OBJECTIVES

The objective of this research is to present the characteristics and the results of the quick-HTA process that was initiated in June 2013 in Romania.

METHODS

Both the health care context and the Romanian legislation covering HTA were studied whilst considering: the reasons behind HTA introduction, the key stakeholders and the HTA process, then a critical appraisal was done covering public HTA reports and the decisions taken by the Ministry of Health (MofH).

RESULTS

1. The reasons behind HTA introduction.

The first steps towards Health Technology Assessment (HTA) were taken in Romania between 1992-2002 when some form of mentorship was performed in this area with Canadian support [1]; later on, from 2002 to 2011 HTA remained a subject only for the academic and research purposes. Only the pressure brought by the Memorandum of Understanding between Romanian Government with International Monetary Fund (IMF), World Bank (WB) and European Commission (EC) reactivated the HTA subject as the meaningful tool to update the Reimbursement List with new drugs [2].

The reimbursement list has not been updated since 2008, this meaning that the Romanian patients have been negated the access to the most innovative molecules in healthcare. This situation appeared to change in 2012 when the Ministry of Health took the responsibility to develop an internal HTA Unit; on June 10th, 2013, the new HTA legislation (Ministry of Health order 724/2013) has been set in place.

The HTA process was designed to be included in the overall process of Market Access through a specific process that involves various stakeholders and a clear sequence of steps. The interactions between the parties implicated in the reimbursement process can be described as a chain of decisions that design a clear trajectory of the molecule towards the final goal of the patients’ access to the reimbursed drug [Figure 1].
Figure 1. Main stakeholders involved in the reimbursement process for a new oncology drug in Romania, 2013.

2. The key stakeholders.

The HTA legislation introduced the following stakeholders for the HTA process:

a. HTA Unit from the Ministry of Health – its main purpose is to evaluate the HTA dossiers submitted by the MAHs and to generate an appraisal that is summarized on the score card and that is translated into positive/negative reimbursement decision.

b. Specialty Commissions from Ministry of Health – it evaluates the relative efficacy and safety and PROs for the molecules, the methodological quality of the submitted documentation, the relevance of the chosen comparator (from the clinical trials).

c. National Commission from Ministry of Health – its main purpose in the HTA process is to evaluate, compare and contrast the evaluation provided by the Specialty Commissions and the HTA Unit and to give the final approval for including a drug in the reimbursement List.

d. Market Authorization Holders – have to submit the HTA dossier and to be at the disposal of the HTA Unit if there is a need for supplementary data.

e. Association of Pharmaceutical Companies – its role is to participate (as observers) in the commission for appeals (Arbitrage Commission).

f. Patients' Advocacy Groups – its role is to participate (as observers) in the commission for appeals (Arbitrage Commission).

The stakeholders’ interactions within the HTA process, from HTA dossier submission to final appraisal report publication is presented in Figure 2.
Figure 2. Stakeholders involved in the HTA process in Romania, 2013.

3. The HTA process.

The HTA process involved the evaluation of multiple types of drugs: new INN, innovative molecules, old molecules that have new indications according to Summary of Product Characteristics (SmPC), biosimilars and generics (that do not have the originator on the Romanian market).

The Romanian HTA system was not a typical HTA system, involving economic evaluations techniques, but a quick-HTA system based on a score card, following the recommendations of the NICE International Report for Romania [3]. The HTA evaluation was made through a score card that summed up 10 points in total. The threshold for the positive reimbursement status had been set at 6 points on the scorecard.

The points were given to a molecule as follows:
- HAS (French HTA body) evaluation (SMR level assessment) – max. 1 point
- NICE/SMC/AWMSG (from UK) evaluation – max. 1 point,
- Number of EU countries with positive reimbursement status – max. 2 points,
- Relative efficacy/effectiveness – max. 2 points,
- Relative safety – max. 2 points
- Relative patient-reported-outcomes (PRO) – max. 2 points.

After dossier submission by the MAHs, the HTA Unit had 90 days to perform the evaluation and to publish the results (decisions) on the Ministry of Health web site. Consequently, in 7 days the MAH could contest the decisions and in the following 5 days after the appeal, the Arbitration Committee had to provide a solution. If the MAH was not satisfied with the solution provided by the Arbitration Committee, then could go for a legal case to the Court.
4. The critical appraisal covering public HTA reports.

The first wave of dossiers was submitted in June 2013, and by December 2013, most of the dossiers submitted within the first round have been evaluated by the HTA Unit and the MoH has made public the score card results for 167 submitted dossiers. There has been an acceptance rate (score above 6 points) of about 77% [4]. Out of all the positive decisions 69% were new INNs (90 molecules), while indication/line extensions were about 16% [Figure 3].

![Figure 3. Percentage of positive appraisal divided by type of molecule](image)

Considering the delay in the reimbursement process in Romania, most of the pharmaceutical companies have submitted HTA dossiers in order to obtain reimbursement for their molecules. Bristol Mayer Squib (BMS) has submitted the largest number of dossiers, followed by Novartis, GSK and Roche and have received positive evaluation outcome for most of their submitted dossiers. [Figure 4].

![Figure 4. Number of submitted dossier by MAH which received positive evaluation](image)
The Romanian healthcare system has been lacking drugs in a lot of therapeutic areas; the patients have had restricted access to the latest molecules for diabetes, autoimmune and neurologic diseases and nevertheless different types of cancer, hence the greatest number of molecules that have received positive HTA appraisal were in these areas. [Figure 5].

The HTA included also biosimilars, all 4 of them receiving positive decisions.

The evaluation process seemed to be going well and the data submitted was robust and well-structured. All stakeholders were confident that 2014 will unlock the access to new innovative drugs and in February 2014 was published a draft of new Reimbursement List which included the results of the quick-HTA process.

Unfortunately, in April 2014, the new Government abrogated this HTA legislation and the already-published HTA reports, claiming that the process didn’t mentioned neither the criteria for exclusion from the List of reimbursed drugs nor the budget impact, within HTA reports. Moreover, the HTA process was moved into the responsibility of the National Agency for Drugs.

CONCLUSIONS

- The initial HTA process seemed to be an important step in the reorganization of the Romanian healthcare system and it was part of a greater process that involves also the readjustment of basic social health insurance, the introduction of the private insurance and other important changes.

- The implementation of the quick-HTA in Romania took a good start, using a mixture of information, from benefits and cost-effectiveness in other countries, to relative effectiveness, safety and PRO. However, the lack of consideration for the local context and the political disagreements led to a temporary suspension of the quick-HTA process.

- Even though the 2013 HTA legislation was abrogated, the new government considered that the update of the reimbursement List is important and issued a new HTA legislation in June 2014. The new legislation took most of the principles of the quick-HTA system, but introduced a budget-impact value on the score card. Its results will be available at the beginning of 2015.
References:


2. C.P Radu, B. Pana, Key Aspects Regarding The Introduction Of Health Technology Assessment In Romania, Management in Health, 2013; 17(2) 4–7


4. Sinteza privind propunerea de lista de medicamente compensate realizată de reprezentanții Comisiei Naționale de coordonare a comisiilor de specialitate ale MS, conform metodologiei aprobate prin Ordinul Ministrului Sănătății nr. 724/2013 (“Synthesis regarding the proposed reimbursement list update developed by the representatives of the National Commission of the Ministry of Health, according with the provisions of the ministerial order # 724/2013”).

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