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REGULATORY FRAMEWORK REFORM FOR HERBAL MEDICINES: A POLICY APPROACH TO ENHANCING ACCESSIBILITY

Ana Cecília Bezerra Carvalho[1,2], João Paulo Perfeito[1], Dâmaris Silveira[2]

[1]Gerência de Medicamentos Específicos, Notificados, Fitoterápicos, Dinamizados e Gases Medicinais (GMESP), Agência Nacional de Vigilância Sanitária (Anvisa), SIA, Trecho 5, Área Especial 57, Brasília 71205-050, DF, Brasil. [2]Laboratório de Controle da Qualidade, Faculdade de Ciências da Saúde, Universidade de Brasília (UnB), Campus Universitário Darcy Ribeiro, Asa Norte, Brasília 70910-900, DF, Brasil. cecilia.carvalho@anvisa.gov.br*

INTRODUCTION

Brazil's stringent regulatory requirements for herbal medicines, particularly regarding quantitative marker controls, have been criticized for exceeding international standards, being close to those required for conventional medicines, and potentially increasing production costs while offering unclear clinical benefits. This study evaluates the alignment of Brazil's framework with global practices (EU, US, Australia, South Africa, WHO) and proposes evidence-based reforms.

MATERIAL AND METHODS

Aimed to evaluate the alignment of Brazil's framework with global practices, a 3-phase mixed-methods approach was employed: firstly, a comparative analysis between Brazilian norms with international documents, mainly from the European Community, United States, Australia, South Africa, and the World Health Organization. Then, a Regulatory Impact Analysis was carried out, identifying and evaluating the points where there was a need for updates in Brazilian regulations and the impacts of the changes to be made. Based on this report, four Public Consultations (CP) were made available in November 2024, to receive contributions from stakeholders (industry, academia, and civil society) for 90 days to evaluate the proposed changes.

RESULTS

The main point identified is related to obtaining and controlling herbal raw materials and the finished product, shifting the focus from markers to considering mainly the complexity of the plant matrix. This new approach reinforces the importance of good agricultural practices, plant material processing, and manufacturing practices to obtain safe and quality herbal medicinal products, ensuring the efficacy of the phytocomplex which is maintained. Regarding the CP (#1,290, #1,291, #1,292, and #1,293), 216 forms were received (28, 5, 5 and 178, respectively, for each CP). The forms contained 320 contributions (244, 23, 4, 49, respectively) and general suggestions on the normative proposals.

CONCLUSIONS

Based on responses, the proposed changes are primarily acceptable, although some specific adjustments are necessary, especially concerning herbal medicines already approved. The main changes are related to the standardization of the process for obtaining herbal raw materials and herbal medicines, which should be better detailed, and adjustments in quality control procedures, bringing the requirements of Brazilian regulations closer to those practiced internationally.