APPLICATION OF HEALTH TECHNOLOGY ASSESSMENT AND PHARMACOECONOMICS IN THE DECISION-MAKING PROCESS IN SELECTED EU MEMBER STATES

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BACKGROUND

The application of Health Technology Assessment (HTA) and Pharmacoeconomics (PE) into real health policies in the selected European countries - Austria, Bulgaria, Croatia, Czech Republic, Germany, Hungary, Latvia, Poland, Romania, Serbia, Slovakia, Slovenia, UK (Figure 1) was analyzed based on the outputs from the conference “Optimization of PE and HTA: Importance for National Health Policy and Cross-Border Cooperation” (Slovakia, 10/2012).

OBJECTIVE

The objective of the paper was to compare the implementation of HTA and PE into the health care systems and to find the most transparent process based on the pre-defined criteria.

METHODS

The primary method used for the analysis was structured evaluation of the outputs from the conference. The other relevant information resulted from the systematic review of PubMed, EMBASE and CENTRAL in years 2011-2012 extended to official websites of public health institutions and officially published data in order to select all papers on HTA/Pharmacoeconomical related to selected European countries.

RESULTS

We evaluated 9 characteristics relevant for the decision-making process:

- Legislative background
- Implementation
- Resource availability
- Process transparency
- Patient involvement

And respecting the deadline of 180 days for issuing a decision.

Every characteristic was deeply studied in all relevant materials including the published articles. We evaluated them by the same weight. Based on pre-defined description characteristic by characteristic (below) one of 3 possible evaluations was taken: Yes (evaluated or present – scored by 5 points), partially yes (scored by 2.5 points), and not present at all (scored by 0 points).

LEGISLATIVE BACKGROUND

The evaluation presented was evaluated as present in case inclusion of HTA in all relevant HTA parameters and was described either in primary or in secondary legislation. Very general description was ranked as partially present.

IMPLEMENTATION

HTA-related legislation is not implemented in all countries. If HTA as regular part of the evaluation was scored as present HTA as voluntary part of the process was ranked as partially present.

BINDING FORCE

If legislation was implemented and binding force was clearly described, it was evaluated as presented. Partial presence was labelled in the situation when binding force in the legislation was not clearly described. If no binding force was described in the legislation, it was evaluated as not present.

INSTITUTIONALIZATION

An independent and separate institution was evaluated as fully present. If a separate institution, although not fully independent, existed, it was evaluated as partially present. It was evaluated as not present if there was only a separate HTA department at the Ministry of Health or Health Fund and thus it was not independent at all.

QUALIFIED HUMAN RESOURCES AVAILABILITY

Presence of more than 5 experts (fully skilled to develop, evaluate and apply the model) per 1 mil of inhabitants was evaluated as fully present. Any 5 experts per 1 mil inhabitants were evaluated as partially present. Absence of fully skilled experts was ranked as not present at all.

EXISTED METHODOLOGY/GUIDELINES

Presence of the methodology or guidelines in any form of the legislation was ranked as fully present. If some parts were somewhere published then it was ranked as partially present.

TRANSPARENT PROCESS

Fully transparent and clear process in every step was evaluated as fully present. In case some steps were not fully clear or transparent then the process was ranked as partially transparent.

PATIENT INVOLVEMENT IN THE PROCESS

There were only two options in this case. Patients were either present (involved) or not.

DESIGNING THE DEADLINE OF 180 DAYS FOR ISSUING A DECISION

Issuing of the decision and its real application within 180 days was ranked as fully present. Issuing of the decision within 180 days without its real application (e.g. delay due to execution) was ranked as partially present. Issuing after 180 days was ranked as not present.

CONCLUSION

One of the criteria was availability of high quality system of human resources which was a strong discriminating factor in smaller central and eastern European countries. High quality system of human resource was not present at all in countries like Romania, Serbia or(Kingdom) the United Kingdom was shown to have the most transparent system. Germany and Austria ranked as the second. Hungary and Poland ranked as the third, followed by Slovakia. The least transparent system was found in Bulgaria and Romania.

DISCUSSION

Romania introduced a new HTA approach for the evaluation of new technologies’ application to get reimbursement during June 2013 [3]. Romania started to use the balance score card consisting of 6 parts. It was based on French evaluation, UK (Scottish or Welsh or English) evaluation, and reimbursement of the technology in EU member states comparable efficacy, comparative safety and recommendation of patient reported outcomes. Budget impact analyses preferably based on the local date was also part of information to be submitted obligatory.

An important characteristic to get highly valid results from HTA – local data availability was not mentioned. In majority of countries in the Central European region, local data were not available or local data were even impossible to generate. In this situation, it was even more unclear how transparency of the process reflected this basic lack of the data.

ACKNOWLEDGMENTS

The data search and translation of the analysis was exclusively funded by an educational grant from the GlaxoSmithKline Slovakia, with no professional or other limitations whatsoever. First manuscript in Slovak language was provided by the employees of the GlaxoSmithKline Slovakia based on request.

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3. J. Tomas, L. Gouveia, J. Ribeiro, I. Zechmeister, “HTA Role of HTA in Health care in the select all papers on HTA/Pharmacoeconomics in institutions and officially published data in order to find the most transparent, high quality system of human resources which was a strong discriminating factor in smaller central and eastern European countries. High quality system of human resource was not present at all in countries like Romania, Serbia or(Kingdom) the United Kingdom was shown to have the most transparent system. Germany and Austria ranked as the second. Hungary and Poland ranked as the third, followed by Slovakia. The least transparent system was found in Bulgaria and Romania.

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