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Committee on Development

2016/2096(INI)

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];

[1] Research and development expenditure for poverty-related and neglected diseases: an analysis of economic and epidemiological data. The Lancet, 2013.

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

Date adopted	8.11.2016
Result of final vote	+: 20 –: 1 0: 3
Members present for the final vote	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
Substitutes present for the final vote	Marina Albiol Guzmán, Agustín Díaz de Mera García Consuegra, Bernd Lucke, Judith Sargentini, Patrizia Toia
Substitutes under Rule 200(2) present for the final vote	Maria Grapini