

# Some comments on the new regulations governing Ethics Committees in Italy

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## Abstract

Italy has recently introduced regulations that profoundly change the arrangement of ethics committees. Specifically, their numbers have been reduced from more than 200 to a few dozen. The decree defining the criteria for their composition and functioning includes regulations intended to improve efficiency and efficacy. The present article provides a brief overview of the new provisions and identifies some critical aspects.

## Key words

- ethics committees
- human experimentation
- legislation

## INTRODUCTION

The law of 8 November 2012 [1] required each Italian region to reorganise its ethics committees by 30 June 2013 in line with criteria laid down in the relevant decree subsequently published on 8 February 2013 under the title "Criteria for the composition and functioning of ethics committees" [2].

The law and the decree introduce significant changes in the organisation of ethics committees.

Among the motivations for this law were the excessive number of ethics committees in Italy (243 in 2012 [3]) and the Health Ministry's intention to simplify and rationalise the complicated regulatory framework governing clinical trials of drugs in Italy.

The law of 8 November 2012 [1] required that each region should reorganise the ethics committees operating in its confines in line with the following criteria:

- the jurisdiction of each ethics committee should include one or more provinces, based on a ratio of one committee per one million inhabitants, subject to the possibility of an additional ethics committee with responsibility for one or more Institutes of Care and Scientific Research (IRCCS);
- in deciding which committees to retain, the region must take into account the numbers of so-called "single opinions" (*pareri unici*, i.e. opinions given by the committee affiliated to the healthcare institution in which the coordinating researcher is employed) issued during the last three years;
- each committee's terms of reference may include clinical trials not only of drugs but also of medical devices, surgical procedures and food products;
- the independence of each committee and the absence of hierarchical relationships between committees must be guaranteed.

The implementing decree of 8 February 2013 [2] defined the operating criteria and confirmed the deadline of 30 June 2013 as the date by which the regions must reorganise their respective networks of ethics committees.

The key measures contained in the decree are:

- committee members must have proven knowledge and experience in clinical trials of drugs and medical devices, as well as in other matters covered by the remit of the ethics committee (Article 2.5);
- appointments are for three years and can be renewed consecutively only once (Article 2.8);
- outside consultants may be invited to advise on specific issues on an *ad hoc* basis (Article 2.6);
- each committee must comprise at least: three clinicians; one locally-practising physician in general medicine; one paediatrician; one biostatistician; one pharmacologist; one pharmacist employed by the local regional health service; the medical director or scientific director of the institution concerned; one specialist in legal and insurance matters or a forensic scientist; one bioethicist; one representative of the healthcare specialisation involved in the trial; one representative of volunteer or patient protection associations; one expert in medical devices; one clinical engineer; one nutrition specialist; one specialist in novel technical and invasive and semi-invasive diagnostic and therapeutic procedures; one geneticist (Article 2.5); the committees' independence must be guaranteed: by the absence of any form of hierarchical subservience to the institution with which they are affiliated; by drawing at least one third of their members from outside the institution; by the absence of any conflicts of interest (Article 3).

On the basis of these provisions, each region has implemented a decree to establish the ethics committees that will operate within its territory.

Given the complexity of the pre-existing situation, the need to review the organisation of ethics committees was widely acknowledged and appropriate measures have been taken, but some aspects of the criteria laid down in the new decree [2] nonetheless invite comment.

## ON THE CRITERIA FOR IDENTIFYING HEALTHCARE FACILITIES WITH ETHICS COMMITTEES

Notwithstanding the recognised need to reduce the extravagant number of ethics committees previously operating in Italy, the drastic reduction implemented by combining several pre-existing committees together could have untoward effects, two of which merit attention. The first is the excessive workload assigned to the new committees: the second is that in many cases the committee will no longer be located on the site where the research is conducted.

In addition, two of the criteria for redrawing the map of these committees could possibly be improved.

The first refers to population density and envisages one committee for each million inhabitants (Article 2.1). However, this parameter does not take into consideration the uneven distribution throughout Italy of institutions that conduct clinical trials. In some regions of Northern Italy there is a high density of hospitals, universities, Institutes of Care and Scientific Research (IRCCS) and industries active in the field of experimentation, while in some regions of Southern Italy there are very few.

The second criterion used by the regions, in accordance with the decree, to establish which ethics committees to retain and which to suppress, is a quantitative one (Article 2.2): the committees that have produced the highest numbers of *pareri unici* in the shortest time over the last three years have been confirmed. The use of criteria based on efficiency appears further to reinforce the bureaucratic nature that these committees have gradually acquired over the years. Since their inception as advisory bodies they have gradually assumed the guise of licensing agencies, a situation that fosters the perception by researchers that they are a hindrance to freedom in research, assigned to tiresome regulatory formalities. This criterion also fails to consider the numerous forms of non-pharmacological research such as research using biological samples, epidemiological studies or public health research.

## ON THE COMPOSITION OF THE COMMITTEES

The decree obliges the committees to include experts in some disciplines (Article 2.5) that are rarely subject to scrutiny by ethics committees (except in institutions specialising in them): nutrition and medical devices, for instance, are areas in which most institutions only rarely conduct trials. The decree also appears not to oblige all specialist members to take part in all committee meetings, their presence being required only when the protocols under examination relate to their specific fields. This could complicate the task of calculating the quorum necessary for a session to be valid. It would perhaps have been preferable to allow the committees, where necessary, to call on external specialists in the specific fields, as provided in the previous regulations [4]. In addition, the presence of only one expert in ethics on an ethics committee of nearly 20 members seems a serious under-representation.

Rather than require the presence on these commit-

tees of experts in areas that may well be involved only rarely in trials, it would perhaps have been appropriate to identify a minimum number of places to be filled by experts in required fields and allow the committees to assign the remaining places according to the specific characteristics of the institute of affiliation.

Finally, the decree requires that “no less than one third of the total” members should be “external to the healthcare institution for which the ethics committee operates” (Article 3.2). The previous regulations (decree of 12 May, 2006 [4]) required that “at least one half of the total members should not be employed in the institution by which the committee is engaged”. This reduction in the minimum number of external members does nothing to encourage the independence of ethics committees.

## ON SOME PRACTICAL ASPECTS

There are other provisions in the decree [2] that could be improved:

- the decree calls for the compensation agreements relating to trials to be signed on the same day as, or within three days of, the meeting of the ethics committee during which the trial is given the go-ahead (Article 2.9). This is effectively unfeasible. As the procedure leading to the Administrator's signature is usually set in motion only after the institution has received formal notification of a committee's opinion, there is usually a time lag. It would therefore be more appropriate to allow the Administration to assess the compensation agreements, leaving to the ethics committee the task only of verifying its congruity with the trial protocol;
- the decree assigns to ethics committees the function of evaluating clinical trials, although it adds that they “may propose initiatives for the training of healthcare operators in matters relating to bioethics” (Article 1). It would instead be desirable to assign them functions of monitoring, consultancy and the promotion of initiatives in the area of research ethics;
- the decree provides for the costs incurred by ethics committees to be covered by the sums paid by commercial sponsors for the evaluation of protocols (Article 6.3): it would be preferable for these expenses to be included among the overheads of the institute of affiliation;
- the new regulations fail to solve the problem of evaluation and consultancy in the field of clinical practice. This calls for resources and responsibilities that could be assigned to special committees distinct and separate from those for the assessment of trials. An approach of this kind was adopted in the Veneto region in 2004 [5].

### *Conflict of interest statement*

There are no potential conflicts of interest or any financial or personal relationships with other people or organizations that could inappropriately bias conduct and findings of this study.

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