European Review for Medical and Pharmacological Sciences 2016; 20: 2758-2759

Commentary
New boundaries of prescription: focus on section 13 of the new Italian code of medical ethics

M. PAPI, R. GIORGETTI, A. TAGLIABRACCI

Department of Biomedical Sciences and Public Health, Università Politecnica delle Marche, Ancona, Italy

Dear Editor,

Each code of medical ethics should undergo periodical revisions and updates inspired by the need to align the ethical evaluation to the latest medical issues determined by scientific progress and the passage of time[1].

However, compared to the advances of biomedical knowledge and practices the considerable time frame spent on code renewal (e.g. an average of 8 years, in Italy) may be considered something that approaches a geological era.

The above-reported consideration allows to agree with the authors that any revision may lose the matching with changed reality

Any new code should, basically, provide an educational background to adapt the behavior to future, potential scenarios, rather than to take a retrospective note of changed conditions in which physicians were already involved.

In terms of novelty, it seems appropriate to point out that one section of new Italian ethic code carries out some relevant changes. We are talking about section 13, which deals with "prescription", in the broadest acceptation of any pharmacological or surgical treatment.

For the first time, a clear statement about guidelines can be found in the ethical code. This prediction follows a new law on medical liability, named "Decreto Balduzzi" from the name of Health's Minister who promoted it. This law substantially changes the penal code about the profiles of medical liability in our country, by introducing a decriminalization of medical injury caused by physicians, who can demonstrate a behavior adherent to guidelines.

This innovation in the new ethical code brings up the importance of protocols and guidelines as medical rules that should drive any medical act. At the same time, it represents a positive meaning of the term "responsibility", differently from what happened the previous version of the ethical code, where the only clearly noticeable meaning of liability was negative and related to defensive medicine.

Moreover, current Code's section 13 better defines the boundaries of "optimal use of resources", making references to clinical efficacy, safety and appropriateness, and in this way trying to adjust both the maximum prudential measures required from Law Courts and the logic of procedural economy. This can be considered as an attempt to combine two potential conflicting aspects: health and economy. On one side, health has to be obviously considered as the stronghold of any patient interest to a complete health condition. On the other side, physicians have to take care of costs, as a medium of resources optimization, necessary for the protection of the community. In this respect, the new version of section 13 introduces the same principles already expressed by the American Medical Association[2].

According to the strategies of the health system to achieve efficacy, quality, reliability and efficiency[3] in connection with clinical risk prevention, the new code highlights autonomy of physician in prescription, an activity that should be considered with particular caution in the case of non-conventional therapies.

The most recent example of questionable and not scientifically supported therapies is that of the "Stamina case". Following the previous versions, the code reiterates that these therapies are not lawful. These treatments indeed fall in the grey area that the code of ethics relegates in as unauthorized ones, overcoming the catchword not to deprive patients of alternative therapies available.

Corresponding Author: Manuel Papi, MD; e-mail: manuel.papi@gmail.com

Such therapies cannot consider the expression of free medical arbitrariness and can be justified, and, only if: (1) the patient suffers a seriously debilitating disease, (2) there are not approved or in-testing-phase treatments for this kind of disease[4]. Similarly to what happens for the use of off-label drugs, in our opinion, it should also be considered an additional requirement, related to scientific evidences about treatment efficacy.

On this issue, we have to consider that off-label use involves well-known and long-used drugs which, according to scientific evidence, can be applied safely and effectively also to treat conditions for which they have not received granted approval. The practice is widespread in various medical disciplines including oncology, rheumatology, neurology, and psychiatry and involves both adult and paediatric medicine, and specifically neonatal patients.

Italian legal and ethical regulations allow off-label prescribing to treat conditions, other than those reported in the marketing authorization, once is provided that: (1) the drug is included in a special list (Law no. 648/1996); (2) the physician takes direct responsibility for the treatment; (3) effectiveness and safety studies are available (II phase trials); and (4) licensed drugs cannot be used to treat the same pathology for different reasons (Law no. 94/1998). The patient's written informed consent is mandatory.

After the case of Avastin/Lucentis[5], new rules have been introduced about off-label prescribing (Law no. 79/2014). This is allowed, free of charge for the patient, even if an alternative drug is available. The off-label drug should possess same effectiveness, safety and fewer costs than registered one.

In this concern, the following recommendations have been recently published to provide guidance to UK physicians, "Before prescribing an unlicensed medicine or using a medicine off-label: (1) be satisfied that there is a sufficient evidence base and/or experience of using the medicine to show its safety; (2) take responsibility for prescribing the medicine and for overseeing the patient's care, including monitoring and follow-up; (3) record the medicine prescribed and, where common practice is not being followed, the reasons for prescribing this medicine". The FDA has no policy in restricting the use of medications to treat conditions for which they have not been authorized[6].

This aims to avoid the limitation of physician's judgment. However, the physician is required to record any off-label drug use and any side effects. The EU has not specifically regulated the matter, and an analogous situation exists in Japan, Canada and Australia. According to some authoritative Australian researchers[7], off-label use is legitimate if it is supported by high-quality evidence, by data obtained in clinical trials and exceptional cases. Outside of these conditions off-label prescribing is unlawful[8].

Conflict of Interest

The Authors declare that there are no conflicts of interest.

References

1) Conti AA. The evolution of the Italian Code of Medical Deontology: a historical-epistemological perspective. Clin Ter 2014; 165: 315-318.
2) Montanari Vergallo G, Busardò FP, Zaami S, Marinelli E. The static evolution of the new italian code of medical ethics. Eur Rev Med Pharmacol Sci 2016; 20: 575-580
3) Turillazzi E, Neri M. Medical error disclosure: from the therapeutic alliance to risk management: the vision of the new Italian code of medical ethics. BMC Med Ethics 2014; 15: 57.
4) Frati P, Frati G, Gulino M, Montanari Vergallo G, Di Luca A, Fineschi V. Stem cell therapy: from evidence-based medicine to emotion-based medicine? The long Italian way for a scientific regulation. Stem Cell Res Ther 2013; 4: 122.
5) Cohen D. Roche and Novartis colluded over wet AMD drugs, says Italian regulator. Br Med J 2014; 348: g2006.
6) Dresser R, Frader J. Off-label prescribing: a call for heightened professional and government oversight. J Law Med Ethics 2009; 37: 476-486.
7) Gazarian M, Kelly M, McPhee JR, Graudins LV, Ward RL, Campbell TJ. Off-label use of medicines: consensus recommendations for evaluating appropriateness. Med J Aust 2006; 185: 544-548.
8) Ruble J. Off-Label Prescribing of Medications for Pain: Maintaining Optimal Care at an Intersection of Law, Public Policy, and Ethics. J Pain Palliat Care Pharmacother 2012; 26: 146-152.