

An ethics for the living world: operation methods of Animal Ethics Committees in Italy

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Abstract

Introduction and objectives. Coinciding with the recent implementation in Italy of the “Directive 2010/63/EU, regarding the protection of animals used for scientific purposes”, the Authors would like to analyse the topic of the introduction of ethical committees for animal experimentation in Italy. This paper furthermore aims to underline some critical aspects concerning the actions taken by Italian institutions to comply with the provisions of EU.

Results and discussion. The implementation of the recent Italian law (Decreto Legislativo n. 26 on 4 March 2014 Implementation of the Directive 2010/63/EU on the protection of animals used for scientific purposes) leans towards a restrictive interpretation of the European provisions about composition and responsibilities of “Ethical Committee for Animal Experimentation”. In the composition of the bodies mentioned, we note a tendency to restrict the composition to few professional figures contemplated by Italian law, without guaranteeing the independence of each committee; also, an absence of hierarchical relationship between a research institution and his committee is apparent. Moreover, a critical aspect is the lack of decision-making powers of these new organisms in terms of ethical evaluation of protocols and research projects.

Conclusions. What EU legislation imposes on the member states is to set up an animal-welfare body (art. 26). This represents a strong incentive for Italy to follow the steps of many other European Countries, where ad hoc ethical committees have been working for a long time. The proper functioning of these bodies may contribute to guarantee the safety and welfare of the animals inside the laboratories, and to balance the protection of animal life and the interests of research.

Key words

- animal experimentation
- Italian Ethical Committee on Animal Experimentation
- animal welfare
- ethics of animal experimentation
- Italy

INTRODUCTION

This work aims to analyse the issue of the introduction and effectiveness of ethical committees focused on animal experimentation in Italy, in the light of the recent Decreto Legislativo (DL.vo) n. 26 on 4 March 2014 “Implementation of the Directive 2010/63/EU on the protection of animals used for scientific purposes”. In Italy, before these regulations were implemented, there was no obligation to provide or refer to a specific institution that defended the welfare of animals used for scientific purposes. Consequently, the committees for ethical valuation of the protocol on animal experimentation were a free choice of research institutes.

The evolution of the debate in the new Directive included discussions about the possibility to include a clause that would make an obligation to provide also an ethical evaluation of the projects about animals [1]. However, in the final text, the removal of the word “ethical” seems to undermine the function of this body of evaluation of the ethics of research projects. This disappointed (at least partially) the expectations of those who believed in a more restrictive legislative guidance. Nevertheless, the requirement, in the present form of the Italian regulation (DL.vo n. 26/2014), to create, in every breeding, supplying or user facility, a body for animal welfare, might represent – regardless the name

chosen – an important opportunity for the proper work of ethical committees, in agreement with what already happens in other Countries. These institutes, required in Italy only for experiments that involve human beings [2], could enhance the ethical reflection on human responsibility towards animals used in research [3].

Indeed the cogency and effectiveness of ethical committees working in a common pattern on national territory can assure an evaluation as sensible as possible of the interests at stakes, and improve the implementation of 3Rs methods [4] in animal-based research, adopted in the context of animal experimentation [5, 6]. In Italy, the three Rs were explicitly a model for the document of the National Committee for Bioethics (NCB), rising from the need of reconciling different values in a balanced and common way. The document deems each point of view worthy of being recognized, such as human welfare, promotion of the scientific research, reduction of pain for the animals used for the experimentation, animal welfare in case of veterinary research, and respect of intimate and personal beliefs of researchers [7].

For this reason, we intend to give a critical evaluation on the subject, also highlighting the critical state of the recent Italian DL.vo n. 26/2014 that conforms to Community obligations.

RESULTS AND DISCUSSION

In Italy the Istituto Superiore della Sanità (Italian National Institute of Health) made a survey through questionnaires, sent to Universities and main research institutes, just before the recent implementation of the EU Directive; the results are as follows [8]:

- 20% of the research facilities do not have any institution/committee for technical-scientific and/or ethical advice;
- 12% of the facilities have two different bodies: one conducts mainly a technical-scientific activity while the other carries out an advisory activity for ethical problems about animals;
- 16% have established bodies for mainly technical support, offering practical aid and advice to researchers;
- 24% have committees with an exclusively ethical advising function on research projects;
- 28% have established committees that carry out both activities.

Furthermore, the composition of these bodies is extremely heterogeneous and consists of a different number of members (between five and twelve), mainly chosen within the same institution, with a degree in medicine (with or without an involvement in animal experimentation), in veterinary medicine, in biological science, as well as technicians, legal advisers and bioethics experts [9].

A serious gap in the critical discussion of the subjects related to experimentation is a frequent lack of experts in bioethics, particularly in animal bioethics. This makes the discussion on morally relevant themes difficult and sometimes cumbersome. Similarly, the effectiveness of the action of these bodies has often been compromised by the absolute lack mandatory creation, besides the lack of clear operating methods [10].

On the same wavelength as the criteria of the Community, Italian legislator has then established with the DL.vo n. 26/2014 the effectiveness of an “Animal Welfare Body” (AWB). This body performs, as well as advisory functions, also function of update, definition and review of working internal monitoring processes (for the benefit of the personnel using animals), including assessment tasks of research projects, supervising of their implementation and verification the correct application of regulations.

It is to be highlighted that, besides what it is established in the Directive 2010/63, the Italian provisions of implementation related to this “body”, include in the art. 26, n. 1, two more letters: “d” and “e”. While the letter “e” concerns a task that is simply “bureaucratic”, namely forwarding applications of authorization, the letter “d” considers specific functions that give a positive interpretation of what is said in the preface n. 31¹ of the directive on this matter. A motivated opinion is required in the national law on research projects, whose content is well specified in the n. 2. This is not provided by the directive, and with that body it creates those Ethical Committees (not provided in previous regulations), wished some time ago in the opinion given by the Italian National Committee for Bioethics, that states: “The legislative intervention should also determine the competences of Ethical Committees for the passage of protocols related to animal experimentation, in order to guarantee the respect of the existing regulations and the protection of animal welfare” [11].

The present art. 25, DL.vo n. 26/2014, establishes that this body must be composed of “at least one person or persons responsible of the welfare and care of animals, the veterinary surgeon of whom at the art. 24 and, in case of a user, a scientific member”. This does not seem to be an obstacle to increase the competences essential to the execution of the delicate tasks assigned. Regarding to the need of promoting the clarity of the committee’s activities, optimizing its operative procedures, and also assuring evenness of the evaluation methods, it is also necessary to define the operational methods of the committee, with particular emphasis on: method of presentation of the request, schedule of evaluation, methodologies of vote and possible interview of researchers.

In fact, although the public’s attitude towards animal experimentation within EU countries changes in relation to the different socio-cultural statuses, increases the sensitivity of public opinion towards animal welfare are widespread and growing [12, 13]. The operation

1 In the Directive 2010/63, the preface n. 31 provides as a matter of fact that “Animal-welfare considerations should be given the highest priority in the context of animal keeping, breeding and use. *Breeders, suppliers and users* should therefore have an animal-welfare body in place with the primary task of focusing on giving advice on animal-welfare issues. The body should also follow the development and outcome of projects at establishment level, foster a climate of care and provide tools for the practical application and timely implementation of recent technical and scientific developments in relation to the principles of replacement, reduction and refinement, in order to enhance the life-time experience of the animals. The advice given by the animal-welfare body should be properly documented and open to scrutiny during inspections”.

of independent ethics committees for ethical review of protocols of animal experimentation may therefore be an important point of convergence between the protection of animals and the interests of research [14].

CRITICAL ASPECTS AND CONCLUSIONS

Even though it is difficult to make predictions on the application of the latest Italian law, some of the operations start to be reported, and they seem to interpret the forecasts about *composition and functions* of these bodies in the EU and National regulations in a very restrictive way. These bodies, in our opinion, regardless of the name adopted by the Italian legislature, might instead perform more ethically significant duties and tasks with more incisive ethical connotation (in line with what happens in other countries).

In the composition of the above-mentioned bodies, it is reported that the overall tendency is to limit the composition to the few professional profiles mentioned in the Italian law². On the contrary, it is to be emphasised that, in designating the minimum professional profiles required for this body to be operational, the Italian DLgs. n. 26 on 4 March 2014 uses the word “at least”, therefore not excluding improvements and additional inclusions of professionals in these institutions. Likewise the art. 26 uses again the word “at least”, to indicate that the functions are not limited to the mere

advice, but they are extended to evaluation and monitor of experiments, both on a normative and on a scientific level.

Specifically, the main problems of these bodies, in order to be operative and have weight in decisions, are represented by:

- a) composition;
- b) equality of roles;
- c) authority (decisional ability);
- d) the independence (conflict of interests).

Regarding the *composition*, a critical point might be the possibility to integrate the body with experts in the field of alternative methodologies, to give advices and views to the persons responsible of the project exactly in their area of expertise. These experts may be identified each time, even as external members, taking into account the topic of the project. The responsibility added to this body by the cited Italian law (art. 26, d-e) actually devalues this activity because the advisory role of the body/committee is merely obligatory, but not binding. These bodies should be entrusted with the responsibility for ethical evaluation of the protocols and research projects, and their implementation procedure [15]. Therefore, in order to justify the function and the social cost of these bodies, it might be necessary to give them autonomy to express a grounded refusal, and to refer to the authorities the requests that have not received the approval of the majority of the members (meaning the person responsible of animal welfare, the veterinary, and the constituents of the scientific member, therefore three or more people).

Finally, the last, but absolutely not the least central issue, is the need to consider that the veterinary (art. 25 in the directive and 24 in the DL.vo n. 26/2014) and the body for animal welfare should actually be both entities with the highest *independence*, both mutual and in relationship with insurance companies working with establishments where they work, because any figure employed in this capacity cannot be considered free from *conflict of interests*. So it is necessary to ensure that these figures do not have an exclusive advising relationship with these Companies, but might be chosen from a national register for experts qualified in these professions.

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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² This is the direction towards which, for example, the Azienda Universitaria San Martino - IST (IRCCS University Hospital San Martino; IST National Institute for Cancer Research) in Genoa and the Istituto Nazionale per lo Studio e la cura dei Tumori Fondazione Giovanni Pascale (National Institute for the Study and Cure of Cancer Foundation Giovanni Pascale) in Naples have moved. Also the Fondazione IRCCS - Istituto Nazionale dei Tumori (Foundation Scientific Institute for Recovery and Care - Cancer National Institute) in Milan has limited the OPBA members to the few profiles in DL.vo n. 26/2014 adding only an expert in statistics. On the same direction is the University Sapienza in Rome that includes as OPBA members the person responsible of user establishments that is in charge in the Department, the veterinary, three users/scientific members (in case these are not yet identified as person responsible of animal facilities), that are appointed by the Department Board among the internal staff or external people that must be expert in scientific, ethical or legal aspects of animal experimentation.

On a different direction, the University of Padua has got in the OPBA composition the following profiles: the Chancellor's Delegate as President; the Persons responsible of Animal Welfare that are called each time the body is involved in specific research projects in exam; Representatives of Scientific Areas interested in animal experimentation (a. Science of medicine: 1 representative; b. Biological Science: 2 representatives; c. Medical Science: 1 representative; d. Agricultural and Medical-Veterinary Science: 2 representative; e. Psychological Science: 1 representative); Expert in Bio-safety; Bioethical Expert; Biostatistics Expert; Ethologic Expert; Jurist; Person responsible of administrative procedure.

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