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Gender-specific medicine: it's the law in Italy

An exceptional result, this is how insiders referred to the arrival in our country of a law on gender-specific medicine. The Lorenzin Decree-Law was approved on 22 December 2017 by the Senate, after an intense amount of work involving people from the institutions and health sector. Then, almost at the end of the legislature, another change, designed to finally open the doors to gender-specific medicine in Italy: the Bill on gender-specific medicine, the first signatory of which was the deputy Paola Boldrini a member of the Social Affairs Commission, was converted into an amendment due to end of legislature requirements, and included as article 3 (*Application and dissemination of gender-specific medicine in the National Health Service*) in the Lorenzin Decree-Law at the end of July 2017, and approved by the Chamber and Senate with the provision's entry into force on 15 February 2018[1].

For the first time there is a guarantee that medicine in Italy will focus on all gender-related applications at national level both in clinical drugs testing (art. 1) and throughout the entire clinical-diagnostic process (art. 3). Particularly, article 3 entitled "Application and dissemination of gender-specific medicine in the National Health System", which is nothing other than a summary of Bill 3603/2016.

It was a fast process, something that not all Bills are fortunate to have. But this hides a ceaseless commitment and determination, set in motion to achieve this objective, which represents an unprecedented result in Italian and European law.

An objective for which Paola Boldrini has worked relentlessly and in synergy with the work of many other people, with the steadfast conviction that a national law is needed to help bypass the autonomous workings of the regional health services and allow gender-specific medicine to be applied and disseminated, on the understanding that the recognition of sex and gender differences in research, diagnosis, prevention and treatment is now an inevitable trend.

The law is the mainstay that represents fairness and appropriateness in care, fully respecting the right to health, based on article 32 enshrined in the Constitution. The Ministry of Health is committed to implementing a Plan to disseminate gender-specific medicine through disclosure, training and information about healthcare practices that take account of gender-related differences in research, prevention, diagnosis and treatment so as to ensure the quality and appropriateness of the services delivered by the National Health Service uniformly throughout the country.

What will happen now? The Ministry of Health will have to draft two of its own application decrees: one, drawing up the Plan for disseminating gender-specific medicine, using the services of the National Centre for gender-specific medicine in the *Istituto Superiore di Sanità*, after consulting with the permanent Conference for State-Regions relations; the other, which will have to define the National Training Plan, together with the MIUR, to ensure that knowledge of sex and gender differences is disseminated in research, prevention and treatment.

All this will have to be prepared and implemented within 12 months from when the law comes into force. The fact that two decrees have to be prepared is not a hindrance and should not give rise to alarm, according to Paola Boldrini, since a number of active, experimental applications already exist nationwide and these may be used as a reference to draft the necessary texts and hence streamline the decree process. On example, regarding university training, is the Permanent Conference of Deans of Medicine and Surgery Degree Courses which in December 2016, in line with the text of the original Bill on gender-specific medicine, unanimously approved a motion that gave rise to the pilot project in which teaching sensitive to sex and gender differences is already up and running in the current 2017-2018 academic year.

So, really important results if one thinks that the need for a gender medicine law has been discussed for more than twenty years. The implementing decrees are being prepared. Certain things are already in place and the innovative system imposed by this law should go hand in hand with the new health plans. This is accompanied by the nascent Observatory on gender-specific medicine which will be coordinated by the *Istituto Superiore di Sanità* and will be the means of monitoring and coordinating the progress of gender-specific medicine in the health field.

This issue also features a number of contributions that are really interesting from the standpoint of purely

social aspects. In the article *Gender differences in three African societies: effects on health management*, the surgeon Piero Narilli from the Sapienza in Rome, talks about the initiatives started in Africa to tackle the social and health emergency he himself experienced at first hand, with the humanitarian missions "Ridare la Luce" ("Bringing back the light"), for the treatment of cataracts, a condition that affects a large part of the population and leads to blindness, and "4 stelle per l'Uganda" ("4 Stars for Uganda") , in collaboration with the Armed Forces, which provides programmes for consultations, general, endoscopic, gynaecological and orthopaedic surgery and laboratory analyses. Gender differences have a completely different character in countries such as Uganda, Mali and Libya, where the conditions of extreme poverty and the religious component have an impact on care and treatment pathways for the population, who are forced for economic reasons to resort to "traditional" medicine[2].

Cerebral haemorrhage and women is the subject discussed by Valentina Arnao, Marta Fedele, Riccardo Altavilla and Valeria Caso in *Conventional vascular and specific risk factors for intracerebral haemorrhage in females.* Cerebral haemorrhage, responsible for 10-15% of all stroke cases, is associated with high rates of mortality and disability. Advanced age, arterial hypertension, amyloid angiopathy, smoking and alcohol consumption are risk factors common to men and women. However, even today, very few studies have been conducted to assess the sex-specific factors related to this condition. The data available at the moment suggest that pregnancy and cerebral vasoconstriction syndrome may be correlated with a greater risk of cerebral haemorrhage in women. However, further perspective studies will be required on large populations to understand the real impact of these factors and suitable treatment and prevention strategies will have to be developed[3].

The role of gender in Parkinson's disease by Marina Picillo, Alessandra Nicoletti, Vincenza Fetoni, Barbara Garavaglia and Maria Teresa Pellecchia, examines the role of gender differences, now recognised as significant by biomedical research, in affecting the risk of developing neurodegenerative diseases. This work has gathered the evidence available on gender differences in Parkinson's disease, with a focus on pregnancy in women with Parkinson's. The women are characterised by having a 'more benign phenotype' to the onset of disease but also feature a greater risk than men of developing over time complications linked to the treatments. Has the time perhaps come to reconsider the concept of the 'more benign phenotype' in women with Parkinson's?[4]

Gender and endocrinological diseases is the focus of the review written by Rosa Lauretta and Marialuisa Appetecchia, from the *Istituto Nazionale dei Tumori Regina Elena IRCCS Roma*, and Massimiliano Sansone and Francesco Romanelli, from *Sapienza Università di Roma*, entitled *Gender in endocrinological disease: Biological and clinical differences*. Gender affects the physiology of men's and women's bodies in the same way as the development of diseases. The key role is played in this sense by the sex hormones, particularly oestrogens, which are capable of activating multiple biological mechanisms underlying the physio-pathological diversity of men and women. In the study the authors actually focus on the effects that the sex hormones have in respect of gender differences in endocrinology. In addition, diseases that are very widespread amongst the population respond to gender diversity, but the same basic metabolism is highly influenced by the sex hormones. Scientific evidence also shows the effect of these substances in the pathogenesis of autoimmune endocrinological diseases and, last but not least, in the response to treatments and their efficacy[5].

Rosy Musumeci and Manuela Naldini from Turin University, in the original *Parenting in Italy: exploring compliance and resistance to the expert-led parenting model during the transition to parenthood*, explore the broad theme of parenting. The article features the stories of 22 middle-class dual-income heterosexual Italian couples, collected between 2010 and 2015 in Turin, before pregnancy and 18 months from the birth of their first child, involving a total of 88 longitudinal interviews. The research investigates the role of scientific knowledge and perinatal and child specialists in defining the notions and standards of 'good' and adequate parenting. This involves analysing ideas and beliefs about the parents' role, which is found to be extremely important in influencing not only the delivery of services to assist parents but also the policy objectives one wishes to pursue[6].

Rita Biancheri, Annalaura Carducci and Rudy Foddis, from Pisa University, together with Antonella Ninci and Chiara Breschi, from INAIL, in the review *Positive strategy for gender differences for integration in risk assessment*, suggest that a gender perspective be applied in relation to workplace health and safety using precise and concrete tools in every production area. The article achieves that purpose, filling an important gap in this specific area of study. The researchers also focus their attention on prevention with an integration perspective. Regarding gender differences in risk assessment, the approach used to be based traditionally on bio-medical factors, whilst the study is more in favour of a broader multidimensional concept of health. It is time for the old methodologies to make way so that psychological, social and cultural factors can be considered. The study opens up new areas for research and new validated experimental models[7].

Luca De Fiore from Il Pensiero Scientifico closes this overview of contributions with the perspective *For gender-oriented scientific communication*. Scientific commu-

nication still suffers from far too much gender-related conditioning. Despite the rise in the number of women in medicine and the even higher number of women enrolled at the Faculty of Medicine, we are a very long way from concrete equal rights between male and female researchers in the medical-scientific field. There is no doubt that this goal is hard to achieve and that action must be taken on several fronts. The male universe occupies an enormously advantaged position also in the field of academic medicine and the production and dissemination of research. One figure for everyone: in 2006 in the United States only one quarter of the university teaching body was represented by women; a female professor earned 20% less than her male colleague. Few articles written by women, few leading female signatories, numerous obstacles impeding a woman's career, not least motherhood. De Fiore comments with a common sense of bitterness that the road to equality is still very long[8].

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