# Assessment of the ten quality decision-making practices; case studies with a pharmaceutical company, a regulatory and an HTA agency

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## Background

- The science of decision making has been established, but research is limited regarding the quality and transparency of the decision-making processes through which medicines become available.
- Indeed, it is not always clear which explicit practices pharmaceutical companies, regulatory authorities and health technology assessment (HTA) agencies are using to arrive at their decisions to ensure quality of the decision-making processes.
- In order for organisations to determine how to improve the quality of their decision-making processes, the Quality of Decision-Making Orientation Scheme (QoDoS) instrument was developed and validated and considered the most promising tool for assessing quality decision making during medicines' development, regulatory review and HTA.
- QoDoS can be used to asses the incorporation of the ten quality decision-making practices (QDMPs; Figure 1), considered to be the best practices in decision making during the lifecycle of medicines.

### Figure 1: The ten Quality Decision-Making Practices

*Quality is difficult to define, but we can define the practices that make up a quality decision-making process*

**Establish who, why and how decisions are made**
1. Have a systematic, structured approach to aid decision making (consistent, predictable and timely)
2. Assign clear roles and responsibilities (decision makers, advisors, contributors)
3. Assign values and relative importance to decision criteria

**Ensure decision quality, relevance and importance**
4. Evaluate both internal and external influences/biases
6. Consider uncertainty
7. Re-evaluate as new information becomes available

**10 Quality Decision-Making Practices**

**Ensure decision transparency and communication**
9. Ensure transparency and provide record trail
10. Effectively communicate the basis of the decision

**Consider decision alternatives and impact**
5. Examine alternative solutions
8. Perform impact analysis of the decision

## Aim and Objectives

### Aim
Evaluate the practicality of QoDoS in identifying the incorporation of the ten QDMPs, through three case studies with a pharmaceutical company, regulatory authority and HTA agency
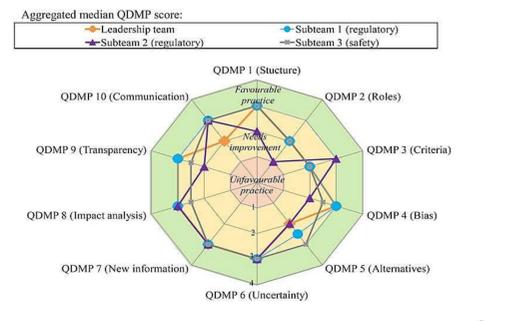
### Objectives
- Evaluate the quality of the decision-making practices of the individuals and their perception of their organisation's decision making
- Identify favourable and unfavourable practices across the ten QDMPs
- Evaluate the feasibility and the perceived benefits of the study method based on feedback discussions as well as lessons learned

## Methods

- The three organisations that were selected for the studies have established decision-making systems based on their size and multinational status (for the company) and maturity level (in case of agencies).
- As many decisions are made on a daily basis, each organisation selected a key strategic decision-making process of interest to them.
- Individuals from a company, regulatory and HTA agency completed QoDoS, consisting of 47 items:
  o QoDoS Part 1 (items 1-23): assessing the perception of organisational practices
  o QoDoS Part 2 (items 24-47): assessing individual practices
- The 47 QoDoS items were mapped to the 10 QDMPs and a median value was calculated for each QDMP.
- Initial feedback discussions were organised with the cohort leaders in order to discuss the relevance and clarity of the results as well as initial perception of the study method feasibility and benefits.

## Results

### Case 1: Pharmaceutical company
- QoDoS was completed by 31 individuals from the company across 4 different sub-cohorts, namely the regulatory leadership team (LT) and three safety/regulatory subteams (SRTs). The following processes were assessed for QoDoS Part 2 (organisational practices):
  o the LT assessed their approach to decision making for submitting a New Drug Application to a regulatory authority
  o the SRTs assessed their perception of the LT's decision making for the same process
- The results (Figure 2) suggest that in general, the three SRTs perceive the practices of the LT as favourable and the results were consistent with how the LT believe they make decisions.
- QoDoS identified a number of QDMPs which may need to be improved, namely QDMP 1 (Have a structured approach to decision making), 2 (Assign clear roles and responsibilities), 3 (Assign values and relative importance to decision criteria), 4 (Evaluate internal and external influences/biases), 5 (Examine alternatives) and 9 (Ensure transparency and provide a record trail).
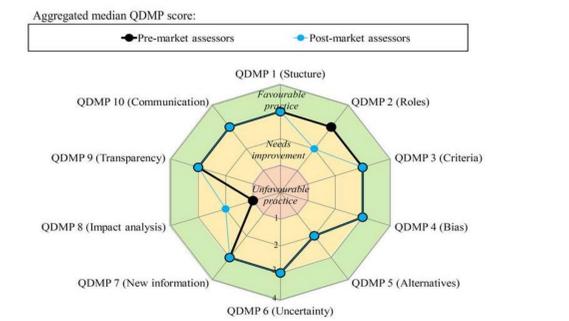
### Figure 2: Ten Quality Decision-Making Practices for organisation's decision making (QoDoS Part 1) for pharmaceutical company leadership team and the three sub-teams

Aggregated median QDMP score:
— Leadership team — Subteam 1 (regulatory) — Subteam 3 (safety) — Subteam 2 (regulatory)

QDMP 1 (Stucture), QDMP 2 (Roles), QDMP 3 (Criteria), QDMP 4 (Bias), QDMP 5 (Alternatives), QDMP 6 (Uncertainty), QDMP 7 (New information), QDMP 8 (Impact analysis), QDMP 9 (Transparency), QDMP 10 (Communication)

### Case 2: Regulatory authority
- Forty responses were received from pre-marketing and post-marketing regulatory authority assessors, evaluating decision-making practices for recommending the marketing authorisation of a medicine and to modify (or not) the marketing authorisation based on new information, respectively.
- The perception of the organisational QDMPs by the assessors was generally in the area of 'favourable practice' and the QDMP scores were generally consistent for pre- and post-market assessors
- Both types of assessors perceived that QDMP 5 (Examine alternatives) as not favourable (Figure 3).
- The differences between pre- and post-market assessors were for QDMP 2 (Assign clear roles and responsibilities), where pre-market responses suggested 'favourable practice' compared with 'needing improvement' for post-market staff; on the other hand, QDMP 8 (Perform impact analysis of the decision), was rated by pre-market assessors as 'unfavourable practice' and as 'needing improvement' by post-market assessors.
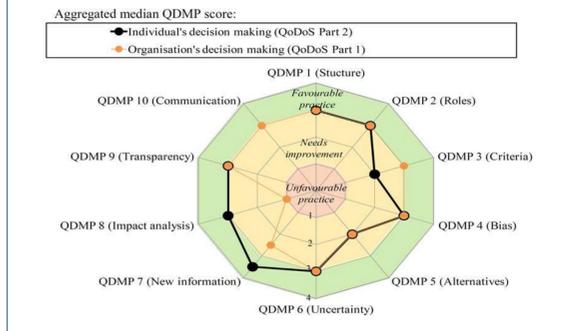
### Figure 3: Ten Quality Decision-Making Practices for organisation's decision making (QoDoS Part 1) for regulatory authority pre- and post-market assessors

Aggregated median QDMP score:
— Pre-market assessors — Post-market assessors

QDMP 1 (Stucture), QDMP 2 (Roles), QDMP 3 (Criteria), QDMP 4 (Bias), QDMP 5 (Alternatives), QDMP 6 (Uncertainty), QDMP 7 (New information), QDMP 8 (Impact analysis), QDMP 9 (Transparency), QDMP 10 (Communication)

### Case 3: HTA agency
- Finally, 25 responses were received from the appraisal committee members of the HTA agency, where the individuals assessed themselves and their organisation for the same decision point, namely regarding the decision-making process when recommending the reimbursement of new medicines.
- The combined results indicate that the members perceive their own decision-making practices as generally 'favourable', both in terms of how the members perceive themselves as well as the organisation (Figure 4).
- The practices with unfavourable or 'needing improvement' medians were QDMP 3 (Assign values and relative importance to decision criteria), QDMP 5 (Examine alternatives) and QDMP 8 (Perform impact analysis of the decision), which is interestingly similar to the results from the regulatory authority.

### Figure 4: Ten Quality Decision-Making Practices for individual's and organisation's decision making (QoDoS Part 2 and 1 respectively) for HTA appraisal committee members

Aggregated median QDMP score:
— Individual's decision making (QoDoS Part 2) — Organisation's decision making (QoDoS Part 1)

QDMP 1 (Stucture), QDMP 2 (Roles), QDMP 3 (Criteria), QDMP 4 (Bias), QDMP 5 (Alternatives), QDMP 6 (Uncertainty), QDMP 7 (New information), QDMP 8 (Impact analysis), QDMP 9 (Transparency), QDMP 10 (Communication)

### Feedback discussions following case studies
- Informal feedback discussions were organised with the group leaders from each study.
- These confirmed the feasibility of the study method as well as initial benefits of the approach, including raising awareness of biases and best practices in decision making, gaining a basis for discussion of the issues in decision making as well as making recommendations for improving the lowest scoring or least consistent practices.
- The discussions also helped to uncover rationale for some differences in responses across sub-groups or when comparing individual and organisational perceptions.

## Conclusions

### Main study outcomes
- This study was the first application of QoDoS in three different settings
  – Company: three regulatory/safety sub-groups assessing the leadership team for the same decision-making process (submitting a new medicine to a regulatory agency)
  – Regulatory authority: two groups of assessors evaluating respective processes for evaluating new medicines
  – HTA agency: one external committee assessing their own practices and those of the organisation for recommending the reimbursement of a medicine
- The results confirmed the initial feasibility of the proposed method for assessing quality decision making-practices during medicines' development, regulatory review and HTA.
- All three case studies demonstrated generally favourable results across the QDMPs, where overall, all three organisations have incorporated the majority of the ten QDMPs, perhaps not surprising, as all three organisations had established decision-making systems.
- Interestingly, the QoDoS demonstrated the need for improvement across a number of practices where some similarities were identified, such as the need for better evaluation of alternatives for the three organisations and the need for better impact analysis for agencies.

### Recommendations
- QoDoS can be applied as a diagnostic instrument within teams, committees or departments in companies, regulatory authorities and HTA agencies for routine assessment of quality of decision making.
- The results could serve as a basis for identifying and discussing favourable and unfavourable practices and obtaining factual information underpinning a change within an organisation.
- Furthermore, the routine application of QoDoS has the potential to change the organisational culture and the individual's approach to decision making with an increased focus on process quality.
- This could in turn help improve the productivity of companies and to ensure agencies are not only undertaking a good-quality review or appraisal, but are also making a quality decision.

## Bibliography

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