

### 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-

### ITALIAN LAW No. 3 of 11 January 2018

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. (18G00019) (OJ General Series no.25 of 31-01-2018)

NB: Entry into force of the provision: 15/02/2018

#### Article 3

#### **Application and dissemination of gender medicine in the Italian National Health Service**

1. Having consulted the Standing Conference for relations between the State, Regions and the Autonomous Provinces of Trento and Bolzano and availing itself of the National Center of Referral for Gender Medicine of the Italian National Health Institute, within twelve months of the date of entry into force of this law, the Health Ministry shall draw up, by means of its own decree, a plan aimed at spreading gender medicine through dissemination, training and indication of health practices that should take into account gender differences in research, prevention, diagnosis and treatment in order to uniformly guarantee the quality and appropriateness of the services provided by the Italian National Health Service throughout the country.
2. The decree referred to in paragraph 1 shall be adopted in compliance with the following principles:
  - a) provision of an interdisciplinary approach between the different medical areas and the human sciences which takes account of the differences deriving from gender to ensure the appropriateness of research, prevention, diagnosis and care;
  - b) promotion and support of biomedical, pharmacological and psycho-social research based on gender differences;
  - c) promotion and support of the teaching of gender medicine, by ensuring adequate levels of training and updating of medical and healthcare staff;
  - d) promotion and support of public information on health and disease management, in a context of gender difference.
3. The Health Minister shall issue specific recommendations addressed to the Orders and Rolls of Health Professions, to scientific societies and to associations of health workers not enrolled in Orders or Rolls, aimed at promoting the application of gender medicine throughout Italy.
4. By decree of the Health Minister, in concertation with the Minister of Education, University and Research, National Training Plan shall be drawn up for gender medicine, aimed to ensure the knowledge and application of a gender-based approach in research, prevention, diagnosis and treatment. To this end, specific studies shall be promoted at degree courses of health professions and in the context of training plans for healthcare organizations with requirements for accreditation in continuing medical education.
5. The Health Minister shall submit an annual report to both Houses of Parliament on the promotion and support actions of gender medicine implemented throughout the country based on the indications referred to in this article, also through the establishment of an Observatory dedicated to gender medicine, set up in institutions supervised by the Health Ministry. Participation in the Observatory does not entitle to the payment of attendance fees, fees, reimbursement of expenses or other emoluments, however denominated.
6. Implementation of the provisions contained in this article shall be carried out within the limits of the human, instrumental and financial resources available under current legislation and in any case without new or increased public finance costs.

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*

Gender Medicine. We need a law. Interview with Paola Boldrini. *Ital J Gender-Specific Med* 2016; 2(3): 130-2.

### **“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-

ic impact. Women have cardiovascular peculiarities that are not only sex-specific, but also an age-dependent. The incidence of cardiovascular diseases is lower compared to men during fertile age, catches up with men in menopause, ultimately surpassing them after 75 years of age. All this stems from endocrine and metabolic changes that occur with the loss of estrogen protection. Young women are less likely to become ill but have increased mortality and complications in case of the onset of ischemic disease.

Inadequate awareness of the incidence of cardiovascular diseases in women is their worst enemy. It is therefore essential that women gain awareness of their individual cardiovascular risk that may be even higher than that of men. The female sex is also more exposed to stress and depression which represent many favoring conditions. In women, the new emerging cardiovascular risk factors (pathologies of pregnancy, eclampsia, recurrent miscarriage, polycystic ovary syndrome, endometriosis, pre-term pregnancies as well as vitamin D deficiency and autoimmune diseases) should be taken into consideration as potential predisposing factors for the future development of cardiovascular diseases. Therefore, correct information and prevention need a better relationship between research, guidelines and dissemination.

Despite these premises, women are still indicated as “special” populations in many guidelines relating to the prevention and treatment of cardiovascular diseases, although they constitute the majority of the general population. Women are different, in cardiovascular disease, also when it comes to therapy which is often started late because they themselves (and often times their attending doctors) underestimate the early signs of disease.

In early 2017, at Centro Cardiologico Monzino in Milan, “Monzino Women” was launched, with the aim of providing quality care through targeted attention to prevention, treatment and management of cardiovascular health issues in women in syn-