

Position statement from the Council of Medical Associations of Catalonia

**CANCER PATIENTS: ONCOLOGY AND PALLIATIVE
TREATMENTS, THERAPIES WITHOUT SCIENTIFIC
EVIDENCE AND PSEUDOSCIENCE**

**With the participation and consensus of the Oncology Society
of Catalonia and the Balearic Isles and the Palliative Care Society
of Catalonia and the Balearic Isles**

COL·LEGIS
DE METGES
CONSELL DE
CATALUNYA

CANCER PATIENTS: ONCOLOGY AND PALLIATIVE TREATMENTS, THERAPIES WITHOUT SCIENTIFIC EVIDENCE AND PSEUDOSCIENCE

This position statement arises from the concern in professional, academic and scientific circles concerning the new increase in the range of alternative therapies and pseudosciences, for which there is no evidence of effectiveness, associated with diseases, especially cancer. This is particularly because of the consequences they can have for patient health and due to the false expectations generated.

The use by patients of incorrect information concerning cancer can be attributed to many factors and various agents are involved, with different responsibilities. Firstly, there are professionals who, either deliberately or through lack of knowledge, induce patients with cancer to follow unconventional treatments, perhaps seeing them as complementary and probably innocuous and forgetting their duty always to offer the most effective treatment depending on the state of knowledge. Secondly, publicity with unproven content both on websites and in the media which, for different reasons, too often gives biased and unfounded coverage of treatment without checking and promotes professionals or others who are practising fraudulently. Thirdly, the authorities, faced with the increase in centres offering alternative therapies, fail to neither regulate or oversee this sector sufficiently nor run awareness-raising campaigns. Finally, through the best intentions, desperation or ignorance, each patient's direct and indirect environment often tries to provide alternatives to those suggested by the medical team responsible for the patient, based on inexperience and ingenuity.

In this context, it is appropriate to recall the rules of good medical practice which establish the correct conduct that must always guide the actions of medical professionals and orientate patients and members of the public.

The basic function of the medical associations is to ensure the protection of the practice of all branches of medicine, always following the good practices duly confirmed by scientific societies. Medical action must be aimed at promoting, maintaining or re-establishing the individual and collective health of people. At the same time, doctors must try to alleviate the pain and suffering caused by the disease and must always care for those who cannot be cured. Doctors must pay particular attention to patients' health and bear in mind that this must come before any other consideration. The first loyalty of all doctors is to the people they are treating, always respecting the principle of welfare, which is the ethical basis behind any medical action.

The practice of *pseudoscientific alternative therapies* is not new. The medical associations have been warning of the risk and negative consequences of these practices since the mid-1990s. We have denounced and pursued doctors and non-doctors through proceedings that have ended in administrative penalties and court convictions. Particularly significant was the legally confirmed suspension of a doctor for recommending that a patient should give up correct chemotherapy and radiotherapy treatment for the cancer she was suffering based on pseudoscientific theories proposed by the alternative Hamer method (now known as German New Medicine). We should also highlight the prison sentence for unqualified practice for a person who passed himself off as a doctor, recommending treatments and pseudotherapies to cancer patients.

Recently, the Management Board of the Medical Association of Barcelona (CoMB) agreed to ban a doctor from practice for recommending and giving information on complementary treatments as alternatives to the established conventional treatment when there was no scientific evidence or clinical effectiveness in the context of the patient's cancer. The patient was induced to follow them in an abusive manner in exchange for payment, and the doctor failed to consider the basic needs put forward by the patient himself.

We must not forget, however, that the vast majority of doctors, including oncologists and experts in palliative care, do their profession rigorously and correctly, as society expect them to do, often combining excellent care with science and research.

The purpose of this document is to define and record the actions doctors must take with respect to cancer patients in accordance with good medical practice and the Ethical Code. It also sets out the behaviour that contradicts the principles of the code in this respect.

In this sense, and specifically concerning cancer patients, the following must be considered:

1. Cancer patients are particularly vulnerable and can suffer considerably

Cancer patients in general are particularly vulnerable. This situation is caused by knowledge of the diagnosis of what is generally a serious disease, frequently associated with an uncertain prognosis. In many of these processes, the appropriate curative treatment includes the application of therapies which are complex and often aggressive. In many cases palliative care is needed from the beginning. This situation frequently becomes disabling and generates great uncertainty in patients' lives, which also results in a considerable degree of mental and emotional vulnerability for the patients and their families.

In recent years there has been a notable increase in the range of treatments available in parallel to those provided by the medical and scientific community through the normal care network. These therapies are often presented as "alternatives", not only to medical treatments but also with respect to the origin or cause of the cancer. The risk of following these treatments is high, as they lead to error and can prevent cancer patients receiving the correct or most effective treatment. They can also result in patients giving up the treatment established by their oncologist or doctor specialising in palliative care.

2. That specific cancer treatment is constantly developing, with advances in knowledge of molecular biology, genetics and pharmacology.

Cancer is a set of diseases with different biological and clinical behaviours. The constant advances in molecular biology over the last few years allow us to discover the differences in the clinical behaviour of tumours due to genetic changes which can also help with the definition and use of more personalised, specific treatments.

The development of oncology processes requires constant research to adapt treatments to the best available scientific evidence. Only with quality research, improving our knowledge and allowing us to introduce new treatments, will we treat patients with the best guarantees of quality and safety. This applies to drug treatments and surgery, as well as radiotherapy for cancer.

3. That surgical treatments, chemotherapy, biological therapies, molecular targets and radiotherapy are the therapeutic tools in oncology validated and agreed by the scientific community.

The health authorities and international bodies establish a secure legal framework for patients and health centres, regulating clinical studies and evaluating their results to determine the effectiveness of new treatments.

Concerning treatment, before a drug, surgical procedure or new form of radiotherapy is approved as a cancer treatment, its effectiveness and safety must be proved in clinical studies, reviewed and approved by ethics committees, ensuring that the objectives of the studies are correct and that they are designed properly. The results must then be assessed by the established international agencies which give final approval for use of the treatment in medical practice, determining its suitability for particular cases and its effectiveness and security.

The international medical community and public and health authorities accept that this is the best way of preventing the administration of out-of-date, useless or unacceptably toxic treatments.

The application of the best available scientific evidence is normally reflected in consensus documents, protocols or clinical practice guides from scientific societies making specific recommendations for professionals involved in treating patients, depending on the diagnosis and classification of the disease into stages (phases). A scale of how strongly the application of different treatments can be recommended in each scenario being discussed is established, depending on the quality and reliability of these publications. So, based on the high-quality meta-analysis data or systematic review of everything from random and controlled studies to expert opinions, up to eight quality categories for the evidence provided by these publications are established. Thus, “first-line” (with the best evidence) and second- or third-line (with less evidence of the benefits) treatments are established. The latter are applied when as the previous ones are contraindicated, poorly tolerated or there is resistance to them. Treatments made obsolete because of the appearance of new, more effective and safer treatments are relegated from the guidelines and should therefore not be applied if good clinical practice is followed.

4. That cancer represents a health challenge for our society.

The principles for cancer care in the Cancer Masterplan for Catalonia determine that care for cancer patients must meet a series of requirements, such as:

- Being patient-focused and taking into account their values and needs.
- Being based on the best available scientific evidence.
- Promoting care close to the patient’s home, maintaining quality of care and taking account of the advantages of specialisation when advisable.
- Promoting training and research to produce new scientific evidence.
- Promoting multidisciplinary care and continuity of care for the patient.

- Integrating psychosocial aspects into patient care. This point has been consolidated in psycho-oncology units and social support services in order to deal with the needs of cancer patients in an integrated way.
- Being based on the evaluation of results.

5. That palliative care is multidimensional treatment necessary to offer integrated care and treatment for cancer patients, from the initial stages of the disease to cure or, if necessary, support in the final stages of life.

In 2002, the WHO defined palliative care as a “approach that improves the quality of life of patients and their families facing the problem associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual”.

In clinical oncology practice (as with other diseases) palliative care is also the organised response to meet the needs of patients and family members who are going through what we call the “terminal” stage of the disease. This is a time when the disease can no longer be controlled, many somatic symptoms appear and there is gradual decline associated with emotional changes linked to adaptation to the loss of functions and affecting both patients and their family members.

6. That palliative treatment forms an indivisible part of medical practice, especially but not only for cancer patients, and that it is carried out in accordance with a body of knowledge and clinical guidelines based on research and consensus among scientific societies.

The basic aims of palliative care are:

- Treatment for pain, other physical symptoms and the emotional, social and spiritual needs and other practical aspects of the care of patients and their families.

- Information, communication and emotional support, assuring patients they will be listened to; will participate in decisions; will obtain clear, honest answers and will be able to express their emotions.
- Continuity of care throughout the progress of the disease, establishing coordination mechanisms between all levels and resources involved.

Scientific research applied to palliative care under the recommendations of the clinical guidelines of scientific societies has demonstrated that not only is the quality of life and satisfaction of patients with advanced phases of cancer better, but that the survival rate in cases when curative treatments do not offer clear benefits actually improves when palliative care is correctly coordinated with the cancer treatment.

7. That many cancer patients often seek help from unconventional treatments without any scientific backing.

Faced with a diagnosis, patients use their social environment, the media, publications or active Internet searches to find information about their disease. In the case of cancer patients, there is plenty of information but it is often not very well founded, and it can be misleading. These searches should therefore always be made on duly accredited medical websites and/or the content checked with the opinions of trustworthy medical professionals with references. When patients are looking for complements for their well-being, they must be informed about the complementary objective and the risks of possible interference with specific cancer treatments. Whenever appropriate, this must be coordinated with the patient's regular medical team and it must be established who is directing the care process.

The nature of many of these unconventional treatments is pseudoscientific. They include diagnostic and curative methods that are supposedly validated by unregulated studies inspired by magical or traditional methods, such as the laying on of hands or other procedures with no scientific basis. Pseudosciences

seek the credibility and prestige of science, making claims for unknown properties of water, for example the supposed action of quantum phenomena, the therapeutic value of supposed natural energies, or diets that cure by alkalinising the body's pH.

Alternative pseudoscientific treatments have been described that have led to serious and even fatal complications. However, the greatest danger for patient health occurs when, placing their trust in an ineffective method, they give up more effective measures such as proven, effective medical treatment. In practice, we find that these pseudoscientific methods are used for various reasons ranging from simple naivety about the true nature of science and the scientific method to deliberate deceit in order to obtain financial or other benefits.

Advertising of medical activity must always be carried out within the legal and ethical framework compiled in the [*"Document de Posició del CoMB en relació a l'activitat de la publicitat mèdica"*](#) (CoMB position statement concerning medical advertising).

It is very important to bear in mind that advertising for medical activity must never promote misleading hopes of cure or give assurances of a definitive cure. It also may not, under any circumstances, induce patients to replace medicine based on scientific evidence or offer alternative therapies with supposedly guaranteed or miraculous results for states of disease or patients which will result in direct or possible harm. Advertising is also legally prohibited from referring to the direct or indirect promotion of products, materials, substances or methods intended for health purposes in cases when they are used for the prevention, treatment or cure of cancer or other tumoral diseases (*Royal Decree 1907/1996, of August, on the commercial promotion of products, activities or services intended for health purposes*).

8. That these “treatments” are often offered to vulnerable patients as “cures” and substitutes for therapies based on scientific evidence.

We constantly see advertising for treatments or miracle cures not based on scientific evidence and with poorly regulated practice. These treatments are sometimes offered as an “alternative” to established cancer treatment. If such a suggestion is put forward by a doctor, confusing the patient about the scientific validity of the proposed treatment, it is particularly serious, as it is a breach of the ethical rules.

In addition, clinical and scientific evidence indicates that the administration of products that are not scientifically proven to be effective or safe can alter the effect of cancer treatment and cause undesirable interactions or side effects that are harmful to patients. Various scientific associations warn cancer patients not to take any kind of natural substance or product, not to follow any treatment without the knowledge of their oncology team and, particularly, not to give up their cancer treatment.

9. That the demand from patients or their families to use unconventional treatments without scientific evidence cannot justify doctors ceasing to clearly recommend that cancer treatment should be followed and continued. Although it is acceptable to refuse treatment, the confusion generated for the patient by the offer of alternative treatments leads to the risk of missing an opportunity to carry out a validated treatment with proven effectiveness.

As different scientific associations also recognise, carrying out “unregulated” or “body-mind” therapies can sometimes help patients cope better with their disease, provided they are offered on a complementary basis. These treatments must be carried out in the integrated context of oncology and/or palliative care teams. No treatment must be applied without the knowledge of the responsible medical team and under no circumstances must it lead to the risk of giving up the established cancer treatment.

The doctor's first duty is to patients. If patients ask for care that goes against good medical practice and could harm their health, the doctor's obligation is to warn them and not to recommend such action. It is a matter of not contravening a bioethical principle of minimums (do no harm) which provides a limit for other principles of maximums, such as autonomy and welfare. These principles may never be used as a subterfuge for recommending or using practices not covered by the available scientific evidence.

10. That the information provided to patients must be clear and understandable in terms of differentiating principal cancer treatments from others, and must make clear the need to follow the indications of their specialist carers.

Concerning the obligation to provide information and informed consent

Information to the patient (and/or family members if the patient consents) is a legal and ethical obligation which must oversee any medical action. It is the duty of the responsible doctor or any professional involved in the care process to give it.

Both the Rights to Information Concerning Health and Patient Autonomy and Clinical Documentation Act 21/2000, of 29 December, (articles 2 to 4 and 6 to 7) and the Ethical Code (rules 22 to 28) provide regulation and include the terms and conditions under which information must be produced in the patient's decision-making process. The whole information process must be recorded in the patient's clinical history.

Concerning the vulnerability of the patient and information

As has already been pointed out, cancer patients are particularly vulnerable. Information and support for them is particularly essential. Although as doctors we have to ensure good quality medical care in human and technical terms, it is also true that we have a duty to give patients as much information as possible

about their state of health, the diagnostic steps, complementary explorations and treatments.

In the case of diseases like cancer, we have to be particularly careful when it comes to informing patients of the changes they are suffering and the prognosis. This information must be understandable, truthful, measured and prudent, expressed with respect, tact and discretion. The information must be given with as much hope as possible, which does not mean generating false hopes or expectations of cure or improvement, and it must be sufficient and adequate for the patients' needs at all times, so they can freely make decisions and consent to treatment.

The right of the patient not to be informed must be respected. However, never, and under no circumstances under this pretext, must a patient be told lies, misled or confused, creating false expectations for misguidedly compassionate reasons or for other purposes. In the patient care process, the doctor must be concerned with both effectiveness and affectiveness, reconciling the rational with the relational, and earning patients' trust to prevent them feeling the need to look for an apparently more comfortable scenario that does not offer potential for curing the disease or improving its symptoms.

Concerning the content of patient information

The doctor must inform patients about treatment along the lines set out in this document and must therefore explain the specific treatments validated and agreed by the scientific community that are most suitable for their disease. The information must include the specific treatment procedure, its benefits, its consequences, such as toxicity, its risks and the most frequent complications, or infrequent ones if they are considered clinically very serious, both general and specific to the patient.

The right of patients to totally or partially refuse treatment, diagnostic tests or medical care must be respected, but they must first be informed in an

understandable way of the likely consequences of refusal, and they must be in condition to understand them lucidly. In such cases, it is important to record any refusal in the clinical history and give patients information about the treatment options that match their preferences.

Concerning information about “complementary” therapies

The ethical precepts are clear and explicit when they indicate that doctors must not use procedures or prescribe treatments with which they are not properly familiar and that are not based on scientific evidence or clinical effectiveness, even though the patient consents to them. This is established in rule 47 of the Ethical Code. Rule 48 of the Code also requires that patients must be given further information when the doctor suggests unconventional or symptomatic treatments. The doctor must inform patients of the need not to give up any necessary treatment, warning them in a clear, understandable way of the unconventional nature of the proposed treatment and the fact that it is not a substitute for other treatments.

In the process of giving information about these complementary therapies, it is important not to confuse patients or induce them to make mistaken decisions. These therapies must always be presented and information on them given in a way that makes it clear that they are complementary to the treatment. Their purpose, and the need not to give up the principal treatment, must be clearly explained and they must never be presented as alternative treatments in a way that could induce patients to think they are possible options for curing their disease.

The exploitation of the anxiety of patients and/or their families by introducing diagnostic and/or therapeutic procedures whose utility has not been scientifically proven or which are futile for the care of cancer patients or for improving their symptoms, giving false hopes, or acting only for financial gain are therefore very serious matters.

If a cancer patient goes in the first place to a doctor who applies these complementary therapies, the doctor must give information on existing treatments based on scientific evidence that are proven to be effective which the doctor does not or cannot practise but which would be appropriate for curing the patient or improving any symptoms. In such a case, the doctor must direct the patient to the monitoring and treatment appropriate for the disease in the terms set out in this document.

Concerning information and coordination between professionals

The whole team of professionals involved in caring for a cancer patient – psychologists, nurses, nutritionists, etc. – also have a leading role to play when it comes to information. They must therefore act in accordance with a plan of action with proven, effective steps, always avoiding giving contradictory information.

Rule 48 of the Ethical Code establishes that a doctor recommending complementary therapies must coordinate with the doctor responsible for the patient's basic treatment. For this purpose, apart from any other coordination activities, it is recommended that the first doctor should provide the patient with a report on the complementary treatments being applied addressed to the doctor (or team) responsible for the principal treatment so any interference or disadvantage of applying it with the principal treatment can be assessed. It is also strongly recommended that if the doctor responsible for the principal treatment finds out about the patient's intention to resort to these complementary therapies or that the patient is following them, he or she should obtain information about the treatments applied and offer guidance to the patient on whether or not it is advisable to follow them.

Finally, if any doctor finds out that a patient is being recommended unregulated therapies for cancer as alternative and/or principal treatments, he

or she must to notify the relevant medical association for the appropriate purposes.

CONCLUSIONS

All doctors treating cancer patients must bear in mind that:

- 1.- In caring for cancer patients, it is very important to remember that they are particularly vulnerable and to bear in mind their values and needs.
- 2.- It is necessary to be particularly rigorous when it comes to giving information, recommending and applying treatments agreed by the medical and scientific community based on the best available scientific evidence from both an oncological and palliative point of view. The patient must be informed about the expected benefits of the treatment, its consequences, discomforts, toxicity, risks and complications (frequent and infrequent if they are clinically considered to be very serious), both generally and specifically.
- 3.- Information and support for cancer patients are particularly important. Extreme care must be taken in the process of giving information about the disease and its prognosis. The information must be understandable, truthful, measured, discreet, prudent and hopeful, but without generating false expectations and making sure that neither the content nor the way in which it is transmitted will adversely affect the patient.
- 4.- The patient's right not to be informed will be respected. Never, and particularly not under this pretext, must a doctor act by lying or confusing a patient due to naivety or for financial gain (which would involve both moral and financial fraud).
- 5.- The right of patients to totally or partially refuse treatment, will be respected, but they must first be informed in an understandable way of the likely consequences of refusal.

6.- Specific cancer treatments are constantly developing with advances in knowledge. This requires doctors to continuously train in order to update themselves so that patients can be treated with the best guarantees.

7.- Cancer patients require multidisciplinary care integrating psychosocial and medical aspects.

8.- Palliative care is multidimensional treatment necessary from the initial stages of the disease to cure the patient or, if necessary, offer support in the final stages of life. Its purpose is to deal with pain and other physical symptoms and provide emotional, social and spiritual support to patients, assuring them they will be listened to and can take part in decision-making.

9.- Doctors may not use procedures or prescribe medicines with which they are not properly familiar and that are not based on scientific evidence and clinical effectiveness, even if the patient consents or requests them.

10.- Some complementary procedures or therapies may sometimes help patients to cope better with their disease. It is desirable if they are offered as an integrated part of the same cancer and/or palliative treatment team. The assumed harmlessness of any treatment for which there is no scientific evidence or proven clinical effectiveness does not justify it being recommended as if it were a validated treatment.

11.- When complementary treatments are recommended, patients must be informed of the need not to give up any necessary treatment. They must be warned in a clear, understandable way of the unconventional nature of the proposed treatment and the fact that it is not a substitute for other treatments. Confusion that may be generated among patients by the presentation of a complementary treatment as an alternative one for their disease may lead them to believe they are following an effective, curative treatment, putting at risk the opportunity for them to continue with a validated treatment whose effectiveness has been proven.

12.- A doctor applying complementary therapies must coordinate with the doctor responsible for the basic treatment (oncological and/or palliative care). For this purpose, if no other form of coordination is possible, the patient should

be provided with a report to be given to the doctor offering the principal treatment.

13.- If a patient informs a doctor responsible for cancer treatment and/or palliative care that he or she is following or wants to follow a complementary treatment, the doctor is recommended to find out through the patient about the treatment being recommended in order to assess whether it is appropriate and if there is a risk of interference with the principal treatment. The doctor must stress the need to continue with the principal treatment.

14.- If it is the oncologist or doctor responsible for palliative care who refers the patient to follow a complementary treatment, he or she should promote coordination with the doctor providing such treatment.

15.- If a doctor discovers that a patient is being recommended unconventional or pseudoscientific therapies as alternative treatments for his or her disease, even though there is no scientific basis for recommending them and they lack the clinical effectiveness required in the context of cancer, whether this is through naivety, for financial gain or for abusive reasons, the doctor must notify the Medical Association for the appropriate purposes.

16.- Doctors under no circumstance may exploit a patient's anxiety or take any action exclusively for financial gain. The first duty of doctors is to their patients, and medical action must be aimed at promoting, maintaining or re-establishing the individual and collective health of people. Doctors must alleviate the pain and suffering caused by the disease and must take care of those who cannot be cured. Particular attention must be paid to the patient's health, which must come before any other consideration.

17.- Advertising must follow the legal regulations and ethical code, as included in the *"Document de Posició del CoMB en relació a l'activitat de la publicitat mèdica"* (CoMB position statement concerning medical advertising).

Any breach of the guidelines contained in this position statement, which contains both the indications for scientific and clinical consensus that must be followed in treating cancer patients and the legal and ethical guidelines that

must be followed in treating and informing them, may amount to a *very serious or serious infringement*, which can result in a *ban on professional practice for up to five years*, depending on the circumstances involved.

Finally, in order to protect patients and the honour of the profession, and considering the powers attributed to them, the Catalan Medical Associations or, as appropriate, the CCMC may carry out the corresponding actions before other administrative and judicial authorities against people or organisations involved in unqualified practice (falsely claiming to be medical professionals) or whenever a serious risk to public health is perceived.

Barcelona, 8 June, 2017

Drafting team:

The following people have been involved in drafting this document: *Dr. Gustavo Tolchinsky* (Secretary of the Barcelona Medical Association), *Dr. Eugeni Saigí* (President of the Oncology Society of Catalonia and the Balearic Islands), *Dr. Helena Camell* (President of the Palliative Care Society of Catalonia and the Balearic Islands), *Dr. Josep Terés* (President of the Barcelona Medical Association Ethics Committee), *Dr. Antònia Sans* (member of the Barcelona Medical Association Ethics Committee), *Dr. Antoni Trilla* (member of the Board of the Barcelona Medical Association), *Mr. Ignasi Pidevall* (Head of Legal Advice at the CCMC), *Ms. Mercedes Martínez* (lawyer advising the Barcelona Medical Association) and *Dr. Jaume Padrós* (President of the Barcelona Medical Association), coordinator of the drafting team.