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EUROPEAN DRUG REIMBURSEMENT SYSTEMS' LEGITIMACY: FIVE-COUNTRY COMPARISON AND POLICY TOOL

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Objectives. In a democratic system, decision makers are accountable for the reasonableness of their decisions. This presumes (i) transparency, (ii) relevance of the decision criteria, (iii) revisability of decisions, and (iv) enforcement/regulation. We aim to (i) evaluate the extent to which drug reimbursement decision-making processes in different contexts meet these conditions and (ii) develop, starting from these findings, a framework for improving the transparency and the relevance of used decision criteria.
Methods. We evaluated the Austrian, Belgian, French, Dutch, and Swedish drug reimbursement systems. Based on this evaluation, we developed a framework for improving the transparency of drug reimbursement decision-making processes. It makes explicit the questions often addressed implicitly during decision-making processes as well as criteria for answering each question.
Results. Transparency of appraisal processes varies across systems. Justification with explicit criteria is generally limited. Although relevant criteria are similar across systems, their operationalization varies and their role in the appraisal process is not always clear. All systems seem to implicitly address five key questions, relating to (i) the medical, therapeutic, and societal need for treatment; (ii) preparedness to pay for treating the condition as a principle and (iii) for using the treatment under consideration; (iv) preparedness to pay *more* compared with alternatives; and (v) actual willingness to pay from public resources.
Conclusions. Transparency of the appraisal process can be improved by using an explicit decision framework. Systematic use of such a framework enhances consistency across decisions, allows justification of value judgments, and thus enhances legitimacy of societal decision making.

Keywords: Drug reimbursement, Decision making, Advisory committees, Pharmaceutical economics

In the context of continuously increasing public expenditure on pharmaceuticals, the efficiency and sustainability of drug reimbursement policies become increasingly important. While the health systems that shape such policies have the same primary objective (to increase and maintain health), constraints force policy makers to make choices toward system sustainability (26). Despite variations in the organization and financing of health care between member states, the European Commission defined three common health system objectives: equity and accessibility, quality of care, and sustainability (12). The US Department of Health and Human Services highlighted similar objectives in its strategic plan 2010–15 (27). Competition between these objectives often forces policy makers to make trade-offs. These trade-offs are primarily a matter of normative choice: countries will aim for a socially acceptable equilibrium between the different objectives. Judging drug reimbursement systems on this outcome is difficult but we can argue that a legitimate policy-making *process* that facilitates decisions in line with public values would optimally serve the stated objectives. Key criteria for legitimacy or accountability for reasonableness according to Daniels and Sabin, are (i) transparency of the decision-making process, (ii) relevance of the decision criteria, (iii) revisability of decisions in light of new evidence and arguments, and (iv) enforcement/regulation of the previous criteria (7). This study evaluates to what extent these criteria are fulfilled in five European drug reimbursement systems with a different organizational and procedural context. The findings of this evaluation prompted for the development of a framework for improving the transparency of drug reimbursement decision-making processes and the relevance of drug reimbursement criteria. This study reports on both the evaluation and the decision framework.

METHODS

We assessed legitimacy of drug reimbursement decision making in five European countries as follows. First, we performed an in-depth analysis of five different European drug reimbursement systems using the analytical Hutton Framework (13). Table 1 presents characteristics of the five systems relevant for this study. Detailed methods and results of the analysis of the performance of these five systems are presented elsewhere

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Table 1. Summary Characteristics of Five National Reimbursement Systems

	Austria	Belgium	France	The Netherlands	Sweden
Regulation/ Enforcement					
National reimbursement agency	HVB	INAMI/ RIZIV	HAS	CVZ	TLV
Expert advisory committee	HEK	CRM/CTG	CT	CFH (and ACP)	TLV Expert Board
Scope of national agency	Outpatient drugs	Inpatient and outpatient drugs	Inpatient and outpatient drugs	Expensive inpatient and outpatient drugs	Outpatient drugs
Final decision maker	HVB	Minister of Health	Minister of Health	Minister of Health	TLV
Implementation of the outcome	Positive list	Positive list	Positive list	Positive list	Positive list
Pharmaceutical budget	Open-ended	Open-ended	Open-ended	Open-ended	Open-ended
Monitoring outcomes	Drug expenditure	Drug expenditure	Drug expenditure	Drug expenditure	Drug expenditure
Appeal options	Content and procedural grounds	Procedural grounds	Procedural grounds	Procedural grounds	Procedural grounds
Transparency					
Reimbursement reports publicly available	No	Yes	Yes	Yes	Yes (not if case is withdrawn)
Relevance					
Appraisal criteria (national level)					
Medical, therapeutic and societal need	Yes	Yes	Yes	Yes	Yes
Added therapeutic value	Yes	Yes	Yes	Yes	Yes
Cost-effectiveness	Yes	Yes	No for first decision		
Yes for revision	Yes	Yes			
Budget impact	Yes	Yes	Yes	Yes	No
Threshold (range) for cost/ QALY	No	No	No	No	No
Revision					
Ad hoc revision	Yes	Yes	Yes	Yes	Yes
Systematic revision	No	Yes, all drugs with recognized added value (class 1)	Yes, all drugs every 5 years	Yes, only expensive inpatient drugs	Case by case, and all drugs enlisted before 2002

Note. HVB, Main Association of Austrian Social Security Institutions [in German: Hauptverband der Österreichischen Sozialversicherungsträger]; HEK, Pharmaceutical Evaluation Board [in German: HeilmittelEvaluierungsKommission]; INAMI/ RIZIV, National Institute for Health and Disability Insurance [in French: Institut National d'Assurance Maladie-Invalidité; in Dutch: Rijksinstituut voor Ziekte- en Invaliditeitsverzekering]; CRM/ CTG, Drug Reimbursement Committee [in French: Commission de Remboursement des Médicaments; in Dutch: Commissie voor Tegemoetkoming Geneesmiddelen]; HAS, National Authority for Health [in French: Haute Autorité de Santé]; CT, Transparency Committee [in French: Commission de la Transparence]; CVZ, Health Care Insurance Board [in Dutch: College voor Zorgverzekeringen]; CFH, Expert Reimbursement Advisory Committee [in Dutch: Commissie Farmaceutische Hulp]; ACP, Appraisal committee [in Dutch: Advies Commissie Pakket]; TLV, Dental and Pharmaceutical Benefits Agency [in Swedish: Tandvårds- och läkemedelsförmånsverket].

(simultaneously submitted paper to the IJTAHC, this issue). Using data triangulation, we investigated policy documents publicly available in English, French, German, and Dutch at the Web sites of the reimbursement agencies, explored (gray) literature and other relevant publications obtained by means of Medline and Cochrane Library searches and provided by our interviewees, and conducted interviews. Interviewees were selected based on their involvement in the drug reimbursement procedure; they were policy makers from different organizations ($n = 48$), a patient representative ($n = 1$), or representatives of the pharmaceutical industry ($n = 8$). Interviews were performed by mail questionnaire (1), phone (2), or face-to-face

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(34), totaling fifty-seven persons (3, 24, 5, 14, 11 in Austria, Belgium, France, the Netherlands, and Sweden, respectively). The number of interviewees was deliberately higher in our own countries in which we started and in Sweden. Although the Swedish Web site provides a great amount of information in English, we needed to ensure complete data on the Swedish system not limited by language restrictions, because of time restrictions, but mainly due to learning effects we could reduce the numbers of interviewees in the subsequent countries. The aim of each interview was to retrieve (up-to-date) information unavailable in policy documents and literature and to obtain further insight into how the systems work in practice. Experts in each country validated all our individual country reports. For this analysis, we selected five European countries: Austria, Belgium, France, the Netherlands, and Sweden. Although this sample size is relatively small, we performed a detailed analysis requiring an intensive search for formal as well as informal information. In these five countries, we observed important differences in structure, organization, and procedures of the systems. Our sample includes (i) healthcare systems with various historical contextual backgrounds: Beveridge-type (Sweden), Bismarck-type (Austria, Belgium, France, and the Netherlands), and managed competitive (the Netherlands) systems; (ii) various types of final decision makers: the reimbursement agency (Austria and Sweden) and minister of health (Belgium, France, and the Netherlands); and (iii) various implementation levels: national (Austria, Belgium, France, and the Netherlands) and regional (Sweden).

Second, based on the findings of the in-depth analysis, we evaluated the five systems' organization, structure, and procedures against the framework for accountability for reasonableness of Daniels and Sabin (7). This ethical-theoretical framework defines four conditions for achieving legitimate and fair coverage decisions for new treatments. The four legitimacy conditions are: (i) Transparency of the decision process: the process must be fully transparent about the grounds for/rationales behind a decision; (ii) Relevance of the decision criteria: the decision must rest on reasons that all stakeholders can accept as relevant to meeting health needs fairly given the resource constraints; (iii) Revisability of decisions: decisions should be revisable in light of new evidence and arguments; and (iv) Enforcement/ regulation: there must be some kind of regulation guaranteeing the previous three conditions.

Although this framework has been criticized (4;19), empirical evidence suggests that priority-setting processes that fulfill the conditions for accountability for reasonableness are perceived as being legitimate and fair (9;14;20;27). Without making any value judgments, we evaluated each country's achievement regarding these legitimacy conditions. There is a conceptual distinction between assessment, appraisal and decision (23). Our evaluation mainly focuses on appraisal.

Third, based on our legitimacy evaluation, we developed a policy tool that can improve transparency and relevance of the drug reimbursement decision-making process in all countries. We unraveled the decision-making process in smaller pieces and identified questions that all systems seem to address to a certain extent, more or less explicitly. After that, we assigned appraisal criteria currently used either explicitly or implicitly to each of the defined questions. This process led to a five-question decision framework, including a set of relevant criteria for each question. Our developed framework provides a tool to structure the decision process, allows reconstruction of the decision process, can improve consistency across decisions, and provides a tool to increase transparency of the appraisal process. Finally, to illustrate the application of our framework, we described how each country addresses the questions and uses the criteria of our framework.

RESULTS

Evaluation of the Four Conditions for Accountability for Reasonableness

Condition 1. Transparency. Although all five systems seem to use similar criteria, the actual role of the criteria in the decision-making process is often not transparent. Assessment reports are usually made public, except in Austria, where evaluation reports (for outpatient drugs) are not published. However, the appraisal process, which leads to an advice or a decision, is rarely made public, although variations exist. The minutes of the French expert committee's meeting are published, including the main points of discussion, the voting results, and a motivated advice. The Belgian system publishes the initial assessment report, applicant responses, and the committee reactions to these responses, whereas the eventual (provisional) advice is withheld. Both countries conceal confidential information upon applicants' request if deemed justifiable by the expert committee. Dutch assessment and appraisal reports are available online and include main points of discussion. Appraisal committee meetings are open to the public. Sweden publishes the final reports online after deliberation with the manufacturer; confidentiality issues stated by the latter are concealed. Noteworthy is that in Sweden pharmaceutical companies can withdraw their case before the final reimbursement decision has been made, in which case no report is published – a guarantee of confidentiality at the cost of transparency.

Condition 2. Relevance of the Decision Criteria and Rationales. Involvement of all stakeholders affected by a decision is thought to facilitate accountability for reasonableness, because it increases the likelihood that the rationales adopted will be relevant and acceptable (8;14). This presumes, though, that all stakeholders understand the decision problem and recognize the choices that have to be made to meet the different healthcare system objectives; that is, they must be aware that resources are limited and fair choices have to be made within such a resource-constrained context (8). All systems ensure stakeholder involvement either through direct representation of stakeholders in the expert committee

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(Belgium and Austria) or through consultation of stakeholders by the expert committee in cases where this committee consists of scientific experts (Sweden, the Netherlands, and France). Only the Swedish expert committee has a patient representative as committee member.

Condition 3. Revisability. Revisability is most important in case of (high) uncertainty about the estimates of efficacy, effectiveness, cost-effectiveness, or budget impact, or if relevant evidence is still being developed. Austria is the only country that has no system of systematic revisions, although *ad hoc* revisions can be initiated. Belgium and the Netherlands have a revision procedure for specific drug classes, which can occur only once after the initial decision and within a window of 1.5 to 3 years (Belgium) or 4 years (the Netherlands). France revises all positive decisions every 5 years. In addition to an ongoing revision of all enlisted drugs before 2002, Sweden decides on a case-by-case basis whether a decision requires revision after a certain number of years. In all countries, depending on the re-assessment results revisions can have consequences, such as delisting or a change in the level of reimbursement or the level of restrictiveness of the reimbursement condition. After revision, reimbursement conditions might become more or less restrictive than during the period of temporary reimbursement, depending on the re-assessment results. In the Netherlands, the first revisions of expensive inpatient drugs that were conditionally reimbursed for a period of 4 years, are discussed now. Yet, their consequences are still unknown.

Condition 4. Enforcement. All countries legally instituted a designated national reimbursement agency. These agencies fall under ministerial responsibility and are audited or certified by external (parliamentary) committees. However, in all countries, little self-evaluation of the system is performed on the process and outcomes. (Parts of) reimbursement processes are monitored only on an *ad hoc* basis. The outcome is mainly monitored on pharmaceutical expenditure. All countries have formal appeal procedures for reimbursement decisions, although there is a variety in how and for what reasons appeal is possible. All countries but Austria allow applicants to appeal against a decision on procedural grounds to an administrative court. In Austria, the Independent Pharmaceutical Commission acts as an appeal court for both procedural and content issues.

Decision Framework for the Transparent Use of Relevant Decision Criteria

The results of our in-depth analysis of drug reimbursement systems showed that all countries use similar criteria in their decision-making process, including severity of disease, added therapeutic value, cost-effectiveness, budget impact, and uncertainty of evidence. However, systems lack transparency about how they deal with each of the criteria in their appraisal process and how their relative importance was judged. By unraveling the decision-making process, we were able to identify five key questions that all systems seem to address to some extent more or less explicitly. We assigned appraisal criteria currently used without much transparency or even implicitly to each of the defined questions. Table 2 displays our developed decision framework.

Five Key Questions in Decision Making

Question 1: Is There a Medical, Therapeutic, and/or Societal Need for This Indication? A pharmaceutical is valuable in as far as it meets a specific need, be it medical, therapeutic, and/or societal (1). The evaluation of 'need' in a specific disease is essentially relative, that is, compared with other indications that need treatment. Medical and therapeutic needs are functions of disease severity and treatment necessity, respectively. The more severe a disease and the less-effective alternative treatments or the fewer the available alternatives, the higher the medical and therapeutic need (11). Need also relates to societal objectives, such as reducing health inequalities. Medical, therapeutic, and societal need can collectively refer to the societal objective of equitably maximizing health or well-being (5;6;22).

In the literature, suggestions to operationalize need criteria have mostly been in terms of disease severity. Examples of approaches include "fair innings" (29), "severity of illness" (18), "proportional shortfall" (24), and "rule of rescue" (17). By taking available treatment alternatives into account when determining disease severity (i.e., disease severity given current treatment options), medical and therapeutic need are addressed simultaneously. Measures to draw conclusions about societal needs, however, remain necessary.

All countries in our study have operationalized need during some phase of their decision-making process. Austria considers societal need when assessing added therapeutic value: drugs benefitting the majority of patients are classified higher in the added therapeutic value classification than those benefiting a subgroup. France defines need in a particular disease area relative to other needs in the healthcare sector through the assessment of the "medical service rendered" (SMR), which is determined by disease severity, level of efficacy relative to adverse effects, the drug's place in therapeutic strategy (particularly with regard to treatment alternatives), treatment properties (preventive, curative, or symptomatic) and public health benefit. As such, the SMR addresses medical, therapeutic, and societal need. An insufficient SMR leads to a negative reimbursement advice.

Other countries only appear to operationalize medical need, the Netherlands formally do so during the appraisal process using disease severity based on the proportional shortfall definition (28;30). Sweden uses medical need and solidarity as one of the three main principles for priority-setting in health care, which is further defined by various levels of disease severity: life-threatening diseases, disease prevention, and less severe acute and chronic diseases (14). Belgium uses necessity of treatment to determine the level of reimbursement, ranging from necessary for life-threatening diseases to symptomatic

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Table 2. Key Questions and Relevant Criteria for Increasing Transparency of Drug Reimbursement Appraisal Processes

Decision	Question	Relevant criteria
Medical, therapeutic and/or societal need	Does the product target a medical, therapeutic and/or societal need?	Medical need: - Life-threatening condition - Severe symptoms Therapeutic need: - Effective alternative treatment available Societal need: - High prevalence - Disease leads to health inequalities - Distance from an acceptable baseline health level
Preparedness to pay for a particular indication	Are we, as a society, prepared to use public resources to pay for a treatment to improve this particular indication?	- Personal responsibility - Affordable out-of-pocket
Preparedness to pay for a particular treatment	Are we, as a society, prepared to use public resources to pay for this particular treatment, given that we are prepared to pay for a treatment to improve this indication?	- Safety and efficacy of the treatment compared to alternative treatment(s) - Quality and uncertainty of the evidence regarding safety and efficacy - Curative, symptomatic, or preventive - Therapeutic value - Significance of health gains
Preparedness to pay more than an alternative	Given that we are prepared to pay for this treatment using public resources, are we prepared to pay *more* than the best alternative treatment?	- Added therapeutic value - Potential savings elsewhere - Quality and uncertainty of the evidence regarding effectiveness - Acceptability of co-payments - Rarity of disease
Willingness to pay: price and reimbursement basis	How much more are we *willing* to pay out of public resources for this particular treatment?	- Added therapeutic value - Incremental costs - Budget impact / ability to pay - Cost-effectiveness ratio - Medical, therapeutic and societal need - Limits to cost sharing - Quality and uncertainty of evidence

treatment. The relative weight of medical need vis-à-vis other needs is in all countries unclear.

Although rarity of a disease was also mentioned by interviewees from all countries as important to decision making, whether rarity *as such* determines need, or the fact that often no alternative treatment exists for a severe disease that happens to be rare, is unknown (16).

Question 2: Is Society Prepared to Pay With Public Resources for a Treatment That Will Improve the Indication in Question? Preparedness to pay is independent of ability to pay and product price, a feature that differentiates "preparedness" from "willingness." Before discussing preparedness to pay, policy makers should determine whether society is prepared to pay for anything that would improve the indication of the treatment under consideration. Preparedness to pay is independent of a particular treatment's need, cost, or effectiveness but might depend on the causes of the disease (e.g., unhealthy or risky behavior), the characteristics of the population groups affected by the disease (e.g., their socioeconomic status) or the nature of the outcome (e.g., relief of a headache). The answer might be "Yes, if. . .", in which case preparedness to pay is subject to conditions.

Although the preparedness to pay out of public resources is not necessarily strictly linked to the medical, therapeutic, and societal need, we found that both judgments are in practice frequently considered equal. This indicates that society believes that treatments for high needs should be able to rely on public funding, regardless of, for instance, personal responsibility. Therefore, countries operationalize this question similarly to the needs question, meaning they are in principle prepared to pay for treatments for high medical, societal, or therapeutic needs.

Question 3: Do We Want to Pay for This Product Out of Public Resources? Societal willingness to pay for the treatment under consideration, given its characteristics, may depend on the effectiveness and therapeutic value of the treatment compared with alternative treatments

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Table 3. Illustrations of the Relationship Between Value-Criteria and Societal Willingness to Pay

Value criterion	How the value criterion influences willingness to pay
Medical, therapeutic and societal need	In *Sweden* priority-setting principles state that persons in greatest medical and therapeutic need should get the highest priority. The Swedish expert committee refers to "marginal utility", which is further defined as "if no alternative treatment exists, cost should be reasonable"; "reasonable", however, remains undefined (15). In *the Netherlands*, the reimbursement agency recently suggested a threshold range for the incremental cost-effectiveness ratio (ICER), where willingness to pay varies within that range depending on disease severity (medical need) (30). The Dutch minister has neither confirmed the range nor endorsed an ICER threshold. In *Austria*, medical need is implicitly considered in the evaluation of the therapeutic benefit, which in turn is strongly related to the price.
Added therapeutic value	*Belgium* and *the Netherlands* apply a binary outcome (i.e., yes or no) for added therapeutic value, thereby not relating societal willingness to pay to the degree of added therapeutic value. *France* and *Austria* classify the degree of added therapeutic value in five and six categories, respectively. Societal willingness to pay is defined in function of the added value category. *Sweden* uses the ICER to determine an acceptable price of a product, thereby directly relating societal willingness to pay to the degree of added therapeutic value.

and whether it concerns a curative, symptomatic, or preventive treatment. It can also depend on the burden of the costs of a treatment, for example, for a relatively cheap treatment, such as paracetamol, the administration costs of reimbursement would be higher than the treatment itself.

All countries evaluate the therapeutic value of each individual drug to evaluate whether the drug should be reimbursed and thus paid for by society. This question is often considered in combination with preparedness to pay (i.e., question 2).

Question 4: Do We Want to Pay More for the Drug Compared With the Comparator?

Whether society wants to pay more for a drug than its comparator depends on the product's added societal value, which depends on its added therapeutic value, potential savings effected elsewhere in the healthcare sector, and the quality and certainty of the evidence on these two criteria.

All countries but Austria use internal reference pricing to determine the reimbursed price for products with equivalent therapeutic value, meaning society is not willing to pay more for the drug than other products with equivalent therapeutic value. Added therapeutic value can be decomposed in several elements; increased efficacy and/or effectiveness and safety get the highest weight in all countries. A drug judged to have added therapeutic value is likely to be reimbursed at a higher price. Although improvement in comfort, ease of use and applicability are mentioned as determinants of added therapeutic value, they are in practice rarely sufficient for a product to be reimbursed at a higher price.

Question 5: How Much More Is Society Willing to Pay With Public Resources for This Treatment?

Societal willingness to pay depends on societal value. This value is determined by all previous criteria and is independent of price. In practice, it is difficult to measure societal value in monetary terms. Therefore, in a supply-driven context, where pharmaceutical companies decide what, when, and at what price to launch a drug, policy makers will in practice have to consider whether the price requested by the company is reasonable given its societal value.

For this purpose, cost-effectiveness and budget impact are used as decision criteria, strongly depending on the previously described value-criteria. While cost-effectiveness is traditionally seen as a criterion for assessing efficiency, it only does so when health maximization is the main objective and a threshold value for the incremental cost-effectiveness ratio (ICER) is defined. All our countries deny using an ICER threshold value or a threshold range, thus confirming the observation of previous studies that the ICER has limited weight in the appraisal process (3;21). Instead of being a criterion for technical efficiency, the ICER can also be used as an instrument or measure to judge the acceptability of an intervention's cost, given its societal value. This requires the weighing of all value-criteria against each other. In this respect, all five countries appear to be willing to pay more for a unit of health gained in case of more severe diseases.

It is difficult to define *a priori* the relative weight of each criterion because decision makers and stakeholders might want to give different weights in different situations. For example, therapeutic value may get more weight when no alternative treatment is available. Interviewees from all countries reported a higher willingness to pay for drugs for rare diseases for which no alternative treatment exists (therapeutic need). This may then suggest the acceptability of a higher cost-effectiveness ratio. The Netherlands also reports a higher willingness to pay for more severe diseases and France and Belgium apply a lower level of cost sharing to drugs for more severe diseases. Table 3 illustrate examples how our countries operationalize the relationship between separate value-criteria and the (additional) willingness to pay.

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Table 4. Illustrations of How Criteria for Judging the Acceptability of a Requested Price Take Value-Criteria Into Account and Can Shape Drug Reimbursement Decisions

Criteria for appraising the acceptability of a requested price	Relation with value criteria
Budget impact	Budget impact is a decision criterion in *all countries* but Sweden. In *Sweden* regional county councils are responsible for the financing and implementation of decisions. The same county councils are also responsible for clinical guidelines, which include financial incentives that stimulate the usage of preferred drugs. *France* and *Belgium* use price-volume agreements (financial risk-sharing agreements). For statins, *Belgium* has defined a "first choice treatment" (reimbursed without conditions) and a "second choice treatment" (subject to the condition that the first choice failed to benefit a patient). *All countries* use financial incentives to influence utilisation (co-payments, co-insurance, deductibles).
Cost sharing	*Belgium* uses "necessity of treatment" (medical need) to define the level of cost sharing. A negative correlation has been observed between the level of cost-sharing and the added therapeutic value of drugs (21), indicating that products for more severe diseases are more likely to be considered of added therapeutic value. In *France*, medical need is one of the criteria determining the SMR rating (Service médical rendu), which determines the level of cost-sharing. Both *France* and *Belgium* use the medical needs criterion to define the level of co-insurance or co-payment, which increases affordability of the most necessary treatments.

Additional criteria helping policy makers to assess the acceptability of a requested price are budget impact and mechanisms for cost sharing. Although these criteria are not value-criteria, they cannot be considered independently. Table 4 illustrates country examples how budget impact and cost sharing can modulate decisions and give incentives to install measures to stimulate value-based medicine.

Finally, uncertainty of evidence may impact upon the appraisal of the value-criteria as well as on the societal willingness to pay. For example, uncertainty about the added therapeutic value in daily clinical practice might lead expert committees to lower their estimate of the added therapeutic value, advise restricted reimbursement, or deny reimbursement altogether. They could also make a temporary reimbursement decision or negotiate a lower price (2). Our five countries deal with uncertainty in budget estimates by the implementation of one or more of the following measures: financial risk sharing agreements, price negotiations, cost sharing, and conditional reimbursement.

DISCUSSION

An in-depth analysis of five European drug reimbursement systems showed that these systems use similar criteria in their drug reimbursement decision processes. The relative importance attached to each of the criteria may vary, but the implicit questions posed during a decision-making process are similar. Our study shows that there is room for improving the transparency and relevance of decision criteria, two legitimacy conditions. Empirical evidence suggests that the four legitimacy conditions defined by the Daniels and Sabin framework actually improve perceived legitimacy, fairness, and quality of decision making, but should be used flexibly (9;10;14;20;25;27).

The public payer is continuously faced with the dilemma of simultaneously ensuring equitable access to high-quality health care and sustainability of the healthcare system. The challenge for policy makers is therefore to find a publicly acceptable balance between the objectives. This is pursued by considering and weighing several criteria in the decision-making process. *Added therapeutic value*, being the most prominent criterion in decision making in all countries, addresses the quality of care objective. *Disease severity*, also important in decision making in all countries, reflects the equity objective. *Cost-effectiveness* addresses the objective of efficiency (maximizing health with a given amount of resources). It is a reimbursement criterion in all countries, be it only for revisions in France. No country, however, uses a fixed ICER threshold value; even threshold value ranges seem unacceptable. *Budget impact*, which also reflects the sustainability objective, is considered in all countries either at the national or at the regional decision level. Although all countries have a more or less open-ended pharmaceutical budget, reimbursement can still be denied for budgetary reasons. *Disease rarity*, a frequently mentioned decision criterion, reflects the equity objective of systems: patients with rare diseases should have equal chances of affordable treatment. It gives companies the opportunity to set high prices and remain somewhat inflexible in price negotiations.

While all these criteria are relevant, their relative importance and how they shape the final decision often remains unclear. This can result in differences in accountability of the systems: the lower the transparency of both formal and informal criteria, the less accountable the system.

Our relatively small sample of countries, not necessarily representative for Europe, could be seen as a limitation to our study. However, important differences were observed in

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structure, organization, and procedures of the drug reimbursement systems, supporting the external validity of our study. A thorough understanding of the explicit and implicit processes taking place during a drug reimbursement decision process required an intensive search for formal as well as informal information. Such an analysis was therefore only feasible in a small number of countries within a reasonable period of time.

Our conclusions could be extended by reviewing actual reimbursement dossiers in these countries. For example, judging the consistency of decision making requires detailed comparison of reimbursement dossiers. Furthermore, different appraisal processes and reimbursement criteria can still produce comparable results in terms of drug expenditures, health gains, and equity. It would be worthwhile to further investigate to what extent these crucial outcomes are sensitive to country differences in reimbursement policy.

We believe, however, that transparency of the drug reimbursement decision process can be improved in all countries by using an explicit decision framework. Our developed framework provides a first provisional tool to structure the decision-making process, it can support the justification of decisions, and is a tool for defining and making explicit the societal choices, which currently often remain implicit. Crucial is the societal acceptability of the decision criteria. Proper justification of the reimbursement advice or decision, with a sufficiently differentiated reflection on the multiple considerations taken into account during the appraisal and decision-making processes and with a clear statement on the final position taken on each key question, ensures transparency and enhances trust in the system. No system can define a general rule applicable to decisions in all situations (3), but the decision process can be reconstructed by providing an explicit answer to each crucial question.

CONCLUSIONS

To reach accountability for reasonableness and thus ensure a legitimate drug reimbursement process, any democratic political system has the obligation to be transparent, use societally relevant rationales in decision making, allow revisability of decisions in the light of new evidence, and enforce the three previous conditions. Many systems currently lack transparency, especially in the use of appraisal criteria. The appraisal process could benefit from using an explicit decision framework specifying the social choices and decisions made during the appraisal process as well as the criteria on which the choices and decisions are based. This would improve accountability and coherence between decisions, and, in turn, enhance legitimacy of societal decision making on drug reimbursement.

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CONFLICTS OF INTEREST

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