A LEGAL ASSESSMENT OF THE ROLE QIGONG PLAYS IN THE EUROPEAN UNION

by
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Abstract

This paper analyses the role that Qigong plays within the European Union ('the Union') whilst assessing whether, and to what extent, it is recognized as a therapeutic method used to maintain and improve the health of individuals. In particular, the paper will examine which boundaries presently deter Qigong from playing a primary and independent role in healthcare from a European Union legal perspective. It will also be argued that civil society might play a key role – through taking responsible lines of action – in stimulating decision-making actors in Europe to gradually integrate Qigong into the national health systems of the Union's Member States. The rationale for this paper is that Qigong is in line with the criteria provided by the Union through various pieces of legislation in the field of health and that therefore, the Union should use the appropriate means (such as a new European NCM Centre) to conduct further research on core NCM, including Qigong, the results of which could eventually help the Union's authorities to provide Qigong with an appropriate level of legal recognition in the European Union, proportional to its therapeutic value.

I. INTRODUCTION

The practice of Qigong was conceived over two thousand years ago to help the practitioner improve his or her mental and somatic health by means of a combination of static and dynamic physical exercises, breathing exercises and meditation. In other words, one could say that the Qigong practitioner seeks overall health through Qigong. In this paper, we will use the legal status granted to Health as a reference point to build legal arguments that, connected to each other, could act in favour of a highest degree of recognition for Qigong in the European Union.

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Presently, health is a right that is recognized internationally. Moreover, we can affirm that it is not just a simple right given that it has been included among the fundamental rights of every human being. The origin of its recognition however, dates back only to 1948 when the global health organization set up by the United Nations came into force. The objective of the World Health Organization ('WHO')[3] was defined in Article 14 of its Constitution[4] declaring that health "shall be the attainment by all peoples" and at "the highest possible level…" The preamble defined health as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity". Further down in the preamble, the right to health was articulated stating: "The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition."

In Europe, the Treaty of the Functioning of the European Union ('TFEU')[5] together with the Charter of Fundamental Rights of the European Union ('The Charter')[6] reinforced the foundations for a European Union healthcare policy; the protection of health has been incorporated among the most relevant rights in the Union (enshrined in the Charter) which seeks to ensure a high level of protection of human health when it comes to all Union policies and activities. Its Article 35[7] defines the right to healthcare which, according to an answer given by European Commission to Written Question E-296/14 (see note 15 below) put by a Member of the European Parliament: "serves as a basis to the overarching principle that everyone should have access to healthcare — preventive, diagnostic and curative treatment — regardless of financial means, gender or nationality." These facts demonstrate the scope of the importance the European Union attaches to public health in its territory.

However, this right is restricted by the conditions established by national laws and practices. In this respect, at present, the organisation and regulation of healthcare

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[3] See http://www.who.int/en/ [accessed June 2015].

[4] The Constitution was adopted by the International Health Conference in New York from 19 June to 22 July 1946, signed on 22 July 1946 by the representatives of 61 States (Off. Rec. Wld Hlth Org., 2, 100), and entered into force on 7 April 1948.

[5] Consolidated version of the Treaty on the Functioning of the European Union, *OJ C 326, 26.10.2012, p. 47–390*. http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:12012E/TXT [accessed June 2015].

[6] Charter of Fundamental Rights of the European Union, *OJ C 83, 30.3.2010, p. 389–403*. http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1431965862079&uri=CELEX:12010P [accessed June 2015].

[7] Article 35 of The Charter of Fundamental Rights of the Union reads as follows:
'Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.'

remains an exclusive competence belonging to Member States and as a result the Union does not determine health policies, nor the provision of health services and medical care. With that said, the Union does however play a major part by supplementing national policies and supporting cooperation between Member States in the field of public health, for instance by stipulating under which conditions patients can receive healthcare treatment in another Member State, or by promoting the use of a European professional card to help professional mobility. In addition, it is important to stress that, in terms of regulation, medicinal products are regulated at the Union level.

With regards to Qigong, the WHO includes this practice among the traditional procedure-based healthcare therapies, [8] defined as therapies that use various techniques, primarily without the use of medication, to provide healthcare. In addition, Qigong is mentioned on the list of Traditional and Complementary Medicine practices that appear in the two global guides that up until now have been published by the WHO on Traditional Medicine Strategy (in the periods 2002-2005[9] and 2014-2023[10]). The purpose of these guides is to provide evidence in favour of the necessity to integrate Traditional and Complementary Medicine into national health systems.

In Europe, Qigong is considered as a discipline part of the Non-Conventional Medicines (NCM), a term that encompasses Traditional Medicine (TM), Complementary and Alternative medicines (CAM). For the sake of clarity, and in order to avoid any terminological confusion, in this text we will refer to Qigong and related medicines/therapies as Non-Conventional Medicines (NCM).

In this paper, we intend to structure the most pertinent information with a view to creating legal arguments for a progressive integration of Qigong – as part of the Non-Conventional Medicines (NCM) – into the legal order of the Union.

II. METHODOLOGY

According to Article 168 of the TFEU, Member States retain the competence to regulate in the field of health. European Union authorities hold, nevertheless, a

[8] WHO. General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine, World Health Organization, Geneva, 2000.

[9] Full text available in http://www.wpro.who.int/health_technology/book_who_traditional_medicine_strategy_2002_2005.pdf [accessed June 2015].

[10] Full text available in http://apps.who.int/iris/bitstream/10665/92455/1/9789241506090_eng.pdf [accessed June 2015].

leading position in this area. Equipped with a wide set of powers, ranging from the promotion of the coordination of national policies to the adoption of measures to meet common safety concerns, the Union's decisions influence the lives of European individuals and therefore should seek to reflect citizen's needs and demands to the highest extent.

In order to assess exactly what role Qigong – as part of the Non-Conventional Medicines (NCM) – plays at the level of the Union, a detailed overview of the activities concerning NCM with regards to both the European Parliament and the Commission will be given. Moreover, the analysis of this paper will be supported by a very real example in a Member State, namely the Region of Tuscany in Italy, in order to illustrate how NCM therapies have been successfully integrated in a public healthcare program.

1. The European Parliament ('EP') [11]

As a political body, the European Parliament's principal task is to determine what the core political questions are, as well as provide political guidance; its members, Members of the Parliament (MEPs) represent citizens from the current 28 Member States.[12] The EP has a wide assortment of tools at its disposal to give voice to European citizens' needs in a timely manner, some of which have been used to bring Complementary and Alternative Medicines into the political agenda in the Union.

To begin with, a substantial step towards this objective was given in 1997 when the Plenary voted and approved 'the Collins report', resolution no. 75 on the *status of non-conventional medicine*.[13] The importance of this resolution lies in the fact that it addresses a number of key points such as medical pluralism, appropriate training of practitioners, codification of the status of practitioners, or extension of the scope of social security in order to cover non-conventional medical disciplines. To be able to achieve all this, the text of the resolution proposes a set of comprehensive measures to help clarify the status of Complementary and Alternative Medicines inside the Union, and what is more important, calls on the pertinent EU institutions to take the necessary initiatives towards the legal recognition and integration of Complementary

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[11] See http://www.europarl.europa.eu/portal/en [accessed June 2015].

[12] See current Members of the European Parliament in http://www.europarl.europa.eu/meps/en/map.html [accessed June 2015].

[13] Resolution A4-0075/97. Full text available in http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+REPORT+A4-1997-0075+0+DOC+XML+V0//EN [accessed June 2015].

and Alternative Medicines inside the Union. On this basis, two years later the Council of Europe adopted its Resolution 1206 (1999);[14] the Council of Europe welcomed the European Parliament resolution and agreed that there were certain grey zones to be further addressed. However, to date no other resolution from the European Parliament that could follow up on the developments that have taken place since 1997 has been approved yet.

Another resource used by the MEPs to point out precise topics is their right to make Parliamentary Questions to the European Commission[15] with several questions having been put forward over the last few years in connection with Non-Conventional Medicines (NCM),[16] the most recent being in 2015 (the most recurrent point pointed out by the MEPs is the need to invest in further research in this area). Unfortunately however, the strength of the replies from the European Commission does not reflect a sufficient specific commitment to NCM.

It is also worth mentioning the EP Think Tank,[17] a department that produces a variety of policy documents at the request of Members of the Parliament. In 2013, the think tank produced a report that summarised the discussions at the Workshop held in Brussels on "Effectiveness of Medicines and Therapies",[18] including a presentation made by Prof Dr Erik Baars[19] on the position and role of Complementary and Alternative Medicines.

To finalise the overview of the Parliament, at present, two informal all-party forums (MEPs for CAM[20] and the MAC Interest Group – MEPs Against Cancer[21]) discuss matters related with NCM in the Parliament, often collaborating and meeting with other stakeholders to ensure that NCM remains high up on the political agenda.

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14 Council of Europe. Resolution 1206 (1999) An European approach to non-conventional medicines; November 4, 1999. In: Official Gazette of the Council of Europe, editor. Resolution. Strasbourg: Council of Europe 1999

15 To consult any Question put since 1999, see http://www.europarl.europa.eu/plenary/en/parliamentary-questions.html?tabType=all#sidesForm [accessed June 2015].

16 See Written Questions E-2920/2003, E-8614/2010, E-10808/2010, E-13535/2013, E-296/14, E-374/14, E-2831/2015.

17 See all documents published by EP Thinktank in http://www.europarl.europa.eu/thinktank/en/home.html [accessed June 2015].

18 Full text available in http://www.europarl.europa.eu/thinktank/en/document.html?reference=IPOL-ENVI_AT(2013)518741 [accessed June 2015].

19 Prof Dr Erik BAARS. MD, MSc Epidemiology, University of Applied Sciences, Leiden, (NL)

20 See http://www.cam-europe.eu/cam-interest-group-meetings.php [accessed June 2015].

21 See http://www.europeancancerleagues.org/mac [accessed June 2015].

2. The European Commission [22]

Known otherwise as the executive branch of the Union, the European Commission represents the interests of the European Union as a whole, and is in charge of several fundamental tasks, several of these being the legislative initiative, the implementation of the Union's budget, and the management and implementation of the Union's objectives.

In this section we seek to connect, to the extent possible, the main specific programmes and legislation approved by the European Commission that may have had an impact on the legal status of Qigong – as part of Non-Conventional Medicines (NCM) – inside the Union. For this purpose, we take account, in chronological order, of diverse decisions that have been taken in the areas of health, services and patients, and in doing so will firstly consider programmes and legislation that are directly related to Non-Conventional Medicines (NCM), including Qigong.

From a general perspective, since 2003 the European Union has created and approved three action programmes in the field of health, the second[23] of which was established by Decision No 1350/2007/EC by the European Parliament[24] in which the text of its recital 24 admits that the programme "*should recognize the importance of a holistic approach to public health and take into account, where appropriate and where there is scientific or clinical evidence about its efficacy, complementary and alternative medicine in its actions."*

In this regard, *Directive 2004/24/EC*[25] specifically targets herbal products, considering that "*the vast majority of medicinal products with a sufficiently long and coherent tradition are based on herbal substances",* able to provide the necessary guarantees of quality, safety and efficacy. With this aim, the Directive establishes in Article 16a a simplified registration procedure called 'traditional-use registration' for herbal medicinal products fulfilling the criteria mentioned in the article, which is basically sufficient scientific literature demonstrating a well-established medicinal use

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22 See http://ec.europa.eu/index_en.htm [accessed June 2015].

23 The second programme of Community action in the field of health (2008-13) http://ec.europa.eu/health/programme/policy/2008-2013/index_en.htm [accessed June 2015].

24 Decision No 1350/2007/EC of the European Parliament and of the Council of 23 October 2007 establishing a second programme of Community action in the field of health (2008-13), *OJ L 301, 20.11.2007, p. 3–13* *http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2007.301.01.0003.01.ENG#text* [accessed June 2015].

25 Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004 amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use, *OJ L 136, 30.4.2004, p. 85–90.* Full text available in http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2004.136.01.0085.01.ENG [accessed June 2015].

with recognised efficacy and an acceptable level of safety. In effect, approval of this Directive could be interpreted as a further confirmation of European citizens' increasing use of Non-Conventional Medicines to complement their choice of alternatives used within the scope of their healthcare.

In 2007, the European Commission approved the 7th Framework Programme (FP 7)[26] of the European Community for research, which incorporated several thematic objectives[27] to be achieved, with the improvement of the health of European citizens being one of them. In this sense, in order to optimize the delivery of healthcare to European citizens, the European Commission recognized the potential value of Non-Conventional Medicines: "*Translating clinical outcome into clinical practice: to create the knowledge bases for clinical decisionmaking and to address the translation of outcomes of clinical research into clinical practice, especially addressing patient safety and the better use of medicines (including some aspects of pharmacovigilance and scientifically tested complementary and alternative medicines) as well as the specificities of children, women and the elderly population.*"

To this end, the FP 7 funded two projects related to NCM, CAMbrella and GP-TCM, which both began in 2010 and were concluded at the end of 2012. CAMbrella [28] was the first Union Research Program on Complementary and Alternative Medicine (CAM), the objectives of which were: To examine CAM, including Traditional Chinese Medicine, on a global level in Europe, and to create a supported network of researchers in the field. At the end of its operating lifetime, the Consortium presented 'The roadmap for European CAM research' strategy document outlining clear conclusions that, 1) CAM is a neglected area of research which needs more activities, 2) CAM research must reflect the needs of citizens, patients, providers and other stakeholders, 3) it must reflect the real-world settings of health care in Europe, and that consequently 4) a centralized and academically supported EU CAM centre would be welcome to facilitate this process.

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[26] 7th Framework Programme for Research and Technological Development http://ec.europa.eu/research/fp7/index_en.cfm [accessed June 2015].

[27] Decision No 1982/2006/EC of the European Parliament and of the Council of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013), *OJ L 412, 30.12.2006, p. 1–43* http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2006.412.01.0001.01.ENG [accessed June 2015].

[28] See http://ec.europa.eu/research/health/public-health/clinical-outcome-into-practice/projects/cambrella_en.html [accessed June 2015].

For follow up purposes, in 2013 a 'Post-CAMbrella' steering group was created. By the end of the year, the steering group agreed to merge with the steering group of the European Chapter of the International Society for Complementary Medicine Research (ISCMR)[29] to constitute, with effect from 1 January 2014, a Task Force named 'EU-Res-CAM' (European Research in CAM),[30] with the aim to be a first step in developing sustainable CAM research in Europe.

In addition, a press note published[31] on the CAMbrella website suggested that CAM could be integrated within Horizon 2020,[32] the Union's Framework Programme for Research and Innovation to be implemented by the European Commission during the period 2014-2020, through a societal challenge, incorporated in its Work Programme 2014-2015, named 'health, demographic change and wellbeing' (SC1),[33] yet in practice, projects in connection with Non-Conventional Medicines don't seem to have any presence in the above mentioned societal challenge.

Working from another angle, the 'Good practice in Traditional Chinese Medicine research in the post-genomic era' (GP-TCM) project[34] was set up with the aim of informing on best practice for the safety and efficacy of TCM in EU Member States, particularly with regards to herbal medicines and acupuncture, using a functional genomics approach. As a result, a collaborative European-Chinese network working together on functional genomics research in TCM ('Good Practice in Traditional Chinese Medicine Research Association – 中医□□范研究学会') was created.[35]

Moreover, the European Partnership for Action Against Cancer (EPAAC)[36] was launched in 2009 following the publication of an apposite Communication from the European Commission which at the beginning of 2014 produced a study on Complementary and Alternative Medicine (CAM) and opportunities for Integrative

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29 See http://www.iscmr.org/ [accessed June 2015].

30 See http://www.iscmr.org/fileadmin/iscmr/editors/documents/EU-Res-CAM/EU-Res-CAM_For_the_Public.pdf [accessed June 2015].

31 Full text available in http://www.cambrella.eu/home.php?il=166 [accessed June 2015].

32 See http://ec.europa.eu/programmes/horizon2020/en/what-horizon-2020 [accessed June 2015].

33 Full text available in http://ec.europa.eu/research/participants/data/ref/h2020/wp/2014_2015/main/h2020-wp1415-health_en.pdf [accessed June 2015].

34 Project 'Good Practice in Traditional Chinese Medicine Research in the Post-genomic Era' http://cordis.europa.eu/project/rcn/90960_en.html [accessed June 2015].

35 See http://www.gp-tcm.org/ [accessed June 2015].

36 See http://www.epaac.eu/ [accessed June 2015].

Oncology[37] including Qigong as a technique based on energetic exercises within the Traditional Chinese Medicines used by patients with cancer.

To conclude the first part of the review of the activities of the European Commission, in September 2014, a report from the Commission on the fight against cancer in the Union,[38] which constituted a basis for determining future action on cancer in Europe, included - in its section aimed to identify and disseminate good practice - [39] a survey designed to collect data related to centres across Europe that use Complementary and alternative medicine (CAM) in cancer care. At the time of writing, results of this survey are not yet published, although the abstract can already be consulted.[40]

As a second step in our review, we will examine other examples of other legislation and initiatives likely to affect the position of Qigong – as part of Non-Conventional Medicines.

Firstly, in the field of patients, there is the *Directive on the application of patients' rights in cross-border healthcare*[41] aims to *"providing rules for facilitating the access to safe and high quality cross-border healthcare in the Union".* Although there is no explicit reference to Non-Conventional Medicines in the text, some of the introductory paragraphs may be interpreted as an open door to services provided by NCM professionals, including Qigong. We will limit the references to: Recital 6 which confirms that all types of medical care fall within the scope of the TFEU, Recital 26[42] which states the right of recipients of healthcare in receiving healthcare

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[37] Complementary and alternative medicine (CAM) in cancer care Development and opportunities of Integrative Oncology. Full text available in http://www.epaac.eu/images/END/Final_Deliverables/D5_Complementary_and_alternative_medicine_CAM_in_cancer_care_development_and_opportunities_of_integrative_oncology.pdf [accessed June 2015].

[38] COM (2014) 584: Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on Implementation of the Communication from the Commission, from 24 June 2009, on Action Against Cancer: European Partnership [COM (2009) 291 final] and Second Implementation Report on the Council Recommendation of 2 December 2003 on cancer screening (2003/878/EC), /* COM/2014/0584 final */. Full text available in http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2014:0584:FIN [accessed June 2015].

[39] See section 2.5 of the report

[40] Support Care Cancer.2015 Jun;23(6):1795-806. doi: 10.1007/s00520-014-2517-4. Epub 2014 Dec 4. http://www.ncbi.nlm.nih.gov/pubmed/25471177# [accessed June 2015].

[41] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, *OJ L 88, 4.4.2011, p. 45–65.* Full text available in http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32011L0024 [accessed June 2015].

[42] "*(26) The right to reimbursement of the costs of healthcare provided in another Member State by the statutory social security system of patients as insured persons has been recognised by the Court of Justice in several judgements. The Court of Justice has held that the Treaty provisions on the freedom to provide services include the freedom for the recipients of healthcare, including persons in need of medical treatment, to go to another Member State in order to receive it there. The same should apply to recipients of healthcare*

provided in another Member State through other means ('other means' could eventually apply to Qigong provided that the appropriate legal framework is created) as well as Recital 27 which however refers to the need of greater legal certainty as regards the reimbursement of healthcare costs (here again, it may be connected with the possibility to create a legal framework that could accommodate Qigong into the modalities of reimbursement of healthcare costs). Moreover, in the Articles of the Directive, Article 3 defines 'healthcare provider' as *"any natural or legal person or any other entity legally providing healthcare on the territory of a Member State",* which could well include Qigong professionals, whereas Article 12 refers to support development of "European reference networks" [43] between healthcare providers and centres of expertise in the Member States, stating that "*European reference networks can improve the access to diagnosis and the provision of high-quality healthcare to all patients who have conditions requiring a particular concentration of resources or expertise, and could also be focal points for medical training and research, information dissemination and evaluation, especially for rare diseases."*

Secondly, in the field of services, the *Professional Qualifications Directive*[44] – based on mutual trust between Member States – introduces a number of changes aimed to simplify the system of recognition of qualifications, hence supporting the mobility of professionals across Europe. Essentially, it works through granting automatic recognition to a limited number of professions whereas for a large majority of professions (regulated professions)[45] it applies a so-called 'general system'. A relevant measure proposed by the Directive constitutes the introduction of a European professional card,[46] aimed to facilitate recognition of qualifications to interested professionals who intend to move around the Union, either on a permanent or temporary basis.

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seeking to receive healthcare provided in another Member State through other means, for example through eHealth services."

[43] 2014/286/EU: Commission Delegated Decision of 10 March 2014 setting out criteria and conditions that European Reference Networks and healthcare providers wishing to join a European Reference Network must fulfill, *OJ L 147, 17.5.2014, p. 71–78.* Full text available in http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:JOL_2014_147_R_0006 [accessed June 2015].

[44] Directive 2013/55/EU of the European Parliament and of the Council of 20 November 2013 amending Directive 2005/36/EC on the recognition of professional qualifications and Regulation (EU) No 1024/2012 on administrative cooperation through the Internal Market Information System ('the IMI Regulation'), *OJ L 354, 28.12.2013, p. 132–170*. Full text available in http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32013L0055 [accessed June 2015].

[45] See the Regulated professions database from the European Commission http://ec.europa.eu/internal_market/qualifications/regprof/index.cfm?fuseaction=home.home [accessed June 2015].

[46] See introductory information http://ec.europa.eu/internal_market/publications/docs/european-professional-card_en.pdf [accessed June 2015].

Finally, in the field of health, the third Programme for the Union's action in the field of health,[47] largely implemented by the 'Consumers, Health and Food Executive Agency' (CHAFEA),[48] was established in 2014 by Regulation; [49] its Annex I contains four thematic priorities in line with the reasoning behind this paper, particularly the first, third and fourth priorities: *(1) Promote health, prevent diseases and foster supportive environments for healthy lifestyles taking into account the 'health in all policies' principle, (2) Protect Union citizens from serious cross-border health threats, (3) Contribute to innovative, efficient and sustainable health systems, and (4) Facilitate access to better and safer healthcare for Union citizens*.

In the same field, looking from a more specific point of view, the 2014 EU Summit on Chronic Diseases[50] took place in Brussels and divided its agenda into five different workshops. Workshop number five included a presentation 'on the role of CAM for Prevention and Treatment In Chronic Diseases'[51] given by Prof. Dr. B. Brinkhaus.[52] Conclusions from workshop number five [53] allude to Complementary and Alternative medicine (CAM) in the following way: *"Complementary and alternative medicine (CAM) can also play a role in prevention and treatment of chronic diseases. According to WHO, traditional medicine is popular in all regions of the world and its use is rapidly expanding even in developed countries; CAM is used by up to 80% of European citizens for two main reasons: support to health maintenance health and disease prevention, and a more personalized and sustainable treatment of chronic illness. Given its unique capacities to provide prevention and treatment as one whole package, support personal empowerment and to motivate healthy lifestyle change, it has significant, but to date hidden potential, to contribute to both prevention and treatment of chronic diseases. Therefore, it is important to*

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47 See dedicated policy website from the European Commission http://ec.europa.eu/health/programme/policy/2014-2020/index_en.htm [accessed June 2015].

48 See http://ec.europa.eu/chafea/index.html [accessed June 2015].

49 Regulation (EU) No 282/2014 of the European Parliament and of the Council of 11 March 2014 on the establishment of a third Programme for the Union's action in the field of health (2014-2020) and repealing Decision No 1350/2007/EC, *OJ L 86, 21.3.2014, p. 1–13.* Full text available in http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2014.086.01.0001.01.ENG [accessed June 2015].

50 See dedicated website from the European Commission http://ec.europa.eu/health/major_chronic_diseases/events/ev_20140403_en.htm [accessed June 2015].

51 See presentation http://ec.europa.eu/health/major_chronic_diseases/docs/ev_20140403_w5co08_en.pdf [accessed June 2015].

52 Prof Dr Benno Brinkhaus, Charité - Universitätsmedizin Berlin.

53 Acting more efficiently on risk factors and determinants - Innovation in prevention and rebalancing and treatment. Full text available in http://ec.europa.eu/health/major_chronic_diseases/docs/ev_20140403_w5co10_en.pdf [accessed June 2015].

further support research and increase of knowledge in this field and have a clear vision about dosage, toxicity, and standardization".

3. Member States

Inside the Union, although only a few Member States have produced national legislation on Non-Conventional Medicines, administrations at local or regional level make use, to varying degrees, of some form of Non-Conventional Medicines in their healthcare systems. From these local and regional administrations, we have chosen the region of Tuscany in Italy as an encouraging example of a public administration that constantly searches for complementary and alternative solutions to offer a complete range of healthcare services to its citizens.

In Italy, healthcare is a competence shared between the National Government and the country's twenty Regions. Concerning Non-Conventional Medicines, Italy's Order of Physicians, Surgeons and Dentists (FNOMCeO) took the first step towards harmonization of rules in this area by recognizing the social value of nine NMC, including Traditional Chinese Medicine, in its "Guidelines with regard to Non-Conventional Medicines" (*Delibera e linee guida su Medicine e pratiche non* Convenzionali) approved in 2002; followed in 2009 by the "Guidelines with regard to training in NCM" (*Linee guida per la formazione nelle medicine e pratiche non convenzionali riservate ai medici chirurghi e agli odontoiatri*). According to the terms of both guidelines, practice of these therapies is considered 'a medical act' and is therefore restricted to medical doctors and odontologists. [54]

It has to be mentioned that indirect recognition of Non-Conventional Medicines has been given through different legislative documents; the most relevant example dates back to the Decree of the Presidency of the Council of February 29, 2001, a measure defining the basic levels of care, Annex 2A of which refers precisely to Non-Conventional Medicines – therapies entirely paid by the patient. In addition, the Institute for Political, Economical and Social Studies (Eurispes) included in its report for 2012, datasheet no. 10, a paragraph concerning use of the most relevant Non-Conventional Medicines, including Traditional Chinese Medicine, in Italy.

[54] Paolo Roberti di Sarsina and Ilaria Iseppato, "Looking for a Person-Centered Medicine: Non Conventional Medicine in the Conventional European and Italian Setting," Evidence-Based Complementary and Alternative Medicine, vol. 2011, Article ID 382961, 8 pages, 2011. http://dx.doi.org/10.1093/ecam/nep048

However, no national law has regulated Non-Conventional Medicines, that is until 2013, when the Government, the Regions and Autonomous Provinces of Trento and Bolzano undersigned the agreement concerning the certification of training and practice of Homeopathy, Phytotherapy and Acupuncture.[55] With regards to access to training and the practice of these therapies, two additional medical related professions were added, that is to say, medical veterinaries and pharmacists. The agreement undoubtedly represents a major step forward to secure the recognition of the added value brought by the integration of NCM in the Italian healthcare system.

In addition, over the pass two decades, some twenty bills were presented to the Senate of the Republic with the objective of incorporating some of the most relevant Non-Conventional Medicines to the national legal order; for example, only in 2013, a number of Senators submitted five different bills;[56] amongst them, bill no. 254[57] which intended to increase recognition of Traditional Chinese Medicine – including, but not limited to, Qigong as a medical gymnastic - and acupuncture. Unfortunately, none of them gained sufficient support to be approved.

Amongst the regions, the region of Tuscany stands out for its determination for the promotion of integrating NCM into the regional healthcare system by using a new approach to healthcare aimed to help citizens reduce pharmacological consumption.

As a matter of fact, the regional healthcare planning (hereafter PSR Tuscany) in the years 1996-1998 (approved by Resolution no. 527/1995) already contained a number of measures directed at enhancing the value of NCM. Since then, a step-by-step strategy has been successfully developed to integrate NCM into the regional healthcare system.

Further on, PSR Tuscany in the period 1999-2001 represented a pioneering breakthrough in Italy by including a specific chapter dedicated to NCM (Chapter IV, H, relative to "Integration of Non-Conventional Medicines in health interventions"). In addition, the PSR allocated funds to support NCM, and also created a NCM

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55 (text in Italian) *Accordo tra il Governo, le Regioni e le Province autonome di Trento e Bolzano concernente i criteri e le modalità per la formazione ed il relativo esercizio dell'agopuntura, della fitoterapia e dell'omeopatia da parte dei medici chirurghi ed odontoiatri". (SALUTE) Codice:4.10/2013/2 (Servizio III) Accordo ai sensi dell'articolo 4 del decreto legislativo 28 agosto 1997, n. 281.*

56 Ddl n. 225, n. 254, n. 256, n.429, n.768 (text in Italian)
http://www.senato.it/ric/sddl/nuovaricerca.do?params.legislatura=17 [accessed June 2015].

57 Bill n. 254 presented by senator D'Ambrosio Lettieri, communicated to the Presidency on 21 March 2013 (text in Italian)
http://www.senato.it/japp/bgt/showdoc/17/DDLPRES/699494/index.html?stampa=si&spart=si&toc=no&parse=si
[accessed June 2015].

regional committee responsible for assessing citizens' demands for NCM and possibilities for NCM research, defining criteria for education, promoting the creation of a register that would include NCM professionals, and orientating citizens willing to be informed about NCM. Later on, in 2002, via resolution,[58] acupuncture was included among the services guaranteed to every citizen in Tuscany.

The Constitutional reform of 2001 expanded the powers of the Regions and granted them legislative power in matters which were to include professions, previously reserved for the National Parliament.[59] The Regional Council of Tuscany took the opportunity given by the reform to fill the legislative gap with a Regulation concerning the practice of complementary medicine on the part of medical doctors, dentists, veterinary doctors and pharmacists approved in February 2007.[60]

Another significant movement completed in 2007 was the creation via Regulation[61] of the "integrated medicine network" (RTmi), recognized as a regional governance structure in the field of healthcare, equipped with its own operational structure.

Moreover, a quarterly newsletter concerning all relevant topics related to non-conventional medicines in Tuscany has been published since 2007[62] (at the time of writing, the last published newsletter dated March 2015 contains an article regarding guidelines on acupuncture and Traditional Chinese Medicine).

The importance of the work carried out in Tuscany has been acknowledged in Europe and has indeed been awarded through experts from Tuscany's inclusion in the CAMbrella project as partners in research, and its accession as an associate member of EPAAC (details can be found above, in the section that details initiatives from the European Commission).

With regard to Qigong, the Regional Council of Tuscany approved in 2005 a Regional law[63] on the well-being and bio-natural disciplines ("*practices and natural,*

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58 Delibera di GR 561/2002, DPCM 29 novembre 2001 "definizione dei livelli di assistenza (LEA)"

59 GROPPI, Tania; SCATTONE, Nicoletta. Italy: The Subsidiarity Principle. *International Journal of Constitutional Law*, 2006, vol. 4, no 1, p. 131-137.

60 Regional law N.9/2007, *BURT, n. 3 del 22/02/2007* (text in Italian) *http://jtest.ittig.cnr.it/cocoon/regioneToscana/xhtml?doc=/db/nir/RegioneToscana/2007/urn_nir_regione.toscana_legge_2007-02-19n9&css=&datafine=20150625* [accessed June 2015].

61 Delibera di Giunta Regionale n. 623/07

62 Notiziario regionale delle medicine complementari http://www.regione.toscana.it/-/notiziario-regionale-delle-medicine-complementari [accessed June 2015].

63 (text in Italian) Legge regionale 3 gennaio 2005, n. 2, Discipline del benessere e bio-naturali. Bollettino Ufficiale n. 3, parte prima del 12 gennaio 2005

energy, psychosomatic, artistic and cultural techniques exercised to facilitate achievement, improvement and maintenance of the overall well-being of the person"), defining Qigong as "long-lived exercises". This regional law was subsequently typified by Resolution n. 1/2009 [64] and completed by Resolution no. 9/2010.[65] Qigong is presently mainly applied in the following fields:[66] oncology, in the treatment of patients with AIDS, drug addiction, pain relief, and in supporting natural childbirth through the reference Centre,[67] the "Centre of Traditional Chinese Medicine Fior di Prugna," [68] located in Florence.

To conclude, the official website from the Region of Tuscany on NCM [69] may be a good reference for any complementary information.

III. RESULTS

According to the World Health Organisation (WHO), the popularity of traditional medicine is gaining momentum throughout the world. Its use is rapidly expanding also in developed countries – for example, in Europe NCM treatments are sought by up to 80% of Union citizens for two main reasons: supporting health maintenance and disease prevention, and providing a more personalized and sustainable treatment regime for chronic illnesses.

In the Union, the provision of NCM presently stems from approximately 160,000 non-medical practitioners and 145,000 medical practitioners with both types of practitioner playing an important role in its provision in Europe. However, the teaching, certification and provision of NCM therapies is unfortunately subject to heterogeneous standards even at regional level which consequently interfere with the free movement of services, one of the founding cornerstones of the EU legal system.

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64 Resolution 28 January 2009, n. 1 (text in Italian) https://www.ars.toscana.it/files/aree_intervento/medicine_complementari/normativa/delibera_cr_1_2009_discipline_benessere.pdf [accessed June 2015].

65 (text in Italian) Resolution 27 January 2010, n. 9 https://www.ars.toscana.it/files/aree_intervento/medicine_complementari/normativa/delibera_cr_9_2010_discipline_benessere_burt.pdf [accessed June 2015].

66 (text in Italian) TCM in Centre Fior di Prugna. See page 11 and 12 http://www.asf.toscana.it/images/stories/med_compl/tecniche.pdf [accessed June 2015].

67 (text in Italian) Information updated to end 2014 http://www.regione.toscana.it/documents/10180/23335/Ambulatori+di+medicine+complementari/0a20215a-3340-45ee-9efb-297295c85992?version=1.2 [accessed June 2015].

68 Centro di MTC Fior di Prugna http://www.asf.toscana.it/index.php?option=com_content&view=article&id=1098:centro-di-medicina-tradizionale-cinese-&catid=124:medicina-alternatica [accessed June 2015].

69 Public website from the Region of Tuscany on NCM (text in Italian) http://www.regione.toscana.it/cittadini/salute/medicine-complementari [accessed June 2015].

Presently, the organisation and regulation of healthcare remains a competence belonging to Member States; thus the EU does not define health policies, nor the organisation and provision of health services and medical care. Instead, its action serves to supplement national policies and to support cooperation between member countries in the field of public health (in accordance with Article 168 of the TFEU).

In this sense, the lack of reconciled health policies across the EU, especially the lack of a common approach to the regulation of NCM, has complicated any efforts to establish EU-wide predictable conditions not only in terms of treatment but also research. Consequently, such a complex situation has had an inevitable impact on individual rights and brings forward the need for a harmonized European and national approach towards patients' rights in cross-border healthcare. This is particularly notable when patients cross borders within the EU in their search for NCM treatments, as they witness extraordinary differences from one country to the next, one such example being the professional background of presumably identical NCM practitioners, who are however, subject to entirely different reimbursement systems.

With that said however, there is light at the end of the tunnel as the Union provides, through its various programmes and pieces of legislation, fragments that could be assembled to form a sound basis for new legislation designed to reflect the current reality of NCM, including Qigong, in Europe.

In the area of healthcare, in particular Non-Conventional Medicines, harmonization is a hill that needs to be climbed step by step. The WHO has taken the lead by publishing a series of benchmark documents for training in different traditional/complementary and alternative medicines,[70] including a document on benchmarks for training in traditional Chinese medicine. But the European Union is now equipped with the right tools - Article 168 of the TFEU provides the Union's authorities with powers to take any initiative that could result in a better coordination among Member States in the field of Public Health - to remain a global actor at the forefront in the international panorama.

Finally, taking into account that a Qigong practitioner's aim is to preserve his/her somatic and mental health, quality of life and ultimately, obtain longevity, we can conclude that Qigong is in line with the objectives of the European Union reflected in

[70] Full texts available in http://www.who.int/medicines/areas/traditional/trm_benchmarks/en/ [accessed June 2015].

the first, third and fourth thematic priorities included in the third Programme for the European Union's action in the field of health (2014-2020).

IV. CONCLUSIONS

In view of the increasing number of citizens claiming access to affordable and individualized people-centred health treatments, decision makers should make supplementary efforts to further support consistent research and increase knowledge in the field of NCM resulting in Non-Conventional Medicines being gradually integrated into the Union Member States' national health systems.

Dr. Margaret Chan, Director-General of the WHO addressed this exact issue in 2008 stating that: "The two systems of traditional and Western medicine need not clash. Within the context of primary healthcare, they can blend together in a beneficial harmony, using the best features of each system, and compensating for certain weaknesses in each. This is not something that will happen all by itself. Deliberate policy decisions have to be made. But it can be done successfully".

In view of the demand for NCM in general, and Qigong in particular, and with the aim of providing Qigong – as part of the Non-Conventional Medicines – with an appropriate legal status, the Union's authorities could use all the instruments at their disposal to build a binding legislative framework. For this purpose, a set of initiatives could be implemented.

First of all, the appropriate Committees inside the European Parliament, which potentially could be ENVI (Environment, Public Health and Food Safety), IMCO (Internal Market and Consumer Protection), ITRE (Industry, Research and Energy) and EMPL (Employment and Social Affairs), could discuss a joint text for a follow up resolution to the European Parliament resolution no.75 approved in 1997 on the *status of non-conventional medicine.* As a result, Qigong professionals might and should have the chance to make their voices heard in the discussions taking place in the European Parliament. To achieve this, the entity representing Qigong at European level could enter into practical cooperation with the correspondent NCM associations, such as EUROCAM, CAMDOC Alliance, EHTPA, to present benefits arising from Qigong to Members of Parliament.

At the same time, the European Commission could, following conclusions from the *Communication from the Commission on the experience acquired as a result of*

application of provisions applicable to traditional herbal medicinal products,[71] use all available means to "*assess the suitability of a separate legal framework for products of certain traditions*" not covered by the simplified registration procedure under Directive 2004/24/EC.

To perform this task, considering recommendations from the CAMbrella project, the two arms of the budgetary authority (Council and European Parliament) of the Union should agree to allocate a sufficient budget to create a European NCM centre that could conduct scientific research on the core NCM therapies, including Qigong, by using a therapeutic approach.

Subsequently, taking into account research results, two measures could be taken: on one side, experts from the European NCM centre could produce guidelines, similar to the benchmark documents published by the WHO, on the Non-Conventional Medicines that fulfill the requirements of quality, safety and efficacy (well-established medicinal use) in Europe; on the other side, the European Commission could launch appropriate consultations to measure the degree of support of Non-Conventional Medicines from civil society and other relevant stakeholders.

This implies that, if strong and widespread support is obtained, the Union's decision makers would have the basis to align the Union's legislation to accommodate provisions related to the Non-Conventional Medicines/therapies that prove necessary guarantees of quality, safety and efficacy.

Clearly, homogeneous legislation would help us all: Member States' authorities could improve the quality of their healthcare systems by increasing the choice of treatments supplied, interested professionals could meet European standard requirements, and patients/consumers could have a clear understanding of where to turn with a high degree of certainty to ensure they receive a treatment that is considered homogeneously safe and effective within the European Union.

More specifically, and with regard to qualifications, Qigong professionals could express their interest at European level to obtain the right to use a European professional card. In this perspective, the involvement of civil society might play a

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[71] COM (2008) 584 final: Communication from the Commission to the Council and the European Parliament concerning the report on the experience acquired as a result of the application of the provisions of Chapter 2a of Directive 2001/83/EC, as amended by Directive 2004/24/EC, on specific provisions applicable to traditional herbal medicinal products (Document on the basis of Article 16i of Directive 2001/83/EC), /* COM/2008/0584 final */. Full text available in http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2008:0584:FIN [accessed June 2015].

key role by means of supporting the appropriate representative at European level who could potentially act as a solid intermediary between all those interested in Qigong (medical and non-medical professionals, practitioners, patients) and all other stakeholders (European Union's institutions, Member State's administrations).

Finally, should the combination of the above mentioned initiatives have positive results, Qigong could be granted with the legal status of therapeutical method in Europe and therefore be gradually included in the list of health treatments that are reimbursable by European Member States' health systems. The question however is this: In real terms, how long will it be before the Union's citizens potentially benefit from this?