Law approved: gender medicine is finally on its way

Paola Boldrini comments on the approval of Article 3 of the “Lorenzin” Bill, which is a summary of the proposed law with the same title presented by the MP in 2016.

The so-called Lorenzin Bill was by the Italian Senate on 22 December 2017 and provides for the first time in Italy that medicine should be gender-based in all its applications at national level, both in clinical trials of medicinal products (article 1) and along the entire clinical pathway (article 3). In particular, the article called “Application and dissemination of Gender Medicine in the Italian National Health System” is nothing more than a synthesis of Bill 3603 with the same title that I signed and submitted to the Lower House of the Italian Parliament in February 2016. It all moved fast, unlike many other bills. It is the fruit of a constant commitment and determination to achieve this objective which represents an unprecedented result in the Italian and European legal system.

It is an objective for which I worked in synergy with many people who are firmly convinced of the need for a national law to help overcome the autonomies of regional health services and to broadly disseminate and apply gender medicine, so that recognising gender differences in research, prevention, diagnosis and treatment is a matter of fact and represents an inevitable development. The law is a linchpin that represents fairness and appropriateness of care, in full respect for the right to health, according to Article 32 of the Italian Constitution.

Now, the Ministry of Health will draw up two application decrees: one will result in the plan for dissemination of gender medicine, availing it-
self of the center of referral for gender medicine at the Italian National Health Institute and consulting the Standing Conference for State-Regions relations. The other will set out, together with the Italian Ministry of Education, the National Training Plan aimed to ensure the dissemination of the knowledge of gender and sex differences in research, prevention, diagnosis and treatment. Everything must be done within twelve months of the entry into force of the law.

We should not be frightened by the need to draw up new decrees, because gender medicine has already had several experimental applications throughout the country and it is possible to refer to these to draw up the necessary texts and expedite the decree process. For example, as regards university training, in December 2016, the Standing Conference of Presidents of Degree Courses in Medicine and Surgery, in line with the text of the original draft bill on gender medicine, unanimously shared a motion, which originated the pilot project that sees the application of knowledge attentive to sex and gender differences, already from the current 2017/2018 academic year.

I am satisfied and frankly gratified by the achieved objective, not at all taken for granted, which I wish to share with the members of institutions, scientific societies and associations, whom I have had the opportunity to meet and appreciate in recent years, people whose competence has given me the necessary energy to face and overcome the many small and large obstacles encountered on the road to the approval of the law.

Ms Paola Boldrini
Italian Chamber of Deputies
Delegation to the Government in the field of clinical trials on medicinal products as well as provisions for the reorganization of health professions and health management at the Ministry of Health.

See also

“Monzino Women”: in Milan, a center dedicated to cardiovascular prevention in women

Cardiovascular diseases are the leading cause of death in women and their recognition and early diagnosis are instruments for effective prevention. In Italy, cardiovascular diseases cause the death of over 123,000 women each year.

Until now, the relevance of cardiovascular diseases in women was scarcely considered and women were under-represented in clinical trials relating to heart disease. Moreover, although the manifestations of the disease are similar in both sexes, a clear understanding of the pathophysiological mechanisms of cardiovascular diseases in women is still lacking. Although heart diseases are more often fatal in women than in men, the treatment of these pathologies in women has been so far based on the results of medical and pharmacological research carried out on male subjects. It follows that some elements are still unclear:

1. differences in cardiovascular disease biomarkers between men and women;
2. impact of pregnancy and pathologies of pregnancy on the development at a later stage of cardiovascular pathologies in the newborn child and mother;
3. socio-economic determinants of health and their effect on the cardiovascular outcome in both sexes;
4. correlation between non-conventional cardiovascular disease risk factors and heart disease (e.g., autoimmune systemic diseases, endocrinopathies);
5. effect of psychosocial factors such as anxiety and stress in everyday life on the development of cardiac symptoms in women.

Increasing aging of the female population calls for a broader reflection on the importance that should be attached to the knowledge, awareness and prevention of cardiovascular disease, even in terms of socio-econom