

Sept. 2016 – Sept. 2017:

1 year as a Gender Equality Rapporteur

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Italian Medicines Agency - AIFA

CD-P-PH 13th Meeting

Strasbourg - September 27, 2017



Agenzia Italiana del Farmaco
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Public Declaration of transparency/interests*

The view and opinions expressed are those of the individual presenter and should not be attributed to AIFA

Interests in pharmaceutical industry	NO	Current	From 0 to 3 previous years	Over 3 previous years
<i>DIRECT INTERESTS:</i>				
1.1 Employment with a company: pharmaceutical company in an executive role	✓	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> mandatory
1.2 Employment with a company: in a lead role in the development of a medicinal product	✓	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> mandatory
1.3 Employment with a company: other activities	✓	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
2. Consultancy for a company	✓	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
3. Strategic advisory role for a company	✓	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
4. Financial interests	✓	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
5. Ownership of a patent	✓	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
<i>INDIRECT INTERESTS:</i>				
6. Principal investigator	✓	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
7. Investigator	✓	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
8. Grant or other funding	✓	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
9. Family members interests	✓	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional

***Emanuele Cesta**, in accordance with the Conflict of Interest Regulations approved by AIFA Board of Directors (25.03.2015) and published on the Official Journal of 15.05.2015 according to EMA policy /626261/2014 on the handling of the conflicts of interest for scientific committee members and experts.



GENDER EQUALITY

The Council of Europe Committee of Ministers Recommendation (2007)17 on **gender equality standards and mechanisms**, establishes:

"1. Gender equality as principle of human rights and women's human rights as an inalienable, integral and indivisible part of universal human rights. Gender equality is defined as a requirement for the achievement of social justice and a sine qua non of democracy.

2. Acceptance of these principles implies not only the elimination of all forms of discrimination, legal or otherwise, on the basis of sex, but also the fulfilment of a number of other requirements that must be seen as qualitative indicators of political will to achieve substantive gender equality or de facto equality".



Gender Equality Rapporteurs

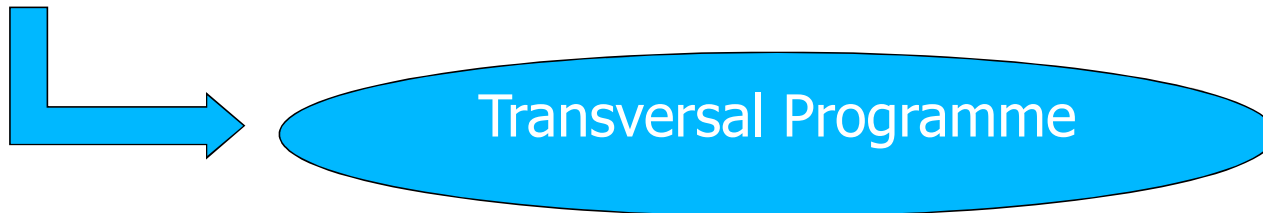
The role of GERs is essential in ensuring that everyone understands the gender mainstreaming strategy in the same way and in providing the impetus needed for its **appropriate** and **effective application**.



Gender Equality Rapporteurs

Most, if not all, Council of Europe committees and monitoring mechanisms can contribute to gender equality in member states by ensuring that their activities integrate a gender perspective [...] **taking account of the likely impact of a proposed activity on both women and men.**

GERs should ensure that a gender perspective is properly integrated during the programming process of their respective committees (i.e. the process of identifying priorities, preparing activity proposals, setting up and implementing the activities, and evaluating the results).



TEST YOUR KNOWLEDGE ON MAINSTREAMING A GENDER EQUALITY PERSPECTIVE	correct	incorrect
1. Women represent 40% of members of parliaments in Europe.		X
2. Women and men have equal access to resources.		X
3. Public policies are neutral; they affect everybody - women and men, girls and boys - in the same way.		X
4. Gender roles are socially constructed; they change over time and differ between and within cultures	X	
5. Gender-mainstreaming requires the equal participation of women and men in all programmes and activities.	X	
6. Mainstreaming a gender equality perspective entails new duties and practices for ministries and civil servants.	X	
7. Gender mainstreaming should replace specific policies for the advancement of women and positive actions.	X	
8. All ministries have duties in relation to the integration of a gender equality perspective.		X
9. Data and statistics on people, in general, should be broken down by sex only if sex-disaggregated information is readily available		X



Gender Inequality

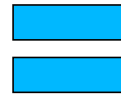
Gender inequality **is not about biological differences** but about the unequal position of women and men in society.

It is about structural, material, social and cultural differences between women and men in all areas of life, including decision making, paid and unpaid work, income, property, education, health, norms, habits, culture or roles attributed to women and men in society.

**These differences are disproportionately
to the detriment of women.**



Gender Equality



Equal Opportunities???



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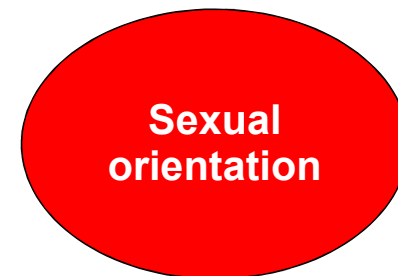
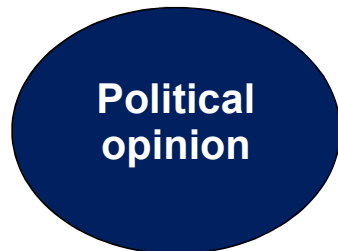
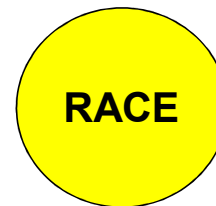
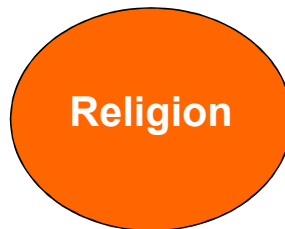
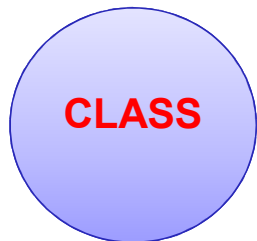
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Gender Equality/Inequality

For the Council of Europe, **Gender Equality** means:

*“an equal visibility, empowerment and participation of both sexes in all spheres of public and private life. **Gender equality is the opposite of gender inequality, not of gender difference**, and aims to promote the full participation of women and men in society.*

Gender equality includes the right to be different, in relation to:



The right to be different:

NOT "THE SAME FOR EVERYONE" BUT "TO EACH HIS OWN"



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In pharmaceutical care, gender differences should not be canceled or fictitiously ignored in tribute to a misunderstood sense of protection:

the so called

DISCRIMINATION

BY GOOD INTENTION



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Discussions and reflections emerged during the year

1 - With respect to Pharmaceutical Care:

Electronic leaflets accommodate the needs of refugees in particular women and children who must have access to correct information about medicines in a language they can understand (Memorandum on electronic leaflets drafted by the Council of Nordic Ministers)

Pregnancy turns into a pre-pathologic condition in all countries, such as India, where «*women die from poor maternal health care*» or whenever it implies a therapeutic choice between the mother or the fetus's health .

The subject of how women and men follow instructions arose a discussion about e-leaflets. Following training at the Council of Europe on gender equality and gender mainstreaming, Mr. Magnusson expressed his concern at how little gender issues actually come up.



Discussions and reflections emerged during the year

2 - With respect to Pharmaceutical Care Indicators:

Do the current Pharmaceutical Care Indicators duly consider women's exposure to risks in daily life as well as in clinical practice?

#1 - As the pharmacies represent the first presidium people turn to in case of health problems, pharmacists and hospital healthcare professionals should ensure adequate consultancy and assistance to female patients.

#2 - As the repartition and allocation of pharmacies on the territory is not uniform, women living in rural and country areas face difficulties in reaching pharmacies or hospitals, especially if old aged, physically disabled, with no family support or unable to drive.



Discussions and reflections emerged during the year

3 – with respect to risks posed by Falsified medicines

Among the 9 main risks that women face when buying fake drugs online, some health damages are peculiar to the female gender (disfiguration, uterine infection, breast cancer and post-partum hemorrhage), whilst the serious consequences arisen by malaria are *“particularly deadly for pregnant mothers and their unborn children”*.

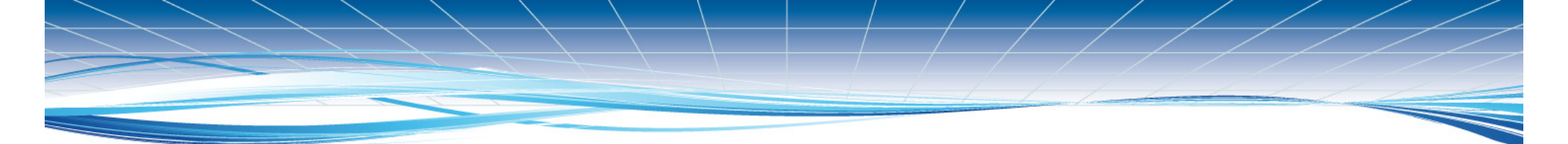
Though it is difficult to customize a “fake drug purchaser”, women are more likely to turn to the illegal online market, being generally poorer, more vulnerable and exposed to violence, physical/psychological stress and social diseases.



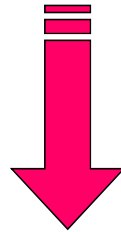
Gender blindness

- ✓ Under-representation of women in pharmacological trials
- ✓ Failed initial trials put at risk molecules which may be useful for the female gender
- ✓ Dose finding based on male individuals
- ✓ Scarce analysis of gender pharmacokinetic and pharmacodynamics differences
- ✓ Scarce investigation on the gender differences in efficacy and toxicity
- ✓ Scarce investigation on the influence of hormonal fluctuation and of the phase of the reproductive cycle





Gender medicine lies on the investigation on biological and socio-cultural differences and similarities and the Promotion of a research aimed at improving health and healthcare systems including not only gender but also the sexual orienteering, age, social-economic status, ethnicity, disabilities.



Gender pharmacology underlines and defines possible differences in drug efficacy and safety with respect to gender, including differences deriving from the complexity of women reproductive cycle.



The “woman paradox”

- ✓ Women have a longer longevity than men
- ✓ Women report and suffer from a higher number of pathologies, disabilities and days of hospitalization
- ✓ Men in old age look sturdier and stronger, but die more and earlier
- ✓ Women live longer but in worse conditions



Gender-oriented initiatives by the Food & Drug Administration

1. Publication of 2 specific Guidelines:

- ❑ Guideline for the format and content of the clinical and statistical sections of new drug applications (1988)
- ❑ Guideline for the study and evaluation of gender differences in clinical evaluation of drugs (1993)

2. Institution of a dedicated Office of Women's Health (1994)

3. Final Rule on the Investigational New Drug Applications (1998)

4. Institution of the FDA-MA Women and Minorities Working Group (1999- Modernization Act)

5. Publication of studies, researches and periodical reports



International mainstreaming initiatives

- ✓ In 2007 the **WHO** instituted the "*Department of Gender, Women and Health*" in the document Gender and Health: "*the necessity to develop gender medicine in order to optimize therapies and prevention with regard to the female target, as a different conduct with respect to the male target is more and more evident*".
- ✓ The **NASA** launched pioneering programs for the study of physiological differences between men and women with respect to space journeys.
- ✓ Departments dedicated to gender medicine in prestigious universities and hospitals - the Columbia University of New York established a "Partnership for Gender Specific Medicine"; the Georgetown University created a "*University Center for the Study of Sex differences in Health, Aging and Disease*".



The European Medicines Agency (EMA)

- ✓ The European regulatory framework provided no specific policies for the involvement of women in clinical trials. The required presence of demographic data, including sex, and related statistics evaluations on any sub-population (among which “women”) in the filing of clinical trials was considered a sufficient provision (ICH Guideline E3-Structure and Content of Clinical Study Reports).
- ✓ In January 2005, via the CHMP, EMA adopted a document to tackle the gender theme in the field of community procedures.
- ✓ Unlike what happened for the geriatric and pediatric population, the drafting of a specific Guideline was not deemed necessary, as the direct and indirect references to gender are (already) included in a series of International Guidelines (ICH) (EMA/CHMP/3916/2005).



Gender-oriented policies in Italy

- ✓ Working table “Women’s health and drugs for women” (ISS-AIFA-ASSR and SIF)
- ✓ Commission on women’s health: Working Group “Gender approach to the health” (2007) which gave birth to the Report “Health State of Women in Italy (2008)”
- ✓ Financing programs in cooperation with the Ministry of university and research, through the Finalized Health Research – Strategic Programs dedicated to the woman’s health
- ✓ National Bioethic Committee



AIFA gender-oriented policies

- ✓ Introduction of gender equality among the criteria taken into consideration by the evaluation committee of the Program Agreements.
- ✓ Specific Gender themes in public tenders for Independent Research Programs funded by AIFA
- ✓ Editorial and educational activities
- ✓ Publication “Drugs and pregnancy” for a proper use of drugs in the mother-infant area
- ✓ Institution of a Gender-oriented working group



AIFA "Drugs and Gender Working Group"

- Scientific support to the Technical-Scientific Committee for evaluating gender-related problems
- Guidelines on gender pharmacological trials and gender statistic analysis
- Sensitizing of Ethics Committees
- Incentive of sponsored and independent gender research
- Dissemination of gender culture, high formation courses, seminars, publications
- More information to the citizenship and sensitizing campaigns



AIFA Press Release on “Drugs and Gender”

In January 2013, the Italian Medicines Agency issued a press release addressed to the pharmaceutical industries submitting registration dossier of new medicinal products, in order to sensitize them to perform a processing of gender-disaggregated data, so to detect any possible difference.

Moreover, a further stratification upon age classes in the analysis of the female population would clearly detect its impact on the variability in therapy response.



How can we further contribute?

- Collect gender-specific data, analysis and evaluations on drug consumption and expenditure in territorial and hospital assistance, and gender differences in adverse reaction spontaneous reports through the National PhV Network
- Evaluate and size women representation in clinical trials and related registration dossiers
- Stimulate the development of a gender culture in institutional tables, committees and working groups, healthcare professionals, pharmacists, citizens and patients.



Not exclusively woman

Both woman and man are subject to gender bias.



Gender medicine should aim at investigating the differences based on the gender, without focusing exclusively on the female gender.



Not exclusively woman

Gender-based medicine therefore has to deal with health issues in both women and men. Thus, gender-based medicine is not about creating a new medical discipline but rather about introducing new perspectives and creating a nexus between genders.

Gender prejudice may as well impact the male sphere when dealing with pathologies usually considered as restricted to the female population (migraine, depression, osteoporosis, etc.)





Gender
Key Indicators?



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Thanks for you attent... ehm...



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