not based on precedent, is that Member States employing a legislative system based on the Code generally require specific legislation to enable non-doctor CAM practitioners to practise. In the UK and Ireland common law has allowed willing patients to be treated by non-doctor CAM practitioners subject to minor legal limitations (in the UK non-doctor CAM practitioners may not advertise that they treat cancer, Bright's disease, venereal disease and diabetes). The profession of medical herbalists has developed in the UK under legislation that enshrined common law principles of a right to treat once permission is given by the recipient, whether or not the person practising is an "authorised health professional" i.e. statutorily regulated.

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<sup>22</sup> <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+REPORT+A4-1997-0075+0+DOC+XML+V0/EN>

In contrast, in several European Member States, including France, Spain, Italy, Austria, and Greece, the practise of medicine except by authorised health professionals has been illegal for many years. Where such restrictions apply, CAM practitioners who are not medical practitioners are sometimes tolerated and occupy a legal grey area. As demonstrated in the examples of a cross-section of different Member States and their CAM legislation below, acceptance of non-doctor practitioners even in established CAM modalities such as osteopathy and chiropractic can take decades to happen. Another underlying influence on the regulation of CAM across the EU is a divide between the more conservative Catholic southern European Member States that operate a strict rule that medicine can only be practised by doctors and their more eclectic and pragmatic Protestant Member State counterparts which tolerate a degree of heterodoxy in the delivery of medical care. The Netherlands and UK are examples of the latter phenomenon.

### **Austria**

Only doctors can practise medicine in Austria and the Austrian Medical Board issues diplomas for doctors specialising in traditional Chinese medicine. It is technically illegal for non-doctor CAM practitioner to practice medicine, and under Article 184 of the Penal Code they may be fined or be imprisoned for three months. However, in practice the courts are tolerant of non doctor practitioners unless problems arise.

### **Belgium**

In Belgium, prior to 1999 anyone who practised medicine, complementary or orthodox, without being a medical doctor was committing a criminal offence. The Colla law of that year promised to alter this situation putting in place four “Commissions” on homeopathy, acupuncture, osteopathy and chiropractic to advise the government on the standards of training necessary so that non-doctor practitioners as well as doctors and other authorised health professionals could legally practise these four modalities.<sup>23</sup> To this end in 2010 thirteen professional organizations of medical and non-medical practitioners of non-conventional medicine (pertaining to these 4 modalities) were approved by a Royal Decree, but despite this, eighteen years after the Colla law was adopted, the process remains stalled because of political opposition to the notion of non-doctors practising CAM, so that, as things stand, only authorised health professionals can legally practise acupuncture, osteopathy and chiropractic.

In the meantime, the Belgian Council of Ministers passed new regulation on homeopathy in July 2013, made official by a Royal Decree published 12 May 2014 by the Ministry of Health. This decreed that the practice of homeopathy should be limited to doctors who must have a degree in homeopathy from an official college or university, and the national teaching

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<sup>23</sup> Non-conventional practices act of 29 April 1999 (Belgian Statute Book of 24 June 1999). Loi du 29 avril 1999 relative aux pratiques non conventionnelles dans les domaines de l’art médical, de l’art pharmaceutique, de la kinésithérapie, de l’art infirmier et des professions médicales. Moniteur Beige, 24 June 1999, 169. The Belgian Parliament (1999). [http://www.ejustice.just.fgov.be/cgi\\_loi/change\\_lg.pl?language=fr&la=F&cn=1999042968&table\\_name=loi](http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=fr&la=F&cn=1999042968&table_name=loi).

centres will have to comply with the European/national CEN quality standards. Homeopaths already practising who do not have a medical, dentistry or midwifery diploma can continue their activities under a “grandfather clause” until they fulfil the new requirements. Practice of homeopathy by non-medical qualified practitioners will be illegal in Belgium. These restrictive measures are not what the legal framework envisaged when the Colla law was passed in 1999.

### Portugal

In contrast to Belgium, Portugal demonstrates that CAM therapies can be constructively regulated by Member States enabling public access to safe and competent treatment. Since 2013 the practice of acupuncture, physiotherapy, homeopathy, traditional Chinese medicine (TCM), naturopathy, osteopathy and chiropractic in Portugal requires a professional licence and higher education qualifications. The new law<sup>24</sup> was approved by the Council of Ministers, and establishes the legal entry qualification for practitioners of acupuncture, homeopathy, osteopathy, naturopathy, phytotherapy and chiropractic. The law applies to all professionals engaged in practice of the above listed treatments. Professional titles are protected and are only allowed to holders of the relevant certificate. The Central Administration of Health Systems maintains an updated, official register of regulated CAM professionals. The practice of these therapies also requires a public registered licence. This law had been originally approved in 2003 and had awaited implementation since that time.<sup>25,26</sup>

### Germany, Switzerland and Liechtenstein

Germany, Switzerland and Liechtenstein operate the unique Heilpraktiker (health practitioner) system. This licenses practitioners who are not members of recognised health professions to practise CAM provided that they have passed an examination in basic medical knowledge and are registered. These practitioners are known as “natural health practitioners.” Iceland and Denmark have similar systems.

Switzerland is a member of the European Free Trade Association (EFTA). Historically the 26 Swiss cantons that comprise the Swiss Federation have had a high degree of legislative independence. However, recent changes have seen the federal government take more control of the way medicine is practised. Surveys conducted by the Swiss Government demonstrated that usage of CAM in Switzerland was popular and that high levels of public use remained unchanged between 2007 and 2012. The surveys showed that most popular CAM modalities in 2012 were homeopathy, naturopathy, osteopathy, herbal medicine, and acupuncture, and that CAM services were desired by the majority of the population.<sup>27</sup> This use was similar to

**Comment [MM5]:** Do you want to add Denmark to this heading as you include it in the text below.

<sup>24</sup> 1st Series No. 168-2-September 2013 1 Law No. 71/2013.

<sup>25</sup> Portuguese Law No 45/2003 of 22 August 2003 on the provision of non-conventional therapies.

<sup>26</sup> <http://portugalresident.com/new-alternative-medicine-laws>.

<sup>27</sup> [https://www.google.co.uk/search?q=Cantons+capital+C&ie=utf-8&oe=utf-8&client=firefox-b-ab&gfe\\_rd=cr&ei=YPWBWPOMB17FaODho5AL#q=Medienmitteilung+des+Dachverbandes+Komplement%C3%A4rmedizin+\(Dakomed\)+und+der+Union+Schweizerischer+komplement%C3%A4rmedizinische+%C3%84rzteorganisationen+\(UNION\)+vom+2.+Mai+2014](https://www.google.co.uk/search?q=Cantons+capital+C&ie=utf-8&oe=utf-8&client=firefox-b-ab&gfe_rd=cr&ei=YPWBWPOMB17FaODho5AL#q=Medienmitteilung+des+Dachverbandes+Komplement%C3%A4rmedizin+(Dakomed)+und+der+Union+Schweizerischer+komplement%C3%A4rmedizinische+%C3%84rzteorganisationen+(UNION)+vom+2.+Mai+2014).

other countries, such as Germany, United Kingdom, United States or Australia.<sup>28</sup> On 17 May 2009, voters with a two-thirds majority voted in favour of complementary medicine in Swiss health care.<sup>29</sup>

It was against this background that the Federal Department of Home Affairs (EDI) determined that Switzerland's mandatory health insurance (OKP) should be extended to include CAM treatments for anthroposophic medicine, homeopathy, herbal medicine and non-acupuncture traditional Chinese medicine, if these are provided by medical specialists with appropriate additional training. The provision of services by non-medical therapists is not affected by this. The costs of these services are also covered by the corresponding supplementary insurances. The decision is to be fully ratified by 1 May 2017.<sup>30</sup>

### The UK and Ireland

In the UK, osteopaths and chiropractors are statutorily regulated like doctors, dentists, nurses and physiotherapists. This means that most insurance companies will reimburse treatments and these professions are accepted into the conventional health-care system. The titles “osteopath” and “chiropractor” is protected by law, and only those included on the statutory Register are entitled to practise as osteopaths or chiropractors. Unregistered **use of the titles “osteopath” and chiropractor** is a criminal offence in the UK. Doctors and physiotherapists, also statutorily regulated, are free to practise complementary medicine. As far as referral to a CAM practitioner by a doctor, The General Medical Council distinguishes between delegation and referral in paragraphs 46 and 47 of Good Medical Practice (3rd Edition, 2001).<sup>31</sup>

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*“Delegation involves asking a nurse, doctor, medical student or other health care worker to provide treatment or care on your behalf. When you delegate care or treatment you must be sure that the person to whom you delegate is competent to carry out the procedure or provide the therapy involved. You must always pass on enough information about the patient and the treatment needed. You will still be responsible for the overall management of the patient.*

*Referral involves transferring some or all of the responsibility for the patient's care, usually temporarily and for a particular purpose, such as additional investigation, care or treatment, which falls outside your competence. Usually you will refer patients to another registered medical practitioner. If this is not the case, you must be satisfied that such health care workers are accountable to a statutory*

<sup>28</sup> Klein SD, Torchetti L, Frei-Erb M, Wolf U. Usage of Complementary Medicine in Switzerland: Results of the Swiss Health Survey 2012 and Development Since 2007. *PLoS One*. 2015 Oct 29;10(10).

<sup>29</sup> [https://www.google.co.uk/search?q=Cantons+capital+C&ie=utf-8&oe=utf-8&client=firefox-b-ab&gfe\\_rd=cr&ei=YPBWPOMBI7FaODho5AL#q=Medienmitteilung+des+Dachverbandes+Komplement%C3%A4rmedizin+\(Dakomed\)+und+der+Union+Schweizerischer+komplement%C3%A4rmedizinische+%C3%84rzteorganisationen+\(UNION\)+vom+2.+Mai+2014](https://www.google.co.uk/search?q=Cantons+capital+C&ie=utf-8&oe=utf-8&client=firefox-b-ab&gfe_rd=cr&ei=YPBWPOMBI7FaODho5AL#q=Medienmitteilung+des+Dachverbandes+Komplement%C3%A4rmedizin+(Dakomed)+und+der+Union+Schweizerischer+komplement%C3%A4rmedizinische+%C3%84rzteorganisationen+(UNION)+vom+2.+Mai+2014).

<sup>30</sup> Verordnung über die Krankenversicherung (KVV). <https://www.bag.admin.ch/bag/de/home/service/gesetzgebung/gesetzgebung-versicherungen/gesetzgebung-krankenversicherung/kvg/aenderungen-in-der-KVV.html>.

<sup>31</sup> GMC, *Good Medical Practice*, 3<sup>rd</sup> Edition (2001), GMC.

*regulatory body, and that a registered medical practitioner, usually a general practitioner, retains overall responsibility for the management of the patient.”*

Since 1990, GPs have been able to employ complementary therapists, but must check that the person employed is suitably qualified and competent to perform the duties for which they are employed.

UK herbal practitioners (including those that practise Ayurveda, traditional Chinese medicine and Tibetan medicine) have the right to prescribe herbal remedies. This common law right to prescribe was originally enacted in the Medicines Act of 1968<sup>32</sup>. In Ireland a similar exemption pertains<sup>33</sup>. This is the only specific CAM regulation on the Irish statute book and CAM modalities of all kinds are widely practised in Ireland.<sup>34</sup>

UK Herbal practitioners and acupuncturists have for many years been in line for statutory regulation like the osteopaths and chiropractors. In 2011, the Health Minister announced that the herbalists, including those practising Ayurveda, Tibetan and Chinese herbal medicine would also be statutorily regulated.<sup>35</sup> A change of ministers meant this was not adhered to, and instead the UK Department of Health has set up another voluntary register, the Professional Standards Authority, as an umbrella organisation for CAM therapies that are not statutorily regulated. Several voluntary associations of CAM practitioners continue to operate outside the PSA and campaign for statutory regulation seeing this as the only way to integrate into the health system and maintain access to their right to practise and access CAM medical products (e.g. herbal medicines). At the time of writing it is impossible to predict the result of Brexit on CAM provision in the UK.

## **France**

France is an example of a Member State that for many years maintained an uncompromising stance against anyone but an authorised health professional practising CAM. However, in recent years there has been a significant change regarding osteopathy and chiropractic. In 2014 the French government agreed two new decrees on standards of osteopathic training required to practise as an osteopath.<sup>36</sup> In 2014 and 2015 three further government decrees were adopted on the training of chiropractors and accreditation of training chiropractic institutions.<sup>37</sup> Osteopaths in France now need to have at least 3 years and 2600+ hours of training. An interim period has been introduced to allow osteopaths to submit their professional qualifications to the Prefecture for approval.

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<sup>32</sup> more recently transferred into the under the Human Medicine Regulations 2012, Chapter 3: Regulation 241

<sup>33</sup> S.I. No. 540/2003 - Medicinal Products (Prescription and Control of Supply) Regulations 2003 – 20 (5)

<sup>34</sup> <http://www.irishstatutebook.ie/eli/2003/si/540/made/en/print>.

<sup>35</sup> Andrew Lansley, Sec. of State for Health, Feb 16, 2011.

<http://www.publications.parliament.uk/pa/cm201012/cmhansrd/cm110216/wmstext/110216m0001.htm>

<sup>36</sup> Decree No. 2014-1043 of 12 September 2014 on the approval of training institutes in osteopathy.

Legifrance.gouv.fr 2014

<sup>37</sup> Decree of 24 March 2014 on the training of chiropractors and accreditation of training institutions  
Chiropractic NOR: AFSH1325188A Consolidated version of 5 February 2015 Legifrance.gouv.fr 2014.

Acupuncture, anthroposophic medicine, homeopathy and phytotherapy (herbal medicine) are regulated by the medical association. “*Le code de santé publique*” (The Code of Public Health), article L4161-1<sup>38</sup>, currently in force states “*persons other than licensed physicians who habitually or continuously diagnose or treat illness, real or supposed, or who perform activities constituting medical procedures are illegally practising medicine.*”

### **The Netherlands**

In the Netherlands both medically and non-medically qualified professionals are allowed to practise. The Individual Health Care Professions Act on 1.12.1997 (*Beroepen in de Individuele Gezondheidszorg*), permitted practice of medicine is open to all with some limitations; some procedures may be carried out only by categories of professional practitioners authorized to do so by law.<sup>39,40</sup>

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<sup>38</sup> [https://www.legifrance.gouv.fr/affichCodeArticle.do;jsessionid=5D1898EAE2B6518BE57B661590A84001.tp\\_dila17v\\_1?idArticle=LEGIARTI000031929940&cidTexte=LEGITEXT000006072665&categorieLien=id&dateTexte=](https://www.legifrance.gouv.fr/affichCodeArticle.do;jsessionid=5D1898EAE2B6518BE57B661590A84001.tp_dila17v_1?idArticle=LEGIARTI000031929940&cidTexte=LEGITEXT000006072665&categorieLien=id&dateTexte=)

<sup>39</sup> Ministerie van Volksgezondheid Welzijn en Sport – NL. The Individual Health Care Professions Act (Beroepen in de Individuele Gezondheidszorg); Act of 11 November 1993, amended December 1, 1997; Text of the act as per 1-1-2001. The Hague 2001.

<sup>40</sup> The procedures specified are: surgical procedures, obstetric procedures, catheterizations and endoscopies, punctures and injections, general anaesthetics, procedures involving the use of radioactive substances and ionizing radiation, cardio version, defibrillation, electroconvulsive therapy, lithotripsy & artificial insemination.

## Section 4 - EU Regulation of CAM medicinal products, herbs, remedies and food supplements

Several CAM practices make use of CAM medicinal products, homeopathic remedies, herbs and food supplements. For the most part these are regulated centrally by the EU.

### Registrations or marketing authorisations for medicinal products

There are five different routes by which herbal, homeopathic or anthroposophic medicinal products can obtain registrations or marketing authorisations. These are:

- A standard marketing authorisation
- A well-established use marketing authorisation (only, for herbal medicinal products)
- Two simplified registration procedures (one for traditional registration of herbal products and the other for homeopathic medicinal products)
- A national registration procedure for homeopathic products.

### Medicines' legislation via Directive 2001/83/EC

This directive requires all medicinal products within the EU to obtain market authorisation. It has a broad definition of what constitutes a medicinal product:

*“(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings;  
(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.”<sup>41</sup>*

These legal definitions set out the essential criteria to be taken into account in determining if a product is classed as a medicine – medicinal *by presentation* (a) and medicinal *by function* (b). These statements have been interpreted by a number of European Court of Justice cases such as the van Bennekom case (1983)<sup>42</sup>, the Ter Voort case (1992)<sup>43</sup> and the Delattre case (1991)<sup>44</sup>. The latter case was important in highlighting that if the packaging of a product gives the impression to the consumer that it is medicinal, this should be taken into account in determining whether a product is a medicine.<sup>45</sup> Medicinal products may fall under both limbs

<sup>41</sup> [https://ec.europa.eu/health/documents/eudralex/vol-1\\_en](https://ec.europa.eu/health/documents/eudralex/vol-1_en).

<sup>42</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A61982CJ0227>.

<sup>43</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A61991CJ0219>.

<sup>44</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A61988CJ0369>.

<sup>45</sup> An account of relevant case law can be found in Valverde JL (ed). *Responsibilities in the Efficient Use of Medicinal Products*. Vol 8 2005/6. IOS Press Amsterdam and in MHRA. *A Guide to What is a Medicinal Product*, 2016. [https://www.google.co.uk/search?q=Directive+2001%2F83%2FEC+as+amended+2016&ie=utf-8&oe=utf-8&client=firefox-b-ab&gfe\\_rd=cr&ei=21R5WIGfOJDEaOy5o-gl#q=a+guide+to+what+is+a+medicinal+product](https://www.google.co.uk/search?q=Directive+2001%2F83%2FEC+as+amended+2016&ie=utf-8&oe=utf-8&client=firefox-b-ab&gfe_rd=cr&ei=21R5WIGfOJDEaOy5o-gl#q=a+guide+to+what+is+a+medicinal+product).

of the definition but the European Court of Justice (ECJ) has confirmed that falling under either limb is sufficient to classify a product as a medicinal product.<sup>46</sup>

### **The “duck test”**

The two assessments, medicinal by presentation and medicinal by function, may simply be summed up in what has famously become known as the “duck test”.

- Does it look like a duck?
- Does it walk like a duck?
- Does it quack like a duck?
  - Yes?
  - ✓ Then it is a duck!

In other words if a herbal remedy, vitamin or mineral is sold or used for medicinal purposes, packaged like a medicine and/or can be shown to have active pharmacological activity, then it likely falls within the scope of Directive 2001/83/EC requiring a market authorisation or traditional herbal medicine registration.

### **Herbal medicinal products**

A herbal medicinal product is made from any part of a plant (including trees, fungi and seaweeds) of which the leaves, seeds, flowers, fruits or roots can be used for their therapeutic or cosmetic properties. Such products may be marketed as herbal medicines under Directive 2001/83/EC or food supplements under Directive 2002/46/EC or used in cosmetic products under Regulation (EC) N° 1223/2009. Herbal medicinal products are marketed as medicines to maintain health and treat disease. Herbal food supplements are available to enable consumers to exercise their choice to supplement their intake of nutrients for salutogenic purposes to maintain health.

Currently herbal medicines, like conventional pharmaceuticals, may in theory apply for a full EU market authorisation when the application concerns a new active ingredient (i.e. a plant that has not previously been authorised to be placed on the market as a herbal medicinal product). To obtain this authorisation, an application consisting of a dossier supporting the medicinal product’s quality, safety, and efficacy needs to be submitted to regulatory authorities. In practice, this route is effectively barred to most botanical medicines since plant medicines contain a large number of phytochemicals and their precise mode of action is hard to determine. This is not the case for chemical drugs containing a single active chemical principle. Another major stumbling block debarring herbal medicines from obtaining a full marketing authorisation is that as they are natural products they cannot be patented. For this reason their drug development via a full marketing authorisation is of no commercial interest to pharmaceutical companies.

### **Well-established use**

The EU’s pharmaceutical legislative framework also allows for a reduced application for medicines that are no longer bound by their data exclusivity. One such type of application is

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<sup>46</sup> Upjohn 1989 C-112/89: “Directive 65/65 (now Directive 2001/83) provides two definitions of the term “medicinal product”: one relating to presentation, the other to function. A product is medicinal if it falls within either of those definitions.”

the well-established use (WEU) medicinal product application requiring a complete quality documentation dossier, but a reduced clinical and preclinical program. Some herbal medicinal products have obtained WEU. However, providing proof of efficacy sufficient for WEU authorisation is frequently too expensive for herbal medicines because they cannot be patented and unlike most conventional pharmaceuticals they are chemically complex.

#### **Directive 2004/24/EC - The Traditional Herbal Products Directive (THMPD)**

In view of the difficulties of authorising herbal medicines and lack of any agreement between Member States about how such products should be marketed, a simplified procedure was introduced by the European Parliament, also known as The Traditional Herbal Products Directive (THMPD) it **was enacted in 2004 and** fully implemented in 2011. The THMPD was intended to remove the differences and uncertainties about the status of traditional herbal medicinal products that existed in the past in the Member States and facilitate the free movement of such products by introducing harmonised rules in this area.

**Comment [MM7]:** Please add

#### **A simplified registration process**

The THMPD provides a simplified registration mechanism for herbal medicinal products with a long tradition. This simplified procedure allows traditional use registration (TUR) of herbal medicinal products provided that there is sufficient evidence of the medicinal use of the product throughout a period of at least 30 years, including at least 15 years in the EU.

The Directive defines traditional herbal medicinal products as:

- having indications exclusively appropriate to traditional herbal medicinal products which, by virtue of their composition and purpose, are intended and designed for use without the supervision of a medical practitioner for diagnostic purposes or for prescription or monitoring of treatment
- being exclusively for administration in accordance with a specified strength and posology
- being oral, external and/or inhalation preparations
- providing sufficient data on the traditional use of the medicinal product; in particular proving not to be harmful in the specified conditions of use and the pharmacological effects or efficacy of the medicinal product being plausible on the basis of long-standing use and experience.

#### **The HMPC**

Alongside these new provisions a Committee for Herbal Medicinal Products (HMPC) has been established at the European Medicines Agency (EMA). The HMPC is tasked with establishing Community monographs for traditional herbal medicinal products and is compiling a list of herbal substances which have been in medicinal use for a sufficiently long time, hence considered not to be harmful under normal conditions of use.

The Member States with the most THMP registrations are the UK, Germany, Poland, and Austria. 18 Member States have registered 20 or fewer herbal products, and three Member States, Denmark, Luxembourg and Malta have not registered any THMPs at all.

### **Hypothetical risks inhibit progress**

Some Member States focus on hypothetical risks. For example, this overcautious approach currently prevents any herb containing furocoumarins from being registered, regardless of the fact that some medicinal herbs members important medicinal plant families (e.g. the genus *Angelica*, with over 60 species of medicinal plants used on a worldwide basis). Similar problems are caused by the requirement for genotoxicity although evidence of safety is provided by evidence of longstanding use. Nevertheless, some Member States require expensive and extensive genotoxicity studies despite the guidance of the HMPC which simplifies the process.

### **Restrictive time frame**

In addition, the stipulation requiring 15 years use within the EU restricts the registration of herbal medicines from non-European medical traditions.

In view of this, it is fair to say that Directive 2004/24/EC has failed to meet expectations. The number of registrations peaked in 2011 falling sharply in 2014 and 2015. Full implementation of the Directive is yet to occur.

### **Anthroposophic medicinal products**

These are products intended for use according to the principles of anthroposophic medicine. They include substances mostly derived from minerals, plants or animals, prepared in different levels of concentration for different routes of application, external, oral or parenteral.

The pharmaceutical Directive 2001/83/EC, does not recognise anthroposophic medicinal products as such. Some can be registered as homeopathic and others as herbal medicinal products. However the most typical and widely used anthroposophic medicinal products cannot qualify either as homeopathic or as herbal medicines and are authorised by the “normal rules” governing pharmaceutical medicines, although these rules are not appropriate for the special characteristics of the products and their use in the practice of anthroposophic medicine.

To date, the only European countries that have authorised a full range of anthroposophic medicinal products are Germany and Switzerland. In both countries the medicines legislators<sup>47</sup> as well as the competent authorities<sup>48</sup> have developed and implemented

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<sup>47</sup> Germany: Law on the circulation of medicinal products (Gesetz über den Verkehr mit Arzneimitteln) Art. 4, (33); Switzerland: Law of the Swiss Institute of Medicinal Products concerning the simplified authorisation of complementary and phytomedicines (Verordnung des Schweizerischen Heilmittelinstituts über die vereinfachte Zulassung von Komplementär- und Phytoarzneimitteln) Art. 4, 2f.

<sup>48</sup> Germany: BfArM - Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for Drugs and Medical Devices) Switzerland: BAG - Bundesamt für Gesundheit (Federal Institute of Health).

appropriate rules to allow a feasible market access guaranteeing a high level of quality and safety.

### **Homeopathic medicinal products**

Homeopathic medicinal products should be manufactured according to a procedure defined in the European Pharmacopoeia (EP) or – in cases where the procedure is not yet included in the EP, in a national homeopathic pharmacopoeia such as the German or the French homeopathic pharmacopoeias.

The registration procedure is not harmonised. Registrations are purely national and applications may thus be treated differently between EU Member States. No medical indications are permitted on product labels, as homeopathy is a highly individualised therapy:

*“Having regard to the particular characteristics of these homeopathic medicinal products, such as the very low level of active principles they contain and the difficulty of applying to them the conventional statistical methods relating to clinical trials, it is desirable to provide a special, simplified registration procedure for those homeopathic medicinal products which are placed on the market without therapeutic indications in a pharmaceutical form and dosage.”* (Directive 2001/83/EC)

Licensing requires a full set of data on the quality of the materials used in manufacturing. This includes data on the whereabouts of the herbal starting materials according to GACP (Good Agricultural and Collecting Practice) standards. These standards are frequently difficult to meet, as homeopathy usually requires only small quantities of plant material as starting substances, and the administrative burden in this context may easily exceed the economic benefit.

### **Aromatherapy products**

Aromatherapy products are marketed to support the practice of aromatherapy. As these are not medicinal products because they are used to improve health in general rather than treat disease, they are subject to cosmetic and general safety law such as Cosmetic Regulation (EC) No. 1223/2009 & The General Product Safety Directive.

**Aromatic medicine products** or medical aromatherapy involves the internal use of essential oils orally or via pessary or suppository to treat diseases. In this context these oils may be considered medicines as defined in Directive 2001/83/EC. Aromatic medicine has its origins in the phytotherapy tradition of Europe and is mostly practised by medical doctors in France and Germany. It is also practised by herbal practitioners (who are not medical doctors) in the UK under exemptions granted to these practitioners under the Human Medicine Regulations 2012 and Ireland where a similar exemption pertains (Medicinal Products Regulations).<sup>49</sup>

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<sup>49</sup> <http://www.irishstatutebook.ie/eli/2003/si/540/made/en/print>.

### **Food supplements**

In the EU, food supplements are regulated via the Food supplements Directive 2002/46/EC. The Directive defines food supplements as “*foodstuffs, the purpose of which is to supplement the normal diet.*” The Directive allows food supplements to be marketed as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities.

### **Blurred borderline between food and medicine**

The borderline between food and medicine remains blurred. Many rules regarding food supplements are still unharmonised and subject to divergent national rules across the 27 EU Member States. These include rules on vitamin/mineral maximum limits and on the permitted use of botanicals and other ingredients with a nutritional and/or physiological effect (bioactive substances). In the absence of EU legislation, some Member States have set maximum levels for vitamins and minerals in their legislation. These include Belgium, Bulgaria, Cyprus, Denmark, France, Italy, Luxembourg, Malta and Slovenia. On the other hand, a number of EU countries have removed existing national limits. These include Spain, the Czech Republic, Romania and Greece.<sup>50</sup> To complicate matters further, Belgium, France and Italy have created the BELFRIT list of botanical food supplements with accepted health claims.<sup>51,52</sup> This can only add to the confusion and lack of harmonisation with respect to the marketing of herbal medicinal products in the EU.

### **Herbal food supplements**

Various plant and herbal extracts are permitted in food supplements together with a wide range of nutrients and other ingredients, including, but not limited to, vitamins, minerals, amino acids, essential fatty acids and fibre.

### **Food v medicine & public confusion**

Directive 2002/46/EC permits as food supplements “*a wide range of nutrients and other ingredients ...including, but not limited to, vitamins, minerals, amino acids, essential fatty acids, fibre and various plants and herbal extracts.*”

This has led to considerable and understandable public confusion about the difference between botanical supplements marketed as food supplements and herbal medicinal products marketed under the Traditional Herbal Medicinal Products Directive (2004/24/EC). There are after all many similarities: Both product types may be presented in dose form as tablets and pills to be taken in measured, small unit quantities, and both product types can have “physiological function” according to EC Directives 2002/46 (Food Supplements) and

<sup>50</sup> <http://www.nutraceuticalsnow.com/articles/2013/04/29/marketing-food-supplements-with-health-claims-in-the-eu-key-challenges-in-2013-and-beyond/>.

<sup>51</sup> <http://www.nutraingredients.com/Regulation-Policy/BELFRIT-leads-Europe-in-botanicals-harmonisation-as-Italy-affirms-1000-strong-list>.

<sup>52</sup> <http://www.foodcomplianceinternational.com/blog/2015/4/20/belgium-notifies-the-belfrit-list-of-plants-to-the-european-commission>.

Directive 2001/83 (Pharmaceutical Directive). Both product types may contain the same ingredient(s) and can make claims for effect. An important difference is that a medicinal product is intended to treat, cure or prevent disease, while a food supplement is intended to maintain or optimise health within the normal health parameters.

A herbal medicinal product should be prescribed “*with a view to restoring, correcting or modifying physiological functions*” (2001/83/EC) while a food supplement provides nutrients and other substances to maintain and support a balanced healthy physiological state.

To complicate matters further, a product may be classified as medicinal in one Member State and a food in another.<sup>53</sup> Individual Member States have permitted a considerable number of food supplements, including botanicals, to be marketed in their jurisdiction. This lack of distinction between medicinal products and food supplements has generated a plethora of borderline botanical-sourced products, which inevitably produce general public confusion and mislead consumers.<sup>54</sup>

### **EU food law**

Some herbs have culinary use or are used for general health improvement and may be classed as foods subject to Community food law. EU food law is governed by Regulation (EC) No 178/2002 and of the general principles and requirements of food law, allowing the European Food Safety Authority to control procedures in matters of food safety.<sup>55</sup> When this legislation was originally enacted, it was not generally perceived that foods might be advertised as having a particular functional (health giving) aspect. However, the increasing body of evidence of some foods and food constituents having beneficial physiological and psychological effects over and above the provision of the basic nutrients has led to an ongoing debate about the marketing of functional foods in the EU that can make specific health claims.

### **Nutrition and health claims**

In December 2006 the European Food Safety Authority (EFSA) adopted Regulation (EC) No 1924/2006 on the use of nutrition and health claims for foods which lays down harmonised EU-wide rules for the use of health or nutritional claims on foodstuffs based on nutrient profiles.<sup>56</sup> These are nutritional requirements that foods must meet in order to bear nutrition and health claims. A main objective of this Regulation is to ensure that any claim made on a food label in the EU is substantiated by scientific evidence and it followed on from other Regulations that also govern this matter.

At present foods sold in the EU can carry a relatively limited number of nutrition and health claims. A nutrition claim states or suggests that a food has beneficial nutritional properties,

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<sup>53</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A61988CJ0369>.

<sup>54</sup> Bilia AR. Herbal medicinal products versus botanical-food supplements in the European market: state of art and perspectives. *Nat Prod Commun.* 2015 Jan;10(1):125-31.

<sup>55</sup> <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32002R0178>.

<sup>56</sup> <http://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:32006R1924>.

such as “low fat”, “no added sugar” and “high in fibre”. A health claim is any statement on labels, advertising or other marketing products that health benefits can result from consuming a given food. Nutrition claims are only permitted if they are listed in the Annex of [Regulation \(EC\) No 1924/2006](#), lastly amended by [Regulation \(EU\) No 1047/2012](#).

A very large number of health claims are presently under review. The consolidated database of Article 13.1 health claims contains the 4,637 entries submitted to EFSA for evaluation.

The EFSA is currently evaluating the references for around 3,300 health claim entries.<sup>57</sup> In theory these regulations require that health claims should adequately demonstrate that they are substantiated by generally accepted scientific evidence, by taking into account the totality of the available scientific data. However, in practice, numbers of suggested claims are somewhat anecdotal and weak, and present no real information for the consumers and/or health practitioners.<sup>58</sup> More significantly, market surveillance is mostly focused on correct labelling but crucially not on actual quality of the products themselves.

EFSA rules are currently laid down in:

- [Regulation 1924/2006 on nutrition and health claims made on foods](#)
- [Commission Regulation No 353/2008 establishing implementing rules for applications for authorisation of health claims](#)
- [Commission Regulation No 1169/2009 amending Regulation \(EC\) No 353/2008 establishing implementing rules for applications for authorisation of health claims](#)

The EFSA’s work includes providing scientific advice on food supplements and food ingredients with regard to:

- [General function health claims under Article 13.1 of the EU Regulation](#) (EC Regulation on nutrition and health claims)
- [New function health claims under Article 13.5 of the EU Regulation](#)
- [Criteria for setting nutrient profiles](#)

### **Clarifying borderline between food and medicine**

A clear legal difference between food supplements and medicines is needed. Within the EU, some member states (e.g. France, Belgium and Italy) currently favour the classification of herbal products as food supplements and do not register any THMPs.

As a consequence the European Food Standards Agency (EFSA) and the HPMC lack a coherent strategy how to give clear and definite guidance to Member States. The potential of the THMP registration scheme can only be achieved by clarifying the therapeutic scope and differences as well as the borderline between herbal products marketed as food supplements and herbal medicines.

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<sup>57</sup> <https://www.efsa.europa.eu/en/topics/topic/article13>.

<sup>58</sup> <http://naturalsolutionsradio.com/blog/natural-solutions-radio-administrator/fears-persist-consumers-will-struggle-understand-efsas-cl>.

### **Strengthening the coordinating role of the HMPC**

The Herbal Medicinal Products Committee (HMPC) within the European Medicines Agency (EMA) works to unify the different standpoints of Member States. In addition, the HMPC prepares monographs and guidelines for registration. Despite the best efforts of the HMPC to date, Member States have failed to apply these guidelines in a coherent manner. As a result THMPs registered in one Member State face difficulties when an application is filed in another Member State using the same data. Despite the fact that the same HMPC guidelines apply, the national competent authorities too often interpret them in completely different ways.

**ends**