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Quality Decision Making in Health Technology Assessment: Issues Facing Companies and Agencies

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Abstract

Objectives: To evaluate the quality of the decision-making processes of pharmaceutical companies during medicines development for evidence generation to support reimbursement of new medicines and the appraisal recommendation decision-making process by health technology assessment (HTA) agencies. *Methods:* Two questionnaires were developed and subsequently piloted for the purpose of content validation. These were sent to 24 pharmaceutical companies and 16 HTA agencies. *Results:* Responses were obtained from 11 companies and 11 HTA agencies. Some similarities were identified between the decision-making processes of companies and agencies, such as the use of committees, having a primarily mixed (qualitative/quantitative) internal decision-making system, as well as the lack of systematic assessments of quality decision making and the relatively infrequent use of formal decision-making frameworks. Nevertheless, the results indicate differences as companies and agencies use diverse processes to arrive at the final decision either through consensus, majority vote, or an individual making the decision. The majority of companies and agencies believe that the quality of decision making can and should be measured. Moreover, organizations considered the occurrence of biases within their organization as pertinent. Finally, almost all the participants felt that there was room for improvement for their organization's quality of decision making. *Conclusion:* These findings are consistent with a published study on regulatory processes and support the need for more consistent and predictable decision-making processes during the life cycle of medicines. This could be achieved through capacity building, systematically evaluating the quality of decision making, and encouraging utilization of formal decision-making frameworks within companies and agencies.

Keywords

decision making, health technology assessment, decision-making framework, decision-making processes, decision-making quality

Introduction

Having a quality decision-making process is common sense to organizations, but not always common practice.[1] A recent study explored the incorporation of the 10 Quality Decision-Making Practices (QDMPs) into the regulatory decision-making processes within international pharmaceutical companies for submitting new medicines to a regulatory agency and within major regulatory authorities for determining whether the medicine should be approved. This study demonstrated that although the QDMPs were considered as relevant by the stakeholders, they are not always incorporated into organizational frameworks to ensure transparency and quality.[2]

Health technology assessment (HTA) is an essential process for ensuring efficient allocation of health care resources. However, the current global HTA environment is diverse and increasingly multidisciplinary, and projects are under way across HTA agencies, pharmaceutical companies, and regulatory agencies to ensure the efficient and effective development of medicines[3] and the improvement of HTA assessments and their appraisal methodologies/practices.[4-10]

Although agencies and companies already take into account the various medical, social, economic, and ethical information needed to carry out their appraisal of new medicines, it is not always clear how the decisions, which require human judgment and interpretation, are made around the data.[11] This applies

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particularly to the appraisal decision-making process of HTA agencies regarding the recommendation of technologies, as well as the strategic process within companies to seek reimbursement in different jurisdictions.

Researchers in the field of decision making and the psychology of judgment have been advocating for the use of more structured approaches to decision making as well as the need to periodically measure the quality of the decision-making process to identify areas for improvement.[12] Although a good process may not always guarantee a favorable outcome because of the uncertainty around the development of medicines, organizations can increase the probability of positive outcomes by having more structured decision-making processes, being aware of cognitive biases and by establishing an organizational culture of constructive debate.[13] Other potential merits of a more structured decision-making process include improved consistency across decisions, transparency to stakeholders, and as decision accountability and trust.[11] Consequently, some of the key stakeholders in this area, including major pharmaceutical companies and HTA agencies, have advocated for the need to explicitly evaluate the quality of the deliberative decision-making processes within companies and agencies.[14]

As many minor decisions are made daily by each organization, the aim of this study was therefore to investigate decision-making behaviors and processes of pharmaceutical companies, focusing on 2 major decision-making processes to support the reimbursement of medicines; first the decision-making process for evidence generation by companies and the technology appraisal process by HTA agencies of the data submitted by companies. Those processes were considered holistically (and not limited to any specific steps or aspects), but the focus of the study was on major strategic decisions made by committees or teams within each organization as part of the respective processes.

Specifically, the objectives were to identify current decision-making practices within those organizations; investigate decision-making framework utilization; assess the use of different methodologies for measuring the quality of decision-making processes; and finally to evaluate the perceived barriers and solutions for quality decision making within such organizations.

Methods

Assessment Tools

Two questionnaires were developed for assessing the decision-making practices of international pharmaceutical companies and HTA agencies (see figure in supplementary material). The questions were adapted from a previously published study on regulatory decision making of companies and regulatory authorities in order to facilitate comparisons between the 2 studies.[2] Since many decisions are made within such organizations on a daily basis, these questionnaires focused on specific high-level decisions, namely, the company process for evidence generation to support an HTA dossier for new medicines and the HTA agency appraisal decision-making process to recommend, restrict, or reject the reimbursement of new medicines. Those processes were considered holistically (and not limited to any specific steps or aspects), but the focus of the study was on major strategic decisions made by committees or teams within each organization as part of each respective process.

The questionnaires were organized into 4 sections: decision-making practices (questions regarding the involvement of a committee, different decision-making types, and decision-making systems), decision-making frameworks (questions regarding the use of a framework and the practices incorporated), challenges/biases (questions focusing on biases), and personal perceptions of barriers and solutions. Company and HTA agency questionnaires contained analogous questions where appropriate.

Study Design

This was a cross-sectional study; participation was invited via e-mail, including follow-ups to nonrespondents, where a maximum of 2 follow-up emails were sent in order to solicit further responses.

IRB Approval

The study protocol received approval from the University of Hertfordshire Institutional Ethics Committee. Since the study participants were either National Health Service patients or staff, it did not require the Local Ethics Committee approval. The recruited participants received a copy of the study protocol describing the purpose of the study and explaining that only aggregated results will be reported prior to their participation. Therefore, their agreement to participate in the study constituted consent.

Study Participants

Study participants were selected based on experience and knowledge using purposive sampling, from those holding senior positions having at least 5 years of experience in a managerial position within major international pharmaceutical companies and HTA agencies. The finalized industry questionnaire was sent to executives within Health Economics and Outcomes Research (HEOR) departments at 24 international pharmaceutical companies with large R&D budgets (>US$1 billion), thereby reflecting innovativeness and the number of decisions made.

The finalized authority questionnaire was also sent to senior executives within 16 major HTA agencies. The focus was on major HTA agencies, which are part of the International Network of Agencies for Health Technology Assessment (INAHTA) or the European Union Network for Health Technology Assessment (EUnetHTA). To optimize sample representation, participants from various-sized organizations and geographical locations were invited, including Australia, Asia, Europe, and North America.

Pilot Study

A pilot study was conducted with 2 companies and 2 HTA agencies to validate content and test the practicality and applicability of the 2 questionnaires. This pilot consisted of questionnaire completion followed by a short feedback form. Overall, pilot results were positive, and participant comments were used to make minor questionnaire revisions.

Definitions

The study participants received definitions of qualitative, quantitative, or mixed decision-making systems (Supplementary Table 1), which were derived from the regulatory questionnaire[2] and originally adapted from a previous study assessing the need for a benefit-risk framework.[15,16]

The participants were asked to select Quality Decision-Making Practices (QDMPs) that were incorporated into their organization's decision-making framework. The QDMPs were developed based on the key issues in quality decision making identified through semistructured interviews with 29 key opinion leaders from authorities and companies.[17]

The different types of cognitive biases that occur during decision making were also investigated. Four main groups of biases adapted from previous research[18] were proposed for this study to underpin the evaluation of bias perception (Supplementary Table 2). This typology focuses on those biases that occur most frequently and that have the largest impact on the internal organizational and business decisions.

Data Processing and Analysis

The responses were tabulated and analyzed using descriptive statistics. All free text responses and comments were coded using processes guided by established methods, including grounded theory[19] and constant comparison method.[20]

Results

Characteristics of the Study Participants

Responses were received from 12 of the 24 executives from companies recruited into the study (50%); 1 declined to complete the questionnaire because of the inability to meet the deadline. Eleven of 24 (46%) gave positive responses, which were used in the analysis, namely, Abbvie, Bayer, Biogen, Eisai, Eli Lilly, F. Hoffmann-La Roche, Merck, Novartis, Pfizer, Sanofi Aventis, and UCB. Ten of the 11 companies were in the top 25 in terms of their R&D expenditure in 2016.

Eleven (69%) of 16 agencies provided responses, including those from Australia (Pharmaceutical Benefits Advisory Committee), Belgium (Rijksinstituut voor Ziekte- en Invaliditeitsverzekering), Brazil (Comissao Nacional de Incorporaca de Technologias), Canada National Agency (Canadian Agency for Drugs and Technologies in Health), Canada Quebec province (Institut national d'excellence en santé et en services sociaux), England (The National Institute for Health and Care Excellence), Netherlands (Zorginstituut Nederland), Poland (Agencja Oceny Technologii Medycznych i Taryfikacji), Scotland (Scottish Medicines Consortium), Spain Basque region (Servicio de Evaluación de Tecnologías Sanitarias), and Sweden (Tandvårds- och läkemedelsförmånsverket). These companies and HTA agencies represented a diverse mix of geographical locations and affiliations.

Part I: Decision-Making Practices

A comparison of committees and systems

Almost all of the companies (10 of 11) and HTA agencies (10 of 11) reported that they have a committee that is involved in the decision-making processes for the generation of evidence to support the reimbursement of medicines. The number of company committee members ranged from 10 to 20. The mean for agency committee members was 20 (range, 9-31). Both groups adopted mixed decision-making systems. For companies, an individual made the ultimate decision based on the respective committee's recommendation (4), the decision was made by consensus (4) or a different process was adopted (2). None of the companies used a majority vote system. Agencies used a majority vote (5; 3 open voting and 2 secret ballot), consensus (4; 2 majority vote if consensus could not be reached) or an individual makes the decision (1). Almost all the companies (8) and agencies (9) used a mixed internal decision-making system with various quantitative and qualitative elements, as opposed to a purely qualitative or quantitative system.

All disciplines across the companies were represented in the committees. The group was split as to whether an individual member of the committee could veto the decision, with 4 stating this could be done, usually by the chair, and 4 that it was not done.

For agencies, other than technical members, a number of stakeholders attended appraisal committee meetings, namely the industry, payers, patient/patient interest groups and lay representatives/public members. An individual in the committee could veto the decision in only one agency, but in most cases (10) the decision could be challenged by external stakeholders, primarily through legal procedures.

Company-specific characteristics

The majority of companies (8) reported that the committees were based in the head office. Companies were mixed as to the timing for filing for regulatory approval; in most cases, the reimbursement committee process occurred either immediately ahead of process to file for regulatory approval (5) or as an iterative process before, during, and after filing (4). For half of the companies (5), this committee was also responsible for generating evidence for seeking regulatory approval. For the companies where this was not the case (5), the majority (3) stated that the committees interacted by ensuring that there was an overlap of members on both committees.

Table 1. Quality Decision-Making Practices (QDMPs) Incorporated Into Organizations' Formal Frameworks.[a]

Quality Decision-Making Practices (QDMPs)	QDMP Incorporated Into Organization's Formal Framework?	
	Pharmaceutical Companies, % (n)[b] (n=6)	HTA Agencies, % (n)[b] (n=7)
1. Have a systematic, structured approach to aid decision making (consistent, predictable, and timely)	67 (4)	100 (7)
2. Assign clear roles and responsibilities (decision makers, advisors, information providers)	100 (6)	100 (7)
3. Consider uncertainty regarding the process	100 (6)	71 (5)
4. Examine alternative solutions	100 (6)	57 (4)
5. Assign values and relative importance to decision criteria	50 (3)	43 (3)
6. Re-evaluate as new information becomes available	100 (6)	86 (6)
7. Evaluate both internal and external influences/biases	33 (2)	43 (3)
8. Perform impact analysis of the outcome	17 (1)	86 (6)
9. Ensure transparency and provide a record trail	83 (5)	86 (6)
10. Effectively communicate the basis of the decision	67 (4)	86 (6)

[a]Only companies and agencies that had a formal framework (as opposed to by "custom and practice") are included.
[b]Number of respondents.

Table 2. Key Measures Proposed by Pharmaceutical Companies and HTA Agencies for Assessing the Quality of Decision Making.

Pharmaceutical Companies	HTA Agencies
1. Formal assessment of the internal decision-making process, including decision transparency and communication	1. External benchmarking of decision-making processes and outcomes compared to other jurisdictions
2. Incorporation of milestones and indicators into process to verify if key factors at each stage are addressed by internal stakeholders	2. Internal assessment of the decision-making process (structure; use of committees and frameworks)
3. Evaluation of HTA success compared to the evidence generated	3. Degree of participation and engagement with stakeholders
4. Analysis of the actual decision and its foundation, including the evidence considered and other influencing factors	4. Formal feedback from internal and external stakeholders regarding the decision making

Agency-specific characteristics

In terms of the criteria used by each committee to make the recommendation decision as defined explicitly by the agency's framework, all agencies (11) utilized cost-effectiveness threshold/range and almost all used comparative effectiveness (10) and budget impact (8), whereas 8 specified other criteria, including burden of disease and unmet need. For the majority of agencies (7), the committee recommendation was nonbinding, for 3 agencies it was binding, and in 1 case it would only be binding if it was a negative recommendation.

Part II: Decision-Making Frameworks

The majority of companies (9) had a framework that formed the basis of the decision-making process for evidence generation to support reimbursement, where 6 were formally defined and codified and 3 were informal by "custom and practice"; that is, the framework had never been clearly agreed but over time had become the practice. The majority of companies (6) developed the framework internally and 2 used mixed internal and external input. For the 2 companies that did not have a framework, the reasons for this were mixed, including the time factor relating to the maturity of the organization, organizational structure or size of the company, the lack of a validated framework, and the fact that the benefits of a framework were not apparent.

All 11 agencies had a framework, where 7 were formally defined and codified and 4 had an informal framework by "custom and practice." The majority of agencies (6) developed the framework using mixed internal and external input, whereas for 2, development was internal.

The incorporation of the 10 QDMPs into company and agency formal frameworks is shown in Table 1. In general, the majority of the 10 QDMPs were incorporated into the company and agency formal frameworks. Only 2 agencies and none of the companies indicated that they had all 10 QDMPs incorporated into their framework. Nevertheless, all the QDMPs that were least incorporated into agency and company frameworks were generally considered as relevant by both groups.

Part III: Measures for Assessing Quality of Decision Making

The majority of companies and agencies did not have formal assessments in place to measure the quality of decision making. The assessments were generally carried out on a systematic basis, by internal groups for companies and a mix of internal and external groups for agencies. Interestingly, most companies (9 of 11) and agencies (7 of 11) believed that there were ways of measuring the quality of decision-making process. Moreover, companies and agencies primarily suggested measures for assessing the process, although currently the majority only assess outcomes (Table 2).

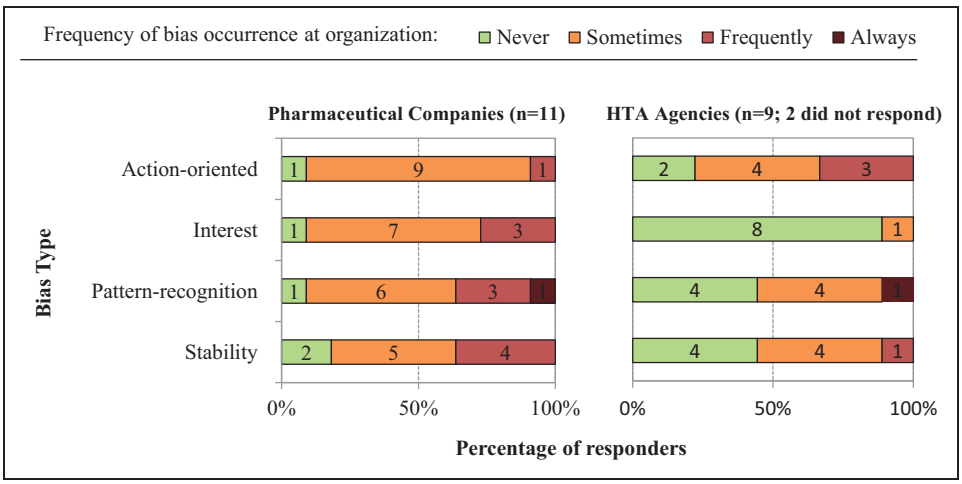

Figure 1. Types of biases and the perceived frequency at which they occur within pharmaceutical companies or HTA agencies during their decision making.

Table 3. Key Barriers and Solutions Identified by Pharmaceutical Companies and HTA Agencies for Quality Decision Making.

	Pharmaceutical Companies	HTA Agencies
Barriers	1. Lack of alignment relating to decision-making processes, requirements, and HTA standards (eg, local vs global; HTA vs regulatory)	1. Poor quality of evidence submitted by companies
	2. Resource and time constraints—need to decide quickly and reluctance to start early	2. Limited data and high levels of uncertainty around the information
	3. Internal decision-making misalignment between HTA and regulatory functions and requirements for evidence generation	3. Lack of knowledge and frameworks with regard to decision making
	4. Lack of in-house knowledge and experience with regard to HTA and reimbursement decision making	4. Internal and external biases, trust issues and political pressures
	5. No feedback loop in identifying the impact of decisions made	5. Time available to make the decision
Solutions	1. Incentivize internal systems to align and facilitate cross-functional collaborations (HTA-regulatory) early in the process	1. Improved methodologies for clinical study design, economic modeling, and price setting
	2. Education, capacity building, and international engagement with external stakeholders (regulatory and HTA)	2. Increased reliance on real-world evidence/data during decision making
	3. More formal review of decision-making process, outcomes, and feedback from stakeholders	3. Education, capacity building and international engagement
	4. Lobby for a more predictable and harmonized HTA environment	4. Define an international framework to enable more structured decision making

Part IV: Challenges and Solutions for Making Quality Decisions

In general, both agencies and particularly companies considered the occurrence of biases within their organization or their influence on the decision making as pertinent. Nevertheless, the perceived frequency of their recognition varied for both groups according to the type of bias (Figure 1).

Almost all the companies (9 of 11) and agencies (9 of 11) believed that decision making within their organizations could be improved. Both groups identified barriers and possible solutions (Table 3) for making a quality decision.

Discussion

This study aimed to evaluate the decision-making processes within pharmaceutical companies during medicines' development for evidence generation to support an HTA dossier for new medicines and the HTA agency appraisal decision-making process to recommend reimbursement restriction or rejection of new medicines. The results provide a unique insight into the organizational practices within companies and agencies, their views of the occurrence of biases, and the potential barriers and solutions for quality decision-making processes.

Other initiatives have been carried out to characterize jurisdictional reimbursement decision-making systems[21,22] and practices[23,24] and to compare the evidentiary requirements from regulatory authorities and HTA agencies. Nevertheless, these studies do not take into account the various approaches organizations implement to ensure a quality decision-making process. Nor do the studies attempt to clarify how decisions, which require human judgment and interpretation, are made around the data by the various committees in companies and

agencies. Consequently, this study has moved beyond simply characterizing the stepwise processes within organizations and aimed to determine the use of frameworks for decision making, the incorporation of best practices into those frameworks, and the use of tools for evaluating the quality of decision making within those organizations.

As this analysis has already been carried out for regulatory authorities and pharmaceutical companies regarding the decision-making processes for regulatory submission and review,[2] the results of the 2 studies are discussed to identify the areas of common strength as well as divergence.

Decision-Making Systems and Committees

Some similarities exist between the decision-making processes of pharmaceutical companies and HTA agencies, such as the use of committees and having a primarily mixed (qualitative and quantitative) internal decision-making system. Nevertheless, the results also indicate that different organizations use diverse processes to arrive at the final decision either by consensus, by majority, or by one individual making the decision, whereas companies make decisions via one individual or through consensus but agencies also use a majority vote system. This may be due to the purpose of the decision made by an agency as opposed to a company, as well as to other factors such as differences in scope, political pressures, or cultural differences between the various organizations.

Divergences in HTA and reimbursement decision-making processes, as well as internal decision-making systems, are consistent with the findings from the study with regulatory authorities and pharmaceutical companies.[2] These differences pose potential challenges faced by regulatory authorities and HTA agencies in trying to align practices and certain evidentiary requirements during the regulatory review and HTA recommendation processes. Alignment, both within and across regulatory authorities and HTA agencies, could increase decision consistency as well as enable potential reliance by one agency on the assessment of data by another.[3,25]

Decision-Making Frameworks and Practices

It was revealed that the majority of HTA agencies and companies have a framework that forms the basis of their decision making, but that is not always formally defined and codified, particularly within companies. Nevertheless, consistent with the results from the regulatory questionnaire,[2] most agencies and companies with formal frameworks have incorporated the majority of the 10 QDMPs into their processes.

The QDMP that was least incorporated into company and HTA agency frameworks were QDMPs 5 (assign values and relative importance to decision criteria) and 7 (evaluate both internal and external influences/biases). This is also in line with the results of the previously reported regulatory study.[2] Those QDMPs that were least incorporated into company, regulatory, and HTA agency frameworks were generally considered relevant and should therefore be implemented by such organizations to maximize decision quality.

Biases, Challenges, and Solutions

Key strategic decisions are susceptible to biases, particularly when the incentives of certain individuals are not aligned with the rest of the organization. Consequently, the different types of cognitive biases that occur during decision making were also investigated. Indeed, almost all the companies and HTA agencies perceived that decision making within their organization was influenced by biases. Type of bias nevertheless varied according to organization type.

For companies, the results were mixed, but in general, companies perceived a higher influence of biases on their decision making compared with agencies, which again was similar to regulatory department results.[2] In general, interest bias (arising in the presence of conflicting incentives) was perceived as the least influential by both HTA and also regulatory authorities,[2] which may be due to strict conflict of interest rules within the various committees at both organizations.

Companies and agencies identified challenges and potential solutions to quality decision making. First, pharmaceutical companies highlighted the misalignment of international HTA requirements. Company respondents also emphasized the need for internal alignment, where HTA company functions are not always fully integrated with regulatory functions in the evidence generation processes and are therefore not consistently involved in decision making during medicines' development, as described previously.[3] As a result, company submissions may not incorporate the necessary evidence to support an HTA dossier in addition to regulatory approval. Potential solutions to these challenges would be to incentivize the alignment of internal systems within companies during medicines development through improved methodologies for decision making and to promote external harmonization of the HTA environment through various international initiatives, such as early scientific advice.[26]

In addition, barriers for decision making identified by HTA agencies centered on the assessment of data rather than on decision making per se, highlighting the current focus on the generation of good-quality information rather than on how decisions should be made around that information.[11] Here, focused education, training and capacity building (such as through creation of teams focusing on decision quality) were highlighted by companies and HTA agencies to develop internal decision-making capabilities.

Decision-Making Assessments

The majority of company departments and HTA agencies believe that the quality of decision-making processes can and should be measured and this was also the case regarding perceptions of company regulatory departments and regulatory authorities.[2] Respondents suggested internal assessments of decision transparency and structure, as well as external

benchmarking as possible areas of assessment in their decision making.

Nevertheless, despite this belief that measuring decision making is key, the majority of organizations do not currently perform such assessments and, if performed, are primarily to assess outcomes rather than process. Consequently, more effort is needed to increase the awareness of assessing and improving the quality of the process to increase the probability of good outcome.

Limitations

A number of questionnaires were completed by one individual from each company or agency, which may be not truly representative of sample or the organization. However, senior decision makers were chosen in order to maximize the potential for the accuracy of their knowledge regarding the decision-making processes and practices within their respective organization.

This study focused on mature HTA agencies, and while it was international in nature and did include responses from several European countries, Australia, Canada, and Brazil, information was not obtained from agencies in certain key European jurisdictions such as Germany or France because of lack of responses. In addition, other countries with less mature HTA systems were considered to be outside the scope of the study in order to ensure relevant and meaningful comparisons. Whereas the response rate achieved for HTA agencies was very good (69%), this was only satisfactory for HEOR company departments (46%). The lack of responses from certain companies and HTA agencies could be a limitation. Indeed, reluctance to participate in this study may reflect the lack of formal decision-making systems within those organizations, which might have influenced the primary findings if they had participated. It would be of interest to repeat this study in the future, in particular ensuring participation from nonrespondents from this study, to determine whether the landscape has changed. Furthermore, this study focused on large established organizations only, which limits the generalizability of the results beyond that sample. It would therefore be of value to apply the questionnaires to newer HTA agencies, as well as smaller companies. The aim would be to identify differences and similarities compared to larger, more established organization.

Conclusions and Recommendations

Currently it seems that organizations involved in the HTA of medicines focus mainly on the data and uncertainty when making decision but insufficient attention is paid to the deliberate decision-making process itself when appraising the information. Although most participants recognized the occurrence of biases within their organization as well as the need to improve the quality of their decision-making process, the majority does not currently perform any such formal assessment, but believe that it can and should be done. The findings of this study demonstrate the relevance of the 10 QDMPs for ensuring quality decision making by companies and regulatory and HTA agencies. Furthermore, they support the need to implement formal decision-making frameworks within organizations and to evaluate the practical implementation of QDMPs throughout medicines' development, regulatory review, and health technology assessment. This could be achieved by formally evaluating the quality decision-making process within companies and regulatory and HTA agencies using the appropriate available tools and measures.[27] Such research could help increase awareness of the importance of quality decision making as well as uncover areas for improvement within companies and agencies in order to promote consistency and transparency to be built into the critical decisions during the lifecycle of medicines. Nevertheless, such research would improve internal as well as external decision-making transparency and accountability to ultimately ensure that the public understand and trust the decisions made by companies and agencies.

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Supplemental Material

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