assessment by CONITEC. This study aims to show how HS is being used to support CONITEC in this issue.

**METHODS:**

As per the EuroScan toolkit, we performed a reassessment of the technologies included in the initial HS report. We searched clinical trial registers, the websites of pharmaceutical companies, conference proceedings, scientific journals, HS databases, and regulatory websites for further information. The data were synthesized and a reformulated landscape of the technological environment for TTR-FAP therapy was presented to the CONITEC Plenary.

**RESULTS:**

The main difference between the initial and final HS output was that tafamidis was approved for use in Brazil, making it the only registered drug for TTR-FAP. Another difference was related to the start of a new clinical trial with diflunisal for TTR-FAP, indicating that this drug could be a potential competitor for tafamidis. It was also possible to add published positive results from a clinical trial with ISIS-TTR-Rx, which were unavailable when the first report was written. Beyond that, it appears that there are two promising gene silencers on the horizon that could represent potential competitors for tafamidis.

**CONCLUSIONS:**

The analysis of tafamidis for incorporation into the Brazilian health system is ongoing, but HS was able to deliver strategic information that could affect the final recommendation of CONITEC.

## PP108 Novel Approaches For Fair And Reasonable Value-Based Recommendations

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**INTRODUCTION:**

Stakeholders from the innovation field in Québec (Canada) have collectively stressed the need to formalize the process for evaluating innovative technologies in the province. In the context of innovation, and more so for non-pharmaceutical technologies where the pace of development is rapid and the lifecycle short, evidence supporting the added value can be limited and uncertainties are common. Therefore, pragmatic approaches are needed to guide recommendations and to assure that the process is rigorous, transparent and fair.

**METHODS:**

Inspired by international experiences, the Institut national d'excellence en santé et services sociaux (INESSS) has developed a novel framework, where four types of recommendations are possible (introduction, refusal, limited or conditional introduction). The starting point is an evaluation of the technology's added value, for the patient, the population and the healthcare system, and the identification of uncertainties. The value of addressing uncertainty with further research is assessed, based on the value-of-information theory, and the distinct characteristics of medical devices are taken into account (e.g. learning curve effect, irrecoverable costs and incremental innovation). Those elements interact to support the formulation of recommendations by INESSS' advisory committee.

**RESULTS:**

The development of the framework was an iterative process supported by the use of the preliminary framework for the assessment of several innovative technologies. Challenges with its use were identified, and led to methodological and operational improvements. So far, the experience with the framework is positive and stakeholders confirm its relevance to support fair and reasonable recommendations for innovations.

**CONCLUSIONS:**

In the rapidly changing landscape of innovation, HTA has to adapt to the challenges of assessing technologies in a context of promise and uncertainties. The framework developed by INESSS is a tool for supporting timely and fair value-based decision-making, which will benefit the healthcare system, and the patients and population it serves.



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