

PP495 Addressing The Interactions Between Health Regulation And Health Technology Assessment In Brazil

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Abstract

Introduction

The interaction of health technology assessment (HTA) and health regulatory agencies has been widespread, especially for decision-making in health system coverage. The objective of this paper is to report the HTA-regulatory interaction in Brazil.

Methods

This is a case study on the interaction between HTA and regulation in Brazil. Technical documents and Brazilian legislation on health regulation and HTA were analyzed. The study was conducted in July 2019.

Results

HTA-Regulatory Interaction in Brazil is still incipient. There is no responsible agency for interaction between agencies, as there is in Europe and Canada, for example. In the last 4 years, cooperation has started between the Brazilian Health Surveillance Agency (Anvisa) and the Oswaldo Cruz Foundation (Fiocruz) for post-registration monitoring of medicines. During this partnership, 170 post-marketing drug opinions were prepared, assisting the regulatory agency in decision-making.

Conclusions

Brazil legislation guarantees essential medicines at low cost or free. The interaction between HTA and regulation has the potential to reduce the time taken to incorporate technology to the patient, in addition to ensuring greater safety for users of the Unified Health System. In this sense, it was observed that the interaction between health regulation and science and technology institutions has innovative potential in this approach.