Title: Rapid HTA and Regulatory Decision Making

Introduction: Pareceres Técnico-Científicos (PTCs) are rapid response documents to support health decision making. The official REBRATS normative publication for guidance and development of PTCs focuses on HTA research and decisions on incorporating technologies into health systems. There was a need to develop a PTC model that takes into account the information needed to base regulatory health decisions, focusing on the Agência Nacional de Vigilância Sanitária and its ad hoc consultants.

Methodology: Description of topics required to construct a regulatory-oriented PTC model.

Results: In addition to the topics cited in the REBRATS publication, there is the need for risk / benefit assessment related to the inclusion of new technology in the national market - publications such as the US FDA Benefit-Risk Framework or PrOACT-URL framework, adapted by EMA, can serve as a methodological basis. Also, the recommendations in national and international guidelines, as well as tertiary bases such as Micromedex and Uptodate, also evaluate the place of importance of the medication in medical decision making. The search for post-marketing notifications for drugs that have been marketed for some time in other countries or for other therapeutic indications is important to highlight additional safety aspects.

Conclusion: Regulatory-prepared PTCs should focus on different information when compared to HTA studies and, based on international publications, the addition of some topics to the prepared document are pertinent to deepening the information needed for regulatory decision-making.