International Journal of Technology Assessment in Health Care, 33:4 (2017), 411–414.
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doi:10.1017/S0266462317000575

IMPACT OF HEALTH TECHNOLOGY ASSESSMENT IN LITIGATION CONCERNING ACCESS TO HIGH-COST DRUGS

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Objectives: The impact of health technology assessment (HTA) in the judicialization of the right of health has not been deeply studied in Latin American countries. The purpose of this study is to review the process of judicialization of the access to high cost drugs in Uruguay and assess the impact HTAs have had on this process.
Methods: The methodology used for this study included a comprehensive literature search in electronic databases, local journals, internal documents developed in the Ministry of Health, as well as conducting interviews with key informants.
Results: Judicialization of the access of high cost drugs has been increasing since 2010. The strategy of the Ministry of Health of Uruguay to decrease this problem included the organization of roundtables with judges and other stakeholders on the basis of HTA, the training of defense lawyers in the use and interpretation of HTA, and the participation of a professional who develops HTA in the preparation of the defense arguments. A year after the implementation of this strategy, 25 percent of writs of protection were won by the Ministry of Health.
Conclusions: Even though the strategy implemented was effective in reducing the loss of litigations, it was not effective in reducing the growing number of writs of protection. It is essential to address this problem in a broad debate and to promote understanding between the parties.

Keywords: Jurisprudence, Technology assessment biomedical, High-cost technology, Writ of protection

Health technology assessment (HTA) has been defined as a multi-stage process that helps to identify an intervention's optimal usage, its appropriate placement in the spectrum of care, and to deliver the intervention to the patients who will benefit from it (1–3).

The primary purpose of HTA for the Ministry of Health of Uruguay is to provide policy makers and other key decision makers with evidence-based information on the relative benefits, safety, and costs of available treatments based on a systematic and transparent assessment process (3;4).

In Uruguay, the National Integrated Health System provides universal coverage for treatments included in the National Formulary, a positive drug list that includes all drugs defined for reimbursement. High cost drugs are included in the formulary by the decision of a commission of government representatives and several other stakeholders (5). The Division of Health Technology Assessment of the Ministry of Health of Uruguay (MHU) provides HTA for each drug that is a candidate for inclusion to inform decisions. After this process, some drugs are not prioritized for inclusion in the formulary by the commission.

In Uruguay, patients can seek access to high cost technologies that have been denied for coverage through litigation (writ of protection) (6). This judicialization is understood by Menicucci and Machado as an influence of the "JUDICIARY over political decisions, taking on roles that should be exercised by the EXECUTIVE and the LEGISLATIVE." Such influence might be through the use of judicial procedures transferring a decision-making power to the JUDICIARY (7). In our country, this situation threatens the Ministry of Health governance processes and the financial sustainability of the National Health System.

The judicialization of the right to health has increased rapidly in Latin America where national constitutions of several countries give citizens guaranteed rights, including the right to health (8). Several authors have explored the impact of HTA and have suggested methodologies to study this phenomenon, but in these publications impact of HTA has not been related to litigation for access to high cost treatments (3;9;10). The purpose of this study is to review the process of judicialization of the access to high cost drugs in Uruguay and to assess the impact that HTA has had on this process.

METHODS

The methodology used for the review process included a literature search in electronic databases (PUBMED and LILACS)

The authors acknowledge all the people who provided information, support (nonfinancial), and comments for this study, especially Silvina Etcharte and Sandra Doldán. We also thank Tara Schuller for her help in English editing. Financial support: There was no formal financial support or funding for this study.

https://doi.org/10.1017/S0266462317000575 Published online by Cambridge University Press

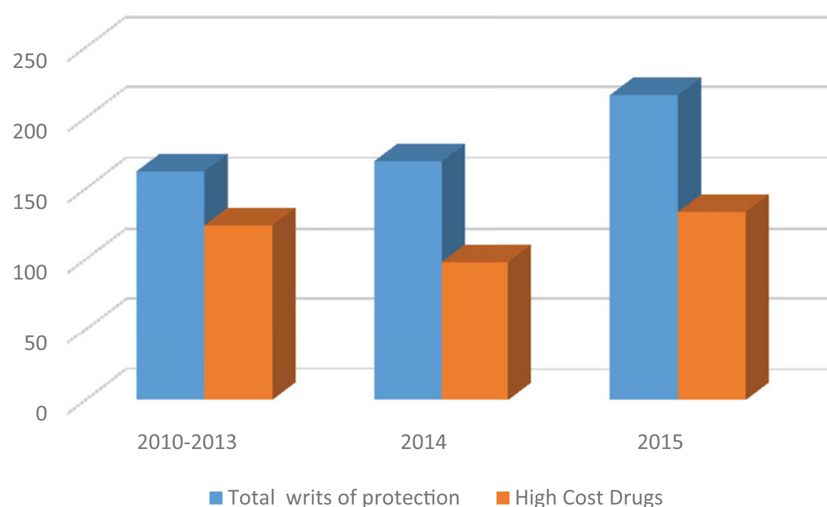

Figure 1. Evolution of the number of writs of protection 2010–15. Uruguay. Notes: The left bar represent the total number of lawsuits; the right bar indicates the proportion of the total that addressed high cost drugs. In 2010, there was just one lawsuit. The average number of lawsuits for high cost drugs per year in 2011–13 was forty-one.

including the terms: technology assessment, litigation, jurisprudence, high cost drugs. Local and regional journals were also reviewed, as well as internal documents produced by the Ministry of Health of Uruguay (MHU). Interviews of key informants from the technical and judicial sections of the MHU were also performed. This information was organized in categories: HTA history in Uruguay, stages of judicialization process, strategies developed by the government to face this problem, and impact of HTA in this process.

RESULTS

Eighty-eight papers were retrieved and reviewed from the search of scientific databases and an additional three working documents were retrieved and reviewed from the MHU. Six interviews of key informants were conducted.

The Health Assessment Division (HAD) of MHU started producing HTA to inform decisions for the inclusion of drugs in the National Formulary in 2010. Since then, an average of fifty-one drugs have been evaluated per year with approximately half of these being high cost medicines.

In 2010, the first writ of protection for cetuximab for the treatment of metastatic colorectal cancer was presented in courts. Since then, the number of writs of protection have increased every year (Figure 1). In the 3 years following the first lawsuit (2011–13), there were 123 writs of protection for high cost drugs (an average of 41 per year). This amount increased every year, reaching 133 lawsuits for high cost drugs in 2015.

The judicial process of writ of protection includes several stages: the presentation of a writ of protection in courts, a first decision by a judge within 3 days, and the possibility to appeal the court decision. Lawyers from the MHU legally represent it in courts and are responsible for its defense.

From 2010 to 2013, almost all writs of protection cases resulted in the requirement of the MHU to provide the drug requested. Even though these drugs were assessed in a transparent process by the MHU and received a negative recommendation for inclusion in the formulary, the legal authorities directed the MHU to provide them to those patient(s) who brought forward the writ of protection. The decision of the courts, however, does not mandate the MHU reverse their decision and include these drugs in the National Formulary. In this context, the MHU recognized that it was necessary to improve communication with the judicial system to explain the process of HTA and the ways decisions are made to maintain the sustainability of the health system.

From the second half of 2013 through 2014, three main strategies were implemented by the MHU in an attempt to decrease the number of court cases: (i) a series of national dialogue roundtables; (ii) the training of defense lawyers in the use and interpretation of HTA; and, (iii) the incorporation of an HTA technical professional in the defense process in courts.

The national dialogue roundtables started in 2012 and they were made formal processes in 2013 and 2014. They included the participation of the main actors linked to the legal enforcement of the right to health including the judicial system, academic institutions, professional organizations, consumer associations, representatives of healthcare providers, and industry. The concepts discussed during these roundtables included(information provided by key informants): the right to health defined in the National Constitution, the allocation of financial resources to cover medications, the economic impact that the prosecutions impose on the state budget, the distortion in the distribution of public health resources, and role of HTA developed by MHU in the defense process.

An HTA technical professional from HAD joined the team of lawyers from the MHU starting in 2013. However, this was

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Table 1. Evolution of the Results in Courts of Writs of Protection of High Cost Drugs: 2011–15, Uruguay

	2011–2013		2014[a]		2015[a]	
	N	%	*N*	%	*N*	%
Lost	118	95	73	74.5	111	83.5
Won	6	5	25	25.5	22	16.5
Total writs of protection	124	100	98	100	133	100

[a]The percentage of writs lost before (2011–13) and after the implementation of the strategies involving HTA was significantly lower both in 2014 ($p < 0.0004$) and 2015 ($p < 0.01$) (Chi2 test).

preceded by ten internal workshops coordinated by HAD in which lawyers were trained in the interpretation of HTA reports to be used as instruments in the legal argument. The main role of the HTA professional was to collaborate in the development of the judicial arguments by providing scientific evidence to the defense and also to participate in several court trials.

During 2014 and 2015 (after the implementation of these strategies), there was a decrease in the proportion of writ of protection cases lost by the MHU. This statistically significant result is mentioned in the note below Table 1 and suggests the influence of HTA in this regard. However, the total number of court cases did not decrease over this period. This is perhaps not surprising because the strategy was developed for lawyers and judges to improve their understanding and use of HTA in court proceedings; it did not target the source of writs of protection, which come primarily from health providers and patients.

DISCUSSION

The judicial processes related to the access to high cost technologies that have been denied coverage began in Uruguay in 2011 and was fully implemented in 2015. Over this period, it has been a growing trend with a focus on expensive drugs.

Uruguay has implemented various strategies to include HTA in litigation for the right to health. However, while these strategies suggest the influence of HTA on the results of court cases by the decreased number of negative verdicts, they have not been effective in decreasing the main problem: the growing number of prosecutions for access to high cost drugs which are not part of the National Formulary.

Some new strategies are being tested in the country to decrease the writ of protection. For example, a Commission has been created in the Ministry of Health to assess patient requests on a case-by-case basis for the purpose of reducing the number of lawsuits brought forward. Another example is the development in 2016 by the MHU of an online course for healthcare staff to inform them about HTAs, and how they are produced and used in decision making about drug coverage. These new strategies will be evaluated in 2017. Additional strategies are planned for the future to raise awareness and discuss this issue among specific patient groups and the general population, who are the main affected parties in this situation.

The judicialization of the right to health not only challenges an explicit priority setting process used by MHU to allocate finite health system resources, but it also may result in providing preferential access to people of higher socioeconomic status who may be more likely to pursue a court case. This situation may increase inequities in the access to high cost drugs across the population.

This problem is growing in the Latin American context, and it is necessary to frame the situation in our country. The judicialization of the right to health is a serious challenge for our society as a whole. Solutions should include a broad debate of the issues with the various stakeholders and building a mutual understating about the affordability of the health system.

CONFLICTS OF INTEREST

The authors have nothing to disclose.

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