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Cultural Diversity and Health, Epistemological and Legal Issues

di Caterina Drigo
Researcher of Constitutional Law
Alma Mater Studiorum - University of Bologna

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Abstract [En]: This essay aims to investigate the connections between culture and the right to health by highlighting whether and to what extent factors attributable to cultural diversity can be integrated into health systems. Starting from the analysis of the international and European panorama, the national and regional reoglatory context is analyzed, with a particular focus on the experience of the Emilia-Romagna Region.

Abstract [It]: Il presente saggio si propone di approfondire le connessioni fra cultura e diritto alla salute evidenziando se ed in quale misura fattori riconducibili alla diversità culturale siano integrabili nei sistemi sanitari. Muovendo dall'analisi del panorama internazionale ed europeo, si analizza il contesto reoglatorio nazionale e regionale, con un particolare focus sull'esperienza della Regione Emilia-Romagna.

Keywords: Culture, Cultural diversity, Right to health, Health systems, Complementary and Alternative medicines
Parole chiave: Cultura, Diversità culturale, Siritto alla salute, Sistemi sanitari, Medicine altenative e complementari

Summary: 1. The right to health and its cultural dimension. **2.** Continued: What space is there for cultural diversity and the recognition of "other" medicines? **2.1.** *Conceptual outlines*. **2.2.** *Epistemological and legal issues underlying the integration of "non-conventional" medicines and practices*. **3.** The international sensitiveness towards non-conventional medicines: the WHO approach. **4.** The European Union context: between caution and weak attempts at uniform regulation. **5.** Non-conventional medicines in Italy: a panorama of variable geometry. **5.1.** *The national context*. **5.2.** *The regional context: complex and differentiated paths of recognition*. **5.3.** *Case study: the integration of cultural diversity factors in the Emilia-Romagna Region*. **6.** Conclusive findings and open questions.

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1. The right to health and its cultural dimension

For us jurists, it is clear that health is a fundamental right of every human being,[1] the protection of which is linked to that of human dignity.[2]

According to the WHO, «[t]he enjoyment of the highest attainable standard of health» must be guaranteed and protected «without distinction of race, religion, political belief, economic or social condition».[3]

These "legal" concepts of health, in turn, presuppose a concept of health with an intrinsically polysemantic and heterogeneous nature. The same idea of health (and its opposite, disease) are characterised by intrinsic variability and open to different notions of medicine and models of physician/patient relationships.[4]

The concept of health is also fundamental to identifying what a constitutional state can and must guarantee to all. Given the fluidity of the ethical, philosophical and scientific options[5], it is, therefore, the political choices that determine the legal assumptions and theoretical starting frameworks.

The notion of health is connected to that of treatment, and from a legal perspective, this evokes concepts such as the autonomy of the individual, the principle of self-determination, the right to receive health benefits, the right to refuse treatment, or the possible imposition of compulsory health treatments when the conditions are met, etc. But health is also something more, it is a «state of complete physical, mental and social well-being and not merely the absence of disease or infirmity».[6] Therefore, health and medicine

[1] Art. 32 of the Italian Constitution. For commentary on this aricle, among others: C. TRIPODINA, *Art. 32*, in S. Bartole, R. Bin (eds.), *Commentario breve alla Costituzione*, Cedam, Padua, 2008, p. 321ff.; R. FERRARA, *Salute (diritto alla)*, in *Digesto (disc. Pubbl.)*, III, Utet, Turin, 1997, p. 513ff; L. MONTUSCHI, *32,1° comma, in Commentario della Costituzione*, edited by G. Branca, *Rapporti etico Sociali, art. 29-34*, Zanichelli, Bologna, 1976, p. 146ff; C. MORTATI, *La tutela della salute nella Costituzione italiana*, in *Scritti*, II, Giuffrè Milan, 1972, p. 433ff.; M. MAZZIOTTI, *Diritti sociali*, in *Enciclopedia del diritto*, XII, Giuffrè, Milan, 1964, p. 802ff.
See also the preamble of the *Constitution of the World Health Organization* (below, note no. 3); art. 25 of the *UN Universal Declaration of Human rights*, («Everyone has the right to a standard of living adequate for the health and well-being of himself…»); art. 35 of the *EU Charter of Fundamental Rights* («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») or art. 11 of the *European Social Charter*.

[2] See, among many, Italian Constitutional Court Judgement nos. 184/1986, 559/1987, 992/1988, 509/2000, 309/1999, 267/1998, 252/2001 and, more recently, also Judgement nos. 5/2018; 62/2020.

[3] Preamble to the *Constitution of the World Health Organization*, at WHO web site.

[4] In the fields of ethics and philosophy multiple models have been proposed. For further details see M. MORI, *The twilight of 'medicine' and the dawn of 'health care': reflections on bioethics at the turn of the millennium*, in *Journal of Medical Philosophy*, 25 (6), 2000, p. 723ff.; R. SEISING, M.E. TABACCHI (ed.), *Fuzziness and Medicine: Philosophical Reflections and Application Systems in Health Care*, Springer, 2013.

[5] There are many concepts of health and disease, not only in a diachronic perspective, but also in contemporary societies: E. COLOMBO, *Trasformazioni sociali e novi modi di pensare la salute e la malattia*, in E. COLOMBO, P. REBUGHINI (eds.), *La medicina che cambia. Le terapie non convenzionali in Italia*, il Mulino, Bologna, 2003, p. 15ff; F. LELLI, *Medicine non convenzionali, Problemi etici ed epistemologici*, Franco Angeli, Milan, 2007, spec. p. 90ff.

[6] Preamble to the *Constitution of the World Health Organization*.

are concepts that not only are open to an individual and collective dimension, but also to an ethical dimension related to health and social service obligations, as well as to a cultural dimension.

By culture is meant a set of knowledge, identity, traditions, skills of a certain environment or group,[7] *health*, and the knowledge and practices related to it, are composed or in any case are also influenced by a cultural factor and can be part of the intangible cultural heritage.[8]

In societies such as today's that are less and less homogeneous, it seems appropriate to verify whether – and if so to what extent with regard to national systems – cultural diversity should be considered and promoted, even legally, by protecting the cultural identities of groups that coexist in certain territories, in compliance with the principle of self-determination, even cultural.[9]

It is estimated that in 2021 as much as 3.6% of the global population qualifies as international migrants (corresponding to about 280, 6 million people, compared to only 84 million in 1970).[10] Of these, 86.7 million are allegedly in Europe.[11]

Especially in some geographical contexts, therefore, societies are increasingly grafted with cultural diversity factors that, if not properly integrated, lead to fractures, ghettos, misunderstandings, malaise and even illness. It becomes crucial, therefore, to promote well-being and equal access to quality health and social services, access that for "others", foreigners, often seems limited by a series of factors such as the presence of language barriers, the difficulty of relating to and understanding different cultures, forms of poverty or more or less severe social exclusion, the lack of documents and the difficulty of relating to bureaucratic apparatuses. Vulnerable migrants and refugees constitute a heterogeneous group (not attributable to a single unit) that must deal with countless health challenges.

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[7] "Culture" in the Treccani dictionary. See also below, note no. 17.

[8] «The 'intangible cultural heritage' means the practices, representations, expressions, knowledge, skills – as well as the instruments, objects, artefacts and cultural spaces associated therewith – that communities, groups and, in some cases, individuals recognize as part of their cultural heritage. This intangible cultural heritage, transmitted from generation to generation, is constantly recreated by communities and groups in response to their environment, their interaction with nature and their history, and provides them with a sense of identity and continuity, thus promoting respect for cultural diversity and human creativity. For the purposes of this Convention, consideration will be given solely to such intangible cultural heritage as is compatible with existing international human rights instruments, as well as with the requirements of mutual respect among communities, groups and individuals, and of sustainable development»: art. 2 of the UNESCO *Convention for the Safeguarding of the Intangible Cultural Heritage* 2003.

[9] The issue of access to medical care for migrants, even undocumented, has been broadly analysed in legal theory and consolidated in case law (see among others recently in G. CERRINA FERONI (Ed.), *Sistemi sanitari e immigrazione: percorsi di analisi comparata*, Giappichelli, Turin, 2019).

[10] Mid -year 2021 data, available at www.migrationdataportal.org. According to the United Nations' *Recommendations on Statistics of International Migration*, an «international migrant» is «any person who has changed his or her country of usual residence, distinguishing between 'short-term migrants' (those who have changed their countries of usual residence for at least three months, but less than one year) and 'long-term migrants' (those who have done so for at least one year)», as defined in *World Migration Report 2020*, edited by the International Organization for Migration, p. 19-23.

[11] Mid -year 2021 data, available at www.migrationdataportal.org, but see also *World Migration Report* 2020, cit., p. 24.

But the study of the demands and practices of migrant care and therapy can also help in understanding the effects of cultural contacts in dynamics of the knowledge of medicinal plants, of the different ways in which therapeutic resources are perceived and used by people and of the biological and cultural contexts that determine the behaviour of social groups.[12]

With regard to the definition of the concepts of *culture* and *cultural diversity,* as elements to be protected and promoted, supranational and international law contribute only partially.

While the European Union values cultural diversity in art. 3.3. TEU, establishing the Union's duty to respect it by supervising the safeguarding and development of European cultural heritage, does not, in parallel, provide any definition of it.

Similarly, international law does not clearly define the concept in question: *cultural diversity* is considered «a defining characteristic of humanity»,[13] whose promotion and protection presupposes that «human rights and fundamental freedoms... are guaranteed».[14] *Cultural diversity* «refers to the manifold ways in which the cultures of groups and societies find expression. These expressions are passed on within and among groups and societies. Cultural diversity is made manifest not only through the varied ways in which the cultural heritage of humanity is expressed, augmented and transmitted through the variety of cultural expressions but also through diverse modes of artistic creation, production, dissemination, distribution, and enjoyment, whatever the means and technologies used».[15]

According to UNESCO, «[c]ulture takes different forms across time and space. This diversity is embodied in the uniqueness and plurality of the identities of the groups and societies making up humankind. As a source of exchange, innovation, and creativity, cultural diversity is as necessary for humankind as biodiversity is for nature. In this sense, it is the common heritage of humanity and should be recognized and affirmed for the benefit of present and future generations».[16]

The very concept of *culture*, underlying and presupposed to that of cultural diversity, appears difficult to delimit in the legal field, being grafting with metalegal elements that make any legal reflection on the subject complex. There is no binding legal definition, and what is specified in the preamble to the *Universal*

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[12] P. MUNIZ DE MEDEIROS, G. TABODA SOLDATI, N. LEAL ALENCAR, I. VANDEBROEK, A. PIERONI, N. HANAZAKI, U. PAULINO DE ALBUQUERQUE, *The Use of Medicinal Plants by Migrant People: Adaptation, Maintenance, and Replacement*, in *Evidence-Based Complementary and Alternative Medicine*, 2012, p. 1ff.
It was also observed that «medical anthropologists have shown that patients often hold different beliefs about disease than do health care providers and that the discontinuity may lead to problems in treatment related to inappropriate or incomplete reactions of health professionals, improper choice of therapy, or insufficient patient adherence to medical choices», E.D. WHITAKER, *The Idea of Health: History, Medical Pluralism, and the Management of the Body in Emilia-Romagna, Italy*, in *Medical Anthropology Quarterly*, 17, 2003, p. 348ff.

[13] Preamble to the *Convention for the Protection and Promotion of the Diversity of Cultural Expressions*, signed in Paris on 20 October 2005, at UNESCO web site.

[14] Art. 2, *Convention for the Protection and Promotion of the Diversity of Cultural Expressions*, cit.

[15] Art. 4, *Convention for the Protection and Promotion of the Diversity of Cultural Expressionsi,* cit.

[16] Art. 1, *UNESCO Universal Declaration on Cultural Diversity* of 2 November 2001, at UNESCO website.

Declaration on Cultural Diversity appears only to be an open, vague, definition that does not allow the identification of models attributable to a taxonomy.[17]

A first fundamental difficulty for the jurist is therefore represented by the fact that reflections on culture and cultural diversity open up concepts that, while having a juridical-constitutional significance, can be fully defined only by drawing on disciplines other than the law. That is, with the tools offered by the law it is not possible to identify and protect «a diversity that is not given by the presence of clearly definable entities or identities, static and precise boundaries, but rather by the coexistence of complex processes that are born, evolve, die through dynamics of contacts, reciprocal integrations, fusions of various types».[18]

A complicating element is the fact that even in the context of so-called Western medicine the link between culture and medicine has a series of intrinsic critical facets that has led to the development of differentiated regulatory models, especially with regard to "sensitive" issues from an ethical OR moral point of view.[19] But a further complicating factor is the fact that when the right to health is brought up, the protection of cultural diversity also raises heterodox "treatments" and approaches with respect to Western medicine (or biomedicine). It is no coincidence that UNESCO has included some types of traditional medicines in the intangible cultural heritage of mankind.[20]

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[17] According to UNESCO, «Culture should be regarded as the set of distinctive spiritual, material, intellectual and emotional features of society or a social group, and that it encompasses, in addition to art and literature, lifestyles, ways of living together, value systems, traditions and beliefs. Noting that culture is at the heart of contemporary debates about identity, social cohesion, and the development of a knowledge-based economy»: *Universal Declaration on Cultural Diversity*, cit., Preamble.

[18] M. PEDRAZZI, *Diversità culturale nel diritto internazionale*, in L. ZAGATO, M. VECCO (eds.), *Le culture dell'Europa, L'Europa della cultura*, Franco Angeli, Milan, 2011, p. 15ff. See also C. DE BEUKELAER, M., PYYKKÖNEN, J. SINGH, (eds.), *Globalization, Culture and Development: The UNESCO Convention on Cultural Diversity*, Palgrave-MacMillan, 2015.

[19] See positions on medically assisted fertilisation or on human embryo trials (e.g. ECJ, *Oliver Brüstle v Greenpeace and V.*, C-34/10 of 18 October 2011, but also Judgement *International Stem Cell Corporation (ISCO) v Comptroller General of patents, designs and trademarks*, C-364/13 of 18 December 2014).
For legal theory see A. KLEINMAN, *Patients and healers in the context of culture*, University of California Press, 1980; B. PFLEIDERER, G. BIBEAU (eds.), *Anthropologies of Medicine. A Colloquium on West European and North American Perspectives*, Springer, 1991; S.M. DI GIACOMO, *Can there be a 'cultural epidemiology'?* in *Medical Anthropol Quarterly*, 13 (4), 1999, p. 436ff, which refers to the concept of «health beliefs of western society», providing an "anthropological" classification of the approach to disease and care provided by Western health systems.
P. LYNN [*Medicine and culture*, Holt Paperbacks, U.S., 1996] a few years earlier had argued that even in Western countries «while doctors regard themselves as servants of science, they are often prisoners of custom». See also G. JUCKETT, *Cross-Cultural Medicine*, in 11 *American Family Physician*, 72, 2005, p. 2267ff; D. LUPTON, *The cultural assumptions behind Western medicine*, in *The Conversation*, 1 January 2013, at *The Conversation*; R. OLORTEGUI-MARIÑO, J. GALVEZ-OLORTEGUI, D. PAREDES-AYRAC, M. VILLAFAN-BRONCANO, *Alternative, traditional, or complementary medicine: A perspective of intercultural therapeutic adherence*, in 17 *Medwave* 15, 2017.

[20] UNESCO has also included some traditional medicines in its intangible cultural heritage: since 2010 the acupuncture and moxibustion of traditional Chinese medicine, since 2018 the therapeutic ablutions of traditional Tibetan medicine, and since 2019 Thai massage. For more information on the intangible cultural heritage of UNESCO, see among others: C. BORTOLETTO, *Il patrimonio immateriale secondo l'Unesco. Analisi e prospettive*, Ist. Poligrafico dello Stato, Rome, 2008; F. OBRINGER, *Chinese Medicine and the Enticement of Heritage Status*, *China Perspectives*, 3/2011, 15 ss.; A. RIORDAN, J. SCHOFIELD, *Beyond biomedicine: Traditional medicine as cultural heritage*, in *International Journal of Heritage Studies*, 21 (3), 2015,

Therefore, cultural diversity must necessarily also be considered in the dimension of care, in the organisation of national and territorial health systems, where there are no centralised systems, as well as integrated by the now indispensable contribution of private individuals in a perspective that promotes both vertical and horizontal subsidiarity.[21] Such integration can take place according to dynamics that are necessarily diversified due to the existence of multiple models of integration of migrants existing in the different legal systems, and even existing within them if considered according to a diachronic evolutionary perspective.

2. *Continued*: What space is there for cultural diversity and the recognition of "other" medicines?

2.1. *Conceptual outlines*

When referring to therapeutic options or practices distinct from so-called Western medicine or biomedicine, the conceptual landscape of reference is extremely varied and complex: «[t]he word 'Medicine' is different for every culture and people who have benefited from it; so, there are as many healing and care systems as there are cultures in the world».[22]

Moreover, public law tends not to deal with the notion of *medicine*, neither Western nor "non-conventional", considering it the jurisdiction of the scientific world, of medical culture. But the identification of what is attributable to *medicine* and therapeutic practice has significant repercussions in the legal field since it contributes to delineating the contours of the right to health.

In the world, so-called biomedicine tends to represent the pillar of healthcare, even though – especially in some contexts – it is flanked by traditional, complementary, or non-conventional medicine.

p. 280ff.; F.H. CUNHA FILHO, T. SCOVAZZI, *Salvaguarda do patrimônio cultural imaterial: uma análise comparativa entre Brasil e Itália*, Brasile, 2020, text at Repositorio UFBA.BR.

[21] With regard to the Italian context, it seems appropriate to mention the contribution of the so-called third sector in providing medical, psychological or psychiatric assistance to foreigners, also acting as a centre for cultural mediation and the reception of "other" concerns different from those of the majority of the community in certain regions. On this point see, *ex multis*, C. DRIGO, *Percorsi di integrazione e inclusione sociale dei migranti nella Regione Emilia-Romagna*, in *Le Regioni*, 5-6, 2019, p. 1753ff.

[22] P. ROBERTI DI SARSINA, A. MORANDI, M. ALIVA, M. TOGNETTI BORDOGNA, P. GUADAGNI, *Medicine Tradizionali e Non Convenzionali in Italia. Considerazioni su una scelta sociale per la Medicina Centrata sulla Persona*, in *Terapie d'avanguardia*, 2012, p. 1ss., p. 6; L. OBADIA, *The Internationalisation and Hybridization of Medicines in Perspective? Some Reflections and Comparisons between East and West*, in *Transtext(e)s Transcultures* 跨文本跨文化 *Journal of Global Cultural Studies*, 5/2009, p. 1ff.

In this regard, the WHO refers to a series of concepts such as traditional medicine,[23] complementary medicine[24], and herbal medicine[25] which include a series of practices, beliefs, theories, therapies that are either used in particular cultural contexts or simply not fully integrated into Western healthcare systems because they contain heterodox elements with respect to the latter, or medicines and drugs that involve the use of plants or their components.

In this paper they will be referred to using the all-inclusive expression *non-conventional medicine* (NCM), with the knowledge, however, that this existing taxonomy is not attributable to the medical and clinical field. In fact, it consists of a set of practices, drugs, and treatments, that are extremely varied and extensive,[26] inspired by different concepts of health and medicine, often being inseparably connected with cultural and religious practices, and which must therefore be studied always bearing in mind the context of reference, that here is the law.

Attention to cultural diversity does not necessarily imply or require incorporating non-conventional medicines into national or territorial health systems. First of all, it implies attention to the factors of cultural diversity, openness, understanding, willingness to listen to and accept concerns according to an inclusive logic that, in our system, underlies article 3 of the Italian Constitution, and also implies attention to the religious factor, which, in turn, often appears difficult to separate from culture.[27]

Compared to other continents, there is a greater distrust of non-conventional medicines in Europe. In Latin America, Australia, Africa, and Asia, the reflection and use of non-conventional medicines are more widespread, more regulated, and, at least in certain contexts, integrated into health systems or even the subject of significant public funding and research.[28] And it is no coincidence that this has happened in these contexts. The reasons are manifold: these are areas where several minorities or indigenous peoples

[23] According to the WHO: «Traditional medicine has a long history. It is the sum total of the knowledge, skill, and practices 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», at WHO Web site.

[24] According to the WHO: «The terms 'complementary medicine' or 'alternative medicine' refer to a broad set of health care practices that are not part of that country's own tradition or conventional medicine and are not fully integrated into the dominant health-care system. They are used interchangeably with traditional medicine in some countries» at WHO web site

[25] According to the WHO: «Herbal medicines include herbs, herbal materials, herbal preparations and finished herbal products, that contain as active ingredients parts of plants, or other plant materials, or combinations» at WHO web site

[26] For an overview of the main non-conventional medicines and their clinical and legal aspects, see D. VASAPOLLO, *Tutela della salute e Medicine Non Convenzionali. Profili clinico-giuridici e problematiche medico legali*, Giuffrè, Milan, 2014; C. CIPOLLA, P, ROBERTI DI SARSINA, *Le peculiarità sociali delle medicine non convenzionali*, Franco Angeli, Milan, 2009; G. GIARELLI, P. ROBERTI DI SARSINA, B. SILVESTRINI, *Le medicine non convenzionali in Italia. Storia, problemi e prospettive di integrazione*, Franco Angeli, Milan, 2007; D. SECONDULFO, *Medicina e Medicine. Le cure 'altre' in una società che cambia*, in *Salute e Società*, 3/2005, Franco Angeli, Milan; P. REBUGHINI, *Origini e contenuti dell'universo delle medicine non convenzionali*, in E. COLOMBO, P. REBUGHINI (eds.), *La medicina che cambia. Le terapie non convenzionali in Italia*, cit., p. 73ff.

[27] Among others, most recently, L.G. BEAMAN, *The Transition of Religion to Culture in Law and Public Discourse*, Routledge, 2020.

[28] *WHO Global Report on Traditional and Complementary Medicine 2019*, at WHO web site.

live, or where migrants are more deeply rooted, or where medicines that for us are "other" are actually traditional and biomedicine is the "novelty". For example, in China traditional medicine has been consolidated for at least three millennia, similarly in India with Ayurvedic medicine. Therefore, taking the current situation as an example, it seems no coincidence that in China anti-SARS-CoV2 treatments that involve the application of traditional medicine treatments according to specific protocols are encouraged at an institutional level (even though they are still criticised by the international scientific community as there is insufficient evidence of their real effectiveness).[29] Without getting into the merits of the therapeutic choices here, it seems significant that, in this context, the cultural factor and the link with traditional medicine have led to the drafting of such a protocol, the scientific evidence of which will obviously be rigorously verified by the competent authorities.

Similarly, also in Africa, Asia, or South America, traditional and herbal medicine are used to face the COVID-19 crisis.[30] The same WHO has acknowledged the effectiveness of certain plants or traditional remedies as a potential pharmacotherapy research candidate against COVID-19.[31]

2.2. *Epistemological and legal problems underlying the integration of "non-conventional" medicines and practices*

The study of non-conventional medicines raises issues other than those related to the mere promotion of cultural diversity. This is a subject that not only presupposes the analysis of the relationship between science and law, but also a liberal reflection on the role of the State, connecting to the concept of welfare state and its conceivable evolution into a caring state.[32]

Should the State guarantee access to alternative care, to "other" care?

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[29] See Chinalink.it; C. WANG, S. SUN, X. DING, *The therapeutic effects of traditional Chinese medicine on COVID-19: a narrative review*, in *Int. J. Clin. Pharm.*, 43(1), 2021, pp. 35 ff.; S.H. NILE, G. KAI, *Recent clinical trials on natural products and traditional Chinese medicine combating the COVID-19*, *Indian J Microbiol.* 30 (1), 2020, p. 1 ff.

[30] V. PAUDYAL ET AL., *Complementary and alternative medicines use in COVID-19: A global perspective on practice, policy and research,* in *Research in social & administrative pharmacy,* Advance online publication, 2021, https://doi.org/10.1016/j.sapharm.2021.05.004

See also *The Place of African Traditional Medicine in Response to COVID-19 and Beyond*, 3.12.2020, at UNESCO web site; R.V. NUGRAHA, ET AL., *Traditional herbal medicine candidates as complementary treatments for COVID-19: a review of their mechanisms, Pros and Cons*, *Evidence-Based Complementary and Alternative Medicine*; 2020, doi: 10.1155/2020/2560645. ; Y. XIONG ET AL., *International policies and challenges on the legalization of traditional medicine/herbal medicines in the fight against COVID-19*, *Pharmacological Research*, 166, 2021, https://doi.org/10.1016/j.phrs.2021.105472; D. SILVEIRA ET AL., *COVID-19: is There evidence for the use of herbal medicines as adjuvant symptomatic therapy?*, *Front Pharmacol.* 11, 2020, p. 1 ff.; N. SRIKANTH ET AL., *Mobile App–Reported Use of Traditional Medicine for Maintenance of Health in India During the COVID-19 Pandemic: Cross-sectional Questionnaire Study*, *JMIRx Med* 2(2), 2021, Avalable at JMIRx Med.

[31] At WHO web site, but see also *Middle East Integrative Health or Complementary and Alternative Medicine Market Report, 2020 – 2027* at *Grand View Research*, 2021.

[32] K. HEE-KANH, *Caring State: A New Vision of Welfare State*, in *Journal of Governamental Studies*, 22/ 2016, p. 5ff; S. BAGNI, *Dal Welfare State al Caring State*, in Various Authors, *Annuario italo-iberoamericano di diritto costituzionale*, ES, Naples, 2014, p. 325ff.

The answer will vary depending on the legal framework of reference and the constitutional and regulatory framework in force.

As far as the Italian legal order is concerned, without prejudice to the constitutional duty to guarantee and protect the health of individuals in a collective dimension (article 32 of the Italian Constitution), can a model of therapy and treatment really be imposed by law? Or, on the contrary, is the guarantee of therapeutic pluralism always legitimate, or does it express a kind of cultural relativism? Are there "multiple sciences" or is science unique and pluralism cannot also apply to science since there is no alternative as in the moral sciences?

Therefore, we come to the issue of extending the right to freedom of care, conceived as an expression of the principle of self-determination.[33] What space can there be, then, for guaranteeing the possibility of options and choice with respect to therapies and practices that do not have a certain scientific basis, but that only express a cultural option of an axiological matrix? And should freedom of choice always be guaranteed and in all cases, or should there be limits? Freedom of choice can only be effectively exercised when we are in a position to "choose" (and properly understand the effects of our choices), and not simply when we decide to disagree with official care and therapy channels.[34]

There is no clear "map" that marks off the territory within which to operate, and consequently, it can be argued that in the absence of sufficiently determined coordinates it is also difficult to make a real choice. As has been argued, «we decide the path, but to do so we must exactly know the territory we will move in, its characteristics, the presence of hazards or passages that are already known and safe».[35]

The identification of the role to be attributed to experts in a sensitive area such as health is one of the central points of bioethical commentary and is also reflected in the very concept of democracy. As argued, «the revision of the contract between science and society is the new frontier of democratic societies: democracy here meaning not so much the prevalence of a majority, but the political vision that tends not to assume any language (even that of science) as authoritative, but that puts in place the institutional methods for repositioning the place to discuss and renegotiate all forms of authority in civil life».[36]

Any limitation of freedoms, including therefore freedom of choice in the medical field, requires public justification and the guarantee of minimum health conditions (understood as maintaining or restoring

[33] P.K. FEYERABEND, *La scienza in una società libera*, Feltrinelli, Milan, 1981, spec. p. 18ff.
[34] F. LELLI, *Medicine non convenzionali, Problemi etici ed epistemologici*, cit., spec. p. 20ff and bibliography indicated therein.
[35] H.T. JR ENGELHARDT, *Manuale di bioetica*, Il Saggiatore, Milan, 1999, p. 115, (our translation).
[36] F. LELLI, *Medicine non convenzionali, Problemi etici ed epistemologici*, cit., spec. p. 70 (our translation), but see also M. TALLACCHINI, *Democrazia come terapia: la governance tra medicina e società*, in *Politeia*, XXII, 81, 2006, p. 15ff; ID., *Bioetica & Democrazia*, in *Politeia*, XIX, 69, 2003, p. 93ff.

the normal functioning of the body), responds to the need to guarantee everyone the same opportunities and also appears to be the necessary prerequisite for the full exercise of citizenship rights.[37]

While the phenomenon of the use of non-conventional medicines is now consolidated and appears irreversible, a delicate balance between the interests and freedom of choice of individuals and the public dimension of the right to health is essential.

Given this, the question arises as to whether a State which provides for the possibility of opting for non-conventional medicines should also, if necessary, finance them.

Again, the answer depends on the legal framework of reference and the constitutional and regulatory framework in force.

In a constitutional state with a strong social focus, the response could be positive, provided that, with respect to the resources invested, they are effective treatments[38] and that multiculturally they can be traced back to certain cultures, including health, both ethnically and philosophically.

The profound differences in the conception of medicine and health underlying western medicine and multiple non-conventional medicines make it impossible to «appeal to a transversal objectivity» of such concepts,[39] consequently, the logic that seems fruitful to follow is not that of a fusion between systems, which are often incompatible with each other, but at most of integration, where «each continues to evolve in its own direction».[40] Obviously, this integration cannot be of a purely theoretical nature «due to the diversity of the two areas, and due to the different demands that the patient can make, depending on his or her needs, the answers needed for his or her specific state of health».[41]

Furthermore, as also anticipated above (para. 1), the model of autonomy and self-determination of the individual also depends on the notions of medicine, health, and the concept of the "good of the patient" from both an individual and a collective perspective: in the perspective of his/her being part of a community,[42] and in this regard there seems to be a lack of a universally valid model that allows all aspects of the individual, collective, scientific and cultural dimensions to be combined according to uniform codes. It follows that while in a plural perspective aimed at interculturality – because the multicultural

[37] F. LELLI, *Medicine non convenzionali, Problemi etici ed epistemologici*, cit., spec. p. 70ff.

[38] When referring to a comparison between so-called official medicine and non-conventional medicine, however, the evaluation of efficacy is not the only means available. The issue raises significant epistemological problems. On this point, extensively, F. LELLI, *Medicine non convenzionali, Problemi etici ed epistemologici*, cit., p. 27ff, but see also M. MORI, *The twilight of 'medicine' and the dawn of 'health care': reflections on bioethics at the turn of the millennium*, cit., p. 738.

[39] F. LELLI, *Medicine non convenzionali, Problemi etici ed epistemologici*, cit., p. 36 (our translation).

[40] S. BRATMAN, *Guida critica alle medicine alternative. Manuale pratico per curarsi senza smarrirsi*, Zelig, Milan, 1999, p. 270 (our translation).

[41] F. LELLI, *Medicine non convenzionali, Problemi etici ed epistemologici*, cit., p. 36 (our translation).

[42] In this perspective, not all decisions of a doctor or a patient are legitimate, especially when they cause a disadvantage to the community, as in the case of therapies that incur collective costs that are difficult to sustain.

and intercultural dimension is what our societies must deal with[43] – each system will find a delicate balance resulting from political choices, hopefully well-considered, and without leaving regulatory gaps that judges must fill as "substitutes" for lawmakers.

3. The international sensitiveness towards non-conventional medicines: the WHO approach

As early as 2000, the WHO prepared a document entitled *General guidelines for methodologies on Research and Evaluation of Traditional Medicine*, aimed at providing a joint discussion on research methodology and a so-called evidence-based evaluation of non-conventional medicines (whether related to traditional or complementary medicines).[44] A few years later, States were invited to develop and implement specific policies on non-conventional medicines with a three-year programme called *Traditional Medicine Strategy 2002-2005*,[45] which the WHO was urged to update and implement following the resolution of the World Health Assembly on Traditional Medicine.[46] Thus, in 2013 the *Traditional Medicine Strategy 2014-2023* was launched,[47] a document that sets itself the objectives of: a) «harnessing the potential contribution of TM (traditional medicine) to health, wellness and people-centred health care»; and b) «promoting the safe and effective use of TM by regulating, researching and integrating TM products, practitioners and practice into health systems, where appropriate».[48]

Thanks to the production of guidelines and technical documents, States belonging to the WHO are thus supported in the development of proactive policies and in the implementation of action plans that

[43] On this point the literature is extensive. See J. RAWLS, *Il diritto dei popoli*, Einaudi, Turin, 2001; J. RAZ, *Multiculturalism: a Liberal Perspective*, in ID., *Ethics in the Public Domani: Essays in the Morality of Law and Politics*, Oxford University Press, UK 1995; J. RAZ, *Multiculturalism*, in *Ratio Juris*, 11, 1998, p. 193ff.; C. TAYLOR, *Multiculturalism*, Princeton University Press, US, 1994; W. KYMLICKA, *Multicultural Citizenship. A Liberal Theory of Minority Rights*, Oxford University Press, UK, 1995; J. TULLY, *Strange Multiplicity*, Cambridge University Press, UK, 1997; M. NUSSBAUM, *Cultivating Humanity*, Harvard University Press, Cambridge, Mass.,1998; B. DE SOUSA SANTOS, *Toward a multicultural Conception of Human Rights*, in *Sociologia del diritto*, 1/1997, at FrancoAngeli.it, but text also at Center for Social Studies University of Coimbra; J. HABERMAS, *The Inclusion of Others*, The MIT Press, Cambridge, Mass., 1998; G. BAUMANN, *The multicultural riddle*, Routledge, New York, 1999; J. RAWLS, *The Law of Peoples*, Harvard University Press, Cambridge, Mass., 2001; S. BENHABIB, *The claims of culture*, Princeton University Press, U.S., 2002.; S. BENHABIB, *The rights of others*, Cambridge University Press, Cambridge, Mass., 2004; F. LEVRAU, P. LOOBUYCKM, *Introduction, mapping the multiculturalism-interculturalism debate*, in *Comparative migration Studies*, 6,1\3, 2018, text at Springer; R. KASTORYANA, *Multiculturalism and interculturalism: redefining nationhood and solidarity*, in *Comparative Migration Studies*. 6, 17, 2018, in https://www.springeropen.com/collections/multiintercult.
According to J. RAZ [*Multiculturalism* in *Ratio Juris*, cit., spec. p. 197ff.], «other traditions», in the liberal context, must be able to be free to exist when they do not go against the liberal framework, and are qualifiable according to the Rawlsian perspective of reasonableness (J. RAWLS, *Liberalismo politico*, Einaudi, Turin, ed. 2012).
[44] Text at WHO web site. For a commentary see R. ROBERTI DI SARSINA, I. ISEPPATO, *Le politiche sanitarie e formative delle medicine non convenzionali nell'Unione europea*, in C. CIPOLLA, P. ROBERTI DI SARSINA (eds.), *Le peculiarità sociali delle medicine non convenzionali*, Franco Angeli, Milan, 2009, p. 40ff.
[45] Text at WHO web site.
[46] WHA62.13, adopted in 2009.
[47] Text at WHO web site.
[48] *Traditional Medicine Strategy* 2014-2023, cit., p. 11.

strengthen or consolidate the role of non-conventional medicines in maintaining the health of the population, focusing on the organisation of health services and systems, promoting the integration of traditional and complementary medicines within health systems, in a perspective that at least in its intentions can progressively allow users to choose from a range of options that is as rich as possible.

As a snapshot of the global situation and current trends, there is the recent *Global report on traditional and complementary medicine* prepared by the WHO in 2019 with the contribution of almost all member States.[49] It follows that, non-conventional medicines, if of proven safety, efficacy, and quality, are a resource that «contribute to the goal of ensuring that all people have access to care». In fact, for large segments of the world's population, «herbal medicines, traditional treatments, and traditional practitioners are the main source of health care, and sometimes the only source of care. This is care that is close to homes, accessible, and affordable. It is also culturally acceptable and trusted by large numbers of people. The affordability of most traditional medicines makes them all the more attractive at a time of soaring health-care costs and nearly universal».[50] Moreover, these types of medicines and practices are also referred to as «a way of coping with the relentless rise of chronic non-communicable diseases», helping to ensure an adequate and satisfactory level of quality of life». [51]

The fact that appears significant is that of the 179 States of the world that have contributed to providing useful data for the drafting of the 2019 report, many have either significantly increased, or in any case developed, national policies on several traditional and alternative medicines. Ninety-eight States have put in place regulations or laws, and as many as 124 States have broadened legislation on herbal medicines. Essentially, 88% of WHO Member States recognise and guarantee the practice of non-conventional medicines, albeit in different forms and types.[52]

An analysis of these data from a diachronic perspective shows how globally the trend is towards greater space for and consideration of the possible role of non-conventional medicines even in those countries firmly linked to Western medicine, even in those countries where non-conventional medicines do not have a role that is closely linked to the dominant culture. This does not imply that non-conventional medicines are an option offered by the various health services as an alternative to biomedicine, on the contrary. And this is not only and not so much for cultural reasons, but rather, at least with regard to

[49] and, in relation to which Italy shines either for its absence or for its minimal contribution, depending on the aspects. Text of the *Global Report* at WHO web site.
[50] Speech by WHO Director-General Margaret Chan at the International Conference on Traditional Medicine for South-East Asian Countries. New Delhi, India, 12-14 February 2013.
[51] Speech by WHO Director-General Margaret Chan, cit.
[52] *Global Report*, cit., p. 11.

liberal democratic contexts, because ethical and bioethical issues are raised with respect to the role to be recognised to the self-determination of the individual, to his/her effective freedom of choice.[53]

The various countries belonging to the WHO approach non-conventional medicines in a heterogeneous way: in some cases, there are well-detailed regulatory frameworks, in others, the NCMs are integrated into health services, in others, there are policies or actions of a programmatic nature, while in others public and private research centres are financed at a national or territorial level.[54]

While Asia has the highest prevalence and practice of NCMs, Europe stands out as the area with the lowest, although in recent years the trend has inched higher both due to the push towards harmonisation made by the EU, at least in some sectors (mainly herbal medicine), and due to the steady increase in migration and the consequent cultural heterogeneity of European society.

One aspect that seems significant is the increasing formal connection between medicine and culture in terms of positive law. For example, Ecuador qualifies itself as an "*Intercultural State*" (art. 1 of the Constitution)[55] and, while a formal integration of traditional or complementary medicines into the health system is not recognised, since 2008 the intercultural vocation of the right to health has been constitutionalised and explicit (art. 358 of the Constitution).[56] Moreover, in 2013 the *Dirección Nacional de Salud Intercultural* (within the MoPH - *Ministerio de Salud Publica*) was created, and both an organic law (*Ley Orgánica de Salud* [LOS]) and a specific national plan were adopted, recognising and promoting traditional (indigenous) medicines and some complementary medicines.[57] Similarly, in Colombia, Peru, and Chile, there is this same intercultural conception of the right to health.[58] In this last country, Law 20.584 has been in force since 2012, which in regulating «*...los derechos y deberes que tienen las personas en relación con acciones vinculadas a su atención en salud*», in art. 7 expressly codifies the right of indigenous peoples to receive

[53] See above, para. 2.2.

[54] The countries where NCMs are most widespread are in Asia, Africa and even Latin America. For example, in South-East Asia there are several cases of NCMs being practised in hospitals as a possible approach to be applied not in competition but in synergy with traditional medicine. If we consider the presence of national NCM programmes, South-East Asia reports the highest percentage of countries – 91% – with a national programme promoting complementary traditional medicines. The second region for the dissemination of national programmes in this field is Africa, where 72% of the countries offer such initiatives, followed by the Pacific region, where the figure stands at 41%. The figure is 37% for the American continent, while the Eastern Mediterranean region stands at 19%, and Europe is the geographical context with the lowest incidence, only 13%. For more details see the *Global Report*, cit.

[55] «Ecuador is a constitutional State of rights and justice, a social, democratic, sovereign, independent, unitary, intercultural, multinational and secular State…».

[56] «The national health system shall be aimed at ensuring the development, protection, and recovery of capacities and potential for a healthy and integral life, both individual and collective, and shall recognize social and cultural diversity. The system shall be governed by the general principles of the national system of social inclusion and equity and by those of bioethics, adequacy and interculturalism, with a gender and generation approach».

[57] For further details see *Global Report*, cit., spec. p. 92 as well as D. HERRERA, F. HUTCHINS, D. GAUS, C. TROYA, *Intercultural health in Ecuador: an asymmetrical and incomplete project*, in *Anthropology & Medicine*, 2018, text at Tandfonline.

[58] For more information on some Latin American cases: J. MIGNONE, J., BARTLETT, J. O'NEIL, AND T. ORCHARD, Best *Practices in Intercultural Health: Five case studies in Latin America*, in 3 (31) *Journal of Ethnobiology and Ethnomedicine*, 2007.

healthcare with «*pertinencia cultural*» in accordance with an intercultural health model agreed to with the representatives of the indigenous communities.[59] In this manner they seek to respect and protect the ancestral care systems and religious, cultural, and spiritual practices, of those belonging to such minorities,[60] even if often, unfortunately, in countries where indigenous peoples are present,[61] those belonging to these communities suffer inequalities in access to quality health services and face a kind of cultural barrier that makes it difficult for them to "trust" and turn to health systems that for their part are often not open to understanding their needs, taking into account their cultural specificities and their traditional medicines. Adequate integration of these elements into general health systems and established care mechanisms could lead to an increase in the quality of health services that indigenous communities receive, including in terms of prevention and less exclusion.

4. The European Union context: between caution and weak attempts at uniform regulation

As well known, the European Union has various competencies in the field of health[62] and has organised specific initiatives over the years with regard to non-conventional medicines.

In fact, since the mid-1990s the European institutions have partially identified ways of recognising and adapting NCMs at a European level.[63]

On 6 March 1997, the European Parliament published the *Report on the status of non-conventional medicines*,[64] proposing the adoption of a special resolution (the *Resolution on the status of non-conventional medicine*) which was then adopted in 1997.[65] This second document noted the progressive increase in the use of non-conventional medicines at a European level and the fact that more and more doctors were opening up to a variety of treatment methods and approaches, to be used in a complementary way to "official" medicine. Furthermore, the importance was expressly considered «to ensure that patients have the broadest possible choice of therapy, guaranteeing them the maximum level of safety and the most accurate information possible on the safety, quality, effectiveness and possible risks of so-called non-conventional medicines, and that they are protected against unqualified individuals». Moreover, despite the "confusion" represented by the heterogeneity of the «whole corpus of medical systems and

[59] Updated text at Biblioteca del Congreso nacional de Cile.
[60] For more details see also A. FERDINAND, A. OYARCE, M. KELAHER, I. ANDERSON, *Reflexiones sobre la ética de la investigación en salud indígena en Chile*, in *Revista Latinoamericana de Bioética*, 18/2018, p. 162ff.
[61] For Brazil see A. MARTINS MENDES, M. SOARES LEITE, E.J. LANGDON, M. GRISOTTI, *The challenge of providing primary healthcare care to indigenous peoples in Brazil*, in *Panamerican Journal of Public Health*, 42/2018, p. 1ff.
[62] On this point, most recently G. DI FEDERICO, S. NEGRI, *Unione europea e salute: principi, azioni, diritti e sicurezza*, Cedam, Milan-Padua, 2019.
[63] Even though to date regulatory uniformity is still far off and each Member State assigns different levels of legal recognition to NCMs, with significant differences even within different sub-states.
[64] Text at European Parliament web site.
[65] A4-0075/97. Text at Cam Europe.eu.

therapeutic disciplines covered by the term 'non-conventional medicine'», for «a broad range of non-conventional medical disciplines» (such as, in particular, «chiropractic, homeopathy, anthroposophical medicine, Chinese traditional medicine (including acupuncture), shiatsu, naturopathy, osteopathy, phytotherapy […]») it was acknowledged that there were forms of «legal recognition in certain Member States» as well as «an organizational structure at a European level and self-regulatory mechanisms».

In the light of these considerations, the European Parliament asked the Commission to launch a series of studies on «safety, effectiveness, area of application and the complementary or alternative nature of all non-conventional medicines», as well as to create a «comparative study of the various national legal models to which non-conventional medical practitioners are subject». All these studies should have been the basis for a process of recognition of non-conventional medicines, distinguishing in particular «non-conventional medicines which are 'complementary' in nature and those which are 'alternative' medicines in the sense that they replace conventional medicine».

Furthermore, the European Parliament asked the Commission to promote proposals for directives aimed at regulating areas that often lie on the border between medical and dietary dimensions, regulating a series of food supplements (mainly produced with herbs, therefore falling within the concept of herbal medicine developed by the WHO) that are often products attributable to a cultural matrix different from traditional European culture. Therefore, in the early 1990s, the European Union adopted a series of directives aimed at herbal or homeopathic medicinal products.[66]

[66] First of all, Directive 92/73/EEC extends the scope of Directives 65/65/EEC and 75/319/EEC on the reconciliation of provisions laid down by legal, regulatory or administrative provisions relating to medicinal products and includes additional regulations for homeopathic medicinal products (Council Directive of 22 September 1992, at http://data.europa.eu/eli/dir/1992/73/oj). Subsequently, Parliament adopted the *Resolution on the Commission report to the European Parliament and the Council on the application of Directives 92/73/EEC and 92/74/EEC on homeopathic medicinal products (COM(97)0362 C4-0484/97)* - Text at eur-lex.europa.eu) which invited the Commission «to submit a proposal to amend Directive 92/73/EEC and a proposal to amend Directive 92/74/EEC» and asked it «to investigate whether, and to what extent, a system of mutual recognition of homeopathic medicinal products can be set up on the basis of binding principles and appropriate standards» and «to lay down rules for the composition of registration requests applicable by all Member States and carrying full guarantees of quality and harmlessness». Just a few years later, Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 introduced a *Community Code relating to medicinal products for human use* (several times amended, most recently in 2019) containing some provisions concerning homeopathic medicines. In 2004, Directive 2004/24/EC introduced a simplified registration procedure for herbal medicinal products in the Member States of the European Union (Text at Eurlex.europa.eu).
More recent was the *Cross-border Healthcare Directive* 2011/24/EU stressing the right of patients to access safe, quality treatment and to receive fair reimbursement for costs incurred. As noted by a recent study, however, those who practice non-conventional medicines «have different levels of training as a basis for their practice, whether they are formally licensed or not and patients have varying expectations of what is available in other Member States depending on experiences from their home country. This heterogeneous situation impacts on CAM patients' rights to access safe treatment and constitutes a challenge to a harmonised national and European review of the Cross-border Healthcare Directive» in: *CAM 2020, The contribution of Complementary and Alternative Medicine to sustainable healthcare in Europe*, at Camdoc.eu. Even more recent is the *Proportionality Test Directive* of 2018 (Directive (EU) 2018/958 *on a proportionality test before adoption of new regulation of professions*) with the aim of ensuring a certain level of uniformity in the rules governing access to the medical professions in the various countries, so that the existence of different regulations from state to state does not result in an undue obstacle to the free movement of workers. It is not yet known whether the states will

In July 1999, the Parliamentary Assembly of the Council of Europe also expressed its opinion on non-conventional medicines, approving Resolution no. 1206, entitled *A European approach to non-conventional medicines*, which reaffirmed the importance of non-conventional medicines as a basis for a possible integrated approach in biomedicine, while acknowledging the presence of "*grey areas*" that need study and standardisation, in this regard welcoming the action taken by the European institutions.[67]

Some interesting platforms for action for non-conventional medicines were created in the mid-2000s. In 2004, the *European Research Initiative on Complementary and Alternative Medicine*[68] was set up, with the aim of acquiring basic knowledge of non-conventional practices and medicines, encouraging the EU Member States to adopt policies and funding programmes to build confidence in NCMs and encourage their spread.

At the same time, the *European Forum on Complementary and Alternative Medicine (Efcam)*[69] was also established, a federation of European federations relating to specific non-conventional medicines and national organisations[70] whose main objective is to achieve equal access to NCMs in Europe, obtaining full legal recognition of them where they are exercised by qualified personnel. In pursuing its objectives, Efcam operates in synergy with the European Parliament through lobbying.

In 2005, the European Commission, together with the *Standing Committee of European Doctors (CPME)*, an organisation representing medical associations from the various European countries, launched the *Open Health Policy Forum – Health Challenges and Future Strategy*, which resulted in a document addressed to the. Commission inviting it to include non-conventional medicines in future initiatives.[71]

Non-conventional medicines were also included in the *Seventh Framework Programme for Development and Research 2007-2013* approved by the European Parliament, and a specific funding channel was set up that was used in the *cambrella A European research network for CAM* project[72] – a network aimed at developing research on non-conventional medicines – which the Emilia-Romagna Region also participated in.

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also standardise the discipline of the exercise of non-traditional medicines, despite the pressure of trade associations. For further details on this point, see a study published by the European Parliament in 2019, *EU Public Health Policies , State of play, current and future challenges*, the text of which can be found at Europarl.europa.eu.

[67] Text at Assembly.coe.int.

[68] operational until 2008

[69] www.efcam.eu

[70] To date it has been joined by associations operating in 23 European countries.

[71] In view of the growing demand for access to NCMs and studies showing their effectiveness (at least some of them). For more information: *Open Health Forum 2005 –Health Challenges and Future Strategy – Evaluation*, at www.ec.europa.eu.; *Eurispes: Rapporto Italia 2010, scheda n 55*, at Eurispes.

[72] At Cam-europe.eu. The acronym «brings together the terms 'CAM' and 'umbrella' to stress the project's effort both to harmonize existing knowledge and to determine the knowledge gaps in this field. Both parts come together in recommendations to the European Commission and the European Parliament on the way forward in Europe for research into CAM». In *The Roadmap for European CAM Research, An Explanation of the CAMbrella Project and its Key Findings*, at Cam-europe.eu.

Also significant is the fact that ema, the *European Medicines Agency*, supports European institutions, first and foremost the European Commission, in the field of medicines (including herbal medicines),[73] promoting regulatory harmonisation and working bilaterally with institutions and countries outside Europe.

Today eurocam,[74] a platform that brings together the largest associations/organisations related to the research and practice of non-conventional medicines, continues to promote the contribution of NCMs to improving health in Europe, even interfacing with European institutions,[75] but if we consider the trends of European policies, it seems that the interest in these medicines has diminished somewhat.

In 2017, the European Parliament organized the workshop *Complementary and Alternative Therapies for Patients Today and Tomorrow* which aim was to provide background and technical information and advice to the members of the ENVI Committee[76] on the latest findings and trends in the field of complementary and alternative therapies.[77]

In that workshop, a representative of the WHO, Dr. S. Espinosa[78], highlighted how WHO encourages the integration of traditional and complementary medicine into national health systems considering it as a way for strengthening health systems in terms of service delivery, workforce, infrastructure, medical products, and information exchange, specifying that «the inclusion of traditional and complementary medicine in the universal health coverage umbrella should be based on indicators with the same standards as for Western medicine. This covers workforce competency and good data on the safety, quality, and effectiveness, of traditional and complementary medical products and practices obtained, while applying the full range of evidence instruments from randomised controlled trials to qualitative research»[79]. Dr. Espinosa concluded with a key message for Europeans, «which is that both the patients and wider public

[73] See for example Herbal medicines 2004-2014.Ema celebrates ten years of harmonised standards across EU *Press release* published in November 2014 by the European Medicines Agency to celebrate the ten years since the introduction of European legislation on herbal medicinal products. Between 2004 and 2014 more than 1300 herbal medicinal products were registered in Europe, having been recognised as "traditional", and more than 600 were approved for sale, having established their widespread use within EU countries.

[74] Official website at https://cam-europe.eu. It should be noted that not all non-conventional medicines are represented: just acupuncture, ayurveda, anthroposophic medicine and herbal medicine, homeopathy, naturopathy or traditional European medicine, osteopathy and traditional Chinese medicine.

[75] To this end, a number of informal working groups on CAMs composed of members of the European Parliament (such as the *CAM Interest Group*: «an informal group of members of the European Parliament with a special interest in Complementary and Alternative Medicine», at https://cam-europe.eu/cam-interest-group-meetings-european-parliament/.

[76] European Parliament's Committee on Environment, Public Health, and Food Safety

[77] The report of the workshop is available at www.europarl.europa.eu, IP/A/ENVI/2017-10 November 2017 PE 614.180. In this document is reported the state of play of complementary and alternative therapies in Europe and it also focuses on the policy and legal framework in Europe and the integration of CAM into EU healthcare systems

[78] Consultant in the Traditional, Complementary and Integrative Medicine (TCI) Unit in the Department of Service Delivery and Safety (SDS

[79] Report on *Complementary and Alternative Therapies for Patients Today and Tomorrow*, cit., p. 16.

will benefit from the integration of Western medicine and T&CM into health systems, bearing in mind that quality, safety and effectiveness are ensured».[80]

Notwithstanding these signals of European sensitiveness towards traditional and complementary medicine, more recently the interest of The EU Union appears to be lessened.

In the ambitious *UE4 Health* programme of the European Commission, focused on post-COVID-19 recovery with a view to improving the health and resilience of health systems, non-conventional medicines are not expressly mentioned.

On 28 May 2020 the Commission also presented to Parliament and the Council a proposal for the adoption of a regulation «on the establishment of a Programme for the Union's action in the field of health – for the period 2021-2027 and repealing Regulation (EU) no. 282/2014 ('EU4Health Programme')»,[81] Annex I of which lists the possible actions eligible for funding, without explicit reference to non-conventional medicines. However, they are not excluded either, as they can potentially be integrated within the lines of action outlined by the Commission in the framework of a series of interventions designed to be dynamic and flexible and able to take into account the evolving needs and priorities of the EU and its Member States, to respond to health crises, and to effectively address inequalities, «providing support and closing identified gaps between countries, regions, population groups and citizens...in health status» and allowing «access to affordable, preventive and curative health care of good quality».[82]

Referring very briefly to the comparative European context, over the last two decades several European countries (including the United Kingdom, France, Austria, and Germany)[83] have not only adapted to the various European regulations governing – albeit partially and sectorally – some non-conventional medicines but have also integrated some additional practices within their health systems, or at least at the level of university education. However, despite increasingly widespread use by the populations of the

[80] Report on *Complementary and Alternative Therapies for Patients Today and Tomorrow*, cit., p. 16.

[81] Brussels, 28.5.2020, COM(2020) 405 final, 2020/0102(COD) at www.eur-lex.europa.eu. The Commission recalls that «Article 168 of the Treaty on the Functioning of the European Union (TFEU) provides the legal basis for the EU's actions in the field of health. Whilst the Member States are responsible for the functioning of their health systems, there are specific areas where the EU can legislate, and others where the Commission can support Member States' efforts. There is already a comprehensive regulatory framework for medical products and technologies (medicinal products, medical devices and substances of human origin), as well as on tobacco legislation, patients' rights in cross-border healthcare and serious cross-border health threats».

[82] Commission Report, cit., at www.eur-lex.europa.eu

[83] Consider Switzerland, where in May 2020 a draft law aimed at the inclusion of NCMs was presented (on this point see A. CHANDRASEKHAR, *La medicina alternativa non è più il parente povero del sistema sanitario svizzero*, 27 April 2020, at www.tvsvizzera.it. Countries such as Finland and Denmark have also taken steps.
For an analysis of the comparative context also consider the contribution of E. CUKANI, *Le cure mediche degli «altri» oltre il modello nazionale di integrazione? Prime riflessioni alla luce di un'analisi comparata*, in B. BERTARINI, C. DRIGO (eds.), *Diversità culturale come cura, cura della diversità culturale*, Giappichelli, Turin, 2020, p. 75ff., as well as ROBERTI DI SARSINA R., ISEPPATO I., *Le politiche sanitarie e formative delle medicine non convenzionali nell'Unione europea*, cit., p. 40ff.

various States and international and EU pressure to work towards harmonisation, the legal status of non-conventional medicines continues to be highly diversified, even within different territories of the same State.

5. Non-conventional medicines in Italy. A panorama of variable geometry

5.1. *The national context*

As mentioned above,[84] the Italian Constitution allows deriving a notion of health in addition to its being a fundamental right of the individual and interest of the community, also including a cultural dimension, evoking that which is the concept of health inferred internationally.[85]

Consequently, some questions arise: in our country is there therefore a right to health that includes the right to be able to be treated according to a system that incorporates non-conventional medicines? And from a different point of view, is there a duty on the part of the public authorities to structure the health system according to dynamics that take cultural diversity into account?

The answers to these questions must necessarily be diversified and will be addressed in the conclusion.

Focusing on the discipline of non-conventional medicines[86], the first fact that appears evident is the absence of a general legislation governing the existing varied panorama, possibly integrating non-conventional medicines and practices (or integrating some of them) into the national health system.

However, the absence of a general regulation does not mean that there is a total disregard for the topic, which instead has been the subject of political and scientific debate over the last 40 years, resulting in some measures that are not always coordinated with each other. [87]

Indeed, the discipline of health and related issues is a material area with overlaps of competencies between the State and the regions. As is well known, pursuant to art. 117 of the Constitution, health protection is a matter of concurrent legislative competence, although the determination of the essential levels in this matter is subject to the exclusive legislative competence of the State (art. 117, paragraph 2, lett. m).[88]

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[84] Para. 1

[85] See above, note 1.

[86] On the status of non-conventional medicines in Italy see S. VILLAMENA, *Medicina «non convenzionale» e sistema sanitario nazionale*, in *Giustamm.it,* 7/2015, p. 1ff.; S. VASAPOLLO, *Tutela della salute e Medicine Non Convenzionali. Profili clinico-giuridici e problematiche medico-legali*, Giuffrè, Milan, 2014; C. CIPOLLA, P. ROBERTI DI SARSINA (eds.), *Le peculiarità sociali delle medicine non convenzionali*, Franco Angeli, Milan, 2009; D. SECONDULFO (ed.), *Medicina e Medicine. Le cure 'altre' in una società che cambia*, in *Salute e Società*, 3/2005; E. COLOMBO, P. REBUGHINI (eds.), *La medicina che cambia. Le terapie non convenzionali in Italia*, il Mulino, Bologna, 2003.

[87] Since the 1980s a number of legislative proposals have been presented in Parliament to regulate the field of non-conventional practices and medicines. For a diachronic reconstruction see P. ROBERTI DI SARSINA, I. ISEPPATO, *Le politiche sanitarie e formative delle medicine non convenzionali nell'Unione Europea*, cit., spec. p. 50ff.

[88] Entire libraries have been written on the division of competences pursuant to art. 117 of the Constitution. For a general overview, please refer to L. CUOCOLO, *Articolo 117, comma 2*, in F. CLEMENTI, L. CUOCOLO. F. ROSA, G.E. VIGEVANI (eds.), *La costituzione Italiana. Commento articolo per articolo*, II, il Mulino, Bologna, 2018, 337ff.; D. MORANA,

In this regard, with the decision no. 424 of 2005 the Constitutional Court clarified that the regulation of non-conventional health professions belongs to the State and not to the regions, «according to the fundamental principle established by art. 6, paragraph 3, of Italian Legislative Decree no. 502 of 30 December 1992 (subsequently confirmed by art. 124, paragraph 1, letter *b*) of Italian Legislative Decree no. 112 of 31 March 1998, and art. 1, paragraph 2 of Italian Law no. 42 of 26 February 1999)»,[89] although there are also regulatory spaces for the regions.[90]

Existing actions regarding non-conventional medicines appear partial, fragmented, and inconsistent. For example, the Italian Presidential Decree dated 29 November 2001, defining the essential levels of care,[91] excluded non-conventional medicines, except for acupuncture, limited to anaesthetic guidance,[92] including them in the category of therapies borne entirely by the patient. Moreover, with Italian Presidential Decree no. 271 of 2000, the practice of acupuncture was included among the additional payable services.[93] A special framework was established for homeopathic medicines, also in the implementation of European directives on the subject.[94] With regard to taxation, homeopathic medicines have enjoyed the same preferential VAT applied to medicines since 2000.[95]

However, it is desirable for lawmakers to offer clarity, especially with respect to the many existing practices and medicines, so that end-users – the people – are concretely able to make informed choices, exercising a truly conscious consensus and not a mere "unconscious dissent" towards biomedicine, also risking relying on fraudulent persons at serious risk to their health.

Moreover, in the absence of clear regulatory positions, the National Federation of Orders of Doctors and Dentists (FNOMCeO), during the National Council meeting in Terni in 2002, approved an important

Articolo 117, commi 3, 4 e 5, in F. CLEMENTI, L. CUOCOLO. F. ROSA, G.E. VIGEVANI (eds.), *La costituzione Italiana*..., cit., p. 346ff.

[89] Declaring unconstitutional Piedmont Regional Law no. 13 of 31 May 2004 but see also decisions no. 353 of 2003, no. 40 of 2006 and 93 of 2008. See below, para. 6.1. (our translation of the case). With regard to Umbria Region see Const. Court, dec. n. 217 of 2015.

[90] See the case of the Emilia-Romagna Region which in 2005, by law, established the professional figure of the naturopath, only partially ruled unconstitutional (Constitutional Court, Judgement no. 138/2009). For more details see below, para. 5.3.

[91] That is *Livelli essenziali di assistenza* (LEA)

[92] Annex 2 to the Italian Presidential Decree of 29 November 2001, *Definition of the essential levels of care*. Today this Decree has been fully replaced by Italian Presidential Decree dated 12 January 2017, *Definition and updating of the essential levels of care, referred to in article 1, paragraph 7 of Italian Legislative Decree no. 502 of 30 December 1992*. (text at https://www.trovorme.salute.gov.it/).

[93] Annex D of Presidential Decree 271 of 28 July 2000, on the *Implementing Regulation of the national collective agreement for the regulation of relations with in-patient specialists*.

[94] See above, § 4, as well as the text published by the Agenzia Italiana del farmaco at www.aifa.gov.it and D. VASAPOLLO, *Tutela della salute e Medicine Non Convenzionali*, cit., spec. p. 39-78.

[95] See number 114) of Table A, part III attached to Italian Presidential Decree no. 633 of 1972 which provides for the 10% rate for «medicines ready for human or veterinary use, including homeopathic products; pharmaceutical substances and medications that pharmacies must be equipped with according to the official pharmacopoeia». This provision also covers «medicines based on substances» (such as plant-based preparations, e.g. syrups and the like).

document entitled *Guidelines on non-conventional medicines and practices*, which attempts to provide a systematic overview of the various non-conventional practices, indicating the conditions for their exercise,[96] in particular requiring that they be practised only by specially trained and qualified personnel.

5.2. *The regional context: complex and differentiated paths of recognition*

The regional dimension appears richer and more complex than the national one. In fact, the regions, especially after the reform of Title V of the Constitution, which gave them concurrent legislative power in the field of health protection, have also taken significant initiatives with respect to some non-conventional medicines.

The Region that first regulated the practice of non-conventional medicines was Piedmont, which in 2002 approved Regional Law no. 25, *Regulation of therapeutic practices and non-conventional disciplines*. The Region intended to establish a register for therapeutic practices and non-conventional disciplines, «with a view to pluralism and freedom of choice of the patient» (art. 1).[97] However, in 2003, with judgement no. 353, the Constitutional Court declared it unconstitutional, and it did so again with the subsequent Regional Law no. 13 of 2004 (*Regulation of bio-natural disciplines*[98]) with judgement no. 424/2005. In fact, according to the Court, the regulation of health professions[99], as well as that of operators of non-conventional medical practices, is reserved to the State.[100]

Similarly, the Constitutional Court also rules other similar regional regulations unconstitutional, such as Regional Law no. 18 of 2005 approved by the Campania Region containing *Regulations on music therapy and recognition of the professional figure of music therapist*,[101] and Regional Law no. 18 of 2004 containing *Regional regulations on bio natural disciplines for well-being* with which the Liguria Region regulated bio natural disciplines – and recognized operators who practised shiatsu, reflexology, watsu, pranotherapy, naturopathy, yoga,

[96] Text at Portale.fnomceo.it.

[97] The ruling specified that «[t]he scope of therapeutic practices and non-conventional disciplines recognised for the purposes referred to in article 1 are as follows: a) acupuncture; b) phytotherapy; c) homeopathy; d) homotoxicology; e) anthroposophical medicine; f) traditional Chinese medicine; g) ayurveda; h) naturopathy; i) shiatsu; j) reflexology; k) osteopathy; l) chiropractic» (art. 2, Italian Law 25/2002) – (our translation)

[98] According to the Region, these practices «aim to promote the state of well-being and an improvement in the quality of life», through «the harmonisation of the person with himself/herself and with the surrounding social, cultural and natural environments» (art. 2, Italian Law 13/2004). For commentary on judgement no. 353/2003 see T. GROPPI, *Nota alla sentenza n. 353 del 2003 della Corte costituzionale*, at www.forumcostituzionale.it, 2004, p. 1ff.

[99] See art. 6, paragraph 3 of Italian Legislative Decree no. 502 of 30 December 1992 and art. 1, paragraph 2 of Italian Law no. 42 of 26 February 1999, as well as art. 117, para. 3 of the Italian Constitution.

[100] In fact, according to the Court, «[f]ollowing the entry into force of the new Title V of the Constitution, the discipline in question is to be considered, as already mentioned, within the scope of the concurrent competence in the matter of 'professions', referred to in art. 117, third paragraph of the Italian Constitution. The relevant fundamental principles, since at this point no new ones have been formulated, are therefore those – according to the relevant case law of this Court (see judgements no. 201 of 2003 and no. 282 of 2002) – enumerated in current state legislation» (pt. 2 cons. in law).

[101] Constitutional Court, Judgement no. 424/2006.

kinesiology, and traditional massage – with the «aim of educating the person in healthy and environmentally friendly lifestyles» as well as «preventing states of physical and mental discomfort by stimulating the vital resources of each individual without pursuing therapeutic or curative purposes» (art. 1, paragraph 2).[102]

In other cases, the Regions have limited themselves to establishing forms of supplementary healthcare with respect to those provided by the National Health Service on the basis of Italian Legislative Decree no. 502/1992,[103] also including some non-conventional practices and medicines.[104]

The case of the Tuscany region is of interest as its sensitivity to non-conventional medicines dates back to the late 1980s, and which, since the *2008-2010 Health Plan*, has included some non-conventional medicines in the essential levels of care guaranteed at a regional level. In 2007 the Region regulated the methods of exercising some non-conventional practices and medicines by doctors, dentists, veterinarians, and pharmacists, with Regional Law no. 9, then amended by Regional Law no. 31 of 25 May 2007 (*Procedures for the use of complementary medicines by doctors, dentists, veterinarians, and pharmacists*), following a State appeal to the Constitutional Court.[105] Law no. 9 of 2007 stands out for its guarantee of the principle of the patient's freedom of therapeutic choice and the doctor's freedom of care, protecting "the exercise of complementary medicines", and in particular homeopathy, acupuncture and phytotherapy.

The Tuscany Region appears to be at the forefront of integrating non-conventional practices and medicines into the healthcare system. Indeed, in February 2011 the *Integrated Medicine Centre* of *the Petruccioli Hospital* in Pitigliano was inaugurated, within which "official" medicine is complemented by non-conventional medicines[106] subject to specific regional regulations for the treatment of a series of diseases.[107]

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[102] Constitutional Court, Judgement no. 40/2006 (our translation). With regard to Umbria Region see Const. Court, dec. n. 217 of 2015.

[103] Article 9 of which, in order to «promote the provision of supplementary forms of health care with respect to those provided by the National Health Service, and in any case directly integrated with them", allowed the establishment of "Supplementary Funds of the Health Service...aimed at expanding the provision of treatments and benefits not included in the uniform and essential levels of care referred to in article 1, defined by the National Health Plan and its implementing measures». On the subject see V. PUTIGNANO, *Attualità e prospettive dei fondi integrativi del servizio sanitario nazionale*, in *Rivista del diritto e della sicurezza sociale*, 2/2007, p. 461ff; P. BORGIA, *Costi delle forme di assistenza sanitaria e integrativa e prospettive di sviluppo*, in *Sanità pubblica e privata*, 1/2005, 48ff; G. GUERRIERI, *Alcune riflessioni sui nuovi fondi sanitari integrativi del SSN*, in *Diritto ed economia dell'assicurazione*, 4/1999, p. 911ff.

[104] For example, some regional resolutions allocated funding to some non-conventional practices and medicines, without however providing for a complete regional legislative discipline. For an overview see S. VILLAMENA, *Medicina «non convenzionale» e sistema sanitario nazionale*, cit., p. 3ff.

[105] The case before the court ended with Order no. 198/2008 with which the Council took note of the abandonment of the appeal filed by the State following the regulatory changes made by the Region.

[106] Homeopathy, acupuncture, phytotherapy.

[107] Specifically: respiratory, gastrointestinal, dermatological diseases, allergies, asthma, rheumatic diseases, in the outcomes of traumas and strokes, in the field of orthopaedic and neurological rehabilitation, chronic pain; to contain the side effects of chemotherapy in oncology and palliative care. See Centro di Medicina integrata di Pitigliano

Today, the *Integrated Medicine Center of the Pitigliano Hospital* is the regional reference structure for integrated medicine activities in the hospital path and most of Tuscany's hospitals provide complementary or non-conventional medicines services. [108]

Nationally, a significant turning point occurred with the approval of the *State-Regions Agreement* of 7 February 2013, followed by a clarification from the Ministry of Health sent by the FNOMCeO with communication no. 9 of 21 January 2015.[109]

It is an agreement with which the guidelines for the training of doctors practising non-conventional medicines and practices have been defined.

For many regions, the approval of this agreement was an opportunity to adopt specially designed regulations, which were not very different from those that had been declared unconstitutional in previous years.

Despite the undoubted significance of this new development, the scope of the agreement is still limited since only doctors and dentists can exercise some non-conventional practices and medicines such as acupuncture[110], phytotherapy[111], and homeopathy,[112] considered to constitute a «medical act» and to be «diagnostic, treatment and prevention systems that accompany official medicine, having as a common purpose the promotion and protection of health, treatment and rehabilitation» (art. 1).

This Agreement also seems significant because, by providing for special lists of qualified professionals thanks to specific training, a logic of integration is proposed and not of mere alternative practices,[113] guaranteeing the principle of freedom of choice of care while respecting public interests that require that admissible practices and therapies meet adequate quality and safety criteria.

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[108] In Tuscany we shall consider also the *Fior di Prugna Center of Traditional Chinese Medicine*, that is a regional reference structure for traditional Chinese medicine; the *Homeopathy Clinic*, that is a regional reference structure for homeopathy; *The Center for Integrative Medicine*, of the Careggi-Florence AOU, that is a regional reference structure for phytotherapy.

[109] Text found at Ordine dei Medici di Modena, , as well as the FNOMCeO communications of 9/2015 and 88/2014 at Portale Fnomceo.

[110] Acupuncture is defined as «a diagnostic, clinical and therapeutic method that makes use of the insertion of metal needles in certain skin areas to restore the balance of an altered state of health» (art. 2 State-Regions Agreement, cit.).

[111] Phytotherapy is defined as a «therapeutic method based on the use of medicinal plants or their derivatives and extracts, treated as needed, which can take place according to epistemological codes belonging to traditional medicine or even within a diagnostic-therapeutic system comparable to that used by official medicine» (art. 2 State-Regions Agreement, cit.).

[112] Homeopathy is defined as «a diagnostic and therapeutic method based on the" Law of Similars", which affirms the possibility of treating a patient by administering one or more diluting substances that, taken by a healthy person, reproduce the symptoms characteristic of his/her pathological state». Moreover, «[t]he definition of homeopathy includes all therapies that use diluted medicines as specified by Italian Legislative Decree no. 219 of 24/4/2006 and subsequent acts». (art. 2 State-Regions Agreement, cit.).

[113] With the exclusion perhaps of homeopathy, whose remedies are often incompatible with those envisaged by "official" medicine. This "principle of integration" is clearly evident in some of the regional regulations implementing the agreement. For example, the Regional Law of Umbria no. 24/2014 expressly states that the Region «favours the acceptance and integration of clinical methodologies from other cultures and other cognitive experiences according to the latest guidance provided by philosophy and science studies according to the concept of epistemological paradigm» (art. 1).

To date various regions have transposed the contents in internal discipline, without additions,[114] others have specified the scope or inserted the content in regional legislative acts, or in any case with supplementary resolutions (with which the admissible practices have also been expanded),[115] while others, although they have been petitioned by FNOMCeO, have not yet done so.[116]

As mentioned above, in many regions some non-conventional practices and medicines are included among the services provided by the public health system,[117] and there are cutting-edge integrated medicine projects.[118]

5.3. *Case study: the integration of cultural diversity factors in the Emilia-Romagna Region*

Attention to non-conventional medicines and, more generally, to the needs of "others" is also strong in Emilia-Romagna.

The region has funded various research projects aimed at assessing the integrability of non-conventional practices and medicines in the health system and has also promoted some legislative initiatives both nationally[119] and internally aimed at regulating some non-medical practices such as naturopathy (Regional Law no. 11 of 21 February 2005),[120] or by providing for the inclusion of some non-conventional practices in subsequent regional health plans.[121] The first reference to non-conventional medicines in an official

[114] The Regions that have already implemented the agreement as drafted without adding articles, clarifications and additions are: Apulia Region, DGR no. 2211 of 26 November 2013; Emilia-Romagna Region, DGR no. 679 of 19/05/2014 as well as DGR 2143/2015; Sicily Region, Decree no. 1742 of 22/10/2014; Sardinia Region, DGR no. 34/22 of 07/07/2015; Lombardy Region DGR no. 4104 of 02/10/2015; Autonomous Province of Bolzano DGR no. 1274 of 03/11/2015; Lazio Region, DGR no. 24 of 02/02/2016, Liguria Region, DGR no. 311 of. 04/05/2018.

[115] Marche Region, DGR no. 23 of 25/11/2013 and Regional Law no. 43 of 23/11/2013 establishing *Procedures for the use of complementary medicines*; Autonomous Province of Trento, DGR no. 2793 of 30/12/2013; Umbria Region, Regional Law no. 24 of 28/11/2013/2014 establishing *Procedures for the use of non-conventional medicines by doctors, dentists, veterinarians and pharmacists*; Piedmont Region, Regional Law no.13 of 23/06/2015 establishing *Procedures for the use of non-conventional medicines*; Tuscany Region, Regional Law no. 9 of 19/02/2007 and subsequent amendments, as well as DGR no. 49 of 28/01/2008 and subsequent amendments

[116] The Regions that have not yet implemented the agreement, even after being petitioned by FNOMCeO, are: Abruzzo, Campania, Friuli Venezia-Giulia, Molise, Basilicata, Calabria, Veneto, Valle d'Aosta.

[117] As in the case of Acupuncture in Emilia-Romagna, Tuscany or Piedmont

[118] In addition to the case of the Integrated Medicine Centre of the Petruccioli Hospital in Pitigliano, other initiatives worthy of note are the Integrated Medicine Centre of the Careggi Hospital in Florence, the Plum Blossom Traditional Chinese Medicine Centre of the Tuscany Centre USL; the Lucca ASL homeopathy clinic; and the Breast Unit at Sacco Hospital in Milan, which includes an outpatient clinic dedicated to homeopathic therapies designed to support people undergoing oncological treatments.

[119] Even though they did not hesitate to adopt any legislative text. For an overview of regional plans and initiatives see *Dossier della Regione Emilia Romagna, no. 186/2009*, *Le medicine non convenzionali e il Servizio sanitario dell 'Emilia-Romagna. Un approccio sperimentale*, at Regione Emilia Romagna; as well as *Rapporto attività e proposte dell 'Osservatorio regionale per le medicine non convenzionali - anno 2005*, prepared by the regional non-conventional medicine observatory, at Regione Emilia-Romagna.

[120] Law on the *Establishment of the Naturopathic Professional Wellness Operator*, declared partially unconstitutional by the Const. Court with Judgement no. 138/2009.

[121] The main regional measures include: DGR no. 779/2006 (*Approval of the 2006-2007 experimental programme for the integration of non-conventional medicines into the Emilia-Romagna health service. Amendments to DGR 334/2005*); DGR no. 1963/2006 (*2006-2007 experimental programme for the integration of non-conventional medicines in the Emilia-Romagna Health Service*

document of the Region dates back to the *1999-2001 Regional Health Plan*, more or less in parallel with the European Parliament's and the Council of Europe's attention to these issues.[122] It was a guiding act within the framework of a special project of the *Regional Health Agency*, the results of which were published in 2003 in a volume drawn up in collaboration with the WHO.[123] Non-conventional practices and medicines were considered as potential clinical organisational innovations of healthcare, to be carefully assessed in terms of quality, safety, appropriateness, and sustainability.

With D.G.R. no. 297 of 23 February 2004, the *Regional Observatory for non-conventional medicines* was established at the *Regional Health Agency*, with the aim of promoting experimental studies and research aimed at evaluating the possible inclusion of non-conventional practices and medicines[124] in the activity plans of the various health offices in the Region and their methods of integration with biomedicine. The activity of this *Observatory* lasted until recently, ceasing to operate from 31 January 2018 (according to D.G.R. no. 79 of 2017). In fact, the Region decided to develop a series of specifically designed research activities aimed at integrating non-conventional practices and medicines into the Regional Health Service.[125]

Emilia-Romagna is also noteworthy for having been part of the European project *CAMbrella, a pan-European strategy for clinical research in non-conventional medicine*, a project funded under the *7th Framework Programme*, which, as mentioned above,[126] aimed to promote a network for research on CAMs

referred to in DGR 779/06 admission to funding and allocation of funds to health companies by way of co-financing); DGR no. 2025/2008 (*Approval of the Plan of activities for the implementation of the 2nd regional experimental programme for the integration of non-conventional medicines into the Emilia-Romagna Health Service*); DGR no. 741/2014 (*Approval of the regional guidelines for the provision of non-conventional medicine services in the Emilia-Romagna Region, the disbursement of which is borne by the Regional Health Fund. Appointment of members of the Regional Observatory for non-conventional medicines*); DGR no. 1209/2009 (*2nd Regional experimental programme for the integration of non-conventional medicines into the Emilia-Romagna health service referred to in DGR 2025/2008. Allocation and granting of funding for multicentre studies to the USL of Bologna and the University Public Hospital of Bologna*); DGR no. 1334/2009 (*2nd regional experimental programme for the integration of non-conventional medicines in the Emilia-Romagna Health Service referred to in DGR 2025/2008. Granting of co-financing and assumption of expenditure commitments for regional actions*); DGR no. 2419/2009 (*2nd regional experimental programme for the integration of non-conventional medicines into the Emilia-Romagna Health Service referred to in its Resolution 2025/2008. Grant of co-financing for projects submitted to the 2009 call and changes to the composition of the Regional Observatory for "non-conventional medicines" (OMNCER) pursuant to DGR 948/2008 and Regional Resolution 2025/2008*); DGR no. 2161/2011 (*2nd Regional experimental programme for the integration of non-conventional medicines into the Emilia-Romagna health service referred to in DGR 2025/2008: correction of material errors of DGR 835/2011 and changes to allocations referred to in DGR 2419/2009 (CUP E35J11000470002)*); DGR no. 8682/2014 *("Approval of the Regional Guidelines for the provision of non-conventional medicine services in the Emilia-Romagna Region, the disbursement of which is borne by the Regional Health Fund. APPOINTMENT OF MEMBERS of the Regional Observatory for non-conventional medicines". Consequential measures*).

[122] See above, para. 4.

[123] Text at Regione Emilia Romagna web site.

[124] Specifically acupuncture, homeopathy and phytotherapy.

[125] For example, the project on the effectiveness of acupressure in the containment of birth pain and acupuncture treatments, as supportive care for women who have had breast cancer operations (in line with initiatives in other regions). These indications can be seen from the *2019-2021 Programme Plan of the Regional Health and Social Agency*, Resolution no. 968 of 18/06/2019, at Regione Emilia-Romagna web-site.

[126] See above, para. 4.

(complementary and alternative medicines) in Europe, offering an overview of the different aspects of CAMs within the EU, to identify the needs of the different stakeholders in this field and to analyse the best way to disseminate information in a careful, pragmatic manner. The central objective of this project was to develop a roadmap for European CAM research, making them appropriate for the health needs of European citizens and acceptable to their national research institutes and health bodies, both public and private.[127]

In parallel with the promotion of research and in the execution of the 2013 *State-Regions Agreement*,[128] since 2016 the Region has undertaken an accreditation process for educational institutions, both public (such as universities) and private, on non-conventional medicines for the training of specialists in acupuncture, phytotherapy, homeopathy, homotoxicology, and anthroposophy.[129]

Therefore, while the region's approach to NCMs is aimed at verifying their therapeutic effectiveness rather than being attentive to the cultural dimension and their underlying conceptions of medicine and health, it has nevertheless demonstrated how a greater sensitivity towards some of these disciplines is now developing by focusing on a possible, synergistic integration with official medicine.

In contrast, in Emilia-Romagna, the attention to the intercultural dimension is evident in the organisational facets of the Regional Health Service.

For the past decade or so the Region's approach to foreign users has been called "migrant-friendly". For example, hospitals in the Region were part of the *2002-2005 Migrant-friendly hospitals*[130] project created by the network of *Health Promoting Hospitals* (HPH). Within this network, the objective is to guarantee a full right to care for the migrant population, improve accessibility to services (by removing linguistic or bureaucratic barriers), improve the usability of services (by encouraging adequate information on the services available), guarantee the quality of care and responsiveness to needs (by implementing cultural skills and promoting organisational adaptation). The approach of the migrant-friendly hospital network, therefore, includes cultural/linguistic mediation, information and educational activities aimed at patients

[127] *The Roadmap for European CAM Research, An Explanation of the CAMbrella Project and its Key Findings*, at cam.europe.eu.

[128] Agreement transposed with DGR no. 679/2014 (*Transposition of the Agreement between the State and Regions concerning the criteria and procedures for the certification of the quality of education and practice of acupuncture, phytotherapy and homeopathy by doctors, dentists, veterinarians and pharmacists*) and DGR no. 2143/2015 (*Definition of the implementing provisions of the State-Regions agreement of 7 February 2013 concerning the criteria and procedures for the certification of the quality of education and practice of acupuncture, phytotherapy and homeopathy referred to in its resolution no. 679/2014: establishment of the Regional Commission for the accreditation of non-conventional medicine schools*).

[129] DGR no. 1955/2016 (*Regional accreditation course of public and private schools of non-conventional medicine, acupuncture, phytotherapy, homeopathy, homotoxicology and anthroposophy referred to in DGR no. 2143/2015*); Executive Decision 19412/2016 (*Procedures for the accreditation of non-conventional medicine schools in the Emilia-Romagna Region*); Executive Decision 5050/2017(*Accreditation of the school "Amab - scuola italo cinese di agopuntura medicina e tradizione s.r.l." for the field of acupuncture*).

[130] See the Migrant-Friendly Hospital project: an initiative to promote the health of immigrants and ethnic minorities that involved the hospital of Reggio Emilia. For more details on this point, see M. CAMPINOTI, F. SANTOMAURO, *Verso un ospedale amico dei migranti*, in *Saluteinternazionale.it*, 2005, p. 1ff. See also Ausl.re.it.

and users, and the training of personnel on intercultural skills. With particular regard to vulnerable groups such as women, information and educational programmes adapted to cultural diversity have been envisaged, including for example empowerment initiatives that make it easier for women to care for themselves and their children. Specific training courses for healthcare professionals have also been organised to raise their awareness of a number of cultural factors related to migration (and the socio-cultural aspects of groups, in relation to the migration and health relationship) and to allow them to develop appropriate communication skills and management of intercultural relationships (e.g. how to ask patients for information or their preferences).

The approach of the Migrant-Friendly Hospitals has also included the active involvement of some immigrant communities, promoting specific prevention and training activities, implementing a series of programmes and projects dedicated to specific categories of migrants (caregivers, prostitutes, asylum seekers and refugees, families[131]), as well as training health promoters and intercultural mediators.

In 2008 WHO's Network of Regions for Health launched the project *Migrants and Healthcare: Responses by European Regions*, in which the Emilia-Romagna Region also participates, with the aim of systematically mapping all the actions and strategies for the health of migrants adopted at a sub-national level in some European Regions.[132]

More recently, the *MyHealth* project was launched, funded by the *European Union's Health Programme 2014-2020*,[133] aimed at increasing and improving access to healthcare for migrants, refugees, and "newly arrived" ethnic minorities[134], in particular, women and unaccompanied minors.[135] This project aims to promote forms of interaction and the strengthening of various health disciplines, as well as to encourage the development of new mobile applications and digital tools.

The main entities that interact with migrants and refugees[136] in various ways were involved in a participatory, people-centred approach. In fact, there is an awareness that for categories of people such

[131] Worthy of note is the *Centre for the health of the foreign family*, established thanks to an agreement between Caritas and the AUSL of Reggio Emilia and active since 1998. Thanks to the presence of physicians, psychologists and intercultural mediators, this centre provides assistance to many undocumented migrants by providing basic medical services, internal medicine, outpatient activities, TB control, obstetrics and gynaecology, paediatric services, dental services, psychological and social support and vaccinations.

[132] See the Report published in collaboration with the WHO: M. BIOCCA, B. RIBOLDI, F. SARTI, *Migrants and Health care Responses by european regions* (MIGHRER), 2012, at Regione Emilia-Romagna web site.

[133] *MyHealth* is one of three projects funded in the 2016 call of the Third Public Health Programme with a total budget of over €1.4 million and is coordinated by the Fundació Institut de Investigación Hospital Universitari Vall d'Hebron, EU health programme https://ec.europa.eu/health/funding/programme_en

[134] Arrived in Europe less than 5 years ago.

[135] The Emilia-Romagna Region - Health and Social Agency is an Italian partner of the project, which involves a total of 11 partners from 7 European countries: Germany, Greece, Ireland, Italy, Spain, United Kingdom, Czech Republic, at Regione Emilia-Romagna web site. Project website: http://www.healthonthemove.net

[136] Health facilities, social services, projects of the Protection system for asylum seekers and refugees (formerly SPRAR), researchers, cooperatives, migrant associations, governmental and non-governmental organisations

as migrants, who have a number of vulnerabilities, access to quality health services and the promotion of well-being are impeded by factors such as the existence of language barriers, the difficulty of relating to and understanding different cultures, forms of more or less severe social exclusion, the lack of documents and the difficulty of interfacing with bureaucratic organisations, etc. As part of this project, initiatives were put in place to map the network of stakeholders, services for migrants, local community projects, and ICT tools,[137] as well as "needs assessment, modelling of health interventions and community health promotion actions in three European cities (Barcelona, Berlin, Brno) with the possibility of adaptation and replication in the regional territory" in a perspective that focuses particularly on the intercultural dimension.

6. Conclusive findings and open questions

The issue of the interconnections between health, medicine, and cultural diversity, read through the prism of "other" and non-conventional medicines raises the question not only, as a prerequisite, of the relationship between law and science and the identification of the role to be attributed to experts in a sensitive area such as health, but is also one of the central points of bioethical reflection and is reflected in the very concept of democracy (see above, para. 2.2). It is a complex issue that also raises questions about the space left to the freedom of choice in the therapeutic field and the role of public authorities.

Repeating the questions asked in the previous pages, in Italy is it conceivable a right to health that includes the right to be able to be treated according to a system that incorporates both traditional and non-conventional medicines? And from a different point of view, is there a duty on the part of the public authorities to structure the health system according to dynamics that take cultural diversity into account?

It seems possible to argue that if it is true that our Constitution requires due attention to cultural diversity (see above para. 1), this does not necessarily imply the integration of all non-conventional medicines and practices into the national health system. It would not even be financially sustainable, at least in a health system like ours.

First of all, due attention to cultural diversity implies attention to the various factors of cultural diversity, it implies understanding, willingness to listen to, and accept, concerns according to an inclusive logic that, with regard to our system, underlies articles 2 and 3 of the Italian Constitution. But it also implies attention to the religious factor that often appears difficult to separate from cultural and health protection factors. By way of example, we can recall the problems that have to do with the respect of some religious rules related to health needs (such as the treatment of diabetic patients during Ramadan), or with the availability of adequate food in hospitals, or with the request for practices such as female genital

[137] Activity being carried out by the Emilia-Romagna region.

mutilation or the issuance of so-called virginity certificates, or with the approach to situations of mental distress, or with the organisation of health systems and hospitals according to dynamics that respect the needs of prayer or with the consideration of relationships between the sexes (e.g. the possibility of a woman being visited by a male doctor). These are areas to which each system responds to in a different manner, sometimes regardless of the integration model pursued.[138]

According to a well-known approach, attention to cultural diversity implies «protecting and encouraging the cultural and material richness of the various cultures (cultural groups) and respecting their identity», and in this sense, it would be justified.[139] But this justification exists provided that openness to "other" cultures is part of a liberal context where the primacy of the fundamental principles of modern constitutionalism is recognised, first and foremost human dignity.

Moreover, every individual must be free to "leave" the cultural group he/she belongs to, and this freedom is essential to individual freedom and the principle of self-determination.

Consequently, wanting to identify the limits of openness to different cultures, these seem to be represented by the same legal and philosophical justification of modern constitutionalism: practices or medicines that can result in conduct or situations that determine an injury to human dignity and that conflict with the value structures and constitutionally defined principles are not admissible.

This order of reflections, even though it originally arose from the analysis of problems related to coexistence between different ethnicities and religions[140] and not specifically related to non-conventional medicines, can therefore be proposed again in relation to them.

Whenever the option that leads to the decision to resort to unconventional practices or medicines is motivated by a cultural choice, by the recognition of belonging to a certain "tradition", both when this connection appears clear (as in the case of Ayurvedic or Chinese medicine), and in cases where such link refers to a particular view of existence, a practice can only be prohibited if it is contrary to the values and principles of modern constitutionalism.[141]

However, this consideration only partially solves the problems related to non-conventional medicines, since it leaves open the fundamental issue: whether science should be considered above all ideological

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[138] On this point recently, E. CUKANI, *Le cure mediche degli «altri» oltre il modello nazionale di integrazione? Prime riflessioni alla luce di un'analisi comparata*, cit.

[139] RAZ J., *Multiculturalism* in *Ratio Juris*, cit., p. 197. According to the Author, it is not a matter of favouring groups over individuals, but rather of the effective realisation of his/her freedom of choice within the framework of recognising the primacy of the individual. At the same time, however, our choices are inseparably connected with our being part of a *culture*, they cannot be placed in a neutral and empty space. Therefore, only because we are part of a culture can we afford to exploit the options that give life meaning (ID. *Ethics in the Public Domani: Essays in the Morality of Law and Politics*, cit., spec. p. 177ff).

[140] On this point, for example, W. KYMLICKA, *Multicultural Citizenship. A Liberal Theory of Minority Rights*, cit.

[141] On this point the bibliography is extensive. See among others A. BARBERA, *Le basi filosofiche del costituzionalismo*, in ID. (ed.), *Le basi filosofiche del costituzionalismo*, Laterza, Rome-Bari, 1997, p. 3ff.

options, whether it is to be considered indisputable as to results, and whether these should be followed in order to guarantee the right to health, and therefore to maintain the minimum conditions of existence. If this were the case, no cultural diversity or tradition could stand in its way.[142]

Conversely, from the point of view of multiculturalism, different cultures are conceived as different ways of achieving the same universal values, so they should not be conceived with an attitude of opposition.[143] But reality has shown us the failure of multiculturalism conceived in this manner.

The only solution to the failure of the multicultural model, as well as that of the rigidly assimilationist model, seems to be the construction of an intercultural model that falls within the constitutional framework of duties and rights and that places the human being and his/her dignity at the centre.

If not all religious or cultural practices can be considered legitimate, in parallel our legal order, and Europe, cannot ignore the challenges posed by the change in the cultural identity of our societies. The government of complex phenomena cannot be left to the good administration of certain contexts, or worse, to the discretion of judges.

Moreover, modifying health systems by integrating "other" medicines, opening them up to migrants, especially if they lack a stable link with the territory, implies implementing interventions that cost and have a great impact on systems already with limited resources, ending up being borne not by "new arrivals", by "others", but by those sections of the population that are more consolidated in a territory and more culturally homogeneous, and sometimes less willing to open up and finance such practices.

As a beacon guiding political and administrative decisions, it seems essential to focus attention on the primacy of the individual and his/her dignity, to be conceived in his/her personal, cultural, and relational, dimension, also in a context of intercultural relations.

Putting the individual at the centre in a context of care means considering an individual first as a person, then as belonging to a group (vulnerable or not), and only lastly as a member of a specific ethnic group, bearer of a series of values of reference and models of behaviour, whose legitimacy must be inscribed in the constitutional context in which they find themselves, within the framework of constitutionally envisaged values, principles, duties, and rights.

Given the existence of a strong link between cultural factors and medicine, between culture and health, there is a dearth of uniform, effective models of integration, in addition to posing a significant social and financial problem for the system, as mentioned above. It does not seem possible to identify neutral, objective assessment criteria for non-conventional medicines and all those practices attributable to

[142] But in this regard it has been argued that if State and Church are separate, the same is true for State and Science. See P.K. FEYERABEND, *La scienza in una società libera*, Feltrinelli, Milan, 1981.

[143] RAZ J., *Multiculturalism*, in *Ratio Juris*, cit., p. 208. One of the biggest objections that Raz has had to face is that his concept of multicultural policy makes it impossible to identify an external criterion for establishing what is admissible and what is not (thus assuming the existence of a culture that is abstractly better and others that are "inferior").

cultural and religious factors. Employing an ethical and political option, each legal system "chooses" which elements to give greater weight to, how much to open up to cultural diversity, which parties to attribute technical health decisions to, how much weight to give science. A critical reflection on non-conventional medicines and cultural diversity in health shows that the problem is not only – or not so much – the role to be assigned to science, but also the role to be assigned to the cultural, philosophical, religious, and existential dimension of certain practices and therapies.[144]

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