

Expert Workshop Sex and Gender in Medicines Regulation and Medical Education

4th March 2015, 09.00-17.30

Room TRE7701, 7th floor, Trèves Building, 74 Rue de Trèves
European Economic and Social Committee, Brussels

Research addressing Sex and Gender (S&G) in biomedical science and health research is a novel and highly promising field. The interaction of S&G related mechanisms leads to different manifestation of diseases in women and men, such as infarction, heart failure, diabetes, rheumatic disease. The European Gender Medicine Project (EUGenMed) will produce an innovative roadmap for the implementation of S&G in biomedical, public health and clinical research and create a European Gender Health Network.

Part 1: Sex and Gender in Medicines Regulation

Translating the evidence from S&G research into regulatory practice will lead to more targeted, effective opportunities for prevention, treatment and care. This workshop will examine how S&G consideration are integrated into Medicines Regulation and information.

Co-Chairs

Dr. Ingrid Klingmann, Chairwoman, European Forum for Good Clinical Practice (EFGCP)
Ms. Hildrun Sundseth, President, European Institute of Women's Health (EIWH)

- 09.00-09.10 **Welcome**
Dr. Ingrid Klingmann, EFGCP, and Hildrun Sundseth, EIWH
- 09.10-09.20 **Opening Address**
Ms. Ingrid Kössler, Member of the European Economic and Social Committee (EESC)
- 09.20-09.40 **Sex and Gender in EU Regulatory Practice**
Dr. Kevin Blake, European Medicines Agency (EMA), UK
- 09.40-09.55 **The case of CVD and Women**
Prof. Dr. Marco Stramba-Badiale, Director, Department of Geriatrics & Cardiovascular Medicine, IRCCS Istituto Auxologico Italiano, Italy
- 09.55-10.10 **Ethics Committee Guidelines—An Example from the Medical University of Vienna**
Dr. Christiane Druml, Vice-Rector, Medical University of Vienna, Austria
- 10.10-10.30 **Discussion**
- 10.30 -11.00 **COFFEE BREAK**
- 11.00-11.20 **Moving Forward: The New Clinical Trials Regulation**
Dr. Fabio D'Atri, Medicinal Products—Quality, Safety and Efficacy Unit, DG SANTE
- 11.20-11:40 **Safe Use of Medicines during Pregnancy and Lactation**
Dr. Lode Dewulf, Chief Patient Affairs Officer, UCB, Belgium
- 11.55-13.00 **Towards a European S&G Roadmap**
Co-Chairs Dr. Ingrid Klingmann, EFGCP, Ms. Hildrun Sundseth, EIWH
EUGenMed - The Research Evidence for Integrating Sex and Gender into Clinical Studies:
Prof. Ineke Klinge - Maastricht Univ. and
Dr. Ute Seeland, Institute of Gender Medicine, Charité—Universitätsmedizin
Patient Perspective: Ms. Sophie Peresson, International Diabetes Federation
Health Professional Perspective: Dr. Katrín Fjeldsted, CPME
- 13:00- 14:00 **LUNCH**

Part 2: Sex and Gender in Medical Education

The failure to acknowledge the impact of sex and gender differences will affect the quality of health care provision, precisely what good medical education seeks to prevent. There must be a commitment to mainstream an evidence-based gender perspective throughout medical curriculum, including in graduate, medical, nursing, rehabilitation, pharmacy, continuing medical education and continuing nursing education programmes. This workshop will examine how S&G consideration can be best integrated into medical education.

Co-Chairs

Dr. Katrín Fjeldsted, President, Standing Committee of European Doctors (CPME), Iceland

Dr. Petra Verdonk, VU University Medical Centre, the Netherlands

14.00-14.15 Welcome and Introduction

Ms. Peggy Maguire, Director General, European Institute of Women's Health, Ireland

14.15-15.00 Panel Discussion A: Examples on How to Best Integrate Sex and Gender in Medical Education

Chair: Chair: Prof. Karen Ritchie, Imperial College London, Director INSERM, Neuropsychiatrie Hôpital La Colombière and EIWH Board Member, France

Dr. Petra Verdonk, VU University Medical Centre: *Making a gender difference. Challenges of sex and gender mainstreaming in medical education*

Prof. Dr. Margarethe Hochleitner, Medical University Innsbruck, Austria: *Integrating sex and gender in different curricula at the Medical University Innsbruck*

Dr. Ute Seeland, Institute of Gender Medicine, Charité—Universitätsmedizin, Germany: *Extension of S&G knowledge in medical education—the concept of eGender*

Ms. Sabine Ludwig, Charité—Universitätsmedizin, Germany: *Curricular integration of sex and gender aspects into the new modular medical curriculum at Charité Berlin*

15.00-15.20 COFFEE BREAK

15.20-16.40 Panel Discussion B: Moving Forward—What are the Opportunities to Integrate Sex and Gender in Medical Education?

Chair: Ms. Sinead Hewson, Managing Partner of The Dendrite Group and EIWH Board Member, the Netherlands

Prof. Dr. Hanneke de Haes, Department of Medical Psychology, AMC-UvA, Netherlands: *How communication was successfully integrated into Medical Education—can we use the same strategy for integrating sex and gender?*

Ms. Kristina Mickeviciute, European Medical Students Association, Lithuania: *How can we address the sex and gender gaps in medical students' knowledge?*

Dr. Katrín Fjeldsted, CPME: *How can we address the sex and gender gaps in medical professional knowledge through continuing medical education?*

Prof. Dr. Harm Peters, Association of Medical Schools in Europe (AMSE), Germany: *Association of Medical Schools in Europa (AMSE): Standard setting and quality assurance*

Dr. Janusz Janczukowicz, AMEE—an International Association For Medical Education, UK: *How can we integrate and coordinate sex and gender into medical education cross-nationally across Europe?*

16.40-17.30 Towards a European S&G Roadmap: Recommendations

16.40-16.45 Prof. Ineke Klinge - Maastricht Univ,NL,Charité—Universitätsmedizin, Berlin and EIWH Board Member.

The EUGenMed Roadmap

Discussion

Dr. Petra Verdonk, VU University Medical Centre

Dr. Katrín Fjeldsted, CPME

Ms. Peggy Maguire, EIWH



European Gender Medicine Network (EUGenMed)

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