



Commitment to self- regulation in relations with industry

Associazione Culturale Pediatri (ACP)

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Introduction

Toward independence and transparency: the reasons for a proposal

The pediatrician's professional activity is pervaded by the promotional initiatives of industry, particularly of companies producing vaccines, drugs, and baby foods. It is therefore necessary to set up the relationship between professionals, medical associations and industry on the basis of principles of independence and transparency, as has happened or is happening in many other countries where ethical culture and professional deontology developed hand in hand with the promotion of a general civic consciousness on the subject of relations between health professionals and industry.

In this matter, professional ethics is a key word since relationships with industry increase the risks of pollution of professional behavior and transgression of internationally and nationally adopted standards, agreements, and codes.

Habitually, it seems that the Italian professional pays little attention to the importance of this issue; the most common attitude is to believe that each person can guarantee about his or her own substantial independence from the sponsorship received. Instead, there is large documentation proving the influence, even in absence of awareness, of industry promotional activity on physician behavior. This can undermine the fiduciary relationship between physician and patient.

The adoption of principles of behavior that guarantee the individual practitioner, the NHS, and its users from undue influence is in accordance with a criterion of justice and would receive public appreciation and increasingly value the activities of the NHS. A further element is that concerning the principle that continuing education is an integral part of a professional activity, even when it takes place outside a relationship of dependence or agreement with the NHS and must therefore be pursued independently from third-party or market interests. Since a large part of the expenses for continuing education are instead supported by industry, including through noncompliance on the part of the NHS administrations, there is a need for increasing transparency in physician-industry relations.

For these reasons, the Pediatricians' Cultural Association (ACP: Associazione Culturale Pediatri) intends to continue having a commitment of self-regulation in the relations with industry and to reintroduce its updated version to its members.

After 14 years since the first version was approved, ACP proceeded with an update and some partial modification of the commitment to consider the evolution of thinking regarding conflict of interest, to clarify some aspects that might have appeared contradictory, and to further specify the activities that represent its scope of application, since some behaviors are now regulated by law and, as such, are no longer subject of a self-regulation. In the process for the revision, which began in late 2011, the following were involved: the Steering Committee and a panel consisting of some representatives of the same Executive, the heads of the secretariats, the ACP editorial director, the editor of ACP Journal (Quaderni ACP) and the ACP past president at the time of the code adoption. Subsequently, the draft circulated among all members and regional groups for further comments and was presented at the 2012 national ACP congress. Following some feedback, a new version was prepared and presented for final approval in 2013. The assembly, after accepting some proposed amendments, approved the commitment in its final form.

To promote an evolution in the relationship between physicians and industry and a more appropriate use of the resources of both

The purpose of adopting a code of conduct is twofold: on one hand, to offer a guarantee of independence from commercial interests to protect the user, the physician himself and his colleagues, and the health service; on the other hand, to promote a relationship with industry aimed at useful and relevant objectives, both in the field of care and in the field of training and research. In particular, for the latter two areas, substantial resources could be recovered from the budgets available to industry for promotion and employment in projects related to actual training and research needs, according to the needs of practitioners and users, and controlled in quality. The self-regulatory effort proposed by the ACP is intended to combine the affirmation of a clear statement of the principles of independence and transparency in the physician's work with the goal of promoting behavior in accordance with these principles, to be implemented through a work of information and communication to members and industry.

ACP will detect and evaluate the effects of the adoption of the commitment and promptly communicate it in a manner to be determined by the Steering Committee. It will also update

the content of the pledge in accordance with the evolving debate on ethical and deontology and with legislative provisions.

Areas of application of the self-regulatory commitment

The areas of application of the commitment are relationships with industries producing drugs, foods, vaccines, equipment, and paramedical products (diapers, pacifiers, gummies, booties, eyeglasses, etc.) insofar as they are strictly pertinent to the professional activity of the pediatrician. It is also deemed appropriate, as a corollary to the initiative and consistent with the social function to protect the health of children proper to the Association, make part in the commitment also a work of information, through its publications and collaterally to its own training initiatives, regarding children's products to be considered inappropriate, unsafe, or unnecessary, or products that violate the International Convention on the Rights of the Child.

References

Essential references of the commitment are: the International Convention on the Rights of the Child (UN); the International Code of Marketing of Breast-milk Substitutes Maternal Milk Substitutes (WHO\UNICEF) and subsequent World Health Assembly Resolutions (hereinafter: International Code); the DM 16/01/02, DM 46/05, DL 219/2006, DM 14/4/08 and DM82/2009; the Code of the International Pharmaceutical Manufacturers Association; the guidelines of the European Union for "best practice" in research; the FNOM code of ethics; the State-Regions agreement for continuing medical education of November 2009 and the subsequent July 2010 decree by which the agreement was implemented; the Commitment of Self-Regulation of the Multisectoral Committee for Maternal Breastfeeding of 12/20/2011. Reference was also made to codes, statements of scientific societies and legislation in the international arena, such as, for example, the 2009 Institute of Medicine USA document, EMA 2010 guidelines and the 2011 standards of the Association of the British Pharmaceutical Industry. The 2009 Farmindustria Code of Ethics was also consulted.

Basic principles of engagement

The basic principles of the commitment are basically two:

- the ACP commits at the national and local levels to disseminate information on the content and compliance with national and international conventions, codes, and laws by industry, and to provide documentation produced by national and International Associations on the subject. The steering committee through the Association's Journal will also take care of the reporting to members of products not strictly related to the profession whose production or marketing is in the violation of the principles of the International Convention on the Rights of the Child;
- the ACP is committed to ensuring that dialogue with industry is in all cases inspired by rules that guarantee the principles of independence and transparency.

Respect for these principles is the basis of the self-regulatory commitment that the ACP assumes and proposes to all its members.

Commitment

1. General Principles

1.1 The purpose of this document is to provide children and their families with a professional practice inspired by transparency and independence from commercial interests.

1.2 The commitment pertains to ACP activities of a national and local nature after successful approval by the Members' Assembly.

1.3 The ACP hereby seeks to promote the behavior of its members toward the industry producing drugs, vaccines, foods, equipment, and paramedical products, in the direction of respect for international conventions and codes and the Italian state legislation.

1.4 The content of the commitment is based on assumptions that refer to ethical and deontology that go beyond the purely legal aspects governing the relationship between industry, individual physicians, and medical organizations/associations as well as conflicts of interest arising from such relationships. The guiding idea is that in these matters the principle that anything that the law does not expressly prohibit is permissible.

1.5 Members are urged to embrace the guiding principles of this document and to promote its contents.

1.6 The document is brought to the attention (nationally, regionally, and locally) of the following public institutions, professional bodies, trade organizations and industry associations that contribute to the performance of members' professional activities. Each member is also invited to disclose the contents of the commitment that inspires the professional practice of ACP pediatricians toward relations with industry to her/his own patients and to the health district.

2. Scientific information

2.1 Each member, while respecting the role of industry representatives and the current regulations governing their activities, should consider whether what is stated verbally or reported in the scientific information material sent or submitted to him/her is consistent in quality and quantity in respect to available evidence, does not conflict with the principles of

ethicality and scientificity, and does not contain misleading messages or messages aimed at commercial promotion.

2.2 Compliance with ethical and scientific principles and internationally adopted codes applies even more to information contained in publications issued directly by the Association, including any advertisements by industry. No conditioning of the journal published by the ACP is permissible either in terms of content nor in the choice of articles. The author must declare any conflicts of interest.

2.3 Acceptance of giveaways of promotional materials is contrary to the principles of this commitment.

2.4 Accepting free samples of infant formula and products covered by the Code International is contrary to the principles of this commitment, even when they are not starting formulas, the offering of which is prohibited by law.

3. Scientific Updating

3.1 Publications, scientific volumes, subscriptions to journals of recognized scientific quality, and scientific materials of a computer nature (software, database links, CD-ROMs, etc.) offered by industry, provided they are not of an advertising nature, may be accepted if this does not conflict with current legislation and the regulations of individual regions. In any case it is advisable that any gift be made to the local group, even in multiple copies, and not to the individual member. Members belonging to local groups are encouraged to promote the establishment of a common and shared resource of scientific updating.

3.2 Acceptance of offers to participate in educational initiatives of non-specific medical or scientific relevance is contrary to the principles of this commitment.

3.3 The production by the ACP of cultural "products," such as indications, recommendations, protocols, guidelines and consensus documents, cannot involve the participation of industry in the costs of their production. For other types of documents, particularly those produced in collaboration with other institutional, professional, and social actors, the provision of independent, non-binding contributions from industry may be considered when there is no direct advertising of a product and when the firm does not violate the International Code standards. In such cases the material may state at the bottom that it was produced with the non-binding contribution of any entity or firm, without any reference to industry products.

3.4 The principles underlying this commitment and the standards and laws to which they refer must become part of editorial proposals in the ACP's publications and topics covered in training courses organized at the national and local levels.

4. Scientific Research

4.1 Participation in research, regardless of type and source of funding, is tied to the existence of a specific protocol, approved by a formally constituted ethical-scientific committee (at Hospitals, ASL or Research Institutes) and, if necessary, authorized in accordance with the law.

4.2 The research participant must have his or her own copy of the protocol and must have taken careful note of it and expressed his or her own opinion before actively participating.

4.3 For participation in industry-sponsored research initiatives, the individual physician is encouraged not to accept any compensation, direct or indirect, while he or she may receive a reimbursement of documented expenses. Any fair financial compensation may be paid to association groups, preferably formally constituted as an association, as a “quid pro quo” for collective participation, for the purpose of supporting the cultural initiatives of the group.

4.4 Unlike those promoted directly by industry, independent research provide that, while making partial or full financial contribution from industry, the ownership of the data lies with the promoting committee or association, which is also responsible for the drafting of the protocol, the processing, analysis and interpretation of the data, the publication and dissemination of the results obtained; all of this independently of the industry funder and with a board that must also be independent and composed of people with no past or present personal consulting relationships with it. In these cases, the collaboration with industry is permitted subject to its commitment, enshrined in a contract, to acknowledge that ownership of the data is the sponsoring committee or association and to allow free publication and dissemination of all results, whatever they have or have not demonstrated, with explicit statement of the sources of funding that made possible the implementation of the research.

5. Health education

5.1 Part of the professional activity is also health education conducted with appropriate materials. The materials used, if produced directly by the ACP or under the auspices of the

ACP or bearing the logo of the ACP printed on it, may be self-produced or produced by third parties, and must meet principles of ethicality, scientificity and cost-effectiveness and be independent of commercial interests. Direct reference to Industry products is not permitted in the produced material, as names of medicinal specialties, but only the mention of the active ingredients.

6. Organization of scientific congresses and meetings

6.1 For the organization of conferences, congresses and scientific meetings, the members should preferentially consider and search for contributions from Health Authorities and other public bodies.

6.2 Collaboration with industry may be considered if the general principles set forth in the introduction and articles that follow are respected. In addition, the scientific contents of the event and the activities of the collaborating firm must be in the respect with the International Convention on the Rights of the Child.

6.3 The scientific contents must meet ethical and scientific criteria, and the modalities organization to criteria of cost-effectiveness; they must also be identified in absolute independence from the possible economic participation of industry. These requirements are also essential for the selection of organizational collaborators (organizational secretariat).

6.4 The list of industries contributing to the initiative and their financial contributions must be disclosed.

6.5 Within the framework of scientific events, no initiatives of a social, cultural or touristic type are accepted if organized by industries.

6.6 In order to ensure the transparency of the work of those who organize, finance and participate in the initiatives, a detailed scientific, expenditure and funding record must be prepared, at the end of the event, by the organizing national or local committee and submitted to the Association's executive board and subsequently disseminated among ACP participants and members. The same final report must be published on the Association's website.

6.7 Convivial or representative initiatives independent of specific scientific activities are not permitted.

7. Organization of the association's national congress

For the organization of the national congress, by a local group each year in collaboration with and under the supervision of the national board, the following rules apply:

- the congress should be guided by principles of cost-effectiveness;
- the venue, preferably, should be institutional (conference hall of municipalities, regions, libraries, Health system, hospital corporations, etc.);
- social events should be limited and low-cost;
- hospitality of speakers should be guided by principles of economy and limited to travel and overnight stay for the nights necessary for participation in the congress;
- the number of speakers and moderators should be limited;
- hospitality for accompanying persons is prohibited;
- the use of printed materials (invitations, brochures, etc.) should be limited, and communications by electronic means are to be preferred;
- the participation fee for members in good standing should be as low as possible to encourage the maximum participation of members in the national event;
- the participation of those who do not intend to take advantage of any sponsorship should be encouraged, including formulas that provide for registration at reduced costs;
- for each national congress, a final balance sheet with details of income and expenses should be published on the association's website (and/or in the Association's magazine).

8. Final Provisions

8.1 No form of relationship may be institutionally envisaged between the ACP and industries that violate the International Code, even when participating in initiatives conducted jointly with other medical societies, health care institutions, public or private entities, non-profit organizations, and parent associations.

8.2 Individual members are encouraged to also behave similarly in their personal dealings with industry representatives.

9. Procedures for implementing the commitment

9.1 The body responsible for promoting the contents of the pledge is the ACP Steering Committee.

9.2 For the exercise of the functions inherent in the commitment, the Executive Board may make use of consultants chosen according to needs.

9.3 The Executive carries out policymaking functions, expresses opinions directly or through consultant's advisory at the request of members and provides documentation on available official sources -scientific journals and official national or international reports relating to industry compliance with National or International Codes.

9.4 In the case of proven violations of the contents of the commitment, the Executive will send a report to both members and the industry involved ■

APPENDIX 1

Notes on conflict of interest

The commitment (also called Code) to self-regulation in dealing with industry was made by ACP back in 1999. The ACP considers always valid the reasons that led to the adoption of that commitment and reiterates its importance in light of subsequent events that have shaped the framework of relations between medicine and industry, particularly with regard to scientific information, medical training, research and institutional relations.

To adopt a code of self-regulation in relations with industry is not a way to demonize the relationship between industry and physicians, but instead means enhancing it with clear rules that are essential for both.

The pharmaceutical industry tends to bear a substantial part of the expenses of physicians continuing education. This practice, although widespread, is at odds with the principle that continuing education is an integral part of professional activity and should therefore be pursued independently from third-party or market interests. On the other hand, the public funds provided for training and research are not always available or easily obtained, even when it would be spent on good quality activities. The conflict of interest arises when it comes to the use of funds that private companies may decide to employ in these areas.

Conflict of interest is a phenomenon of our time, often involving our profession and cannot be eliminated by either a decree or a decalogue of rules. Therefore, it is necessary to have clear rules that prevent it, that avoid an interference with the physician's freedom of judgment and choice, and give patients the certainty that our intervention, free from conditioning, is the best possible one for his or her health.

The basic points of the conflict of interest can be summarized as follows:

- A. A conflict of interest is realized when there is a reasonable presumption that individuals or organizations in relationship with each other may, more or less consciously, set aside their primary interest (in the case of physicians, the promotion

- of patients' health and public health) in favor of secondary interests their own or others' interests (e.g., personal gain, or a derived economic profit).
- B. The declaration of a conflict of interest is only the first step toward limiting the commercial conditioning. Even though it is often considered sufficient, the declaration of a conflict of interest can be falsely reassuring, since it can give the impression that the relationship between physicians and industry have been adequately regulated in such a way as to avoid conditioning of judgment, this is often not true. It is therefore necessary to go beyond the mere declaration of the presence of a conflict of interest and move toward the adoption of preventive and regulatory mechanisms.
 - C. It is possible, and indeed the most frequent occurrence, for conflict of interest to occur without violating legal norms, that is, without committing a wrongdoing based on existing legislation. Conflicts of interest, professional ethics and legal norms should be kept distinct.
 - D. A medical organization may find itself in a conflict-of-interest situation if it receives funding from a commercial company, which may wish to influence the organization's public standing to the point of distracting it from its primary responsibilities. For the conflict to arise, it is not necessary that the secondary interests override the primary ones; it is sufficient that the possibility exists for this to happen. Thus, the presence of conflict does not automatically mean that there is or there was a previous unethical behavior.
 - E. Medical organizations represent the “public face” of a profession, and their actions largely condition the degree of trust and respect placed in them by citizens, society and public opinion. To undermine this trust by one's behavior it means eroding the foundations of civil coexistence and relations between citizens, and thus failing in one's moral and professional duty ■

APPENDICE 2

Panel composition

<i>Paolo Siani</i>	Acp President
<i>Carlo Corchia</i>	Panel coordinator, Neonatology Working Group (WG) chair
<i>M. Francesca Siracusano</i>	Executive Bureau (EB)
<i>Enrico Valletta</i>	EB
<i>Maria Luisa Zuccolo</i>	EB
<i>Peppe Cirillo</i>	EB, Inequalities and Chronic Diseases WG Chair
<i>Rosario Cavallo</i>	Infectious Diseases WG Chair
<i>Sergio Conti Nibali</i>	Nutrition WG Chair
<i>Luciano De Seta</i>	Hospital Care WG Chair
<i>Laura Reali</i>	Medical Education and Research WG Chair
<i>Angelo Spataro</i>	Mental Health WG Chair
<i>Giacomo Toffol</i>	Environmental Health WG Chair
<i>Federica Zanetto</i>	Regional Referents Coordinator
<i>Giancarlo Biasini</i>	Editorial Director of Quaderni ACP Journal
<i>Michele Gangemi</i>	Editor of Quaderni acp Journal
<i>Giorgio Tamburlini</i>	ACP President when drafting the previous version of the commitment(1999)

Local groups who contributed

ACP Milan

ACP Latium