



SPANISH ASSOCIATION OF PAEDIATRICS

Position statement from the Spanish Association of Paediatrics Medicines Committee concerning the use of alternative medicine and pseudo-science in children[☆]



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Received 22 April 2019; accepted 24 April 2019
Available online 23 September 2019

KEYWORDS

Complementary therapies;
Alternative medicine;
Child;
Homoeopathy;
Consensus

Abstract Currently, there are some therapies that are being practiced without adjusting to the available scientific evidence. The terminology is confusing, encompassing terms such as “alternative medicine”, “natural medicine”, “complementary medicine”, “pseudoscience” or “pseudo-therapies”. The Medicines Committee of the Spanish Association of Paediatrics considers that no health professional should recommend treatments not supported by scientific evidence. Also, diagnostic and therapeutic actions should be always based on protocols and clinical practice guidelines. Health authorities and judicial system should regulate and regularise the use of alternative medicines in children, warning parents and prescribers of possible sanctions in those cases in which the clinical evolution is not satisfactory, furthermore responsibilities are required for the practice of traditional medicine, for health professionals who act without complying with the “lex artis ad hoc”, and for the parents who do not fulfil their duties of custody and protection. In addition, it considers that, as already has happened, Professional Associations should also sanction, or at least reprobate or correct, those health professionals who, under a scientific recognition obtained by a university degree, promote the use of therapies far from the scientific method and current evidence, especially in those cases in which it is recommended to replace conventional treatment with pseudo-therapy, and in any case if said substitution leads to a clinical worsening that could have been avoided.

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[☆] Please cite this article as: Piñeiro Pérez R, Núñez Cuadros E, Rodríguez Marrodan B, García Cabrera L, Manzano Blanco S, Escrig Fernández R, et al. Posicionamiento del Comité de Medicamentos de la Asociación Española de Pediatría en relación con el uso de medicinas alternativas y seudociencias en niños. An Pediatr (Barc). 2019;91:272.

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PALABRAS CLAVE

Terapias complementarias;
Medicina alternativa;
Niños;
Homeopatía;
Consenso

Posicionamiento del Comité de Medicamentos de la Asociación Española de Pediatría en relación con el uso de medicinas alternativas y seudociencias en niños

Resumen En la actualidad existen numerosas terapias que se practican sin ajustarse a la evidencia científica disponible. La terminología es variada y confusa, englobando términos como «medicina alternativa», «medicina natural», «medicina complementaria», «seudociencias» o «seudoterapias». El Comité de Medicamentos de la Asociación Española de Pediatría considera que ningún profesional sanitario debe recomendar tratamientos no avalados por la evidencia científica, y que las actuaciones diagnósticas y terapéuticas deben estar siempre basadas en protocolos y guías de práctica clínica. Considera que es responsabilidad y obligación de las autoridades sanitarias y del sistema judicial reglamentar y regularizar el uso de medicinas alternativas en niños, advirtiendo a los padres y a los prescriptores de las posibles consecuencias en aquellos casos en los que la evolución clínica no sea satisfactoria. Se deberían exigir las mismas responsabilidades que a la práctica de la medicina tradicional, o a los profesionales sanitarios que actúan sin ajustarse a la «lex artis ad hoc», y a los padres que no cumplen con sus deberes de custodia y protección. Este Comité considera que los Colegios Profesionales deberían reprobar o corregir a aquellos profesionales sanitarios que, bajo un reconocimiento científico obtenido por un título universitario, practiquen, impulsen o promuevan la práctica de una medicina alejada del método científico y la evidencia actual, sobre todo en aquellos casos en los que se recomiende sustituir el tratamiento convencional por una seudoterapia, y en todo caso, si ello da lugar a un empeoramiento clínico que se podría haber evitado, valorando incluso posibles sanciones.

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Introduction

A present, there are numerous therapies offered claiming that they can cure diseases, relieve symptoms or improve health that are not backed up by scientific evidence. These therapies are presented as guaranteed and validated to society, even though there is no conclusive evidence on their results. The terminology used to describe them is also diverse and confusing, and includes terms such as “alternative medicine”, “naturopathy”, “complementary medicine” and others with a marked derogatory bent, such as “pseudosciences” or “pseudotherapies”. In general, all these practices distance themselves from or reflect a distrust of conventional medicine, which pseudoscientists generally refer to as “allopathic medicine”.¹⁻³

Many *pseudotherapies* are based on providing families care in a relaxed and quiet environment. This produces a placebo effect that frequently masks the lack of effectiveness of these treatments. Based on the principles of medical deontology, it is clearly unethical to make use of this placebo effect without informing the customer. All these practices unfold under the relative permissiveness of a legal system that only hints at potential scamming or fraud, which are very difficult to prove, as many patients will exhibit improvements in health related to the natural course of the disease rather than the application of a *pseudotherapy*. The risk to patients, and in particular to children, arises when “alternative medicine” become the first or only choice to address any given health problem.¹⁻³

The use of pseudosciences in Spain

Every year, the Fundación Española para la Ciencia y la Tecnología (Spanish Foundation for Science and Technology) publishes reports⁴ on the social perception of science and technology in Spain based on data from population surveys. We ought to highlight salient conclusions from the 2018 report, for instance that 1 in 3 Spaniards believes that antibiotics can cure viral infections. Fifteen percent believe that the first humans lived at the same time as dinosaurs. Also, 12.6% considers that consumption of genetically modified fruits can change the genes of the individual that eats them. And 11.9% thinks that it is the sun that goes around the Earth. If we extrapolate these results, the last percentage just mentioned corresponds to approximately 5 million Spaniards. And one of the most alarming findings was that 26.3% of the population (more than 10 million people) reported having used *pseudotherapies* in lieu of conventional medical treatment.

Also alarming is the first report⁵ on the deaths attributable to *pseudotherapies* in Spain, published in January 2019 by the Asociación para Proteger al Enfermo de Terapias Pseudocientíficas (Association for the Protection of the Ill from Pseudoscientific Therapies, APETP). This report concluded that the figure probably exceeded 1000. The APETP is clear in its message: “pseudosciences kill”.

In the scientific letter recently published by Tornero et al.⁶ in ANALES DE PEDIATRÍA, the authors expressed that the estimated prevalence of the use of alternative medicines varied significantly based on the country and the study design. Thus, a systematic review comprehending the

European Union⁷ found prevalences ranging from 0.3% to 86% (in Spain, from 15% to 47%). In order to determine the proportion of use of pseudosciences for treatment of health conditions in the paediatric population of Spain, Tornero et al.⁶ analysed the data for the variables “appointments with complementary and alternative medicine providers in the past 12 months” and “consumption of homeopathic and natural medicinal products in the past 2 weeks” obtained in National Health Surveys carried out in Spain by the Instituto Nacional de Estadística (National Institute of Statistics). The authors found that the proportion of children that made visits to homeopathic providers decreased from 2.4% in the 2011–2012 survey to 1.3% in the 2017 survey ($P < .001$); this decrease was also observed in the total population. This trend stood in contrast to the stability through time of the proportion of the population that visited naturopathic doctors and acupuncturists and to the increase in the use of “other” alternative therapies.

Legal framework in Spain

As previously described by Tornero et al.,⁶ there is considerable variation in the legislation on complementary and alternative medicine between countries in the European Union. In Spain, for instance, there is no specific national law governing the use of natural therapies. However, Law 16/2003 and Royal Decree 1277/2003 regulate the safety and quality of health care facilities, giving the government of each autonomous region the authority to approve the establishment of facilities offering non-conventional therapies.

To use homeopathy as an example, until 1994 the sale of homeopathic products required compliance with the general regimen for authorisation of medicines, which established as a prerequisite that the manufacturer provided evidence on its efficacy.³ However, in 1994 the European Council Directive 92/73/EEC was introduced in Spanish legislation by means of Royal Decree 2208/1994, regulating the authorisation of homeopathic products.⁸ The main requisites for authorisation at this time were:

- Oral or topical route of administration.
- Absence of any specific therapeutic indications in the label or any other written information on the medicinal product.
- A sufficient degree of dilution to guarantee the innocuousness of the medicine. The medicinal product could not contain more than 1 part per 10 000 of the mother tincture or more than 1/100th of the smallest dose used in allopathy with regard to active principles whose presence in an allopathic medicinal product resulted in the obligation to submit a doctor’s prescription.

Since then, regulations have been gradually modified, and in April 2018 a new law was passed⁹ by which the marketing of these products requires passing the safety and quality controls established by the Agencia Española del Medicamento y Productos Sanitarios (Spanish Agency of Medicinal Products and Medical Devices, AEMPS). In adherence to this law, the labelling of these products must expressly declare that there are no indications for their

use. Products that fail to meet these requirements are to be withdrawn from the market.

Training and information

Some public universities in Spain have offered postgraduate courses on homeopathy. The members of this well-known “shame list” include the Universidad de Sevilla (which withdrew this course in 2009), the Universidad de Córdoba (discontinuation in 2013), the Universidad de Zaragoza (discontinuation in 2014) or the Universidad de Barcelona (discontinuation in 2016). There are still universities (mainly private and distance-education universities) that continue to offer these courses.^{3,10}

In social media, the debate rages on, even if it is entirely unaccountable from a scientific standpoint. Nevertheless, there are initiatives that ought to be acknowledged, such as *#HomeopatíaSuma*, in which a group of homeopathic doctors contravene the classic pseudoscientific dogma of refusing to integrate with allopathic medicine. This group invites patients to adhere to the prescriptions of traditional physicians, regardless of any additional pseudotherapies they may have voluntarily chosen to pursue.

Changes in Spain

In October 2018, the Ministry of Health, Consumption and Social Welfare and the Ministry of Science, Innovation and Universities first established in Spain, ahead of other European countries, a Plan for the Protection of Health from Pseudotherapies.¹¹ Significant antecedents include the 2011 Situation Analysis Document of the Ministry of Health, Social Policy and Equality on the Situation of Natural Therapies¹² and the creation in 2012 of the Spanish Network of Agencies for the Evaluation of Health Care Technologies and Services of the National Public Health System of Spain (REDETS).¹³ But it was not until 2018 that a formal action plan was officially promoted and endorsed by the government.

The need for a specific action plan stems from the possibility of therapies unsupported by scientific evidence being promoted by false advertising and posing an immediate risk to health, especially if they are used in substitution of conventional treatment. Furthermore, it is the duty of the authorities to defend health care as a fundamental right of citizens, who should accordingly receive truthful information to be able to recognise which treatments are based on scientific evidence and which are not, so they are better informed in their choices.^{3,11}

The Plan for the Protection of Health against Pseudotherapies¹¹ consists of 4 strategic lines.

The first strategic line involves generating, disseminating and providing information on pseudotherapies based on the current scientific evidence. Among its objectives is a project on health communication with the goal of identifying pertinent interest groups and determining the optimal medium to reach them. Another aim would be to establish alliances with scientific societies, professional boards, universities, associations and civil society. In short: to reach out to citizens and to provide them with high-quality information.

The second line is aimed at preventing misleading advertising of pseudotherapies. This would require the

amendment of several existing Royal Decrees. The most urgent measures involve extending liability to advertisers of products, activities or services with the supposed end of improving health of which the effectiveness or safety has not been proven. Another proposed measure is reinforcing the regulations regarding penalties for the advertisement of a medicinal product that has not been authorised for commercialisation.

The third line aims to guarantee that all health care activities be performed by professionals with formal and accredited training, and to eradicate the practice of *pseudotherapies* in health facilities. This would also require the amendment of 2 current Royal Decrees issued in year 2003.

The fourth and last strategic line involves the establishment, in coordination with the Ministry of Science, Innovation and Universities of Spain, of actions to reinforce the principles of scientific knowledge and evidence-based intervention in the education of health providers. That is, to banish pseudosciences from university curricula. In addition, it aims to improve the training of health care professionals on the subject of protecting individuals from *pseudotherapies*.

Position of the Committee on Medicines of the Asociación Española de Pediatría

The Committee on Medicines of the Asociación Española de Pediatría (Spanish Association of Paediatrics) (CM-AEP), is an independent group of experienced paediatricians, and it considers that no health professional should ever recommend treatments that are not supported by scientific evidence, and that diagnostic and therapeutic interventions should always be based on clinical practice guidelines and protocols that are based on the current scientific evidence. This is what the law demands¹⁴: “medical practices considered appropriate to treat the patient at the time the patient is receiving treatment”, that is, the practice of the principle of *lex artis ad hoc*.

In the specific case of very young children, the use of therapies of unproven effectiveness is even more senseless, as the resulting placebo effect will only have an impact on how the parents perceive the health of their own children, while foregoing available evidence-based treatments may pose a threat to the life of a minor. Even the *pseudotherapies* practiced by paediatricians themselves or their ignorance about the different existing *pseudosciences* can be deleterious to children.¹⁵⁻¹⁷

Although the estimates on the prevalence of the use of *pseudosciences* vary, the CM-AEP believes that the health authorities and the legal system are responsible for regulating and standardising the use of alternative medicines in the paediatric population, warning parents and prescribers of potential penalties in cases where clinical outcomes are not satisfactory and minors are deprived of opportunities for a cure, in the same way that, in the field of traditional medicine, health professionals that do not practice in adherence of the *lex artis ad hoc* principle and parents that do not fulfil their duties of caring for and protecting the minor are held liable for their actions.

In addition, the CM-AEP considers that, as already proposed in the past,¹⁸ all boards of health care

professionals should reprimand, discipline or even penalise health providers who, while holding the accreditation given by a university degree, practice, promote or advance the practice of medicine that is not based on current evidence and scientific knowledge, especially in those cases where they recommend pseudotherapies or substitute them for conventional treatment, and always if such a replacement results in the preventable worsening of a clinical condition.

Funding

This document has not been funded by any outside sources.

It has not been previously presented in any conferences, congresses or symposia.

Conflicts of interest

The authors have not had any conflicts of interest to declare in relation to the document presented here in the past 5 years.

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