CLINICS

EDITORIAL

The challenge for ''multilingual'' scientists in Brazil

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The main missions of the university are the production and dissemination of knowledge, with education and research serving as the fundamental pillars of these missions. The extent of the university's role is reflected in its social commitment to the community. However, in medicine, this ''extended'' role involves promoting health care for citizens. In general, all academic institutions and their faculty are evaluated externally according to their performance of these criteria. Therefore, a university professor of medicine in the Brazilian model must teach, conduct research and also treat patients.

In recent years, Brazilian national scientific policy (which is determined by the Ministry of Education through the Coordination for the Improvement of Higher Education Personnel [CAPES], the governmental agency that evaluates and regulates postgraduate programs) has begun requiring a high level of research performance from university teachers, with the aim of improving the quality of national scientific production and with a particular focus on innovation.

In most developed countries, medical practice and medical scientific research are supervised by regulatory agencies. The primary purpose of these agencies is to protect and preserve the rights and interests of the population, thereby untethering them from those of industry and the scientific community. For example, in the United States, the FDA (U.S. Food and Drug Administration) is responsible for protecting public health by ensuring the safety and efficacy of drugs, biological products and medical devices, as well as food, cosmetics and tobacco products. As a science-based regulatory agency, the mission of the FDA is to promote excellence, protect health, prevent disease, prolong life and promote the welfare of American citizens. Therefore, studies performed to gain FDA approval of drugs, devices and their associated medical treatments must obey strict scientific standards, which greatly increase the cost and time required to gain final approval. In Europe, the 'CE Marking' (from French Conformité Européene) acts in a similar capacity to the FDA, deciding whether a product complies with the essential requirements of European health legislation and with safety and environmental protection policies.

In Brazil, these practices are also regulated by strict governmental and civilian agencies. However, both the difficulties inherent in bureaucracy and the complexity of the requirements limit the progress of research, as this complexity is ultimately responsible for considerable difficulties.

Created in 1999, the National Health Surveillance Agency (ANVISA) is an autarchy that covers all aspects related to the regulation of products and services that affect the health of the population. Similar to the American FDA and the European CE Marking, the function of ANVISA is to protect public health and to intervene in hazardous production and the use of services and products being subjected to sanitary surveillance. However, there is no proper communication or information exchange between ANVISA and international regulatory agencies. The lack of this type of collaboration can incur a large waste of national resources during the approval of drugs or medical materials that have already been extensively tested outside Brazil.

The National Committee for Ethics in Research (CONEP) was created in 1996 as a collegiate body, with advisory, educational and policy and strategy formulation roles within the National Health Council and independence from corporate and institutional influences. It also has a multi- and transdisciplinary composition and includes representative members of the community.

CONEP's task is to examine the ethical aspects of research involving humans. Its mission consists of establishing and updating the guidelines and standards for the protection of research subjects and coordinating the network of research ethics committees of the institutions at which research is performed. CONEP evaluates and monitors the following areas: research protocols in special fields, such as genetics and human reproduction; new equipment; health devices; new procedures; indigenous populations; projects involving biosafety; and projects with foreign participation. CONEP also forms the board of appeals for issues falling within above-mentioned areas.

Although the roles of the various regulatory agencies are well defined and always aimed at protecting society, in practice, interagency interactions can be improved to increase access to them and facilitate clinical research without compromising their main function of ensuring the safety and quality of medical products used in Brazil.

A device or medication that has not been approved by ANVISA may not be imported unless a clinical study of

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the item has been approved by CONEP. CONEP is the government agency that controls research in Brazil, and it has the autonomy to allow the importation of consumables and equipment for scientific research purposes without registration through ANVISA.

However, researchers communicate with the research ethics committees (CEPs) of their respective institutions, but the CEPs do not communicate with CONEP or ANVISA. Therefore, researchers are also responsible for submitting their projects to CONEP, which increases paperwork and makes it even more difficult to conduct national clinical studies.

Another problem is that ANVISA and CONEP often fail to interact with each other, creating the need for researchers to engage in dialogues with both agencies. This situation is even more dramatic when we consider that the evaluation metrics and bureaucratic procedures/requirements are not uniform across agencies, forcing the researcher to be "multilingual" and to learn how to engage in "dialogues" with all the agencies, which requires dedicating time and effort toward a task that is outside his/her area of expertise.

After securing approval for a clinical trial protocol, logistical difficulties remain because the organizations for research funding (state foundations that support research, such as FINEP and CNPq) each require their own set of procedures that are independent of each other.

In Brazil, medical researchers are generally also actuating physicians (care function) and teachers (teaching function); they therefore find it difficult to pay attention to the research approval process while providing the required dedication to the development and execution of projects. As a result, research groups are often forced to hire other professionals to perform bureaucratic functions, making clinical trials more costly and time consuming and sometimes even unfeasible, particularly for smaller teams. These conditions may help explain the low level of resources made available for research and development through the investments of global pharmaceutical companies in Brazil.

We highlight the need a better interface between ANVISA and international entities and between CEPs and governmental agencies. These improvements would allow researchers to limit their interactions to the CEP of their institution, which would optimize efforts and speed up and reduce the costs of clinical trials in Brazil. Consequently, the whole society would ''profit'' from the increase in national scientific production.