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Joint submission for the the session of the United Nations Human Rights Council on Italy by the Associazione Luca Coscioni and Science for Democracy

The Associazione Luca Coscioni (ALC) was founded in 2002 by Dr. Luca Coscioni, an Italian Professor of Economics with Amyotrophic Lateral Sclerosis, to promote freedom of scientific research with particular attention to that concerning embryonic stem cells (ESC). Dr. Coscioni died in 2006 after having promoted a referendum campaign to reform an Italian law on reproductive techniques, which, among other things, was prohibiting ESC research. During his tenure as secretary of the ALC Dr. Coscioni received the support of some 100 Nobel Laureates that endorsed his support for science.

Since the inception, the Association's modus operandi has tried to mirror the "scientific method". As a matter of fact, for the last 17 years, the ALC has reached out to experts, researchers and scientists to involve them in preparing technical documents to assist the drafting of legislative and policy proposals; at the same time, it has urged them to become the champions of their own cause, believing that it is in the public interest to hear scientists when "evidence-based" decisions are invoked. In addition to reaching out to national, regional and international decision-making bodies, the Association has mobilized public opinion, with popular and media campaigns, petitioning, international appeals, recurring, when necessary and appropriate, to civil disobedience as an instrument to promote change. Since 2016 it has prepared several "shadow reports" for the UN Committee on Economic Social and Cultural Rights to address the lack of documentation by Member States on the ascertainment of article 15 of the International Covenant on Economic, Social and Cultural Rights (ICESCR).

Science for Democracy (SfD) is an international platform established in 2018 to promote the Rule of Law through the affirmation of the so-called "right to science", the adoption of evidence-based decisions as well as the promotion of public debates to foster human development. SfD aims to consolidate democracy as the institutional framework better equipped to advance the Right to Science globally. Issues central to the activities of Science for Democracy are the environment and its various ecosystems, human freedom, health and quality of life. Anyone can join the platform. Since its inception, SfD has reached out to the UN Committee for Economic, Social and Cultural Rights (CESCR) as well as other organizations and individuals to engage them in view of the full adoption of the right to science by the UN Council on Human Rights in 2019. SfD has also petitioned European Institutions, the Members of the European Parliament and the Member States of the EU to account for the Right to Science in the 9th Framework Program for Research and Innovation of the European Union (2021 – 2027), advocating for the increase of resources, the funding of cutting-edge research, and the establishment of an independent and transparent process of evaluation of the innovation and policy impacts of the projects funded.

The ALC and SfD have organized several side-events at the United Nations offices of Geneva and Vienna to promote the inclusion of science related issues within the wider human rights discourse.

Background and framework

❖ **Science and decision making**

Driven by the continuous development of knowledge and applications in the biomedical field made possible by technological innovation, the relationship between science and law is crucial when it is necessary to take legislative decisions. A normative approach based on the principle of scientific reasonableness appears to be a necessary element, albeit not exclusive (as it must support and not substitute value-based decisions), within the law-making process.
It favours also the legitimacy of laws which goes to regulate medical or scientific issues:

a) a legislative process which is open to the contribution, often decisive, of scientific community, on the basis of experiences now consolidated on a comparative level [1,2];
b) a legislative text structured to allow its adaptability to the constant medical-scientific development that characterizes the biomedical field;
c) choices that guarantee a regulatory space reserved to the autonomy of individuals directly involved in the biomedical field (patients, doctors, researchers).

In this regard, the European Court of Human Rights has stated [3,4] that national authorities must perform a «thorough assessment» of rules governing medical or technological issues at stake, taking into account the dynamic developments in science and society which must be kept under review.

❖ **The human right to health and the human right to science**

The ICESCR requires States Parties to guarantee the right to health (Article 12) and the right to science (Article 15).

The right "to enjoy the highest attainable standard of physical and mental health" covers a range of freedoms and entitlements, including the right to be free from non-consensual medical treatment. Three categories of State obligations derive from the right to health. The obligation to respect requires States to refrain from interfering directly or indirectly with the right to health. The obligation to protect requires States to prevent third parties from interfering with the right to health. The obligation to fulfil requires States to adopt appropriate legislative, administrative, budgetary, judicial, promotional and other measures to fully realize the right to health.

While the exact scope of application of art. 15 (1b) ICESCR is still under definition, the right to science can be considered as including: the right to enjoy the benefits of scientific progress and its applications, the right to access scientific knowledge, and the right to participate in scientific development. The latter covers not only the freedom of research for scientists, but also the "opportunity for all to contribute to the scientific enterprise", as stated by the Special Rapporteur in the field of cultural rights Farida Shaheed [5].

I. Scientific advancement, human rights and human biology

❖ **Assisted reproduction technologies (ART) and research with human embryonic stem cells (hESC)**

Despite the contribution of national, including constitutional, and international case-law in ensuring compliance between Law 40/2004 on medically assisted procreation (MAP), constitutional principles and fundamental human rights in general, several critical aspects remain both in terms of effective access to lawful services and the legislative framework *per se*.
In fact, while the blanket ban of heterologous fertilization has been overthrown by the Constitutional Court in 2014, the availability of gametes for donation to third parties is still very poor. Similarly, access to pre-implantation genetic diagnosis (PGD) appears not properly guaranteed, despite the ban for fertile carriers of a transmissible genetic disorder to accede to MAP and PGD has been removed by the Constitutional Court in 2015.
Additionally, the ban of research on embryos interferes with scientific progress and the opportunity to discover new therapies for unmet diseases, leading to a violation of Art. 12 and 15 ICESCR.
Italy should remove the remaining prohibitions of Law 40/2004, also in light of the many decisions made by the Constitutional Court [6], to avoid that judicial interventions remain the only effective way to obtain access to PMA techniques, i.e. allow same-sex couples and single persons to access PMA. Also, Italy should regulate the donation of human blastocysts not suitable or intended for reproductive purposes to national research.

❖ Maternal surrogacy in Italy

Surrogacy in Italy is regulated under Art. 12, paragraph 6, Law 40/2004 on MAP, which punishes whoever, in any form, produces, organizes or advertises the sale of gametes, embryos or surrogacy, with imprisonment from three months to two years and a fine ranging from 600,000 to one million euro.
Therefore, many couples or individuals decide to embark on a surrogacy journey abroad, in compliance with foreign law, despite the uncertainties about the legal effects arising out of this choice, once back to Italy. In fact, no Italian legislation establishes any principle applicable to Italian citizens doing surrogacy abroad.
This legislative vacuum often leads Italian intended parents to fight prolonged battles before Italian Courts to obtain recognition of their rights as parents, legitimately acquired abroad. Some of them have, sometimes, also faced criminal charges for the crimes of alteration of status by means of misrepresentations (art. 567, § 2, Italian Criminal Code) or misrepresentations of personal qualities to a public official (art. 495, § 2, no. 1, Italian Criminal Code) and some others have seen their non-genetic, but legal children, declared adoptable.
This situation also affects same-sex families and their children who, often, cannot enjoy, in their residence country, the same legal status they enjoy in their birth country.
Different recognition of children's parental rights on Italian territory and violation of children's fundamental rights (i.e. inheritance rights, freedom of movement), including their right to personal and family identity, are some of the consequences of this legislative gap.
In light of what mentioned above, Italy should adopt norms to fill the lack of regulation concerning surrogacy to: protect the rights of children born from surrogacy abroad, regulate altruistic surrogacy at the national level, end discrimination and protect individuals' fundamental rights, including reproductive rights and self-determination.

❖ Abortion and contraception

Women's reproductive rights, as fundamental human rights, include the right to access legal and safe abortion.
Although under Law 194/1978 abortion in Italy is permitted if the continuation of pregnancy represents a danger to the physical or psychological health of the woman, effective access to abortion is often hindered.
A first problem concerns the high number of conscientious objectors allowed by the law among medical doctors in public hospitals, as well as conscientious objections made by medical structures in their entirety. On this issue the Parliamentary Assembly of the Council of Europe (PACE), the European Committee of Social Rights, the Human Rights Committee and the Committee on Economic, Social and Cultural Rights have already expressed their concern.
A second issue is represented by the method commonly used for therapeutic abortion. Medical abortion is rare in Italy (unlike in the majority of European countries) and in most Regions patients are hospitalized for three days while taking the necessary pills. This practice, which determines an unnecessary increase of expenses of the National Health Service, is not only in contrast with Art. 15 of Law 194/1978 – which recommends "the use of the more modern techniques of pregnancy termination which are physically and mentally less damaging to the woman and are less hazardous" – but it is also in violation of the right to reproductive health guaranteed under Art. 12 of the ICESCR. As stated by the CESCR Committee in General Comment No. 22 (2016), "the failure or refusal to incorporate technological advances and innovations in the provision of sexual and reproductive health services, such as medication for abortion, (…) jeopardizes the quality of care".
As recognized by the PACE in Resolution No. 1607 (2008), the best way to reduce abortions is to improve contraception, including emergency contraception. Italy should guarantee access to emergency contraception without medical prescription to all women and girls, including underage girls and include any means of contraception among the expenses reimbursed by the National Health Service.

- **Provisions for informed consent and advance health directives**

More than a year after the adoption of Law 219/2017 "Provisions for informed consent and advance directives", the effective application of its provisions is still hindered by bureaucratic obstacles. The absence of a centralized database for the collection and storage of advance health directives makes it difficult for Italian citizens to express their wills and access their data when necessary. Although the allocation of two million euros [7] and other 400,000 euros [8] for the creation of a national electronic database, municipalities and citizens still lack proper guidance from the MoH on how they could record individuals' wills and access relevant information when needed. The 2018-2020 budget law mandated the adoption of a ministerial decree containing rules for the recording of information was expected by 30 June 2018 [7]. As of 28 March 2019, no instructions have been provided by the MoH. The lack of general information and the absence of an effective mechanism aimed at gathering personal data and make them accessible when needed is in contrast with fundamental freedoms and entitlements including the right to life and health, the freedom of self-determination and human dignity, as enshrined in the Italian Constitution, in European and International human rights law instruments.

Although Art. 12 of the Decree Law 179/2012 has introduced the use of regional "health electronic records", the service is active in only 13 out of 20 regions.
Italy should take immediate action to provide clear guidance for the recording and collection of citizens' advanced directives, together with the possibility to access those information when needed.

❖ **Assisted suicide and euthanasia**

Law 219/2017 allows citizens to decide in advance whether they would accept, or refuse, any medical treatment in the case they lost their capacity to self-determine. Italy still imposes an absolute ban on "assisted suicide" and "euthanasia". In its order 207/2018, the Constitutional Court held that an absolute ban on assisted suicide does not take into consideration specific circumstances of sick persons arising from the development of medical and technological sciences and therefore not imaginable at the time when the criminal provision was introduced. With the same order, the Court called on the Parliament to better regulate end-of-life care issues by 24 September 2019. As of March 2019, only popular bill C. 2 (XVIII parliamentary term) is before the competent Committees of the Chamber of Deputies [9] but no progress by Parliament or government can be reported in the adoption of the law. Italy, given her rapidly ageing population that sees over 22% of the citizens over 65 years of age, should consider end-of-life care and rights as a priority issue in the institutional agenda and take immediate action towards the adoption of proper legislation in compliance with international human rights standards and order 207/2018 of the national Constitutional Court.

III. Scientific advancement, human rights and new bio-tecnologies

Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR), New Plant Breeding Techniques and "old" Genetically Modified Organisms (GMOs)

New plant breeding techniques (NPBTs) allow a much more rapid and precise introduction of favorable traits in plants including relevant crops compared to classical breeding approaches. Also, they are a valuable tool in basic plant research. Since CRISPR invention in 2012, CRISPR-based gene editing techniques have been by far the most widely used NBTs. Although the mutations introduced in the plant's genomes by CRISPR are identical to those that occur naturally, the plants obtained by CRISPR are currently considered as GMOs.
A sentence of the European Court of Justice of the 25 July 2018 ruled that NBT plants fall within the 2001/18/EC directive, which defines GMOs. Ruling CRISPR as GMO is inconsistent as all other mutagenesis techniques, normally much more invasive than CRISPR, are exempt from the 2001/18/EC. Also, ruling CRISPR as GMO dramatically limits its use in plant breeding in Europe, with negative effects for both agriculture and basic plant research.
Italy allows research both on GMOs and CRISPR plants but prohibits GMO cultivation, including BT corn that is permitted in other European countries. Also, in Italy there have not been identified experimental fields for studying GMO and CRISPR plants. While the first

decision has significant structural economic implications (GM plants must be imported) the second is hindering the right to perform scientific research.
Following the sentence of 25 July 2018 and the general disagreement of the scientific community, the European Commission has asked for a further scientific opinion to high-profile chief scientific advisors (SAM [10]) in November 2018.
Many critical points have been raised by the SAM that have been suggested might be solved by revising the GMO directive [11]. More evidences are available today on products safety and should be taken into account by countries that, like Italy, do not allow GM plants to be grown. Italy should review the implementation of the 2001 EU GMO directive to regulate the product rather than the technique used to make it.

IV. Scientific advancement, human rights and animal testing

❖ The Legislative Decree 26/2016 on the use of animals for scientific purposes

In Italy the use of animals for scientific purposes is regulated by Legislative Decree (Lgs.D.) 26/2016 which implements the EU Directive 2010/63. According to this law, all researches involving the use of animals must be authorized by the Ministry of Health and carried out in authorized establishments.
The law is aimed at protecting the welfare of animals used for basic and biomedical research, whose use must be justified by presenting a project to the Ministry, assisted by the Istituto Superiore di Sanità as a scientific evaluator, which authorizes the use of animals according to the methods described. The law defined a marked change of pace in the field of animal experimentation and, consequently, in the daily life of researchers. In fact, although the Lgs.D. 26/2016 has filled a regulatory void, the way in which it is applied by regulatory bodies is seriously compromising the development of Italian research in the biomedical field, with important and significant repercussions in terms of scientific and economic development for the country. Delays in the issuing of authorizations, lack of approvals not always justified, ineffective communication and lack of transparency in the evaluation process are the aspects that are progressively weakening both the academic and private research in Italy.
The 2016 regulation requires the Ministry to respond to requests within 40 working days. This term is constantly disregarded. An average of 4/6 months is estimated before receiving an opinion. Frequently, the authorization arrives for a reduced number of months and animals compared to those requested by the Researcher, without any explanation given. Alternatively, the Ministry requires integration or clarification without clear reasons delaying the time of authorization. A badly applied law becomes a wrong law. Italy should respect the law by issuing the decision, whether positive or negative, in 40 working days and a better transparency and communication in the evaluation of the projects.
The Italian regulation places also a ban on the breeding of dogs, cats and non-human primates for research purposes, including for the conduct of minimally invasive experiments which do not require sedation. Furthermore, it prohibits xenotransplantation and research on drugs of abuse. These restrictions make it difficult for Italy to make progress in biomedical research and be competitive at the international level. Italy should review her animal research law to ensure proper balance between biomedical progress and the protection of the welfare of all animals used in research. This would make her national legislation comply with the requirements set out in the EU Directive 2010/63 and with the international human rights standards in the field of health and science.

V. Access to health services, goods and facilities

❖ Mental health

The conditions of Italy's mental health system, highlighted by the Health Ministry Report and by independent analysis by the Italian Society for Psychiatric Epidemiology, are worrying for several reasons. Only 3.5% of the health budget is dedicated to it (other countries such as France, Germany, Spain and UK spending over 10%). This is happening when all statistics indicate an increase in psychological discomfort among the population, evidenced by enquiries from ISTAT [12], CENSIS [13] and the Observatory for psychopharmaceuticals. Mental health services also need to confront new and extraordinary needs: from community management of psychiatric patients who commit crimes, after the permanent closing of the Forensic Psychiatric Hospitals, to the conditions of psychological suffering for non-EU migrants, associated to precarious social and existential conditions, to the real "hidden epidemic" of people who simultaneously use controlled narcotics and have psychological problems.
The data from the different regional health systems signal other unacceptable inequalities of access to the Mental Health Departments, and macroscopic differences in the caring processes, which should be provided according to the best scientific evidence and not according to the "postal code lottery". In this sense, the fear of those believing that such inequalities will increase with the progress of the "differentiated regionalism" seems well-founded, in the absence of a central function of address and evaluation.

❖ The Convention on the Rights of Persons with Disabilities

On 25 August 2016, the UN Committee on the rights of persons with disabilities expressed worries in reference to the report on Italy for the variations from region to region within the country and the unequal access to people with disability to services according to the place in which they live. It underlined the need to name a focal point for the rights of persons with disabilities in every region, to do a monitoring of the absence of discrimination and equality of treatment everywhere in the country. Italy is exhorted to review the support system of the administrator to support the decision-making process, to recognize "sign language" and to establish an independent national institution for human rights in line with the Paris Principles [14].
Since 2016:

- nothing of what is described above has been done;
- the country still lacks a reform of the health system that respects the principle of equal access to treatment; the full application of the UN Convention on the rights of people with disability; the removal of architectural barriers through the launch of policies in line with an independent life and the update of the list of Essential Levels of Assistance and the tariff list of aids and prosthesis.
- In addition, the "right to a signature" is not guaranteed for people who cannot do it manually.

It is noticeable in addition that:
The adoption of the second programme of biennial action for the promotion of the rights and the inclusion of persons with disabilities No. 289 of 12 July 2017 [15] presents problems. Besides not being realistic, it does not mention a plan of action to adhere to the important observations

of the UN Committee on persons with disabilities of March 2016, that, among other things and with a certain emphasis, noted what Italy is lacking in terms of reliable instruments to monitor/verify the effective application of the UN Convention. In addition, the National Observatory on the condition of persons with disabilities – which designed the document of this Programme – is in no way the organ foreseen by the Convention, as it does not possess the requisites of autonomy and representation, necessary to be the point of contact with the Committee according to the Paris principles.

❖ The living conditions of persons with disabilities

Even in the presence of a remarkable legislation, the concrete living conditions of persons with disabilities are very often at the limits of acceptability, to the point that many experts started asking whether it still makes sense to speak of rule of law for the people concerned. The effective societal inclusion and a direct involvement in active life from disabled people – necessary precondition to fully develop their personality – still remains a not even remotely achieved goal. The marginalisation and lack of inclusion that people with disabilities face is the result of an approach of discrimination towards the "different" which is still rooted into society and institutions, that increasingly puts weaker people in the background, because they could be a source of perturbation of general well-being and peacefulness. In such a context, Italy needs first of all to take all necessary steps to allow the full enjoyment of the rights foreseen in international documents and guarantee to people with some forms of disability the possibility to fully enjoy conditions for a free and dignified existence, thus fully carrying out the dispositions of articles 2 and 3 of the Constitution.

❖ Medical research on controlled narcotic and psychotropic substances

Cannabis

In Italy since 2007 it is possible to prescribe cannabis-based products for a series of conditions. Since 2014, after an agreement between the Ministries of Health and Defence, the Florence Military Pharmaceutical Institute produces cannabis inflorescences for therapeutic use (FM2); the need estimated by the government in 2018 was between 700 and 1000 kg for the next few years. In 2014 cannabis was placed in schedule II of the national law on drugs. Even though in Italy there are centres of advanced research for pre-clinical trials, there are very few human trials with cannabis, despite since 2014 therapeutic cannabis is administered for some diseases listed in the decree of 9 November 2015. Italian research to date has been carried out mostly thanks to the goodwill of health workers in the surgeries that prescribe therapeutic cannabis. Italy should adopt a clear regulatory framework to allow and fund research of FM2 and clinical trials with cannabinoids.

Other controlled substances

Other psychotropic substances are listed in Schedule I of the 1961 UN Convention on drugs, which contrary to Schedule II includes many restrictions on production and circulation. Schedule I contains heroin, psilocybin, mescaline, cocaine, amphetamines, for which possession involves severe criminal sanctions excluding their potential therapeutic use. These same controlled substances, in particular psilocybin, MDMA and DMT, are the focus of advanced research in

institutions such as Imperial College London, the New York School of Medicine, the Sant Pau Hospital in Barcelona, among others. In some cases, the state of research has moved beyond the preclinical phase and ongoing studies tend to show the therapeutic properties for diseases such as pain in oncological patients, PTSD, and some forms of drug dependencies. The financing of this research is mostly private or from not-for-profit organisations; in the UK it also receives public financing. In Italy research and clinical trials do not exist for substances in Schedule 1, not due to a clear prohibition but because of a chain of causes linked to the complications of using substances under strict national and international controls.
In terms of health rights, Italy needs to improve her data collection system relative to the real national need of cannabinoid or derived from cannabis products and increase its national production, including through public-private partnerships; in terms of the right of science, Italy should support studies on cannabis-based products, starting from the varieties that she produces; finally, in terms of the right to science, Italy should promote studies on other controlled substances aimed at introducing benefits from a wider range of therapies for various conditions including treatment for problematic drug users.

VI. Investment and evaluation policies in scientific research

❖ Investment in scientific research and Gross Domestic Product (GDP)

According to a document published in 2018 by the National Council for Research [16], Italian scientific research has been for decades living a situation of under-financing with respect to all main developed countries, with investment in proportion of GDP almost half the European average of 3% [17]. Inside this structural hardship, the South of the country is recognised as a particularly suffering and underdeveloped area. To try and recoup the marked delay in investment, the European Union has granted conspicuous funds dedicated to the Target Regions 1, including Campania, Puglia, Calabria and Sicily. The central government has not used this help, spending only half the funds and delaying the payment of projects up to five years after the grant and reporting date. Such delays are bringing the scientific research system to collapse, impeding even the simple payment of bills in some structures that survive by taxing the competitive financing received by researchers. By now, the latter see their professionality and ability to conduct research of the same level as that of other international actors debased and offended. Italy should significantly fund national research institutes and universities to meet her commitment to invest 3% of national GDP.

VI. Gender equality in the workplace and science

According to the 2017 report "The Pursuit of Gender Equality: An Uphill Battle" [18] by the Organisation for Economic Co-operation and Development, in Italy, almost 40% of all graduates in science, technology, engineering and mathematics (STEM) is represented by women against a 31% average in OECD countries. Despite the number of male employees continue to be higher in the ICT sectors, a gender gap in this area persists.

A key challenge for Italy remains that of facilitating the entry and stay of women in the labour market, less than half of working-age women are employed, and the gender gap in the employment rate, equal to 18 percentage points, one of the highest among the OECD countries. While gender gaps in employment are particularly high among the least qualified, skilled and scientific jobs, significant imbalances still exist.
Italy should make STEM more attractive for women and reduce the gender gap in employment. Also, it should capitalize on the benefits of progress of women in STEM to stimulate innovation and business development. Finally, should exploit new technologies to offer the opportunity to promote flexible working hours that help both men and women in STEM to reconcile the time devoted to work and that dedicated to the family, with potential positive effects on the balance of gender in the activities of domestic work and care of members of family.

- **Embedding evidence-based evaluations of the living environment in the Italian institutional practices**

The importance of linking the research lying on the intersection of human health and the living environment with policy-making is recognized by the Healthy City Network of the World Health Organization [19] and by the UN Global Compact Cities Programme [20]. Such transdisciplinary research field investigates the quality and impacts of urban and rural habitats on human health and ecosystems; by so doing, it contributes to advance the practice of evidence-based evaluation of plans, programmes and policies within institutional practices and to inform the respective social debates. Since the entry into force of the Environmental Impact Assessment (EIA) Directive in 1985 and the Strategic Environmental Assessment (SEA) in 2001, the European Union has given great impulse to the adoption of evaluation approaches that strive for a balance among human, environmental and spatial development. The EU structural research funds contribute to this objective further.
In Italy, the implementation of the Environmental Impact Assessment (EIA) Directive led to the establishment of the first Ministry of Environment (Law 349/1986). Generally, relevant and following evaluation frameworks from the national to the local level guarantee the publicity and accessibility of procedures. Nevertheless, two main limitations to their effective implementation seem to characterize the Italian context, namely:

a) The high degree of variability of legal frameworks and of relevant procedures;
b) The inability of evaluation processes to penetrate public debates effectively.

These limitations, well-documented in literature, may cause the replication of analyses, methodological and procedural inconsistencies among them and changes of the actors involved within the very same evaluation process (as seen in e.g. the Lyon-Turin High Speed Rail project). This impasse could be partially overcome by establishing an independent 'science-policy' agency with the mandate of elaborating evidence-based evaluations of the impacts of plans and projects on human health and the environment irrespective of any contingent political mandate. Such independent body could be better suited to establish a trustworthy dialogue with citizens and informing public debates on the living environment based on accessible evidence-based evaluations, therefore responding to UN recommendations.

❖ **Evaluation of scientific research**

Increasing competition among scientists for research funding and academic positions has lead worldwide to the phenomenon known as "publish or perish", which pressurizes scientists into continuously producing "publishable" results. This has been linked to conflict with their objectivity and integrity [21].
The pressure on the system is largely due to the practices of evaluation of research at all levels (single papers, individual scholars, departments, universities and research institutions), and expressed with an increasing attention to university rankings and journal metrics. Centralised research assessments are emerging in several countries. The situation is particularly worrying in Italy, where the National Agency for the Evaluation of the University and Research (ANVUR), a governmental agency whose board members are directly appointed by the Ministry of Education, is in charge of the national research assessment (VQR), quality assurance for teaching, as well as evaluating the scientific qualifications for the candidates for university professorship (ASN). This is an exceptional situation in terms of governmental control on research and universities.
Since 2010, Italy has adopted a dual system of evaluation for the VQR, using peer review together with an automatic scoring algorithm based on bibliometric indicators [22]. This approach, validated in a series of studies with undisclosed conflicts of interest, has been shown to contain uncontrolled biases in the final results [23]. The evaluation has had a direct effect on public policies (such as the distribution of fundings among universities), and represents a dangerous precedent of non-evidence based policy making, where the scientific justification for the decisions made are constructed *ex-post* and not by independent scholars.
The assessments performed also suffer a transparency issue. The agency refused to disclose the data necessary to replicate the evaluations tests, as well as the data necessary to compute the bibliometrics thresholds [24] that a candidate needs to meet in order to apply for the national scientific qualification (ASN). This makes independent investigation from the public impossible.
These issues could be partially solved by changing the governance and the structure of ANVUR, that should become a fully independent body, and by a complete disclosure of the evaluation practices and of the methods used thereby (to be modified according to the suggestions expressed by the National University Council [25]) .

❖ **Research funding policies for rare diseases**

Even though the European Commission has identified rare diseases as a priority in public health since 1993, this research field has not been included in the priority agenda for 2019 issued by the Italian Ministry of Health (MoH).
As a further evidence of the low interest for rare diseases, a 2017-2020 National Plan for Rare Disease has not yet been provided.
In 2018 the MoH contributed to the "E-Rare 3" programme - the third phase of the ERA-NET "E-Rare" programme - with a budget of one million euros.
The 2018 E-Rare call has supported EU, non-EU and associated countries to conduct research activities in the field of rare diseases. However, Italian regulation does not allow academic research centres to receive funding from the MoH. This situation, together with the lack of

resources invested in scientific research, hinders the possibility to make progress in research of rare diseases.

Italy should consider rare diseases within her research priorities and include academic research centres for the allocation of available resources.

Italy should also establish a national research agency responsible for the monitoring of the allocation of resources.

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