

EUROCAM

RESPONSE TO THE COMMISSION'S PHARMACEUTICAL STRATEGY

1 SEPTEMBER 2020



General considerations

EUROCAM represents 60,000 organised patients/citizens, 250 national CAM[1] associations and a substantial proportion of the 400,000 doctors, veterinarians and practitioners in the sector of Traditional and Complementary Medicine (T&CM)[2] across Europe. EUROCAM welcomes the Commission's Roadmap towards a Pharmaceutical Strategy for Europe and fully endorses the Commission's statement that "people across the EU expect to benefit from equal access to safe, state-of-the-art and affordable therapies".

Currently, one in two EU citizens uses T&CM as part of their healthcare.[3] Millions of EU citizens are convinced of the benefits, have confidence in the high safety profile and express a high level of satisfaction with T&CM. They would like to see increased integration of T&CM into healthcare systems. To see T&CM reach its full potential across the EU, full availability, accessibility and affordability of these medicinal products needs to be in place.

However, the high demand of T&CM is not reflected in EU or national health policy or provision. Citizens experience many barriers that limit their access to and use of T&CM. For example, the availability of herbal, homeopathic, and anthroposophic medicines, is severely limited in several EU member states. This lack of availability inhibits the demand by EU citizens for low risk, health enhancing T&CM medicines, hampering the capacity of doctors, veterinarians and practitioners to provide effective T&CM treatments. It also undermines the potential benefit of these products in helping to tackle specific health issues prioritised by the Commission e.g. combating anti-microbial resistance, managing non-communicable diseases (NCDs) and sustaining healthy ageing.

These availability issues were documented in the Matrix Insight report[4], an external study commissioned by DG Health and Food Safety for the Pharmaceutical Committee and published on the Committee's website in November 2014. The report said that further work is 'expected to inform policy options for the Commission to consider in order to address the issue of unavailability', and that a need for further action in this area was needed. Such action, the report said, 'should focus on ensuring that the process of authorisation of herbal, homeopathic and anthroposophic medicinal products is more consistent, both with the text of the existing provisions and between Member States.' Unfortunately, little has changed ever since.

[1] CAM or Complementary and Alternative Medicine refers to a broad set of health care practices that are used in tandem with or instead of mainstream biomedical therapies.

[2] The World Health Organization (WHO) uses the term 'Traditional Medicine' when referring to traditional health care practices, such as e.g. traditional Chinese/Japanese/Korean/Tibetan medicine, Ayurveda, etc. We use the term Traditional and Complementary Medicine (T&CM) in conformity with the WHO.

https://www.who.int/health-topics/traditional-complementary-and-integrative-medicine#tab=tab_1

[3] [Cordis.europa.eu](https://cordis.europa.eu)

[4] [EC.europa.eu: Study on the Availability of Medicinal Products for Human Use](https://ec.europa.eu/study-on-the-availability-of-medicinal-products-for-human-use)

General considerations -2-

The growing demand for T&CM medicinal products presents an opportunity for the EU, with its expertise in the manufacture and regulation of T&CM medicinal products, to endorse its responsibility as global leader in this field and play a role in ensuring safety and security for this growing demand.

T&CM medicines, as currently used in primary and clinical care across Europe, have an important role to play in the face of major health challenges in the EU such as multimorbidity, polypharmacy, antimicrobial resistance, chronic and non-communicable diseases and an ageing population. The effectiveness of these forms of treatment are demonstrated by a growing body of scientific research. In addition, they can contribute to the sustainability of health systems by significantly reducing treatment costs.

In 2019, a new report from the World Health Organisation Global Report on Traditional and Complementary Medicine 2019 confirms the growth and importance of traditional and complementary medicine. In his foreword to the report, WHO Director General, Dr Tedros Adhanom Ghebreyesus, calls on policy-makers, health professionals and the public to capitalise on the potential contribution of T&CM to “help tackle the unique health challenges of the 21st century”, saying that is “...an important and often underestimated health resource... especially in the prevention and management of lifestyle-related chronic diseases, and in meeting the health needs of ageing populations.” He argues that at a time when “consumer expectations for care are rising, costs are soaring, and most budgets are either stagnant or being reduced”, traditional medicine should be an option “offered by a well-functioning, people-centred health system that balances curative services with preventive care.”

Specific considerations

1. The problem the initiative aims to tackle

The Pharmaceutical strategy roadmap rightly identifies several challenges. One of these challenges is the fact that “[i]nnovation efforts are not always aligned to public health and health systems’ needs. Innovation does not always correspond to public health and health systems’ needs. Therapies or medical technologies for major unmet needs [.....] are not developed because of science limitations or lack of interest from industry to invest. In addition, the lack of a common understanding of the concept of unmet medical needs between stakeholders and decision makers contributes to this problem.” This concept issue needs to be examined more in depth as a wealth of means and experience in T&CM already exists to contribute to health policy also complying with the One Health approach and the EU Green Deal. The concept of T&CM medicines is often incompletely understood by decisions makers and needs to be included in policy making.

2. What the initiative aims to achieve and how

According to the Roadmap, “the overall goal of the Pharmaceutical strategy is to help to ensure Europe’s supply of safe and affordable medicines to meet patient’s needs and support the EU pharmaceutical industry to remain an innovator and world leader.”

Specific considerations -2-

T&CM can substantially contribute to this goal, as follows:

2.1. Overall goal – Ensuring the supply of safe medicines to meet patient's needs

Adverse effects noted in T&CM research literature are rarely of a serious nature, but individual risk levels may vary from one CAM therapy to another. Herbal medicinal products can cause adverse effects in several ways: side-effects of their active substances, adulteration or contamination, overdose, or by inappropriate prescription. WHO published guidelines providing practical technical guidance for monitoring the safety of herbal medicines within pharmacovigilance systems[5]. Homeopathic and anthroposophic medical products are considered to be safe. Appropriate regulation and standards of practice within the T&CM sector minimise any potential risk.

Professional CAM associations consider user safety as paramount and have therefore established guidelines for training, certification and practice, as well as requiring professional insurance and operating robust codes of ethics and complaints procedures.

The good safety profile of T&CM is a cogent reason for T&CM to be integrated into health systems, thereby reducing some of the more high-risk biomedical interventions which inevitably pose more risks to patient safety.

2.2. Overall goal – Ensuring the supply of affordable medicines to meet patient's needs

T&CM medicinal products are predominantly low cost and not patentable, often produced from ingredients of natural origins.

2.3. Overall goal – Supporting the EU pharmaceutical industry to remain an innovator and world leader

T&CM medicinal products are already produced in the EU, mostly if not completely by small or medium sized companies. Nevertheless, they are part of the “EU pharmaceutical and health industry”. High standard products rooted in T&CM systems have an outstanding prospect of strengthening the position of the EU in health matters.

The Pharmaceutical Strategy enumerates several specific objectives, as follows:

2.4. Specific objective – Ensuring greater access and availability of pharmaceuticals to patients.

Access to efficient, safe, and affordable medicines should be high on the EU agenda in the pursuit of equitable and sustainable healthcare. Official regulation and established production methods of T&CM medicinal products exist throughout Europe.

However, their availability is severely limited by a lack of capacity and specific expertise on T&CM in the medicines agencies and a lack of harmonisation between the Member States. The Matrix report (see above) suggested the need for further action that should focus on ensuring that the process of authorisation of T&CM medicinal products is more consistent, both with the text of the existing provisions and between Member States.

[5] World Health Organization (2004) Guidelines on safety monitoring of herbal medicines in pharmacovigilance systems, WHO, Geneva, Switzerland

Specific considerations -3-

Ensuring greater access is also in line with the European Parliament resolution of 2 March 2017 on EU options for improving access to medicines (Recital text, section D)[6], which stated that “patients should have access to the healthcare and treatment options of their choice and preference, including to complementary and alternative therapies and medicines.”

2.5. Specific objective – Ensuring affordability of medicines for patients and health systems financial and fiscal sustainability

T&CM medicinal products are reasonably priced pharmaceuticals because they are not patentable, produced from ingredients of natural origins. See above comment

2.6. Specific objective – Enabling innovation including for unmet medical needs in a way that harnesses the benefits of digital and emerging science and technology and reduces the environmental footprint

T&CM offers pharmaceuticals in a wide variety by using only ingredients of natural origins. Generally speaking, the environmental footprint from T&CM is minor in comparison to that from biomedical drugs.

2.7. Specific objective – Supporting EU influence and competitiveness on the global level, reduce direct dependence on manufacturing in non-EU countries, seek a level playing field for EU operators.

The demand for T&CM is constantly growing in Europe as well as abroad and concerted action supported by the EU will not only meet the demand but create new possibilities of sharing existing and new developed resources.

[6] https://www.europarl.europa.eu/doceo/document/TA-8-2017-0061_EN.pdf?redirect

APPENDIX 1:

Additional information

T&CM treatment in
different contexts:



01

CANCER PATIENTS

02

**NON-ANTIBIOTIC TREATMENT IN PATIENTS WITH
INFECTIONS**

03

**THE IMPACT OF T&CM PHARMACEUTICALS ON THE
ENVIRONMENT**

Patients with cancer using T&CM

Patients with cancer often use T&CM methods such as acupuncture, meditation, herbs, and dietary supplements in addition to their conventional cancer treatment. The use of these methods in Europe is estimated to be 37% but varies considerably across the different European countries. According to a systematic review[7] the prevalence of any T&CM use (since cancer diagnosis) in children with cancer ranged from 6% to 100%.

The majority of participants accept and value their conventional clinical treatment, using T&CM alongside it rather than instead of it. They turn to T&CM for additional support in the following areas[8]: desire for active participation in treatment, desire for good communication, to relieve side effects of cancer treatment or symptoms of cancer, desire for a more holistic approach, and to reduce the spread of the disease and prolong life.

Integrative Oncology

In response to the increasing role that people with cancer and survivors have in managing their own care, the growing usage and evidence-base of CAM, and the importance of a therapeutic alliance between conventional cancer care and CAM that respects the treatment preferences and values of patients, the concept of **integrative oncology** has emerged within hospitals and community settings.

The US Society for Integrative Oncology (SIO)[9] is “the premier multi-disciplinary professional organization for integrative oncology, whose mission is to advance evidence-based, comprehensive, integrative healthcare to improve the lives of people affected by cancer.” SIO has consistently encouraged rigorous scientific evaluation of both pre-clinical and clinical science, while advocating for the transformation of oncology care to integrate evidence-based complementary approaches. The vision of SIO is to have research inform the true integration of complementary modalities into oncology care, so that evidence-based complementary care is accessible and part of standard cancer care for all patients across the cancer continuum.

Growth of Integrative Oncology

There is a steady increase in the number of cancer centers offering integrative oncology in North America, Australia, and Western Europe[10]. A large majority of the 45 National Cancer Institute (NCI)-designated comprehensive cancer centres in the USA now offer integrative oncology services both within the hospital setting to inpatients and outpatients and at other community locations for outpatients, including acupuncture and massage, meditation and yoga, and consultations on nutrition, dietary supplements and herbs.

[7] Diorio C et al (2017). Global Use of Traditional and Complementary Medicine in Childhood Cancer: A Systematic Review. *Journal of Global Oncology*, 3(6):791-800.

[8] Evans MA et al (2007). Men with cancer: is their use of complementary and alternative medicine a response to needs unmet by conventional care? *European Journal of Cancer Care*, 16: 517-525

[9] Retrieved from <https://integrativeonc.org>

[10] Grant SJ et al (2019). Integrative Oncology: International Perspectives. *Integrative Cancer Therapies*, 18(1): 1-11

Patients with cancer using T&CM

Over the last decade integrative oncology in the USA has grown by 30%. The Memorial Sloan Kettering Cancer Center provides a comprehensive website on natural products and other complementary therapies – MSK About Herbs[11], which has had over 20 million visits to date.

Europe as well has seen a significant increase in the number of cancer centres offering integrative oncology. A mapping study conducted in 2013[12] among 236 cancer centres showed that nearly 50% of the responding centres provided integrative oncology services. Treatments most often used in Europe include anthroposophic medicine, homeopathy, acupuncture, herbal medicines, vitamins/minerals, nutrition, and relaxation techniques.

The Joint Action “European Partnership on Action against Cancer” (EPAAC) was an initiative started by the European Commission in September 2009 with the support of many partners. One of the deliverables collected and reviewed the evidence on the use of Complementary Medicine (i.e. T&CM) in oncology and proposed criteria for a correct dissemination of the information for clinicians, patients and decision-makers; to map the European structures/centers which provide services of integrative oncology (the mapping study mentioned in the previous paragraph) and put them in network activating synergies and a permanent co-ordination among the centers of integrative oncology. It is titled “Complementary and alternative medicine (CAM) in cancer care – Development and opportunities of Integrative Oncology” and available from the EPAAC website[13].

An increasing evidence base

The evidence base for the effectiveness of T&CM for psychological support, symptom control in cancer and adverse effects of conventional cancer treatment is increasing. Reviews that have been published of the evidence of acupuncture, homeopathy, mistletoe therapy, herbal medicine or other naturopathic treatments, and aromatherapy/massage for cancer patients suggest that T&CM therapies may have benefits on measures of Quality of Life, psychological wellbeing, adverse effects of cancer treatments, and may impact on survival[14].

Numerous references on the effectiveness of T&CM (CAM) therapies can also be found at CAM Cancer, a web resource hosted by NAFKAM, Norway's National Research Centre in Complementary and Alternative Medicine[15], located at the Institute for Community Medicine, Faculty of Health Sciences, UiT – The Arctic University of Norway; it is a World Health Organization collaborating centre for Traditional Medicine.

[11] <https://www.mskcc.org/cancer-care/diagnosis-treatment/symptom-management/integrative-medicine/herbs>

[12] Rossi E et al (2015). Complementary and alternative medicine for cancer patients: results of the EPAAC survey on integrative oncology centres in Europe. Support Care Cancer, 23:1795-1806

[13] http://www.epaac.eu/images/END/Final_Deliverables/D5_Complementary_and_alternative_medicine_CAM_in_cancer_care_development_and_opportunities_of_integrative_oncology.pdf

[14] Rossi E et al (2017). Add-On Complementary Medicine in Cancer Care: Evidence in Literature and Experiences of Integration. Medicines (Basel), 24:4(1).

[15] <http://cam-cancer.org/en>

Patients with cancer using T&CM

The Society of Integrative Oncology (SIO) publishes online monthly updates of relevant literature[16]. Each month, SIO Research Committee co-chairs select recent papers to be listed on the website, based on search criteria that focus on original clinical research in human populations spanning a full range of T&CM modalities. SIO has also published several Integrative Oncology Practice Guidelines. Experts who specialize in defined categories of integrative or complementary therapies were asked to review the scientific literature and categorize the interventions into specific levels of utility that take into account the methodological strength of supportive evidence, benefits versus risks, practicality, and value.

In 2009 SIO issued the first evidence-based clinical practice guidelines[17] for doctors to consider when incorporating T&CM therapies into the care of cancer patients. These guidelines clearly advocate evidence-based complementary therapies that support patients through their standard anticancer treatment, help reduce adverse effects, and improve their quality of life. More recently, the Society published guidelines for the care of breast cancer patients[18], which conclude that “there is a growing body of evidence supporting the use of integrative therapies, especially mind-body therapies, as effective supportive care strategies during breast cancer treatment. Many integrative practices, however, remain understudied, with insufficient evidence to be definitively recommended or avoided.”

Conclusion

EUROCAM takes the position that T&CM approaches can be safely used as a part of integrative oncology, in particular to mitigate disease symptoms and side effects of conventional biochemical treatment. It also helps provide social, psychological and nutritional guidance for patient re-integration and rehabilitation. A multidisciplinary approach is of paramount importance. In addition, T&CM has the potential for the primary and secondary prevention of cancer through counselling on healthy lifestyle, nutrition and supporting the human power of ‘salutogenesis’[19] throughout life.

[16] <https://integrativeonc.org/recent-research-findings>

[17] Deng et al (2009). Evidence-Based Clinical Practice Guidelines for Integrative Oncology: Complementary Therapies and Botanicals. *Journal of the Society for Integrative Oncology*, 7: 3, 85-120

[18] Greenlee H et al (2017). Clinical Practice Guidelines on the Evidence-Based Use of Integrative Therapies During and After Breast Cancer Treatment. *CA Cancer Journal for Clinicians*, 67(3):194-232.

[19] Antonovsky A (1996). The salutogenic model as a theory to guide health promotion. *Health Promotion International*, 11: 11-18

Non-antibiotic treatment of infections – reducing AntiMicrobial Resistance

It is well known that antibiotic-resistant infections are rapidly rising, the pipeline of effective new antibiotics is drying up and there is currently no viable market for new antibiotics. Instead of solely relying on new antibiotics, which will engender further AMR, we need to adopt other strategies, including preventing infections from occurring in the first place by making the population more resilient.

Role of pathogen and host

The vital role of the host's ability to repel invaders based on a properly functioning immune system, has been neglected. In practice, infection is always the result of two factors: exposure to a pathogen and a person's individual susceptibility. The partial approach which focuses only on the infecting organism is also reflected in research, which has been directed at finding the most potent way to kill the germs, whereas there is little research that investigates ways and means in raising the effectiveness of the immune system.

Both of these approaches have their own merits. For a patient who is seriously ill and affected by highly virulent bacteria, there is no argument, that antibiotics can be life saving.

On the other hand, antibiotics do not offer an adequate solution for a patient who has had recurrent infections and has taken several courses of antibiotics. In this case it is the patient's susceptibility that needs to be addressed. Antibiotics are also not the most appropriate treatment for patients with minor acute infections.

When it comes to the host's ability to repel invaders, basic requirements to keep the immune system strong include quality sleep, regular exercise, healthy food, relaxation practice and healthy relationships. In building and maintaining resistance to infectious illness, T&CM therapies have an important role to play here because they mobilise and stimulate the self-regulating capacity of the organism, thus increasing its resilience. Greater resilience leads to a swift and sustained recovery from infections and a reduced susceptibility to future infections and less reliance on antibiotics.

Some studies have shown that GP surgeries employing GPs additionally trained in T&CM have lower antibiotic prescribing rates compared to conventional practices based on additional prevention and treatment of infections strategies.[20],[21]

[20] van der Werf ET et al. (2018) Do NHS GP surgeries employing GPs additionally trained in integrative or complementary medicine have lower antibiotic prescribing rates? Retrospective cross-sectional analysis of national primary care prescribing data in England in 2016. *BMJ Open* 2018;8:e020488

[21] Grimaldi-Bensouda L et al.(2014) Management of upper respiratory tract infections by different medical practices, including homeopathy, and consumption of antibiotics in primary care: the EPI3 cohort study in France 2007-2008. *PLoS One* 2014;9:e89990.

Non-antibiotic treatment of infections – reducing AntiMicrobial Resistance

One Health Action Plan

The Commission, in its Communication of 29 June 2017 on a European One Health Action Plan against Antimicrobial Resistance (COM(2017)0339) states that they will "work with stakeholders to [...] provide incentives to increase the uptake of diagnostics, antimicrobial alternatives and vaccines" and "support research into the development of new antimicrobials and alternative products for humans and animals as well as the repurposing of old antimicrobials or the development of new combination therapies."

European Parliament resolution of 13 September 2018 on a European One Health Action Plan against Antimicrobial Resistance (AMR) (2017/2254(INI)) called on the Commission to invest in public and private research and innovation to develop, among others, new treatments and antimicrobial alternatives. There is growing evidence that T&CM treatment strategies can provide non-antibiotic alternatives leading to the prescription and consumption of fewer antibiotics and some of these treatment strategies have been shown to be effective in systematic reviews.

The EU farm to fork strategy asks for a reduction of use of antimicrobials of 50 percent by 2030. Together with the request of the EU regulation on organic farming asking for primarily use of homeopathy and herbal therapy (phytotherapy) in farm animals on organic farms these are strong arguments for research projects in this field.

It is therefore strongly recommended that the potential of T&CM in reducing the problem of AMR is given serious consideration and that further research is carried out in this area to determine in which conditions, both in human and veterinary healthcare, specific T&CM modalities are particularly effective. Compared with other avenues of such as the identification and development of new antibiotics, such trials would be relatively easy and inexpensive to carry out, yet in return for this small investment, the potential rewards could be highly significant.

Pharmaceuticals in the environment

Drastic measures are needed to regulate environmental risks in the transition to a toxic-free environment under the European Green Deal, while maintaining public interest and public health as lead priorities. Europe needs a clean and fair pharmaceutical sector, which operates without harming the environment.

The environmental impacts from T&CM vary from one modality to another, but generally speaking the environmental impacts from T&CM are minor in comparison to those from conventional healthcare.[22] The current provision of biomedicine is vastly more damaging than the provision of most T&CM medicines in terms of energy use, reliance upon oil and pollution of the environment, although direct comparison is not feasible for all services. However, there may be many potentially fruitful areas where conventional medicine is struggling, such as with AMR, or multimorbidity in the elderly. Additionally, it is broadly agreed that prevention must be at the core of sustainable healthcare; the most sustainable approach being one that minimises care needs by preventing ill-health and supporting people to manage their own health as effectively as they can.[23]

All in all, T&CM diminishes the release of harmful pharmaceutical effluents into the environment, thus helping mitigate the risks of spreading AMR, water pollution, and additional long-term impacts on human health and the environment. Europe needs a clean and fair pharmaceutical sector, which operates without harming the environment. It is, therefore, imperative that the EU must promote and improve green public procurement policies to increase demand for more sustainable medicines that are less harmful for the environment such as T&CM medicines.

Conclusion

It is crucial that the European Commission's new Pharmaceutical Strategy for Europe ensures access to affordable and quality medicines in Europe whilst guaranteeing everyone's right to a healthy and sustainable environment. Public interest and public health should prevail as lead priorities when regulating the pharmaceutical sector. T&CM medicinal products combine prevention, cure, cost-efficiency and sustainability. T&CM has a role to play in a holistic health system and infrastructure in Europe. T&CM has a contribution to make to meet to the goals of Art. 168 of the Treaty on the Functioning of the European Union which obligates the Union to improve public health, prevent physical and mental illness and diseases, and obviate factors which compromise physical and mental health.

[22] Chatfield K. (2018) Traditional and Complementary Medicines: Are they Ethical for Humans, Animals and the Environment? Springer Briefs in Philosophy, Springer Nature, Switzerland.

[23] Naylor C, Appleby J (2013) Environmentally sustainable health and social care: scoping review and implications for the English NHS. Journal of health services research and policy, 18(2):114–121.