Ethics, regulatory and pharmacovigilance

OC - (8535) - AN OVERVIEW OF RESEARCH ETHICS COMMITTEES OPERATING IN LUSOPHONE AFRICAN COUNTRIES

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Background: In 2017, a North-South partnership was created, to strengthen Bioethics Committees in Lusophone African Countries (LAC), by joining the forces of National and Institutional Research Ethics Committees (REC) and Universities in Angola, Cape-Verde, Mozambique and Portugal. This study is part of an EDCTP2 sponsored project and aimed to describe key RECs operating in LAC, its establishment dates and further characteristics.

Methods: Document analysis and interviews with REC representatives of five ALC were conducted in April 2018. Legal documents were obtained through official national sources.

Results: We identified four National Ethics Committees, created between 2000 and 2008 by ministerial or governmental decree; only S. Tomé e Principe doesn't have an established REC. In Angola, the National REC was created in 2000, and since 2007, seven Institutional Committees were implemented at Faculty levels. National REC in Cape-Verde and Guinee-Bissau (CNES) are unique and were founded in 2007 and 2009 respectively. In Mozambique, National REC (CNBS) dates back to 2002, and since 2011, 8 Institutional Committees were formed; they functioned as a network under the umbrella of CNBS. Most National REC have representatives from health professional associations, lawyers, civil society and religious communities and have regular meetings (usually monthly). The number of members ranges between 6 (CNES) and 13 (CNBS). In 2007, around 200 protocols were reviewed by CNBS and 29 by CNES. Most of the National REC members attended training activities in bioethics but at different levels.

Conclusions: Few publications described REC operating in LAC; this study fills this gap by reporting historical and functional characteristics of RECs in five LAC. Additional tools based on quantitative and qualitative approaches are being developed to assess more in-depth REC operational characteristics and to identify their needs in order to target training and capacity building initiatives underlining our EDCTP2 funded project.