

**INTRODUCTION:**

The Brazilian public health system (SUS) provides technologies based on the best available scientific evidence. However, there is a large number of lawsuits against the government for access to non-standard technologies, a phenomenon called “judicialization of the right to health”, which disrupts the system’s operating logic. The aspect of judicialization that most impacts the health system involves unregistered technologies without scientific evidence of superiority being comparing to the alternatives already offered in the country. The aim of this study is to report experience of the National Committee for Health Technology Incorporation in the Brazilian Health System (CONITEC) to mitigate the effects of the judiciary, with the elaboration of informative documents about technologies directed towards policy-makers, patient, users of system health, professional health and other stakeholders.

**METHODS:**

The main judicialized technologies in the country were identified and then a meeting with experts was realized to discuss a more appropriate format for these documents. After defining the format, a review of the literature was carried out to identify the best available evidence of those health technologies.

**RESULTS:**

A question-and-answer (QA) format document was drawn. The QA addressed information on the use of the technology for a specific clinical condition. Health registry and price in Brazil, if it has already been evaluated by CONITEC and its respective recommendation, as well as strategies of care and therapeutic alternatives available in the SUS were included. Their content has been adapted to a lay language and all of the documents were made available on the CONITEC website in the “Law and Health Section”.

**CONCLUSIONS:**

The availability of QA represents a strong link between evidence and actions in health. For, they enable broad access to quality information by the lay public and stakeholders who seek information to support evidence-based decision-making.

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# PD60 Public Consultations And Their Influence On Health Decisions

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**INTRODUCTION:**

Public consultation is one of the phases provided by the law that rules the health technology incorporation process in Brazilian Public Health System (SUS). In the Brazilian model, anyone can participate as long as he/she identifies her/himself. During the decision-making process these suggestions are analyzed by the National Committee for Health Technology Incorporation (CONITEC) and, sometimes, they are responsible for changing a preliminary recommendation for a technology. This study aims to identify the health technologies for which CONITEC revised the initial negative recommendations due to the contributions received during the public consultation.

**METHODS:**

A descriptive study using as input data the information on coverage decisions available on the CONITEC website.

**RESULTS:**

Since CONITEC’s creation until October 2017, CONITEC enacted 241 public consultations. Fifteen cases of change to the preliminary negative recommendation were found and among these eight (53 percent) had the economic studies or proposed technology price reconsidered by the companies. In the other seven decisions, the Board also regarded as important the reasons for changing the initial recommendation: new evidence on efficacy and safety as well as the analysis of different outcomes previously unconsidered in the preliminary assessment.

**CONCLUSIONS:**

During the public consultations, besides technical-scientific information, personal experiences and opinion reports on each health technology analyzed, CONITEC received new price offers and economic studies from the applicants. This new material has allowed, in some cases, these technologies to become competitive and to be included as alternatives to those already available,

provided there is no clinical impairment. This study reinforces the importance of the public consultation and social participation in the process of health technologies incorporation in Brazil, considering its capacity to add new information to the decision-making process.

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## PD61 HTA Regional Network In The Central Region Of Brazil: Survey In 2016

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### INTRODUCTION:

The Federal District in Brazil has about 2.9 million inhabitants and the public health system is focused on medical specialties, with one university hospital and twenty regional hospitals. This ecosystem is favorable for fostering health technology assessment (HTA) to improve the efficiency and effectiveness of health care. The objective was to identify institutions that could form a HTA network to support decision-oriented evidence in the public health system.

### METHODS:

Stakeholders from the hospitals and training/research institutions in the Federal District were surveyed. An online questionnaire (Google Docs) was developed to identify the potential and capacity of institutions to analyze or produce clinical and economic evidence. Two HTA seminars were held to spread knowledge about HTA and to encourage stakeholders to complete the survey.

### RESULTS:

The questionnaire response rate was thirty-five percent (25/70). Fifteen institutions were cited by the respondents as having the potential to build a HTA network. Twelve of the institutions produced rapid reviews and clinical guidelines, but only three of these had an organized priority setting process or produced assessments at the request of the hospital manager. The challenges identified were training and willingness of decision makers to organize HTA units in the hospitals.

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### CONCLUSIONS:

An executive group was created which defined a strategy to support the implementation of HTA units as part of the HTA National Network (REBRATS). A regulation proposal was also created to encourage decision makers to activate a HTA network in the Federal District.

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## PD62 Off-Label Use Of Medicines For Public Health Needs

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### INTRODUCTION:

The use of drugs for clinical conditions that differ from those approved in prescribing information (product labels) is known as off-label use. In Brazil, the Brazilian Health Regulatory Agency (ANVISA) is the official organization that regulates the use of health technologies. For technologies to be incorporated into the Brazilian public health system, registration with ANVISA is mandatory. However, occasionally, it is necessary to evaluate technologies for off-label use in the interests of public health. This study aimed to identify the health technologies recommended by the National Committee for Health Technology Incorporation (CONITEC) with an off-label indication between January 2012 and October 2017.

### METHODS:

A descriptive study was undertaken using data available on the CONITEC website.

### RESULTS:

The study identified seven drugs with a favorable recommendation for off-label use: everolimus, sirolimus, and tacrolimus as immunosuppressants in transplant recipients; clozapine for bipolar affective disorder; pentoxifylline for cutaneous leishmaniosis mucosa; risperidone for adults with autism spectrum disorder, and bevacizumab for age-related macular degeneration and diabetic macular edema. For these decisions the Committee considered the scientific evidence available for the indication proposed, the severity of the disease, and the existence or absence of alternative treatments. This was possible because Brazilian legislation allows

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