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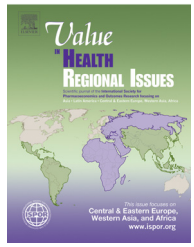

Health Economic Data Requirements and Availability in the European Union: Results of a Survey Among 10 European Countries

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ABSTRACT

Objectives: To compare data requirements and their availability for health economic (HE) evaluations in five countries in Central/Eastern Europe (CEE) (Poland, the Czech Republic, Slovakia, Hungary, and Romania) and five countries in Western Europe (WE) (the United Kingdom, France, Germany, The Netherlands, and Sweden). **Methods:** A questionnaire was developed and distributed to market access personnel from Pfizer who were asked to complete the questionnaire either from their own knowledge or with support of external experts. The questionnaire focused on the obligation to conduct HE assessment for reimbursement submissions, local HE guidelines, applied discount rates for future costs and effects, willingness-to-pay thresholds, and available data sources. **Results:** HE is mandatory in all CEE and three WE participating countries for reimbursement applications of innovative drugs. Usually, cost-effectiveness analysis and budget-impact analyses are required. The preferred outcome of cost-effectiveness analysis is quality-adjusted-life years. In Romania, France, and the Czech Republic, guidelines could not be identified at the time of the survey. The applicant usually prepares HE evaluations; in Sweden, the United Kingdom, The Netherlands, and Poland, unlocked models have to be presented for scrutiny. Discount rates vary from 1.5% to 5%, and, usually, is the same for costs and outcomes (except in The Netherlands and Poland). Only the United Kingdom, Poland, and Slovakia have an explicit willingness-to-pay threshold. In Poland, it is based on the gross domestic product per capita, and in Slovakia, it is based on multiples of average monthly salary. Differences were found on data availability. In WE, data can be acquired easier than in CEE. Health insurance funds do not provide their data unless they were published. Patient registries are either not available in CEE or difficult to access, so applicants mostly rely on retrospective medical chart data, hospital information systems, or expert panels. **Conclusions:** We found similar requirements for HE analyses in CEE and WE but differences in data availability. This results in less accurate inputs across the CEE, influencing analyses' outcomes.

Keywords: Central and Eastern Europe, cost-effectiveness, data availability, data requirement, health technology assessment, Western Europe.

Introduction

The continuous influx of health care technologies across European Union (EU) member states together with limited financial resources have put more emphasis on identifying those innovations providing best value for money. Structured health technology assessment (HTA) has therefore been implemented across Europe. Cost-effectiveness (CE) and also budget impact (BI) analyses represent an important part of HTA in most of the countries, including Central and Eastern European (CEE) countries. Hence, not surprisingly, CE and BI analyses are rapidly emerging in these countries.

But CE studies and BI analyses require data, and the general feeling is that such data are much less available in CEE countries than in Western European (WE) countries. We conducted a survey among 10 CEE and WE member states, with the aim of comparing data requirements and their availability for health economic (HE) evaluations.

Methods

A total of 10 countries participated in the survey, five representing Central and Eastern Europe (the Czech Republic, Hungary, Poland, Romania, and Slovakia) and five representing Western Europe (France, Germany, The Netherlands, Sweden, and the United Kingdom). The project was supported by an educational grant from Pfizer.

A common 11-item questionnaire was developed and sent out to participating countries (see Appendix 1 found in Supplemental Materials found at http://dx.doi.org/10.1016/j.vhri.2014.06.003). Health economics and outcomes research representatives from Pfizer in individual countries were asked to complete the questionnaire either from their own knowledge or with the support of local experts. Data obtained were synthesized and rechecked locally by local experts in HTA to avoid bias or misinterpretations.

Conflict of interest: The authors have indicated that they have no conflicts of interest with regard to the content of this article.

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The questionnaire included the following items:

1. CE and BI analyses—mandatory/voluntary part of the reimbursement submission.
2. Presence/absence of an official HTA agency.
3. CE and/or BI analyses included/not included in legislation.
4. Methodological guidelines for CE analyses present/absent.
5. Presentation of unlocked CE models to decision makers obligatory/optional.
6. Required perspective of CE analyses—health care/societal.
7. Discount rate for costs and benefits in CE analyses.
8. Choice of the comparator used in the CE analyses.
9. CE threshold.
10. Availability of data sources used in CE and BI analyses including epidemiology, resource utilization, and costs.
11. Unavailable or difficult to obtain data necessary for CE and BI analyses; ways how to overcome missing data.

Results

CE analysis is a mandatory part of the HTA for innovative drugs in all CEE and three of the participating WE countries (The Netherlands, the United Kingdom, and Sweden). BI analysis is usually also required, with the exception of Romania and Sweden, where only CE analysis is mandatory.

All survey participants from WE countries have an official HTA agency, a review body that reviews and/or produces and disseminates assessment reports on medical technologies. Most of the agencies are governmental institutions. In the CEE region, only Poland and Hungary reported an official and functioning governmental agency (note that during 2013, Romania established a formal HTA agency at the Ministry of Health). In addition Poland has several private entities that focus on providing not only HTA reports, systematic reviews, data collection, and evaluation but also training and educational activities.

With the exception of Germany, HE is included in the legislation of all participating CEE and WE countries, usually as a part of a complex HTA process. In France, the reimbursement decision is currently mainly based on the medical benefit of the assessed intervention; for the pricing decision, BI is taken into account. Furthermore, CE data are required only during reassessment after a product is launched. Changes are, however, discussed; that is, CE should be included into the assessment and appraisal process upfront. In most of the other countries, CE is an important parameter for the reimbursement decision (the United Kingdom, Poland, The Netherlands, Sweden, the Czech Republic, and Slovakia). Besides the clinical evaluation (safety, efficacy, and effectiveness) of the assessed technology, its BI and CE are usually considered before reimbursement is granted. Quality-adjusted-life years (QALYs) seem to be the preferred outcome in CE analyses not only in WE countries (the United Kingdom, The Netherlands, and Sweden) but also in several CEE countries (Poland, Slovakia, Hungary, and the Czech Republic).

Not all countries applying HE evaluations in the decision-making process follow local guidelines for HE analyses. In Romania and the Czech Republic, official guidelines could not be identified at the time of the survey (note that in 2013, CE and BI guidelines were published in the Czech Republic by the local pricing and reimbursement authority).

Reimbursement files that include HE evaluations are usually prepared by the applicant (industry) and submitted to local agencies. In Sweden, the United Kingdom, The Netherlands, and Poland, full, unlocked models have to be presented for scrutiny. In CEE countries except Poland, the presentation of models is not obligatory, but when they are used they have to be described in detail and applicants might be asked for clarification or additional information requested by authorities. Differences also exist in the communication between applicants and authorities during the HTA process across countries. While in several countries, applicants are given the opportunity to present HE results to a multidisciplinary committee (Slovakia) or clarify uncertainties in written form (the United Kingdom and Poland), other agencies do not organize hearings (the Czech Republic, The Netherlands, Romania, Poland, and Hungary). In Sweden, applicants might be invited in specific situations, while in The Netherlands scientific advice might be obtained before submitting an official reimbursement dossier.

Only 4 of the 10 countries require a comprehensive societal perspective in the CE analysis (The Netherlands, Sweden, France, and Poland); however, in other countries, societal costs are optional (Romania and the Czech Republic), without an impact on the decision.

The most common annual discount rate used in the CE baseline scenario varies between 1.5% and 5% (Table 1) and, with the exception of The Netherlands and Poland, is the same for costs and outcomes.

One of the crucial parts of the CE analysis is the comparator's choice because all countries use a comparative assessment. In most countries, the comparator is the standard intervention, which is expected to be replaced by the new technology (The Netherlands, the United Kingdom, Sweden, Poland, Hungary, and Slovakia) or the most cost-effective technology, if more comparators can be considered. In some countries, the comparator is either not specified (the Czech Republic, France, and Romania) or explicitly identified by authorities (Germany). Although preliminary advice on comparator selection is possible in some countries (e.g., The Netherlands), the final decision on the appropriate comparator's choice is made during the HTA process (Germany, The Netherlands, Sweden, and the Czech Republic).

Only three of the assessed countries have an explicit willingness-to-pay (WTP) threshold. In the United Kingdom, the threshold of £20000 to £30000 is currently applied with some exceptions (e.g., end-of-life interventions). In Slovakia, a WTP threshold based on multiples of average monthly wage was introduced and is included in legislation. If interventions prove an incremental cost-effectiveness ratio of less than 24 average wages (~€18,500/QALY), they are considered as cost-effective and quite likely to be included into reimbursement lists. The range of 24 to 35 average monthly wages (about €27,000/QALY) enables conditional reimbursement for 2 years with an agreed budget cap. Technologies with a higher incremental cost-effectiveness

Table 1 – Commonly used discount rates for costs and benefits.

Countries	Discount rates for future costs and health benefits (%)	
	Health effects	Future costs
The Netherlands	1.5	4
The United Kingdom	3.5	3.5
Sweden	3	3
France	NA	NA
Germany	Not defined	Not defined
Romania	Not defined	Not defined
Poland	3.5	5
Hungary	3.7	3.7
The Czech Republic	3	3
Slovakia	5	5

NA, not available/applicable.