

COMMENTARY

Are the Italian ethics committees ready for Europe?

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The Law of 3 January 2018 established in Italy the “National Centre for the Coordination of Regional Ethics Committees for Clinical Trials of Medicines and Medical Devices for Human Use” and reduced the number of ethics committees in the country to 40. This Act should, amongst other things, facilitate Italy’s compliance with the provisions set forth in European Regulation (EU) 536/2014. Hopefully, in addition to the provisions set forth in the Law, the National Centre will strive to foster the harmonisation of ethics committee procedures, in order to reform Italian legislation on the evaluation of clinical trials and, more generally, biomedical studies.

Key words

- ethics committees
- human experimentation
- legislation

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

The implementation of the Law, which makes the Regional Authorities responsible for establishing the local ethics committees in their area, involved a significant reduction in the number of local ethics committees in Italy [3]: from 243 committees in 2012 to just 93 in 2014. In the meantime, mergers have taken place in some regions and the number of local ethics committees currently stands at 72.

The following year, the European Union adopted and implemented Regulation (EU) 536/2014 of the European Parliament and of the Council of 16th April 2014 on clinical trials on medicinal products for human use, repealing Directive 2001/20/EC [4]. The Regulation establishes a new set of harmonised rules that all member states are required to apply in all clinical trials performed throughout the European Union (EU).

Pending the full implementation of the Regulation (which, as established in article 99, will occur six months after the publication in the *Official Journal of the European Union* of a notice regarding the full functionality of a portal and a database containing the data and the information submitted in accordance with the same Regulation), the Italian Government passed Law no. 3 of 11 January 2018 [5], which introduces, in articles 1 and 2, important changes in the procedures for the au-

thorisation of clinical trials and regarding the organization and operation of ethics committees.

The Law also envisages a further reduction in the number of local ethics committees: a Ministerial Decree (replacing regional provisions) will be issued establishing 40 local ethics committees and 3 committees of facilities with national competence. As regards the establishment of the local committees, there must be at least one for each region (article 2, subsection 7) [5].

One particularly important provision of the law is the establishment, within Agenzia Italiana del Farmaco (Italian Medicines Agency, AIFA), of the “National Centre for the Coordination of Regional Ethics Committees for Clinical Trials of Medicines and Medical Devices for Human Use” (in Italian: Centro di coordinamento nazionale dei comitati etici territoriali per le sperimentazioni cliniche sui medicinali per uso umano e sui dispositivi medici) [5].

According to the Law, the National Centre:

- is responsible for the coordination, guidance and monitoring of the assessment of the ethical aspects concerning clinical trials on medicinal products for human use performed by the local ethics committees;
- intervenes, when requested to do so by the individual local ethics committees, to provide support and advice;
- may be involved in the procedures regarding the evaluation of clinical studies requiring review following adverse event reports;
- monitors the activities performed by the local ethics committees and reports breaches of the terms set forth in the aforesaid Regulation (EU) no. 536/2014 [4];

- in cases of inertia or, in any case, cases of failure to comply with the terms set forth in said regulation, it suggests that the Ministry of Health suppress the non-compliant local ethics committee;
- provides general guidance in the interest of procedural uniformity and compliance with the terms for the assessment of clinical trials on medical devices and medicines for human use.

The reduction in the number of ethics committees and the establishment of the National Centre are the result of a lively debate [6] regarding the organization of ethics committees that, in Italy and the whole European Union, followed the adoption of Regulation (EU) 536/2014 [4], during which a number of different proposals emerged [7, 8] (including that of centralising the assessment of all the clinical trials conducted in Italy with a single committee for the whole of the country).

The ethics committees have high expectations from the National Centre: it is hoped that it will put an end to the fragmentation and lack of homogeneity that currently characterise the country's ethics committees.

As specified in article 2, subsection 4 of the Law [5], the fifteen members of the National Centre were appointed by specific Ministry of Health Decree on 19 April 2018 [9]. According to the same Law, of the National Centre members appointed by the Ministry, two were put forward by the Conference of Regional and Autonomous Provincial Authorities and three were put forward by the most representative patient advocacy groups (the Law mentions "at least two"). The remaining members are university professors and directors working for national health institutions (including my-

self). According to the Law, meetings of the National Centre may be attended by the Chairs of the National Bioethics Committee, National Committee for Biosafety, Biotechnology and Life Sciences and the Italian National Institute of Health. The implementation Decree appointing the fifteen members increased the three participants to four (with the addition of the General Manager of the AIFA) [9].

The commitment must be, first and foremost, to perform at least those duties that are attributed to the National Centre by law [5]. However, hopefully, it also be to reorganize or reform many other areas that require national intervention. The most urgent of these are:

- the review of the procedures for the evaluation of observational studies (starting from the very definition of "observational study" [10]);
- the review of regulations governing "no profit" [11] studies;
- the harmonisation of the procedures for the assessment of studies other than clinical trials (studies involving biological samples, epidemiological studies, etc.);
- the organization and promotion of clinical ethics committees providing guidance on clinical cases in medical facilities, rather than being dedicated to the assessment of clinical trials.

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*I declined the post of President of the National Centre and assumed the role of Vice President.

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