REPORT

on promoting gender equality in mental health and clinical research (2016/2096(INI))

Committee on Women’s Rights and Gender Equality

Rapporteur: Beatriz Becerra Basterrechea

PR_INI
CONTENTS

MOTION FOR A EUROPEAN PARLIAMENT RESOLUTION ......................................................... 3
EXPLANATORY STATEMENT ................................................................................................. 20
OPINION OF THE COMMITTEE ON DEVELOPMENT ......................................................... 23
RESULT OF FINAL VOTE IN COMMITTEE RESPONSIBLE .............................................. 28
FINAL VOTE BY ROLL CALL IN COMMITTEE RESPONSIBLE .......................................... 29
MOTION FOR A EUROPEAN PARLIAMENT RESOLUTION

on promoting gender equality in mental health and clinical research
(2016/2096(INI))

The European Parliament,

– having regard to the Treaty on the Functioning of the European Union, and in particular its Article 19 and its Article 168, which lists ensuring ‘a high level of human health protection’ among the objectives of all EU policies,

– having regard to the Charter of Fundamental Rights of the European Union, and in particular Articles 21, 23 and 35 thereof,


– having regard to the Commission Green Paper entitled ‘Improving the mental health of the population - Towards a strategy on mental health for the European Union’ (COM(2005)0484),

– having regard to the EU-Compass for Action on Mental Health and Well-being,

– having regard to the Comprehensive Mental Health Action Plan 2013–2020 of the World Health Organisation (WHO),

– having regard to the WHO’s Global Strategy for Women’s, Children’s and Adolescents’ Health 2016-2030,

– having regard to the Mental Health Declaration for Europe of 2005, signed by the WHO, the Commission and the Council of Europe,

– having regard to the WHO’s European Mental Health Action Plan 2013-2020,

– having regard to the European Pact for Mental Health and Well-Being of 2008,

– having regard to the Commission’s Joint Action on Mental Health and Well-Being (2013-2016),

– having regard to General Comment No.14 of the UN Committee on Economic, Social and Cultural Rights on ‘The right to the highest attainable standard of health’ (UN Doc.
E/C.12/2000/4) and to General Comment No 20 on ‘Non-discrimination in economic, social and cultural rights’ (UN Doc. E/C.12/GC/2009),

– having regard to Recommendation CM/Rec(2010)5 of the Committee of Ministers of the Council of Europe to member states on measures to combat discrimination on grounds of sexual orientation or gender identity,

– having regard to Rule 52 of its Rules of Procedure,

– having regard to the report of the Committee on Women’s Rights and Gender Equality and the opinion of the Committee on Development (A8-0380/2016),

A. whereas the right to the highest attainable standard of physical and mental health is a fundamental human right and includes an obligation of non-discrimination; whereas everyone should have access to healthcare; whereas access to mental healthcare is an issue of crucial importance with a view to improving the quality of life of European citizens, fostering social inclusion and ensuring economic and cultural development in the Union;

B. whereas in a global context marked by an ongoing economic crisis and a sharp rise in unemployment, in particular among young people and women, the incidence of mental health problems such as depression, bipolar disorders, schizophrenia, anxiety and dementia is steadily increasing;

C. whereas the WHO defines mental health as physical, mental, and social wellbeing, and not just the absence of disease or infirmity; whereas according to the WHO, ‘mental disorders’ denotes a range of mental and behavioural disorders, such as depression, bipolar affective disorder, schizophrenia, anxiety disorders, dementia and autism; whereas the WHO defines mental health as a state of emotional and psychological wellbeing in which an individual is able to use his or her cognitive and emotional capabilities, function in society, meet the ordinary demands of everyday life, establish satisfactory and mature relationships with others, make a constructive contribution to social change and adapt to external conditions and internal conflicts;

D. whereas mental health must be seen and addressed holistically, by taking account of social, economic, and environmental factors, requiring a psychosocial all-of-society approach to attaining the highest possible level of mental well-being for all citizens;

E. whereas a holistic strategy on mental health and wellbeing must include a life-cycle perspective, taking into account different factors that affect individuals of different ages; whereas the specific vulnerabilities of teenage girls and older women must be taken into account;

F. whereas physical and mental health are interlinked, and are both central to general wellbeing; whereas it is recognised that poor mental health can lead to chronic physical conditions and that those with chronic physical conditions are more likely to develop mental health conditions; whereas despite the known links between the two, research on physical health is often prioritised over that on mental health;

G. whereas women’s and girls’ mental health is adversely affected by a variety of factors,
including prevalent gender stereotypes and discrimination, objectification, gender-based violence and harassment, workplace environment, work-life balance, socio-economic conditions, absence or poor quality of mental health education, and limited access to mental healthcare;

H. whereas almost 9 out of 10 people suffering from mental health problems say they have been affected by stigma and discrimination, and more than 7 out of 10 report that stigma and discrimination reduce their quality of life;

I. whereas attention must be paid to geographic factors of mental health and wellbeing and to differences between urban and rural environments, inter alia in terms of demographics, access to care and service provision;

J. whereas the hormonal changes during perimenopause, and the time after menopause, may affect a woman’s emotional health and lead to mental health problems, including depression and anxiety; whereas hypersensitivity to symptoms may hinder timely detection and appropriate treatment;

K. whereas determinant factors of mental health and wellbeing vary between men and women and age groups; whereas factors including gender inequality, income disparities, women’s greater exposure to poverty and overwork, socio-economic discrimination, gender-based violence, malnutrition and hunger expose women further to mental health problems; whereas according to the WHO, there is no significant gender difference in the case of severe mental disorders but women have higher rates of depression, anxiety, stress, somatisation and eating disorders, while men have higher rates of substance abuse and antisocial disorders; whereas depression is the most common neuropsychiatric disorder and is more likely to affect women than men; whereas it is also the most common illness among women in the 15 to 44 age group;

L. whereas mental health conditions and mental wellbeing are often overlooked, ignored, or suppressed, due to stigma, prejudice or lack of awareness or resources; whereas this leads many of those with mental health conditions not to seek care, and for doctors to fail to diagnose patients, or at times diagnose wrongly; whereas the diagnosis of mental health conditions is heavily gendered, with women more likely to be diagnosed with certain conditions than men;

M. whereas in particular lesbian and bisexual women, as well as transgender and intersex persons, face specific mental health issues arising from minority stress, defined as the high levels of anxiety and stress caused by prejudice, stigmatisation and experience of discrimination, as well as medicalisation and pathologisation; whereas LGBTI people may face specific mental health and wellbeing challenges which must be taken into account in any mental health strategy;

N. whereas the forms of somatisation occurring most frequently in women and more likely to be diagnosed in women than in men include fibromyalgia and chronic fatigue, the main symptoms being pain and exhaustion, although women have many other symptoms that are common to other diseases;

O. whereas transgender identities are not pathological, but are deplorably still considered mental health disorders, and most Member States request such diagnoses for access to
legal gender recognition or transgender-related healthcare, even though research has shown that the ‘gender identity disorder’ diagnosis is a source of significant distress for transgender persons;

P. whereas depressive disorders account for 41.9% of all cases of disability resulting from neuropsychiatric disorders among women, as compared to 29.3% among men;

Q. whereas the WHO has estimated that depression affects 350 million people and causes 850,000 deaths every year; whereas by 2020 this illness will be the second leading cause of inability to work;

R. whereas gender-variant prepubescent children are still subjected to unnecessary and harmful diagnostic practices, while every child should be able to safely explore their gender identity and expression;

S. whereas, because of a variety of factors, primarily concerning different gender roles and gender inequalities and discrimination, depression is approximately twice as prevalent among women as it is among men, and transgender people show significantly elevated levels of suicide ideation and attempts; whereas studies show that imposed traditional gender roles negatively affect women’s mental health and wellbeing;

T. whereas not enough attention is paid to mental health and wellbeing in education systems across Member States, or in the workplace, given that mental health is often highly stigmatised or a taboo subject; whereas education on mental health fights the stigma surrounding the subject, and it should address gender-specific vulnerabilities, gender stereotypes and discrimination facing women and girls;

U. whereas men and boys experience gendered mental health conditions; whereas in Europe, men are almost 5 times more likely to commit suicide than women and suicide is the biggest cause of death for men under the age of 35; whereas men are 3 times more likely than women to become alcohol-dependent and are more likely to use (and die from) illegal drugs; whereas men are less likely to access psychological therapies than women; whereas men and boys face gender stereotypes surrounding masculinity which may encourage repression of emotions or resort to anger, and these have an impact on men’s mental health, as well as on the phenomenon of gender-based violence;

V. whereas there are about 58,000 suicide cases a year in the EU and a quarter of those who commit suicide are women, and whereas suicide continues to be a major cause of death;

W. whereas the psychosocial all-of-society approach to mental health requires policy coherence for wellbeing, coordinating healthcare, education, employment, economic and social policies in order to attain higher overall levels of mental wellbeing;

X. whereas eating disorders such as anorexia and bulimia are increasing among adolescent and post-adolescent girls;

Y. whereas the long-term physical and mental health effects of eating disorders such as anorexia and bulimia have been well documented, as has the gender dimension of their causes;
Z. whereas at work women are more exposed to psychological and/or sexual harassment, which causes psycho-physical problems among those subjected to it;

AA. whereas social care models that address mental illness through sport, arts, or social activities should be taken into account in public health programmes in respect of prevention, treatment, and rehabilitation;

AB. whereas people with disabilities risk suffering exacerbated mental health conditions;

AC. whereas sex and relationship education is key for overcoming gender stereotypes, tackling gender-based violence, and improving mental health and wellbeing for both girls and boys and women and men;

AD. whereas mental health conditions and illnesses are one of the main causes of incapacity, adversely affecting health, education, the economy, the labour market and the EU’s welfare systems, causing large-scale economic costs and a significant adverse impact on the EU economy, giving further impetus to the need to tackle mental healthcare in a holistic, comprehensive, and gender-sensitive manner; whereas, according to a study conducted by the European Depression Association (EDA), one in 10 workers in the EU has taken time off work for depression, costing society an estimated EUR 92 billion, mainly as a result of lost productivity;

AE. whereas within the EU, Malta has 185 psychiatric beds per 100,000 people, while Italy has 8; whereas there are 163 mental health nurses per 100,000 people in Finland, while the figure for Greece is 3;

AF. whereas above and beyond biological characteristics, women’s mental health depends on factors such as the education that they have received, the extent to which they have internalised social and cultural values, norms, and stereotypes, the way in which they have lived through and assimilated their experiences, the attitudes that they have towards themselves and others, the roles that they play, and the obstacles and pressures facing them;

AG. whereas taking account of women’s diversity and their physiological distinctness from men, and incorporating these factors into both preventive and treatment-oriented health policies addressed to women, with specific measures targeting vulnerable and marginalised groups, would strengthen the effectiveness of those policies;

AH. whereas for various reasons female subjects have been excluded from toxicology, biomedical research and clinical trials, and whereas large gender gaps in research limit how much we know about the difference between women’s health and men’s; whereas, as a result, biomedical research has tended to reflect predominantly a male perspective, mistakenly assuming women and men to be identical in areas where physiological differences exist; whereas there is a lack of research on the specific needs of intersex women;

AI. whereas the exclusion and under-representation of women as subjects and of gender and sex as factors in biomedical research and clinical trials put women’s lives and health at risk;
AJ. whereas Regulation (EU) No 536/2014 on clinical trials of medicinal products for human use introduced requirements for taking account of gender in trials, but the implementation of this regulation needs to be evaluated; whereas the regulation does not specify any considerations regarding women other than for pregnant and breastfeeding women;

AK. whereas specific strategies to implement guidelines for the study and evaluation of gender differences in the clinical evaluation of drugs have not been developed by the European Medicines Agency (EMEA), despite the fact it has acknowledged that ‘some of the factors that influence the effect of a medicine in the population may be important when considering potential differences in response between men and women’ and that ‘gender-specific influences can also play a significant role in drug effect’;

AL. whereas the impacts of such drugs or medication as contraceptive devices, antidepressants and tranquillisers have on women’s physical and mental health are still poorly understood, and require further research with a view to eliminating harmful side-effects and improving care delivery;

AM. whereas the sex and gender dimensions of health imply that women face a number of specific health risks over their lifetimes;

AN. whereas there is a lack of comparable data on available, accessible and quality transgender-specific healthcare, and products used in hormone replacement therapy are not properly tested and licensed;

AO. whereas maternal mortality is regarded as a major marker of health system efficiency, quality and performance;

AP. whereas lack of access to of sexual and reproductive rights, including safe and legal abortion services, endangers the life and health of women and girls and of all persons with reproductive capacity, increases maternal mortality and morbidity, and leads to the denial of life-saving care and to an increased number of clandestine abortions;

AQ. whereas in all countries with available data, significant differences in health exist between socio-economic groups and between women and men, in the sense that people with lower levels of education, occupation and/or income tend to have systematically higher morbidity and mortality rates; whereas these health inequalities are one of the main challenges for public health policies today; whereas adverse socio-economic conditions, poverty and social exclusion have a significant negative impact on mental health and wellbeing;

AR. whereas comprehensive, age-appropriate, evidence-based, scientifically accurate and non-judgmental sexuality education, quality family planning services and access to contraception help to prevent unintended and unwanted pregnancies, reduce the need for abortion, and contribute to the prevention of HIV and STIs; whereas teaching young people to take responsibility for their own sexual and reproductive health has long-term

positive effects, lasting throughout their lifetime and having positive impact on society;

AS. whereas one in four births in the EU is now by caesarean section and, statistically, attendant health problems for mothers and children are increasing;

AT. whereas there are already dangerous gaps in provision in some Member States as a result of closures of maternity hospitals and the considerable reduction in the number of midwives and obstetricians;

AU. whereas restrictions and budget cuts imposed by national governments in the area of public health and education also make access to health and mental health services more difficult and this impacts disproportionately on women, especially single mothers, and on large families;

AV. whereas female migrants, refugees and asylum seekers may additionally suffer from sometimes very serious medical conditions as a result of a lack of proper treatment or face specific problems related to reproductive health, such as complications with pregnancy and childbirth and potential additional psychological trauma such as antenatal and postnatal depression, as well as a risk of traumatic exposure to, or consequences of, (sexual) violence and abuse, and specific risks to their mental health and well-being; whereas there are several specific challenges to providing mental health care to these categories, the extent of which varies depending on a range of factors, including where the persons have come from and the amount of time they have spent in the host country;

AW. whereas women suffer from certain forms of cancer such as breast, uterus and cervical cancers that exist predominantly among or are exclusive to women;

AX. whereas women suffering from cancer who have been subjected to surgery and invasive treatments such as radiotherapy and chemotherapy are in general more prone to depression;

AY. whereas only 10 EU Member States have set the target of screening 100 % of the female population for breast cancer, and whereas only eight have such a target for cervical cancer screening;

AZ. whereas illnesses such as osteoporosis, musculoskeletal problems and central nervous system illnesses such as Alzheimer’s and/or dementia are linked to hormonal changes that women experience at the time of menopause, or earlier because of hormonal treatments; whereas, although it is known that women are affected by these illnesses with a higher frequency than men, the gender dimension of research on such topics has been weak;

BA. whereas endometriosis is an incurable disease affecting about 1 in 10 women and girls (i.e. roughly 180 million women worldwide and 15 million within the EU); whereas this illness frequently leads to infertility and often causes high levels of pain and mental health problems, thus making it highly incapacitating for various aspects of work and of personal and social life;

BB. whereas physical and psychological gender-based violence and violence against women
and their impact on victim’s health constitute a fundamental barrier to the achievement of gender equality and women’s full enjoyment of the freedoms guaranteed by fundamental human rights;

BC. whereas women and girls who are subjected to female genital mutilation are exposed to serious short- and long-term effects on their physical, psychological, sexual and reproductive health;

BD. whereas intersex persons subject to genital mutilation also experience effects on their physical, psychological and sexual and reproductive health;

BE. whereas transgender people are still exposed to forced sterilisation in gender recognition procedures in 13 Member States;

BF. whereas systematic and adequate data collection on violence against women is crucial in order to ensure effective policymaking in the field, both at central and at regional and local levels, and monitor the implementation of legislation;

BG. whereas women who have been subjected to gender-based violence suffer after-effects, often for life, in their physical and mental health; whereas according to the WHO’s World Report on Violence and Health\(^1\), the repercussions which gender-based violence has on women can take a variety of forms: physical effects (bruising, fractures, chronic pain syndromes, disability, fibromyalgia, digestive problems, etc.); psychological and behavioural effects (alcohol and drug abuse, depression and anxiety, eating and sleep disorders, feelings of shame and guilt, phobias and panic attacks, low self-esteem, post-traumatic stress disorder, psychosomatic disorders, suicidal and self-harming behaviour, insecurity in later relationships, etc.); sexual and reproductive effects: gynaecological disorders, infertility, complications during pregnancy, miscarriages, sexual dysfunction, sexually transmitted diseases, unwanted pregnancy, etc.); and fatal effects (murder, suicide, death from a sexually transmitted disease, etc.);

Gender equality in mental health

1. Calls on the Commission and the Member States to follow up on the EU-Compass for Action on Mental Health and Well-being with an ambitious new strategy on mental health, promoting a holistic psychosocial all-of-society approach, which includes a strong gender pillar and ensures policy coherence on mental health;

2. Notes that in the EU, 27 % of the adult population, including both men and women, have experienced at least one episode of mental illness;

3. Calls on the Member States to take measures and allocate sufficient resources to ensure access to healthcare and specifically to mental health services – including women’s shelters – for all women, independently of their legal status, disability status, sexual orientation, gender identity, sex characteristics, race or ethnic origin, age or religion; calls on the Member States and the Commission to address the disparity in access to mental health provision;

\(^1\) Krug, Dahlberg, Mercy, Zwi and Lozano, 2002.
4. Notes that more research is needed on the mental health impact of gender-based violence, including verbal and psychological violence, harassment and intimidation;

5. Calls on the Commission, the Member States, and local authorities to ensure that their mental health strategies address the mental health challenges that could be faced by LGBTI people; encourages Member States to implement the recommendations contained in the Council of Europe’s document CM/Rec(2010)5, and to take account of the specific needs of lesbians and bisexual and transgender persons when developing health policies, programmes and protocols;

6. Calls on the Member States to promote the setting-up of psychological support centres for cancer patients in order to provide them with psychological support throughout their treatment and rehabilitation process;

7. Draws attention to the serious situation faced by women with disabilities, who are more often at risk of difficulties that are directly related not only to their disabilities, but also to increased social isolation and involuntary inactivity; calls on the Member States to systematically increase the accessibility of preventive psychological care for women with disabilities, and to provide psychological support for women caring for a seriously disabled child; highlights the need for a strategy and sharing of best practices on mental health and wellbeing for women and girls with disabilities;

8. Calls on the Commission and the Member States to promote information and prevention campaigns and other initiatives to raise public awareness of mental health problems and to overcome stigma; urges the Member States and the Commission to invest in formal, informal and non-formal education for mental health and wellbeing for all age groups, with an emphasis on gender-sensitive mental health conditions such as depression, anxiety or substance abuse; calls on the Member States to ensure that schools have the appropriate frameworks in place to identify and support those suffering from mental health problems, including gender aspects, and to ensure the accessibility of mental health services; notes that 70 % of children and young people who experience a mental health problem have not received appropriate intervention at a sufficiently early age;

9. Calls on the Commission, the Member States and the European Institute for Gender Equality (EIGE) to increase the collection of regular data on mental health at EU and national level, and in particular on the prevalence of depression, with the data collected being disaggregated at least by sex, gender, age group and socio-economic status and including sexual and reproductive health indicators;

10. Believes that the action taken at EU level on mental health and wellbeing should involve leading figures in the political, health, educational and social spheres, together with social partners and civil society organisations; considers it essential that mental health should cease to be a taboo subject in certain social environments;

11. Insists that the link between socio-economic conditions, mental health and wellbeing is crucial to policy coherence on mental health, since poverty and social exclusion lead to greater mental health problems; notes that the feminisation of poverty and austerity policies that disproportionately impact women put women’s mental wellbeing at greater risk;
12. Highlights the importance of social mental health treatment and care, such as through sport, music, arts and cultural activities, as an important element in health service delivery, and one which reduces the economic and human cost that mental health problems can bring to bear on individuals and society as a whole; calls on the Commission and the Member States to invest more in social mental health care programmes, such as social prescribing;

13. Notes with concern that only 13 EU Member States are known to the WHO to have a national suicide prevention strategy; calls on the Commission and the Member States to establish and implement a national suicide prevention strategy and for measures to be taken to reduce the risk factors involved in suicide, such as alcohol abuse, drugs, social exclusion, depression, and stress; also calls for systems to be set up to provide support following suicide attempts;

14. Recognises the impact of the media, and particularly the internet and social media, on mental health and wellbeing, particularly for young women and girls, and notes that more research must be done on the subject; notes that media cultures that emphasise women’s age and physical appearance potentially cause women and girls adverse effects on their mental health and wellbeing such as anxiety, depression, or obsessive behaviour; underlines that effective tools, including legal measures, must be developed to deal with online bullying, harassment and objectification; highlights the need to develop an ambitious strategy on e-mental health and wellbeing, and to promote and work with stakeholders to develop emerging e-therapies; recognises that a media strategy on mental health must involve all stakeholders, including publishers and the advertising industry, who must adopt ethical standards so as to avoid the objectification of women and promotion of gender stereotypes;

15. Points out that some women have a distorted perception of their image due to media, stereotyped advertising and social pressure, and develop eating and behavioural disorders, for instance anorexia, bulimia, orthorexia, binge eating disorder, or bigorexia; supports a gender-sensitive approach to eating disorders and the need to mainstream it within the discourse on health and in information addressed to the general public; calls on the Member States to set up assistance and support contact points in schools to provide psychological support to students, in particular adolescent girls, who are more prone to developing eating disorders;

16. Welcomes the fact that, for the first time, world leaders are recognising the promotion of mental health and wellbeing and the prevention and treatment of substance abuse as health priorities within the global development agenda;

17. Raises serious concerns over the provision of mental health care and facilities to refugee women and girls in Europe, particularly those living in makeshift conditions across Member States; highlights that detention of refugees and asylum seekers without effectively and efficiently processing their asylum claims is in violation of international law and has a negative impact on their mental health and wellbeing; calls on the Member States to protect women asylum seekers in detention who report abuse, and stresses that these women are to be provided with immediate protection, including ending detention, speeding up relocation and promoting support and counselling; calls on the Member States to delink health policies from immigration control by allowing
access to basic healthcare services and not imposing a duty to report undocumented migrants on healthcare practitioners; asks the Member States, moreover, to implement the multi-agency guidelines on protecting and supporting the mental health and psychosocial wellbeing of refugees, asylum-seekers and migrants in Europe, as prepared by WHO/Europe, UNHCR and IOM;

18. Points out that women often have to work a two-in-one working day, that is to say, a day’s work at their place of employment and a day’s work at home, because men do not devote themselves sufficiently to the responsibility of household tasks and bringing up daughters and sons, causing many women to suffer from depression, anxiety, and stress, in addition to feelings of guilt at their failure to look after the family in the proper way, that being the role traditionally assigned to women;

19. Condemns a widespread new sexist stereotype which has it that the modern woman has to shine in her studies and at work, but must satisfy traditional expectations by being a good wife and home-maker and a perfect mother while also keeping her looks, a behaviour pattern that causes many women to feel stress and anxiety;

20. Calls on the Commission, the Member States and local authorities to develop specific tailored policies in order to provide mental health services to groups of vulnerable women in marginalised communities and to those facing intersectional discrimination, such as refugee and migrant women, women facing poverty and social exclusion, intersex and transgender persons, ethnic minority women, women with disabilities, older women, and women in rural areas;

21. Highlights the importance of a life-cycle approach to mental health, where every age-group’s needs are addressed in a coherent and comprehensive manner, with an emphasis on adolescent girls and older women, who on average report a lower rate of life satisfaction than men of the same age groups;

22. Recommends that in the case of pregnancy, mental healthcare should begin as soon as possible in the first trimester, in order to make it possible to identify specific conditions that may require surveillance, recognise social problems for which women may need help from social or mental health services and inform women on pregnancy-related issues; calls for greater comprehensive and local obstetric care provision, extending to midwives and obstetricians, to be guaranteed in all EU Member States, and stresses the particular significance of that challenge for rural areas; stresses that psychological healthcare is just as important as physical healthcare and notes that between 10 and 15% of women in the EU who have just given birth suffer from postnatal depression; stresses the importance of women having access to psychological and medical care after miscarriages and the need for a sensitive and personal approach; calls on the Commission and the Member States to promote, develop and provide early detection and treatment of postpartum psychosis and depression;

23. Underlines that social and employment policies, particularly policies on work-life balance, must take a holistic approach taking women’s mental health and wellbeing into account, and calls on the Commission and the Member States to work together with trade unions, employers, health professionals and civil society in order to develop a holistic and gender-sensitive approach to mental wellbeing at work; notes the importance of providing mental health training to those in management positions in
both private and public sectors;

24. Recognises the important role of formal and informal carers, who are overwhelmingly women, in mental healthcare; calls for particular attention to be paid to the role of formal and informal carers in mental health, and particularly to the role of women carers, as well as action to protect the mental health and wellbeing of the carers themselves;

25. Urges the Commission and the Member States to include the mental health and wellbeing challenges faced by men and boys due to gender stereotypes leading to a greater likelihood of substance abuse and suicide than is the case for women; underlines that policies on men’s mental health must also take into account the perspectives of age and lifespan, socio-economic condition, social exclusion, and geographic factors;

**Gender equality in clinical trials**

26. Underlines the fact that clinical trials of pharmaceutical products on both men and women are necessary and that these should be inclusive, non-discriminatory and performed under conditions of equality, inclusion and non-marginalisation, as well as being reasonably reflective of the population that would use the products; suggests that clinical trials should also take account of specific vulnerable population groups such as paediatric and geriatric patients and persons from ethnic minorities; is of the opinion that gender-disaggregated data should also be collected after commercialisation of the products, in order to record the different side-effects, alongside research and data on the implementation of the relevant EU legislation by Member States;

27. Expresses its deep concern at the fact that the failure to improve women’s representation in clinical trials and biomedical research results in putting women’s health and lives at risk, and emphasises that clinical trial methodologies and design must allow for stratified analysis by age and gender; stresses, therefore, the urgent need to incorporate gender differences into clinical procedures in the mental health field;

28. Highlights the importance of the publication of the results of clinical trials so that the methodology is transparent and accessible;

29. Recalls that infectious diseases (e.g. HIV and malaria) and adverse pregnancy outcomes (e.g. stillbirth) are highest in low- and middle-income countries (LMICs); calls for pregnant women to be included in clinical trials as a way to reduce morbidity and mortality in mothers and infants;

30. Demands that the labels on pharmaceutical products clearly indicate whether trials on women took place or not, and whether men and women may expect different side-effects; calls on the Member States to encourage research on the long-term effects of products used in hormone replacement therapy;

31. Asks the Commission to incentivise projects at EU level focused on how women are treated in clinical research; considers that such projects should involve health authorities at all levels and the pharmaceutical industry, by way of developing specific strategies for implementing the guidelines on studying and assessing gender differences in clinical trials;
32. Calls on the Commission and the Member States to invest in awareness-raising campaigns to encourage women to participate in clinical trials;

33. Urges the EMEA to draw up separate guidelines for women as a special population in clinical trials;

34. Calls on the Member States, when applying Regulation (EU) No 536/2014 in clinical trials of medicinal products for human use, to use a methodological approach for clinical trials that guarantees an adequate representation of men and women, paying special attention to transparency as regards the gender composition of participants, and, when considering the proper implementation of this regulation, to specifically monitor the level of representation of men and women;

35. Urges Member States, the EMEA, and relevant stakeholders to ensure that sex and gender factors are introduced at the earliest stages of research and development of medication, before the stage of clinical trials; emphasises the need for improved sharing of best practice among research institutions and healthcare providers across Europe on the subject;

36. Underlines that urgent action is required to correct gender gaps in clinical trials in areas of health where such gaps are particularly harmful, such as in medication for Alzheimer’s, cancer, treatment of strokes, anti-depressants, and cardiovascular diseases;

37. Emphasises that concerted action must be taken by researchers and all relevant stakeholders to eliminate harmful side-effects of medication that specifically affect women, as in the case of anti-depressants, contraceptives and other medicines, in order to improve women’s health and the quality of healthcare;

38. Notes with concern that gender discrimination and inequality occur in health and social care research in developing countries, thereby affecting the development of appropriate and targeted treatments; points out, in particular, that patients in developing countries are inadequately represented in pharmacological research; notes that special populations, including children and pregnant women, have been neglected in tuberculosis drug development; stresses the need to collect and store samples for pharmacogenetic study in future clinical trials based on gender; recalls that women’s different biological and physiological make-up requires proper information about the effect of drugs on their bodies;

39. Notes with concern that the increase in offshoring medicine testing to Africa and other underdeveloped regions may result in serious ethical violations and infringements of fundamental EU principles such as the right to health protection and healthcare; points out that not having access to affordable healthcare, health insurance or affordable medicine, gives vulnerable people, particularly women, no other choice but to participate in clinical trials in order to receive medical treatment, possibly unaware of any risks entailed;

40. Notes that it is a proven fact that women take greater quantities of psychotropic drugs than men, but that there are very few studies on gender differences regarding the effect of those drugs, which are prescribed for women and men without distinction and in the same doses; expresses its concern at the fact that women suffer to a greater extent from
adverse effects of psychotropic drugs because they are excluded from clinical trials and no account is taken, therefore, of the female physiology; also points out that women, seek more often than men to resolve their mental problems with the aid of psychotherapy;

**General remarks**

41. Calls on the Commission and the Member States:

(a) to promote healthcare by ensuring easy access to services and the provision of adequate information tailored to men’s and women’s specific needs and the exchange of best practice in the field of mental health and clinical research;

(b) to take stock of the specific health needs of women and men and to ensure the integration of a gender perspective in their health policies, programmes and research, from their development and design to impact assessment and budgeting;

(c) to ensure that prevention strategies specifically target women who are at risk of intersectional discrimination such as Roma women, women with disabilities, lesbians and bisexual women, migrants and women refugees and women living in poverty, as well as transgender and intersex people;

(d) to recognise gender-based violence and violence against women as a public health issue, as stated in WHO Resolution WHA49.25 of 25 May 1996, which directly impacts on women’s mental health and wellbeing;

(e) to ensure rapid development of the EU-wide survey on the prevalence of gender-based violence for implementation within the European Statistical System, as confirmed in Eurostat’s 2016 work programme, and to collect regular, disaggregated data, in particular on the prevalence of depression, this data being disaggregated at least by sex, age group and socio-economic status;

(f) to support civil society and women’s organisations that promote women’s rights, and to work to ensure that women have a voice in European and national health policy issues and that European and national health policies respond to their needs;

(g) to incentivise programmes that address the specific needs of women concerning illnesses such as osteoporosis, musculoskeletal problems and central nervous system illnesses such as Alzheimer’s and/or dementia, including those that inform women about prevention methods and offer training to medical staff;

(h) to pay extra attention to the special needs of women diagnosed with chronic fatigue syndrome or fibromyalgia by providing them with adequate high-quality health care services;

(i) to increase funding to foster research on the causes and possible treatment of endometriosis, as well as the drafting of clinical guidelines and the creation of reference centres; to promote information, prevention and awareness-raising campaigns on endometriosis, and to provide means for the training of specialised health professionals and for research initiatives;
42. Calls on the Member States to adopt policies for improving the average health level of the population by eliminating the health inequalities affecting disadvantaged socio-economic groups; calls, in this context, for active engagement in a range of policy sectors, with regard not only to public health and healthcare systems, but also education, social security, work/life balance and city planning, always engaging with a clear gender equality perspective;

43. Calls on the governments of developing countries to mainstream gender in mental health policy, and to develop policies and programmes that address both the specific needs of women for mental health treatment and the social origins of psychological distress; notes with concern that, especially in Least Developed Countries, the exclusion of women from biomedical research is often the result of lack of information and awareness campaigns, the roles they play as mothers and caregivers and their lack of decision-making freedom in their households; strongly believes that better balance in gender roles and obligations, income security, equal access to education, labour market integration, more effective measures to promote work-life balance, especially for single mothers, the development of social safety nets and poverty reduction would further redress gender disparities in mental health;

44. Considers that sexual and reproductive rights include access to legal and safe abortion, reliable, safe and affordable contraception, and comprehensive sexuality and relationship education;

45. Considers it regrettable that sexual and reproductive rights are severely limited and/or apply only subject to certain conditions in several EU Member States;

46. Is of the opinion that the increasing number of medical professionals who refuse to perform abortions in Member States represents another threat to the health and rights of women; urges the Member States to ensure that there is at least a minimum number of health professionals available to perform abortions in hospitals;

47. Calls on the Member States to prevent, ban and prosecute the forced sterilisation of women, a phenomenon that affects in particular women with disabilities, transgender and intersex persons, and Roma women;

48. Underlines the fact that screening procedures in the early stages of cancer, along with information programmes, are considered to be among the most effective cancer prevention measures, and calls on the Member States to ensure that all women and girls have access to such screenings;

49. Stresses that empowering women and promoting gender equality is crucial to accelerating sustainable development and thus ending all forms of discrimination against women and girls, including those occurring in mental health and clinical research, and is not only a basic human right, but also has a multiplier effect across all other development areas (SDG 5);

50. Considers that the Member States have an obligation to guarantee local obstetric care provision as a public service and to ensure that midwives are available in rural and mountain regions too;
51. Calls on the Member States’ health authorities to recognise endometriosis as an incapacitating illness, since this would allow the women affected to be treated free of charge, even in the case of costly treatments and/or surgery, and would permit special sick leave from work during the most acute periods, thus avoiding stigmatisation in the workplace;

52. Urges the Member States, the Commission and relevant agencies to ensure full access to high-quality physical and mental healthcare for all refugees, asylum seekers and migrants, particularly vulnerable women and girls, as a matter of universal human rights and, in the longer term, to adequately prepare their national health systems for incoming refugees and asylum seekers; highlights the need for gender-sensitive mental health training of immigration, asylum, and law enforcement staff and officials who work with refugees, asylum seekers and immigrants, especially those who work with vulnerable women and girls; considers that these necessary healthcare measures should include provisions such as safe accommodation and sanitary facilities for women and children, legal counselling and access to sexual and reproductive health and rights, including contraception, support for survivors of sexual violence, and safe and legal abortion;

53. Calls on the EU and the Member States to put an immediate end to current austerity policies and cuts in public spending which affect services that are crucial to the attainment of a high level of healthcare protection for all women and men and girls and boys in the EU, regardless of their background or legal status;

54. Calls on the Member States to ensure free access to health services for unemployed women, women in rural areas and women pensioners on low incomes who cannot pay for medical checks and treatment themselves;

55. Recommends that after the birth of a disabled child or a child with a life-threatening illness women should be provided with special support, including free access to long-term paediatric home care, palliative paediatric care and specialised and easily accessible psychological support;

56. Stresses that the achievement of the right to health for all prevails over the protection of intellectual property rights and depends on investment in European health research, including health technologies and drugs for poverty-related and neglected diseases (PRNDs);

57. Deplores the cutting of public health budgets by Member States, and is disappointed at the fact that the annual budgets for programmes designed to prevent gender-based violence and violence against women in all Member States are much less than the actual cost of such violence, be it economic, social or moral in nature; supports the Member States in increasing expenditure to support programmes aimed at preventing violence against women and effectively helping and protecting victims;

58. Calls on the Member States to take measures in the health-related field of early detection and support to victims of gender-based violence, and to apply health protocols in cases of assault, which should be referred to the appropriate courts with a view to speeding up the legal procedure; also calls on the Member States to guarantee the right of access to information and integrated social assistance, to be provided through permanent urgent care services specialising in multidisciplinary professional services;
59. Welcomes the moves by the Commission for ratification by the EU of the Istanbul Convention, and regrets that many Member States have not yet ratified it; urges the Council to ensure the accession of the EU to the Istanbul Convention as soon as possible;

60. Stresses that prostitution is also a health issue, as it has detrimental health impacts on persons in prostitution, who are more likely to suffer from sexual, physical and mental health traumas, drug and alcohol addiction, and loss of self-respect, as well as a higher mortality rate, than the general population; adds and stresses that many of the sex buyers ask for unprotected commercial sex, which increases the risk of detrimental health impacts, both for persons in prostitution and for the buyers;

61. Calls on the Member States to prevent, ban and prosecute female genital mutilation and genital mutilation affecting intersex persons, and to provide mental health support, in conjunction with physical care, to victims and to those individuals likely to be targeted;

62. Encourages the Commission and the Member States to pay special attention to the most vulnerable or disadvantaged groups, and to launch intervention programmes for them;

63. Considers that the lack of comparable, comprehensive, reliable and regularly updated gender-disaggregated data results in discrimination for women’s health;

64. Recalls that healthcare and health policy are a competence of the Member States and that the role of the Commission is complementary to national policies;

65. Instructs its President to forward this resolution to the Council and the Commission.
EXPLANATORY STATEMENT

Health is more than a biological issue, representing according to the World Health Organisation, ‘a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.’¹ Both the biological concept of sex and the social construct of gender matter in health at all levels and impact differently on women and men’s health, access to health and health-care².

Unequal access to resources coupled with other social factors produce unequal health risks and access to health information, care, and services for women and men. In addition to this, biological differences imply that women have particular health concerns and needs, especially related to their sexual and reproductive health. Science has proven that there are biological differences between men and women well beyond the reproductive organs. For example, heart disease is the leading cause of death among women. Signs and symptoms of heart attacks are different in men and women, and women are more likely to die within a year of a heart attack.

Only recent research on women’s heart conditions and symptoms has proved that women suffer from cardiovascular heart diseases (CHD) in much higher numbers than men³, but these diseases come later in life, manifest themselves through different symptoms as compared with men, and should be treated differently in terms of medication allocation. However, research and practice still fail to take adequate account of differences between men and women in terms of health, illness and treatment. Despite making up over half of the EU population, women are underrepresented in biomedical research.

Existing research indicates gender inequalities in health status, health-related behaviour, access to health and treatment. Policy makers and medical research must question and investigate the causes of these inequalities and offer effective answers. For example, biomedical research continues to be based on the unstated assumption that women and men are physiologically similar in all respects apart from their reproductive systems, and it ignores other biological, social and gender differences, which have a considerable impact on health.

It is the case for pain: women have pain more often and more intensely and painkillers are less effective with women than with men. In many cases, preventive and curative strategies apply to women while they have been tested only on men and might therefore have little or even a counterproductive effect.

The report would specifically include the case of endometriosis as an example of discrimination on women’s diseases’ research and treatment.

As to mental health, according to the WHO, lifetime prevalence rates for any kind of psychological disorder are higher than previously thought, are ever increasing and affect nearly

¹ Preamble of the Constitution of the WHO.
² ‘Unequal, Unfair, Ineffective and Inefficient Gender Inequity in Health: Why it exists and how we can change it’, Final Report to the WHO Commission on Social Determinants of Health September 2007.
³ Traditionally regarded as a male disease, cardiovascular disease (CVD) is the number one killer of women worldwide. It also is a major cause of serious illness and disability, costly to healthcare systems and destroying women’s quality of life. In the EU, CVD remains the top cause of death for women in each of the twenty-seven EU countries. Only during the last decades has awareness been rising how CVD affects women differently from men, alerting women to their risk. Death from CVD accounted for 43% in women and 36% in men in the EU. See http://eurohealth.ie/wp-content/uploads/2013/02/Women-and-CVDfin.pdf
half the population. Although overall rates of psychiatric disorder are almost identical for men and women, there are significant gender differences in the patterns of mental illness. Gender determines the differential power and control men and women have over the socioeconomic determinants of their mental health and lives, their social position, status and treatment in society, and their susceptibility and exposure to specific mental health risks. Gender differences occur particularly in the rates of common mental disorders such as depression or anxiety.

Public policies in the health sector theoretically sometimes acknowledge that gender is a significant health determinant across the life cycle\(^1\). However, women’s health needs are not fully and consistently integrated into European and national health policies. The lack of a consistent and integrated approach to women’s rights and gender issues within health policy needs to be urgently addressed, and is crucial for the attainment of a high level of human health protection for all, as guaranteed by the EU Treaties\(^2\). To be effective, all aspects of health policies, currently to a large extent gender-blind in practice, must include a women-specific approach and make full use of gender mainstreaming as a tool.

**EU Health policy: lack of a gender equality perspective**

The EU is required by its founding treaties to ensure that human health is protected as part of all its policies, and to work with the EU countries to improve public health, prevent human illness and eliminate sources of danger to physical and mental health. Europe 2020 aims to turn the EU into a smart, sustainable and inclusive economy promoting growth for all – one prerequisite of which is a population in good health.

EU health policy, implemented though the Health Strategy, focuses on prevention, equal chances of good health and quality healthcare for all (regardless of income, gender, ethnicity, etc.), tackling serious health threats involving more than one EU country, keeping people healthy into old age and supporting dynamic health systems and new technologies.

The Council has endorsed universality, access to quality care, equity, and solidarity as common values and principles underpinning the health systems of the EU Member States\(^3\). The concept of universality requires that no person be barred access to health-care. Solidarity is related to the financial structuring of national health systems to ensure this universal access. Equity implies equal access according to need, regardless of ethnicity, gender, age, social status or ability to pay.

In addition, the European Charter of Fundamental Rights guarantees that everyone has the right of access to preventive health-care and the right to benefit from medical treatment under the conditions established by national laws and practices. These principles are complemented by a general gender-mainstreaming obligation enshrined in the European Treaty which applies also to the work of all European and national decision-makers in the field of health policy.

---

1 Council of the European Union, Conclusions on Women and Health, 2005; Conclusions on Health and Migration in the EU, 2007; Conclusions on Roma Inclusion, 2008; Resolution on the health and well-being of young people, 2008.
2 Article 168 TFEU.
Health systems should aim to reduce health inequalities, among which gender is recognised as a determinant. It is therefore both a legal and a social responsibility for relevant decision-makers at the European and national level to fully integrate women’s experiences and needs when defining public policies in the health sector. Unfortunately, the panorama of the current situation shows that this is at present not the case.

The primary responsibility for health-related policies in the EU lies with the Member States. The EU nevertheless has a competence in health promotion and disease prevention and a role to play in coordinating and providing support to Member States in order to attain a high level of human health protection. Women’s health has been addressed as a policy issue at the EU level in the context of the social and economic determinants of health and specific age groups. In theory, the EU recognises that gender – alongside age, education, economic and civil status – is a significant determinant for health and health-care. The European Commission Directorate General for Public Health has published several reports including data on the situation of women’s health and access to health-care. In practice, these documents were not followed-up with concrete policy actions and programmes to address women’s health needs and European public health policies broadly remain gender blind.

Despite the existing Treaty obligation to integrate a gender equality perspective in all the activities of the EU (gender mainstreaming), this is rarely done in European Commission policy papers and even less so in its actions and programmes. In particular, insufficient resources and attention are given to gender equality issues and women’s needs in EU-sponsored research in relation to health.
9.11.2016

OPINION OF THE COMMITTEE ON DEVELOPMENT

for the Committee on Women’s Rights and Gender Equality

on promoting gender equality in mental health and clinical research
(2016/2096(INI))

Rapporteur: Florent Marcellesi

SUGGESTIONS

The Committee on Development calls on the Committee on Women’s Rights and Gender Equality, as the committee responsible, to incorporate the following suggestions into its motion for a resolution:

1. Stresses that the achievement of the right to health for all prevails over the protection of intellectual property rights and depends inter alia on investment in global health research, including health technologies and drugs for poverty-related and neglected diseases (PRNDs);

2. Recalls that PRNDs affect more than one billion people, claim millions of lives every year and are primarily endemic in developing countries; notes that tools to prevent, diagnose and treat PRNDs are often still lacking or unsuitable for the conditions of individuals and communities in developing countries;

3. Recalls that EDCTP2 (second programme of the European & Developing Countries Clinical Trials Partnership) is intended to contribute to reducing the social and economic burden of poverty-related diseases in developing countries, in particular in sub-Saharan Africa, by accelerating the clinical development of effective, safe, accessible, appropriate and affordable medical interventions for poverty-related diseases, in partnership with sub-Saharan Africa;

4. Notes with concern that gender discrimination and inequalities occur in health and social care research in developing countries, thereby affecting the development of appropriate, targeted treatments; in particular, points out that patients in developing countries are inadequately represented in pharmacology research; notes that special populations, including children and pregnant women, have been neglected in tuberculosis drug development; stresses the need to collect and store samples for pharmacogenetic study in future clinical trials, based on gender; recalls that women’s different biological and physiological make-up requires proper information about the effect of drugs on their
bodies;

5. Recalls that infectious disease (e.g. HIV and malaria) and adverse pregnancy outcome (e.g. stillbirth) are highest in low- and middle-income countries (LMICs); calls for pregnant women to be included in clinical trials as a way to reduce morbidity and mortality in mothers and infants;

6. Recalls that according to the WHO, while ‘mental disorders’ denotes a range of mental and behavioural disorders, such as depression, bipolar affective disorder, schizophrenia, anxiety disorders, dementia and autism, ‘mental health’ is conceptualised as a state of well-being in which the individual realises his or her own abilities, can cope with the normal stresses of life, can work productively and fruitfully, and is able to make a contribution to his or her community; welcomes the fact that, for the first time, world leaders are recognising the promotion of mental health and well-being and the prevention and treatment of substance abuse as health priorities within the global development agenda;

7. Recalls that mental health is heavily gendered; stresses that gender inequality, income disparities, women’s greater exposure to poverty and overwork, socio-economic discrimination, gender-based violence, including violation of their sexual and reproductive rights, malnutrition and hunger, expose them further to the mental health disorders of depression and anxiety; calls on the Commission to address the root causes of the failure to include women in clinical trials and to allocate more resources for research, prevention, treatment and support services for women; more broadly, stresses the need to promote economic inclusion of all (SDG 10), for example by improving the regulation and monitoring of financial markets and institutions, and to enhance through lifelong education the competence of primary healthcare providers to recognise and treat women’s mental health disorders with a view to redressing gender discrimination in healthcare;

8. Highlights the fact that the World Health Organisation (WHO) reports no significant difference between genders in the case of severe mental disorders such as schizophrenia and bipolar disorder, while high gender difference prevails in the case of depression and anxiety;

9. Stresses that empowering women and promoting gender equality is crucial to accelerating sustainable development and thus ending all forms of discrimination against women and girls, including those occurring in mental health and clinical research, and is not only a basic human right, but also has a multiplier effect across all other development areas (SDG 5);

10. Calls on the governments of developing countries to mainstream gender in mental health policy, and to develop policies and programmes that address both the specific needs of women for mental health treatment and the social origins of psychological distress; notes with concern that, especially in Least Developed Countries, the exclusion of women from biomedical research is often caused by lack of information and awareness campaigns, their fulfilment of their role as mothers and caregivers and their lack of decision-making freedom in their households; strongly believes that better balance in gender roles and obligations, income security, equal access to education, labour market integration, more effective measures to promote work-life balance, especially for single mothers, the development of social safety nets, and poverty reduction would further redress gender
disparities in mental health;

11. Deplores the fact that the EU has not incorporated the principles of its global health policy into its innovation strategy; deplores the fact that there are no binding provisions in any of the mechanisms which ensure that Poverty-Related and Neglected Diseases (PRND) R&D funded through the EU will produce accessible, affordable and suitable medical products for the most vulnerable and endangered categories of the population, or that research data will be openly accessible; stresses the need to strengthen local research and development tailored to each country’s needs and, more broadly, to invest in global health research and development (R&D) to strengthen national health systems and to achieve universal healthcare coverage, including by pooling resources; calls on the EU to increase EU spending to these ends;

12. Notes that while 26 PRNDs contributed to 14% of the global disease burden, they received only 1.4% of global health-related R&D expenditure;¹

13. Calls on the EU to promote effective and fair financing of research that benefits the health of all and ensures that innovations and interventions lead to affordable and accessible solutions; in particular, models that dissociate R&D costs from the price of medicines should be explored, including opportunities for technology transfer to developing countries;

14. Notes that the past 20 years have seen a considerable shift in the location of industry-sponsored clinical drug trials, these tests being increasingly carried out in low- and middle-income countries, where it is easier to find subjects and less expensive to conduct clinical trials, and where regulatory constraints are either less stringent or less actively monitored;

15. Notes with concern that the increase in offshoring medicine testing to Africa and other underdeveloped regions may result in serious ethical violations and infringements of fundamental EU principles such as the right to health protection and healthcare; points out that not having access to affordable healthcare or health insurance, as well as access to affordable medicine, gives vulnerable people, particularly women, no other choice but to participate in clinical trials in order to receive medical treatment, possibly unaware of any risks entailed;

16. Calls on transnational pharmaceutical companies to fulfil their corporate responsibility to respect human rights, as enshrined in the United Nations Guiding Principles on Business and Human Rights, when engaging in clinical trials in low- and middle-income countries; deems that they should ensure the proper protection of participants’ safety and rights, and the conformity of their practices with the highest ethical standards and international guidelines, as set in the Declaration of Helsinki of the World Medical Association (DoH), as well as the Council for International Organisations of Medical Sciences and WHO guidelines on Good Clinical Practice (GCP);

17. Urges the EU regulatory authorities to ascertain that the same standards regarding clinical trials are complied with both within and outside their jurisdictions before granting drug

market authorisation;

18. Calls on developing countries to develop a robust legislative framework with a functional independent control system that complies with the World Health Organisation (WHO) Guidelines on Good Clinical Practice (GCP) for trials on pharmaceutical products and the Declaration of Helsinki (DoH) of the World Medical Association (WMA);
### RESULT OF FINAL VOTE IN COMMITTEE ASKED FOR OPINION

<table>
<thead>
<tr>
<th>Date adopted</th>
<th>8.11.2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result of final vote</td>
<td></td>
</tr>
<tr>
<td>+:</td>
<td>20</td>
</tr>
<tr>
<td>–:</td>
<td>1</td>
</tr>
<tr>
<td>0:</td>
<td>3</td>
</tr>
<tr>
<td>Members present for the final vote</td>
<td>Louis Aliot, Nicolas Bay, Beatriz Becerra Basterrechea, Ignazio Corrao, Raymond Finch, Enrique Guerrero Salom, Maria Heubuch, György Hölvényi, Teresa Jiménez-Becerril Barrio, Arne Lietz, Linda McAvan, Norbert Neuser, Cristian Dan Preda, Elly Schlein, Eleni Theocharous, Paavo Väyrynen, Bogdan Brunon Wenta, Anna Záborská</td>
</tr>
<tr>
<td>Substitutes present for the final vote</td>
<td>Marina Albiol Guzmán, Agustín Díaz de Mera García Consuegra, Bernd Lucke, Judith Sargentini, Patrizia Toia</td>
</tr>
<tr>
<td>Substitutes under Rule 200(2) present for the final vote</td>
<td>Maria Grapini</td>
</tr>
</tbody>
</table>
RESULT OF FINAL VOTE IN COMMITTEE RESPONSIBLE

<table>
<thead>
<tr>
<th>Date adopted</th>
<th>29.11.2016</th>
</tr>
</thead>
</table>
| Result of final vote | +: 19  
-: 11  
0: 0 |
| Members present for the final vote | Daniela Aiuto, Beatriz Becerra Basterrechea, Malin Björk, Vilija Blinkevičiūtė, Iratxe García Pérez, Anna Hedh, Mary Honeyball, Teresa Jiménez-Becerril Barrio, Elisabeth Köstinger, Agnieszka Kozłowska-Rajewicz, Florent Marcellesi, Angelika Mlinar, Angelika Niebler, Maria Noichl, Marijana Petir, João Pimenta Lopes, Michaela Šojdrová, Ernest Urtasun, Elissavet Vozemberg-Vrionidi, Jadwiga Wiśniewska, Jana Žitňanská |
| Substitutes present for the final vote | Biljana Borzan, Stefan Eck, Rosa Estaràs Ferragut, Clare Moody, Sirpa Pietikäinen, Marc Tarabella, Monika Vana, Julie Ward, Anna Záborská |
### FINAL VOTE BY ROLL CALL IN COMMITTEE RESPONSIBLE

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>19</td>
<td>+</td>
</tr>
<tr>
<td>ALDE</td>
<td>Beatriz Becerra Basterrechea, Angelika Mlinar</td>
</tr>
<tr>
<td>EFDD</td>
<td>Daniela Ainto</td>
</tr>
<tr>
<td>GUE/NGL</td>
<td>Malin Björk, Stefan Eck, João Pimenta Lopes</td>
</tr>
<tr>
<td>PPE</td>
<td>Sirpa Pietikäinen</td>
</tr>
<tr>
<td>S&amp;D</td>
<td>Vilija Blinkevičiūtė, Biljana Borzan, Iratxe García Pérez, Anna Hedh, Mary Honeyball, Clare Moody, Maria Noichl, Marc Tarabella, Julie Ward</td>
</tr>
<tr>
<td>VERTS/ALE</td>
<td>Florent Marcellesi, Ernest Urtasun, Monika Vana</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>11</th>
<th>-</th>
</tr>
</thead>
<tbody>
<tr>
<td>ECR</td>
<td>Jadwiga Wiśniewska, Jana Žižňanská</td>
</tr>
<tr>
<td>PPE</td>
<td>Rosa Estarás Ferragut, Teresa Jiménez-Becerril Barrio, Agnieszka Kozłowska-Rajewicz, Elisabeth Köstinger, Angelika Niebler, Marijana Petir, Michaela Šojdrová, Elissavet Vozemberg-Vrionidi, Anna Záborská</td>
</tr>
</tbody>
</table>

| 0 | 0 |

**Key to symbols:**
- + : in favour
- - : against
- 0 : abstention