

CHAMBER OF DEPUTIES OF THE ITALIAN PARLIAMENT

A bill of Law

Proposed by the following deputies:

Vargiu, Capua, Oliari, Vezzali, Cusin, Cimmino, Librandi, Materrese, Peipoli, Quintarelli, Vecchio

Legislation concerning Gender Medicine

Submitted to the Chamber on 5th August 2013

My right honourable colleagues,

Women and men will be affected by differing pathologies during their lifetime and will show differing symptoms even for the same pathology. It is a fact, for example, that women fall ill more often and take more medication than men. Moreover, diseases common to both men and women such as osteoporosis, arthritis, arthrosis and mental illnesses affect women more than men due to various factors such as biochemical, physiological and social differences.

Breakthroughs in research, although not focused on in current medical-scientific literature, clearly demonstrate that gender differences have a huge impact on the incidence and the development of various pathologies. Pathologies often result in a diversity of symptoms, clinical paths and outcomes depending on gender.

Cardiovascular diseases are a case in point: while such diseases are the principal cause of death for both men and women, the incidence of heart disease in women tends to occur at least ten to twenty years later in age than in men, and to result in differing clinical cases and pathways according to gender.

The distinctive nature of female biology and behaviour calls for the raising in awareness of preventative healthcare and treatment of diseases specifically for women, and female patients need to be given more gender-specific information about their pathologies. The current medical approach is to treat female patients as if they were male organisms, thereby providing them with inappropriate medical care.

Until now, clinical studies have been based exclusively on the concept that the end patient is male. This methodological error is due, according to pioneers in the field of gender medicine, to prejudice and a lack of courage within the scientific community. The consequence of such practices is to put women at a disadvantage in relation to men, with serious shortcomings and asymmetry in terms of the type of medical care they receive. The existence of flaws in the current system calls for the adoption of gender medicine at all stages of medical and pharmacological research; including the design, performance and management of clinical research.

In view of expert opinion on gender medicine, The World Health Organization has introduced the *equity act* lending weight to the idea that non-discrimination should be promoted through the provision of appropriate medical care. In 2011, The European Parliament passed a resolution recommending that more attention be given to women's health and inviting member states to encourage and support medical and pharmacological research into the specific pathologies that affect women at all ages.

Introducing a series of national regulations which acknowledge the importance of gender medicine would raise its status within the scientific community, and would be a significant step in the right direction. It is a step which many in the medical field welcome as a sign of progress. It would undoubtedly do much to contribute to broadening the medical and pharmacological cultural vision towards one which pays more attention to the entire lifecycle of women, and thus goes beyond the current approach of focusing on compartmentalized phases in a woman's life with an almost exclusive interest in women's reproductive role.

Regulatory action at a national level is an absolute necessity in order to guarantee legal standards that would allow for the creation of an organizational framework based on the experiences and know-how of individual Regions which have already made headway in establishing gender medicine practices in Italy.

Some Italian Regions such as Tuscany, Puglia, Piedmont and Emilia-Romagna have already introduced local regulations favouring the incorporation of gender medicine in regional healthcare. Further positive examples in the field include the work of the national watchdog for women's health. This body was set up in 2005 with the express aim of engaging in research, providing information and education and generally putting a spotlight on women's health in collaboration with authorized bodies on a national scale; The Italian Health and Gender Group has also contributed to gender medicine by organizing educational programmes for the general public, as well as training courses for healthcare workers.

In conclusion, the proponents of this bill of legislation wish to promote gender medicine at a national level and view gender medicine as fundamental in light of a scientific and medical paradigm shift which rightly takes into account the relative biological differences between men and women.

The ultimate goal of the proposed bill is the provision of medicine based on scientific evidence and personalized according to gender in order to ensure more gender appropriate medical care and treatment, and, as a result of this, an eventual reduction in costs to the national healthcare system.

To accomplish this, this bill of law necessitates the involvement of staff working within institutions and in the medical field to make information on the topic public, and to raise awareness about gender medicine through regular, ongoing training and research projects.

The governmental bodies included in this process will include: the Ministry of Health; the Ministry of Education, Universities and Research; Regional government; the National Health Institute, the

Italian Medicines Agency; the institute of regional health boards, and the European Medicines Agency.

The proponents of the bill wish to stress the pressing necessity to address and correct the clearly discriminatory nature of current medical care and research, and bring it into line with Article 32 of the Constitution.

The proposed bill includes six Articles: the first states the end goal and the objectives of the proposed law; the second officially recognizes the importance of gender medicine by introducing it at a national level and promoting its adoption in regional and provincial health policy; Article 3 indicates the measures required to support and promote gender medicine research, while Article 4 outlines the measures needed to make a gender medicine approach more widespread within the scientific community, starting with medical and surgery students; Article 5 calls for the creation of a national Committee to oversee gender medicine provision; and lastly, Article 6 establishes its legal enactment.

A Bill of Law

Article 1

1. The present law introduces clearly defined regulations with regard to gender medicine, in order to guarantee national healthcare provision of a superior quality and which is more gender-appropriate in nature.
2. In compliance with Article 32 of the Constitution, this law:
 - a) Establishes the need for gender medicine to be introduced at a national level by taking an interdisciplinary approach involving various medical fields which is fundamental to guaranteeing appropriate medical care.
 - b) Promotes teaching and research, guarantees effective ongoing and recurrent training of medical personnel, as well as educating the general public about gender differences regarding clinical pathologies and their treatment.
 - c) Sets up a national gender medicine monitoring committee.
 - d) Promotes and supports research into gender medicine.

Article 2: *(promotion and support of gender medicine)*

1. The Ministry of Health, in agreement with the autonomous regions of Trento and Bolzano shall incorporate the promotion and support of gender medicine as part of national health policy. This will be undertaken using an interdisciplinary approach that involves the various

medical fields concerned, in order to ascertain the administrative criteria required to provide a national health care service which takes into account gender-specificity.

Article 3: *(Promotion and support of research in the field of gender medicine)*

1. The Ministry of Health shall finance annual key projects on gender medicine and shall introduce tax incentives to encourage and advance scientific, medical and pharmaceutical research into gender medicine as part of a series of promotional measures to achieve the aforementioned objectives.
2. The Ministry of Health, in agreement with the autonomous regions of Trento and Bolzano shall promote the nationally uniform advancement of scientific, medical and pharmaceutical research into gender medicine over a three-year period between 2013-2015 in order to uphold and comply with Article 32 of the Constitution which establishes the right for an individual to receive appropriate personalized therapeutic care specifically with regard to gender variables. This shall be achieved with the collaborative participation of the National Health Institute (ISS), the Italian Medicines Agency (AIFA), the National Institute of Regional Healthcare (AGENAS), local healthcare authorities, scientific research institutes, hospitals, nursing homes and medical schools.
3. The Ministry of Health, in collaboration with AIFA and ISS and in compliance with directives issued by the European Medicines Agency (EMA), shall make specific recommendations to prevent gender discrimination in all phases of clinical trials.

Article 4

(Gender medicine teaching; campaigns and training courses, ongoing and recurrent training programs for medical personnel)

1. Private and state universities can introduce modules in gender medicine as part of degree programmes in medicine and surgery, and specialization courses in specific fields of medicine. An interdisciplinary approach from a gender medicine perspective is to be fostered through regular training courses, masters and PhDs in gender medicine.
2. The Ministry of Health shall undertake to launch regular gender healthcare awareness campaigns designed to provide accurate information for the general public on matters concerning gender medicine.
3. The autonomous regions and provinces of Trento and Bolzano can implement gender-awareness-raising campaigns for healthcare workers and patients in state hospitals, authorized and/or subsidized private hospitals and healthcare services. To achieve this

end, the autonomous regions and provinces shall refer to expert knowledge gained in gender medicine in other EU member states.

4. AGENAS shall draw up guidelines which take into account gender differences.

Article 5

(National Committee to monitor gender medicine)

1. The creation of a National Committee for Gender Medicine under the Ministry of Health with the responsibility of collating, coordinating and sharing epidemiological and clinical data in order to achieve equal rights to health care. The creation of this monitoring body shall incur no additional cost to the national budget, and will be set up in close collaboration with AIFA, AGENAS and ISS and with the Ministry of Education.
2. The aforementioned Committee shall deliver an annual report to the Chamber which will inform the Chamber of the progress and development of the measures taken to promote and support gender medicine on a national level.

Article 6:

(Legislative enactment)

This bill of law shall come into effect the day after its official publication in *La Gazzetta Ufficiale* (the official journal of Italian law).