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ORIGINAL RESEARCH ARTICLE

Evaluation of the Quality Decision-Making Practices Utilized by the Zambia Medicines Regulatory Authority Technical Committees

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Abstract

Background A consistent and transparent approach is essential for quality decision-making in the review and approval of medicines. This is achieved through the use of a standard and well-defined framework, as the decisions made should not be influenced by any biases. While most National Medicines Regulatory Authorities (NMRAs) have designed frameworks to assess the quality of their decisions, many have not been implemented. A well-structured framework improves consistency and predictability in the decision-making process. The Quality of Decision-Making Orientation Scheme (QoDoS) has been widely adopted as a leading framework for this purpose. This study aimed to assess the decision-making processes of two technical committees operating within the Zambia Medicines Regulatory Authority (ZAMRA) using the QoDoS framework developed by the Centre for Innovation in Regulatory Science (CIRS); determine areas of improvement for routine assessment of quality of decision-making and its acceptability with respect to ZAMRA; and suggest ways of improving the lowest-scoring Quality Decision-Making Practices (QDMPs) and how these may be implemented into the decision-making framework to ensure consistency.

Methods The framework was used to assess the quality of the decision-making process and subsequent implementation of the ten QDMPs. The study included five members from the Technical Committee for Human Medicines (TCHM) and seven members from the Technical Committee for Veterinary Medicines (TCVM) at ZAMRA, all responsible for recommending the approval or rejection of applications following scientific review. The validated QoDoS questionnaire was electronically distributed to the members, and data were analysed using descriptive statistics.

Results Analysis of the QDMPs across the 12 committee members indicated that both human and veterinary medicines technical committees generally perceived their individual and organizational decision-making practices as favourable. Favourable QDMPs included QDMP 2 (assigning clear roles and responsibilities of the stakeholders involved in the review and approval of medicines), QDMP 4 (evaluate both internal and external influences or biases), QDMP 6 (considering uncertainty), QDMP 7 (re-evaluate new information as it becomes available), QDMP 9, (ensure transparency and keep a record trail) and QDMP 10 (effective communication of the basis of the decision). However, areas for improvement were identified in QDMP 1 (systematic structured approach), QDMP 3 (decision criteria), QDMP 5 (alternatives) and QDMP 8 (impact analysis) within the TCVM, as well as in QDMP 3 and QDMP 8 within the TCHM.

Conclusion This study assessed committee members' perceptions of the implementation of QDMPs in the review and approval of medicines. It was demonstrated that most of the best QDMPs were implemented, except for four QDMPs that needed improvement, namely having a systematic structured approach, decision criteria, alternatives and impact analysis.

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Key Points

Application of the Quality of Decision-Making Orientation Scheme (QoDoS) framework enabled structured assessment of decision-making practices within Zambia Medicines Regulatory Authority technical committees.

Most Quality Decision-Making Practices were perceived as favourable, particularly transparency and communication.

Lower scores were observed in structure, decision criteria, alternatives and impact analysis.

Findings suggest areas for strengthened consistency and formalization of decision processes.

1 Introduction

While the science of decision-making is well established, its application in the context of medicines development, regulatory review and marketing authorization remains underexplored [1]. To enhance its decision-making process, the organization should measure itself to be able to assess whether the improvements made have an impact on the quality of the decision-making [2].

Many National Medicines Regulatory Authorities (NMRAs), responsible for regulation of medicines within a country, have focused on strengthening their review processes by adopting Good Review Practice Guidelines [3]. However, the quality of the final regulatory decision is inherently linked to the quality of the decision-making process that precedes it [4, 5]. Despite NMRAs having the same information submitted for registration of medicines, the decision made is not always the same [6]. It is therefore important to measure the quality of the decision-making process and not just the outcome of the review process of medicines [7]. The use of a decision-making framework, being aware of cognitive biases and establishing an organizational culture are important factors as they ensure that the review process is consistent and increase the probability of better-trusted outcomes [8, 9]. Transparency also increases the credibility of the decisions made as it enhances trust in the review process [2, 10].

Although most NMRAs report having some form of decision-making framework in place that forms the basis for their decision-making process, these are often not implemented or are inconsistently applied. In most cases, validated frameworks are either not clearly defined or not adopted across the organization [7]. This variability can undermine the consistency and predictability of regulatory outcomes. The public and key stakeholders increasingly expect NMRAs to reflect the expert understanding of the advanced science [11]. Decision frameworks facilitate a clear understanding of the factors that lead to the regulatory decision [11].

2 The Development of the Quality of Decision-Making Orientation Scheme (QoDoS)

NMRAs routinely make decisions concerning new medicines, necessitating the integration of various tools in the process to ensure the decisions made are both scientifically sound and transparent [2]. As such, many NMRAs have developed decision-making frameworks to ensure improved quality in the decision-making process [1]. While there is no universally accepted framework, the Quality of Decision-Making Orientation Scheme (QoDoS) is the most commonly used framework that has been used by a number of NMRAs throughout the lifecycle of the medicines [1, 4]

Many organizations endeavour to improve internal decision-making practices to ensure that quality is built into the review process of medicines [5]. In response to this need, the Centre for Innovation in Regulatory Science (CIRS), in collaboration with Cardiff University, developed the QoDoS instrument for use by NMRAs to assess the quality of the decision-making process in the development and review process of medicines [7]. This helps increase awareness of any biases and best practices, identifying areas of improvement [4].

The QoDoS tool aims to determine whether decisions are being made in a structured and systematic way, identify the presence of cognitive biases and support continuous improvement of organizational decision-making [11]. The QoDoS was initially developed to support the evaluation of the regulatory review process in emerging markets and the impact of these processes on patients' access to medicines [12].

This tool measures the quality of the decision-making process throughout the lifecycle of the medicines and assesses the quality of the decision-making from the perspective of the individual and the organization involved in the development, review and delivery of the medicines [13, 14]. Donelan and colleagues [15] developed the ten key practices known as the Quality Decision-Making Practices (QDMPs), which serve as the basis for measuring and improving decision-making processes.

The developed QoDoS tool is used to measure the incorporation of these ten QDMPs into operational processes [13]. Prior to the development of this instrument, many

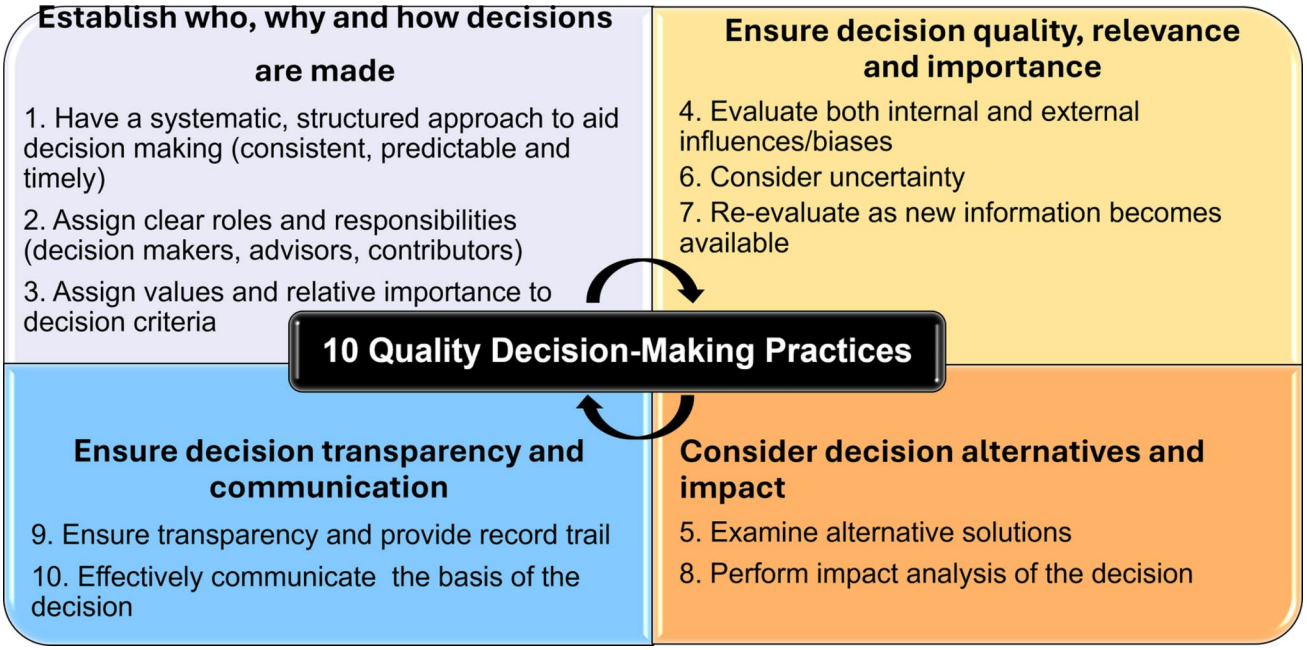

Fig. 1 The ten Quality Decision-Making Practices

frameworks focused mainly on the specific process steps and principles regarding the decision-making during the development and review of medicines. However, they did not account for the subjective elements such as behaviour and influences that affect the process with which individuals and organizations make decisions [4]. The developed ten QDMPs are organized into four broad areas, namely 'Establish who, why and how decisions are made', 'Ensure decision quality, relevance and importance', 'Consider decision alternatives and impact' and 'Ensure decision transparency and communication' (Fig. 1) [15, 16].

Applying a structured and systematic approach (QDMP 1) through the use of frameworks, guidelines and standard operating procedures (SOPs) ensures that processes yield better consistency, predictability and timeliness [17]. This also makes it possible to compare current practices with past decisions. The second QDMP of assigning clear roles and responsibilities to the individuals involved in the decision-making process should be clearly defined, transparent and well communicated so as to manage expectations. The third QDMP of assigning values and relative importance to decision criteria should determine the relevant criteria for the decision to ensure that they are in line with the decision context and overall objective. The fourth QDMP is evaluation of both internal and external influences or biases. The different stakeholders involved in the decision-making process have to be aware of the subjective influences and biases that impact outcomes and aim to minimize their influence. The biases to be considered include action-oriented bias, which is being overconfident in one's own judgement, interest-oriented bias and pattern recognition and stability bias, which is the preference for the status quo and the tendency for inertia in the presence of uncertainty [2, 7, 14]. The fifth QDMP examines alternative solutions during the entire lifecycle of medicines development so as to identify any cultural or organizational influences. QDMP 6 considers uncertainty where NMRAs need to re-evaluate the decisions made as new information becomes available. The seventh, eighth, nineth and tenth QDMPs involve performing impact analysis of decision-making, then ensuring transparency and providing a record trail. The decision made should be consistently documented for easy audit, and lastly, the basis of the decision made should be communicated [2, 7, 14]. The criteria of best practices should incorporate having a systematic, structured approach to aid decision-making; assigning clear roles and responsibilities; assigning values and relative importance to decision criteria; evaluating internal and external influences/biases; examining alternative solutions; considering uncertainty; re-evaluating with new information; performing impact analysis of the decision; ensuring transparency; and communicating the basis of the decision [2, 7, 14].

3 ZAMRA's Decision-Making Practices

The Zambia Medicines Regulatory Authority (ZAMRA; 'the Authority') is a statutory body that is mandated by law to regulate and control medicines in Zambia [18]. The main objective of the Authority is to ensure that all medicines and allied substances being made available to the general

public meet the set standards of quality, safety and efficacy [18]. Like many NMRAs, ZAMRA has established systems in place that document its decision-making processes for the review and approval of medicines. These include defined SOPs and guidelines [17]. The review process of medicines in ZAMRA involves receipt and screening of the application and sequential scientific review conducted by qualified experts. The review follows the global set standards such as the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Medicines (ICH) guidelines to ensure that the medicines being approved meet the set standards of quality, efficacy and safety [19]. Upon completion of the assessment, applications are taken to the technical committees for consideration and, thereafter, either approval or rejection of the application [17]. While ZAMRA does employ a decision-making framework, the quality of its decisions is not routinely assessed to determine whether best practices are implemented. Therefore, this study helped identify the best practices being implemented and those that needed improvement to strengthen the quality of decision-making in the review process. The assessment of the QDMPs used within ZAMRA provides an oversight into current strengths and gaps in the NMRA's decision-making process. The study focused on assessing the decision-making practices employed by the technical committees, as they are responsible for recommending the approval of medicines before they are placed on the market.

The aim of this study, therefore, was to assess the quality of decision-making practices used in the approval process of medicines by the ZAMRA, using the most commonly applied assessment tool, the QoDoS. The objectives of the study were to:

1. Evaluate the quality of the decision-making process from the perspective of individual committee members and their perception of organizational practices using the QoDoS instrument.
2. Use the QoDoS instrument to determine areas of improvement for routine assessment of quality of decision-making as well as its acceptability with respect to ZAMRA.
3. Suggest ways of improving the lowest-scoring QDMPs and how these may be implemented into the decision-making framework to ensure consistency.

4 Methods

4.1 Study Design

A cross-sectional study design was implemented during the period of August to December 2024, using the QoDoS instrument, a validated self-initiated questionnaire [13]. This study was designed to examine the implementation of the 10 QDMPs outlined in the QoDoS questionnaire by a technical committee for human and veterinary medicines, each reflecting the decision-making environment of the technical medicines for human medicines, technical committee for veterinary medicines and ZAMRA as an agency.

4.2 Study Collection Tool

The QoDoS questionnaire developed by the CIRS was used in the study. The QoDoS questionnaire includes 47 items designed to capture study participants' views on personal and organizational decision-making practices for major decisions undertaken. Refer to the electronic supplementary material.

The questionnaire consists of the following parts:

- Part I: Organizational-level influences: This section comprises two domains—'Approach' and 'Culture'—designed to assess an organization's decision-making approach and culture.
- Part II: Individual-level influences: This section comprises two domains—'Competence' and 'Style'—designed to assess an individual's decision-making competence and style.

The first part assesses the organizational decision-making practices, capturing respondents' perceptions of the decision-making environment, procedures and institutional supports under which regulatory decisions are made. The second part assesses individual decision-making practices, capturing respondents' perceptions of their own behaviour during committee deliberations. Participants were asked to respond to organizational-level items from the perspective of their role within the technical committee operating under ZAMRA procedures. In this context, 'organization' was interpreted to mean relating to the regulatory decision-making environment in which the participants function when serving as committee members. This structure enables differentiation between gaps attributable to individual practice and those attributable to organizational systems, which may require different improvement strategies (e.g. training verses procedural reform).

Study participants rated each of the 47 items in the QoDoS questionnaire using a 5-point Likert scale, reflecting the frequency with which a given practice occurred: not at all = 0% of time; sometimes = 25% of time; frequently = 50% of time; often = 75% of time; always = 100% of time.

QoDoS items were categorized as either favourable or unfavourable practices. Based on this classification, the 5-point Likert scale responses were converted into numerical scores. For items representing favourable practices, the following scores were assigned: not at all = 0; sometimes

Table 1 QoDoS items mapped to the 10 QDMPs [14]

QDMPs	QDMP short name	24 QoDoS individual items	23 QoDoS organizational items
1. Have a systematic, structured approach to aid decision-making (consistent, predictable and timely)	Structure	24, 25, 27, 30, 32, 35, 36, 39, 40, 43	3, 4, 11, 13, 14
2. Assign clear roles and responsibilities (decision makers, advisors, contributors)	Roles	37	15, 23
3. Assign values and relative importance to decision criteria	Criteria	33, 34, 44	6, 7
4. Evaluate both internal and external influences/biases	Bias	38, 42	5, 17, 20, 21
5. Examine alternative solutions	Alternatives	28	8, 9
6. Consider uncertainty	Uncertainty	26, 45	10, 18
7. Re-evaluate as new information becomes available	New information	46	12, 19
8. Perform impact analysis of the decision	Impact	31, 47	1
9. Ensure transparency and provide a record trail	Transparency	29, 41	2, 16
10. Effectively communicate the basis of the decision	Communication		22

Underscored items indicate those that correspond to 'unfavourable practice', whereas non-underscored items indicate those which represent 'favourable practice'

QDMP Quality Decision-Making Practice, *QoDoS* Quality of Decision-Making Orientation Scheme

= 1; frequently = 2; often = 3; always = 4. Conversely, for items representing unfavourable practices, the scoring was reversed scores: not at all = 4; sometimes = 3; frequently = 2; often = 1; always = 0 (Table 1).

4.3 Study Participants

The selected study cohort consisted of 12 individuals from the human ($n = 5$) and veterinary ($n = 7$) technical committees of ZAMRA. This included the entire membership of the two committees. Purposeful sampling was used to select the participants. These participants were selected due to their responsibility for ensuring the regulatory, quality and safety aspects of medicines for market authorization. The two committees are responsible for recommending approval or rejection of the products. The members were all external experts not directly employed by ZAMRA. These are qualified professionals with vast experience drawn from the following fields: internal medicine, clinical pharmacy, clinical pharmacology, veterinary medicine, toxicology, epidemiology or biostatistics, herbal medicine, pathology, paediatrics and infectious diseases.

4.4 Study Procedure

The study was carried out in two phases, following the same procedure to ensure consistency. A workshop was conducted first to introduce the study to the participants, where QoDoS experts provided an explanation of the instrument and its terminology to ensure consistent interpretation of items. This was followed by the anonymous completion of the QoDoS questionnaire. The study was first conducted with the TCHM and then the TCVM. All members selected for this study ($n = 12$) completed the validated QoDoS questionnaire that was distributed electronically. Acceptability of the QoDoS framework was assessed qualitatively based on participant engagement, including completion rates, participation in feedback sessions and responsiveness to proposed recommendations.

4.5 Data Processing and Analysis

Data collected from completed questionnaires were entered into an Excel database and analysed using descriptive statistics. There was no missing information, and the entry data was double-checked by the study investigators. The scores for the individual QoDoS items were codified based on the categorization in Table 1. This was then used to calculate the overall score for each QDMP by taking a median across the relevant QoDoS item scores. For confidentiality reasons, only aggregated results are shown here and no data that identify an individual are reported. No inferential statistical comparisons were undertaken due to the small sample size ($n = 12$).

The overall scores across the ten QDMPs were presented using radar charts and modified box plots. Radar charts displayed the median overall scores, while the box plots illustrated the interquartile range (25^{th}–75th percentiles) as grey boxes, with medians represented by white diamonds. In both types of visualizations, traffic light colour coding was used according to the overall QDMP scores, where a score of < 1 = 'unfavourable practice' = red, a score of ≥ 1 and < 3 = 'needs improvement' = yellow and a score of ≥ 3 = 'favourable practice' = green.

A session was then held to provide feedback to the members on areas in which the Authority was performing well and those that needed improvement. Lastly, a follow-up meeting was held to discuss the results, and recommendations were made on structured decision-making practices.

5 Results

The results are presented following the participation of 12 members of ZAMRA technical committees (seven five from the TCHM and seven from the TCVM) with the results presented in two parts:

Phase I: The TCHM
Phase II: The TCVM.

5.1 Phase I: The Technical Committee for Human Medicines (TCHM)

Within ZAMRA, individual and organizational decision-making behaviours have the potential to influence the consistency, transparency and robustness of regulatory outcomes. These practices were assessed across the five technical committee members (Fig. 2). Findings from this analysis indicate that committee members perceived their individual decision-making practices as favourable, suggesting confidence in the review process.

A total of seven out of the nine QDMPs obtained a median score of ≥ 3, which places them in the area of 'favourable' practice from the individual members' perspective. These included QDMP 1 (Structure), QDMP 2 (Roles), QDMP 4 (Bias), QDMP 6 (Uncertainty), QDMP 7 (New information), QDMP 8 (Impact) and QDMP 9 (Transparency). The practices highlighted for improvement included QDMP 3 (Criteria) and QDMP 5 (Alternatives). For QDMP 8 (Impact), the responses ranged from 'favourable' to 'needs improvement', with the majority identifying this practice as 'favourable'. QDMP 10 was not applicable for the individual's perspective as they do not communicate with the applicants.

The members of the TCHM understood that culture does not affect individual decision-making but is relevant to the organization. Three members indicated that they 'frequently' use intuition in decision-making, one indicated 'often' and one answered 'always', therefore, affecting the quality of the decisions made. The roles and responsibilities of the stakeholders (QDMP 2) involved in the review and approval of medicines were clear, therefore, indicating this practice as 'favourable'. From the individual members' perspective, the qualitative and quantitative values of the decision-making criteria (QDMP 3) are sometimes or not at all assigned; hence, this was determined to be 'unfavourable' in practice. The assessment of QDMP 4 was found to be 'favourable'. QDMP 5, examining alternate solutions, was perceived as needing improvement. The sixth QDMP, considering uncertainty, was 'favourable'. The members indicated that they do not continue with projects that should be terminated. Concerning the practice of performing impact analysis of the decision made, one member rated it 'not at all', two members rated it 'sometimes' and the remaining members gave it a 4, 'always'. Individual members indicated that they always understood the importance of the decision. QDMP 9 was indicated to be 'favourable', as the individuals always and often make transparent decisions.

An analysis of the responses from the organizational perspective indicated that eight out of the ten QDMPs obtained a median score of ≥ 3, which places them in the area of 'favourable' practices, while two QDMPs (3 and 8) need improvement (Fig. 3).

The practices that obtained a median score above 3 and hence deemed 'favourable' included QDMP 1 (Structure), QDMP 2 (Roles), QDMP 4 (Bias), QDMP 5 (Alternatives), QDMP 6 (Uncertainty), QDMP 7 (New information), QDMP 9 (Transparency) and QDMP 10 (Communication). The practices identified as 'needing improvement' included QDMP 3 (Criteria) and QDMP 8 (Impact analysis). For QDMP 8 (Impact), the responses ranged from 'favourable' to 'needs improvement', with most identifying this practice as 'unfavourable'. Responses for QDMP 7 ranged between 'favourable' to 'needsimprovement', and for QDMP 3, responses ranged from 'favourable' to 'unfavourable'.

The assessment of the combined responses for the individual and the organizational practices for the human medicine committee members revealed that seven of the practices are 'favourable', as shown in Fig. 4.

QDMP 3 was 'unfavourable' from both the individual and organizational perspectives. Some differences were observed in the responses for QDMP 5 (Alternatives) and QDMP 8 (Impact). The assessment of the alternative solutions revealed that individual members felt that it is 'unfavourable' though they perceived that of the organization as being 'favourable'. This suggests that, although the organization is perceived as open to using better and more innovative alternatives, there may still be room for improvement in how committee members present such contingencies and achievable options. Assessment of impact analysis indicated that individuals responded that impact analysis (QDMP 8) was 'favourable' from their perspective, while they thought that the practice for the organization was 'unfavourable' and, therefore, needed improvement.

5.2 Part II: The Technical Committee for Veterinary Medicines (TCVM)

An analysis of the ten decision-making practices among the seven technical committee members for veterinary

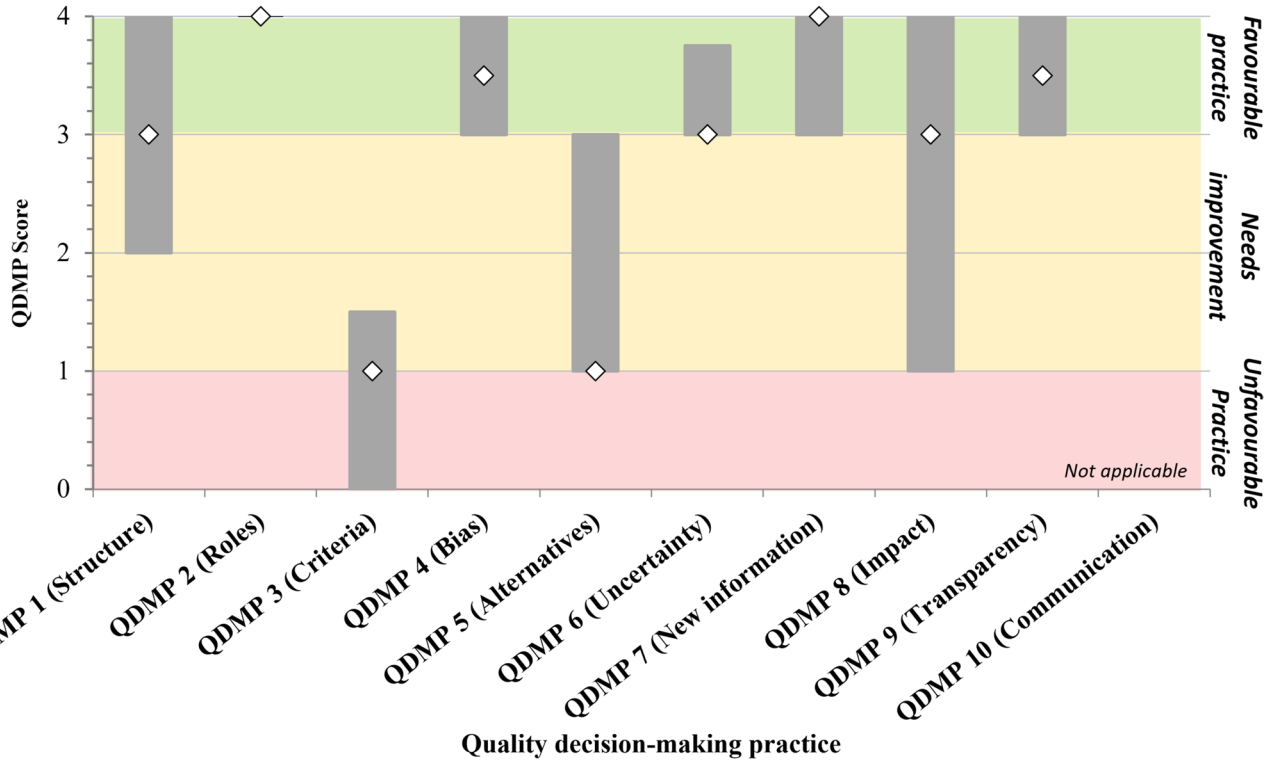

Fig. 2 Median and variance combined responses of the TCHM (n = 5): QoDoS *individual* items mapped to the ten QDMPs. *Box* = 25th and 75th percentile; *diamond* = median. *QDMP* Quality Decision-Making Practice, *QoDoS* Quality of Decision-Making Orientation Scheme, *TCHM* Technical Committee for Human Medicines

medicines indicated that members perceived their individual practices as generally 'favourable' across most of the ten QDMPs. QDMPs 1 (Structure), 2 (Roles), 4 (Bias), 6 (Uncertainty), 7 (New information) and 9 (Transparency) obtained a median score ≥ 3 and, hence, were favourable practices. The three QDMPs that they felt needed improvement included QDMP 3 (Criteria), QDMP 5 (Alternatives) and QDMP 8 (Impact) from the individual perspective, as shown in Fig. 5.

The only QDMPs with differences in the median scores from the individual's perspective were QDMP 1 (Structure) and QDMP 5 (Alternatives), whose responses ranged between 'needs improvement' to 'favourable', and QDMP 8, whose responses ranged from 'favourable' to 'unfavourable', as shown in Fig. 5.

Concerning organizational practices, seven out of the ten QDMPs obtained a median score of ≥ 3 and, hence, were considered 'favourable' practices. These included QDMP 2 (Roles), QDMP 4 (Bias), QDMP 5 (Alternatives), QDMP 6 (Uncertainty), QDMP 7 (New information), QDMP 9 (Transparency) and QDMP 10 (Communication). QDMP 1 (Structure), QDMP 3 (Criteria) and QDMP 8 (Impact) obtained median scores of < 3 and, hence, needed improvement, as shown in Fig. 6.

From the individual and organizational perspectives, the QDMPs that 'need improvement' included QDMP 1 (Structure), QDMP 3 (Criteria), QDMP 5 (Alternatives) and QDMP 8 (Impact). The members stated that they often make consistent decisions based on their knowledge and the structured approach. The members indicated that they had been trained in decision-making though they observed that the organization does not conduct any training. The members indicated that sometimes the decisions made are influenced by organizational politics. For QDMP 4, at least half of the members perceived that the organization's decision-making practices are 'sometimes' influenced by external stakeholder demands. The same members perceived that the decisions are sometimes made with emotions and are impacted by recent or dramatic events. With regards to QDMP 5, individual members expressed that the organization is often open to using better alternatives and encourages innovative decision-making. On the issue of uncertainty (QDMP 6), the members felt that both them and the organization frequently consider uncertainty in decision-making and they sometimes underestimate problems that adversely impact decision-making. For QDMP 7, the members felt that the organization frequently re-examines decision-making when new information is available. On the impact analysis (QDMP 8) of the decision made, the members understood the importance of

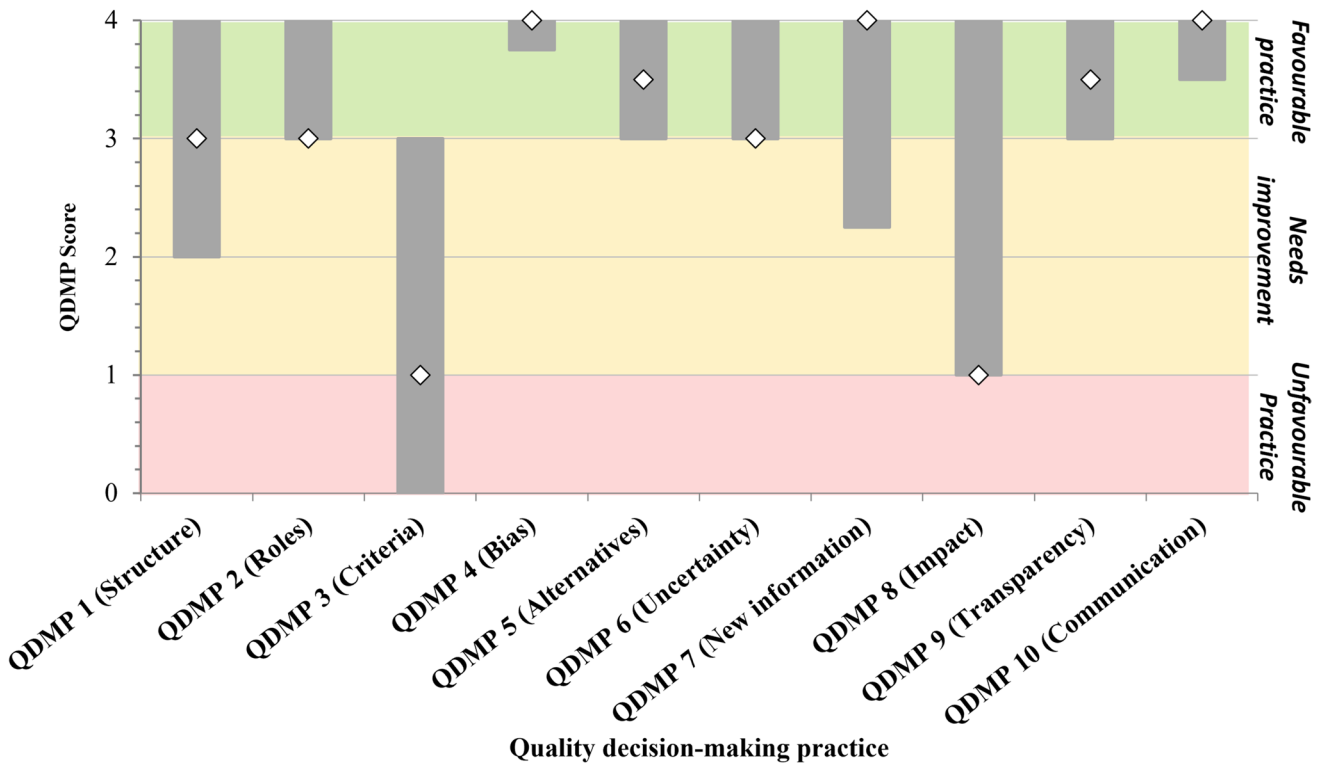

Fig. 3 Median and variance combined responses of the TCHM (n = 5): QoDoS *organizational* items mapped to the ten QDMPs. *Box* = 25th and 75th percentile; *diamond* = median. *QDMP* Quality Decision-Making Practice, *QoDoS* Quality of Decision-Making Orientation Scheme, *TCHM* Technical Committee for Human Medicines

the decisions made though they felt they could make better decisions. The members felt that the organization frequently evaluates the impact of the decisions. For QDMP 9, ensuring transparency, the members stated that the decision-making process is transparent and that they do not make the same mistakes as those experienced in the past, and half of the members perceived that the organization 'sometimes' makes the same mistakes made in the past. Lastly, for QDMP 10, although some felt that the organization needs to improve the way it communicates its decisions, most of them believe it does communicate these.

The only QDMPs with differences in the median scores between the perception of the organization's decision-making practices and the perception of the individual's decision-making practices for the veterinary committee were QDMP 1 (Structure) and QDMP 9 (Transparency), as shown in Figs. 5 and 6.

The combined results of the responses for the seven members for the TCVM showed that they perceived their individual and organizational practices as generally 'favourable', as shown in Fig. 7.

QDMP 8 (Impact) needs improvement from both the individual members' perspective and the organizational perspective. Some differences were observed between how individuals make decisions and how they perceived the organizational practices. For QDMP 1, while the assessment of the structured approach was 'favourable' for the individuals, the members perceived that the organizational practice 'needs improvement'. The assessment of the decision criteria (QDMP 3) was 'unfavourable' for the individual and 'needs improvement' for the organization. The assessment of the alternatives was 'favourable' for the organization, while for individuals, it needed to be improved.

It should be indicated that ZAMRA's SOPs and technical committee guidelines align strongly with QDMPs relating to procedural governance and accountability. This alignment may contribute to the favourable scores observed for QDMP 2, QDMP 9 and QDMP 10. In contrast, QDMPs requiring structured decision-analytic tools such as explicit decision criteria (QDMP 3), systematic structured approaches (QDMP 1) and formal impact analysis (QDMP 8) are less commonly operationalized within regulatory SOPs and may therefore depend more on individual expertise and committee practice. This may partly explain the lower scores observed for these domains.

From these results, it was observed that the QoDoS instrument or framework is beneficial to ZAMRA as it has helped identify its strengths and weaknesses in the area of decision-making in the review and approval process of

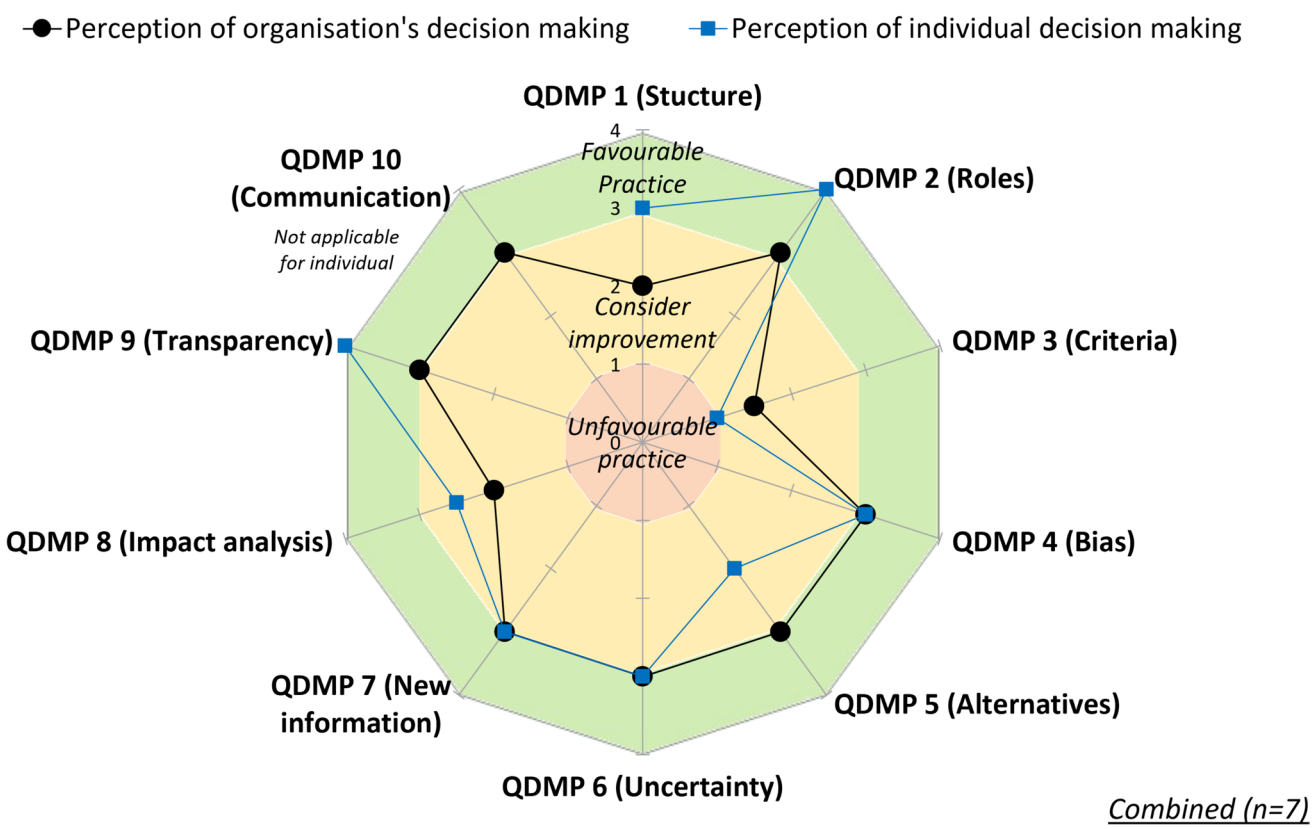

Fig. 4 Median combined responses of the TCHM ($n = 5$): Organizational vs individual QoDoS items mapped to the ten QDMPs. *QDMP* Quality Decision-Making Practice, *QoDoS* Quality of Decision-Making Orientation Scheme, *TCHM* Technical Committee for Human Medicines

medicines. In addition, all participants engaged fully in the QoDoS assessment and subsequent feedback discussions, indicating that the framework was acceptable to the technical committees as a tool for evaluating and reflecting on decision-making practices.

The following are the recommendations from this study. The Authority should:

1. Conduct decision-making training for the technical committee members so that they are aware of the ten QDMPs and implement them in those areas that need improvement in the decision-making process.
2. Clearly define a framework for the decision-making processes.
3. Improve the practices that scored poorly, which include impact analysis for both the individual and organizational perspective.

6 Discussion

The quality of the decision-making process is critical in the regulatory review of medicines as it ensures access to quality, efficacious and safe medicines [16]. Having a defined framework improves stakeholder trust in the entire process. The study assessed the practices that are utilized by the technical committees for human medicine and veterinary medicines as they recommend products for approval. It was observed that the Authority has incorporated most of the best practices within the technical committees, with a few areas needing improvement, including systematic structured approach, criteria assessed, alternatives reviewed and impact analysis for the veterinary committee and criteria, alternatives reviewed and impact analysis for the human medicine committee. The QoDoS framework assessed the decision-making practices that are favourable, unfavourable and needing improvement from both the individual and the organizational perspectives. From the ten QDMPs assessed, seven of them were considered favourable from both technical committees, while two practices needed improvement, which included assigning values and relative importance to decision criteria and impact analysis. The study generally reported favourable results across the ten QDMPs among the two technical committees. Some differences were noted in the responses on the perception of the individual members on how they make decisions. This was because of the level of training that they have received outside ZAMRA and, more so, that the Authority

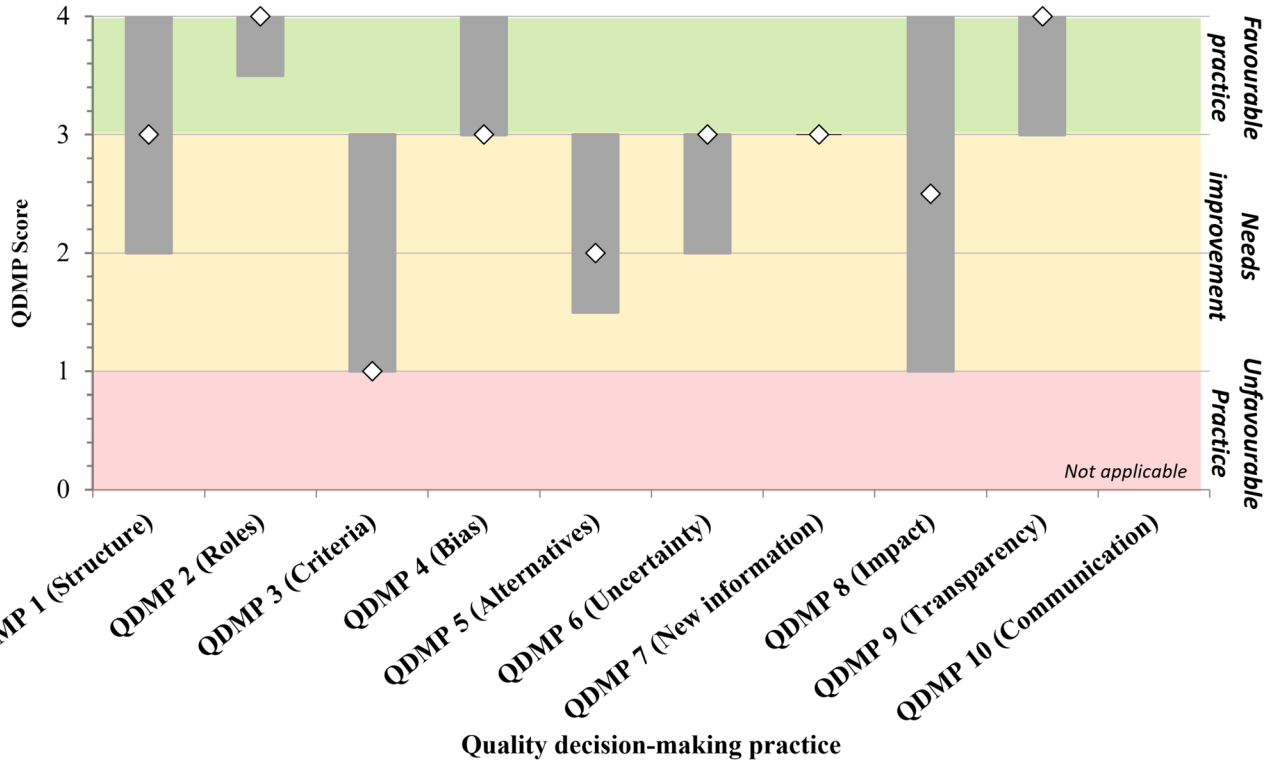

Fig. 5 Median and variance combined responses of the TCVM (n = 7): QoDoS *individual* items mapped to the QDMPs. *Box* = 25th and 75th percentile; *diamond* = median. *QDMP* Quality Decision-Making Practice, *QoDoS* Quality of Decision-Making Orientation Scheme, *TCVM* Technical Committee for Veterinary Medicines

does not provide any training to its members on the decision-making process. From the assessment of the QDMPs being implemented by the Authority during the approval process of veterinary and human medicines, a number of variations were observed in the scores of the responses by the members of both the TCHM and TCVM. Some variations were observed for some practices between the two committees. Members of the TCHM indicated that the QDMP 1 was favourable, while those from the TCVM indicated that this practice needed improvement. The difference in the responses could be attributed to the fact that the organization does not train the members in the science of decision-making, which can sometimes affect the way they perceive certain things. It has been observed that training in decision-making within institutions improves the way decisions are made, as it reduces biases [20, 21]. Therefore, there is a need for the organization to make the members aware of the decision-making practices being implemented and that these should be used at all times to ensure consistency in the decisions made. Differences in the scores could be due to differences in the individuals' perception of the organization due to poor transparency and documentation of the practices or different experiences of the individual members [5].

This study demonstrated that there is a gap in the knowledge concerning the practice of quality decision-making in regulatory decisions. Both committees indicated that QDMP 3, assigning values and relative importance to decision criteria, needed improvement. It was noted from the study that the responses between the two committees were mostly similar, indicating that, to some extent, the best practices are implemented during the approval process of both veterinary and human medicines. The decisions made are documented, therefore, maintaining a record trail. This was consistent with the study conducted by Bujar et al. [5] that indicated that most NMRAs interviewed had a system in place to document their decision-making for major decisions, defined by SOPs and guidelines. Bujar et al. [1] conducted a similar study, which focused on the NMRAs, where the QoDoS questionnaire was administered to a total of 38 individuals from 12 regulatory agencies to identify biases and best practices. Differences in the way decisions are made in the development and regulatory review of medicines were noted. As seen in this study, it was also noted that the participants felt that the quality of their decision-making process could be improved through training. Research has shown that while individual decision-making approaches are often more structured than organizational ones, there is a

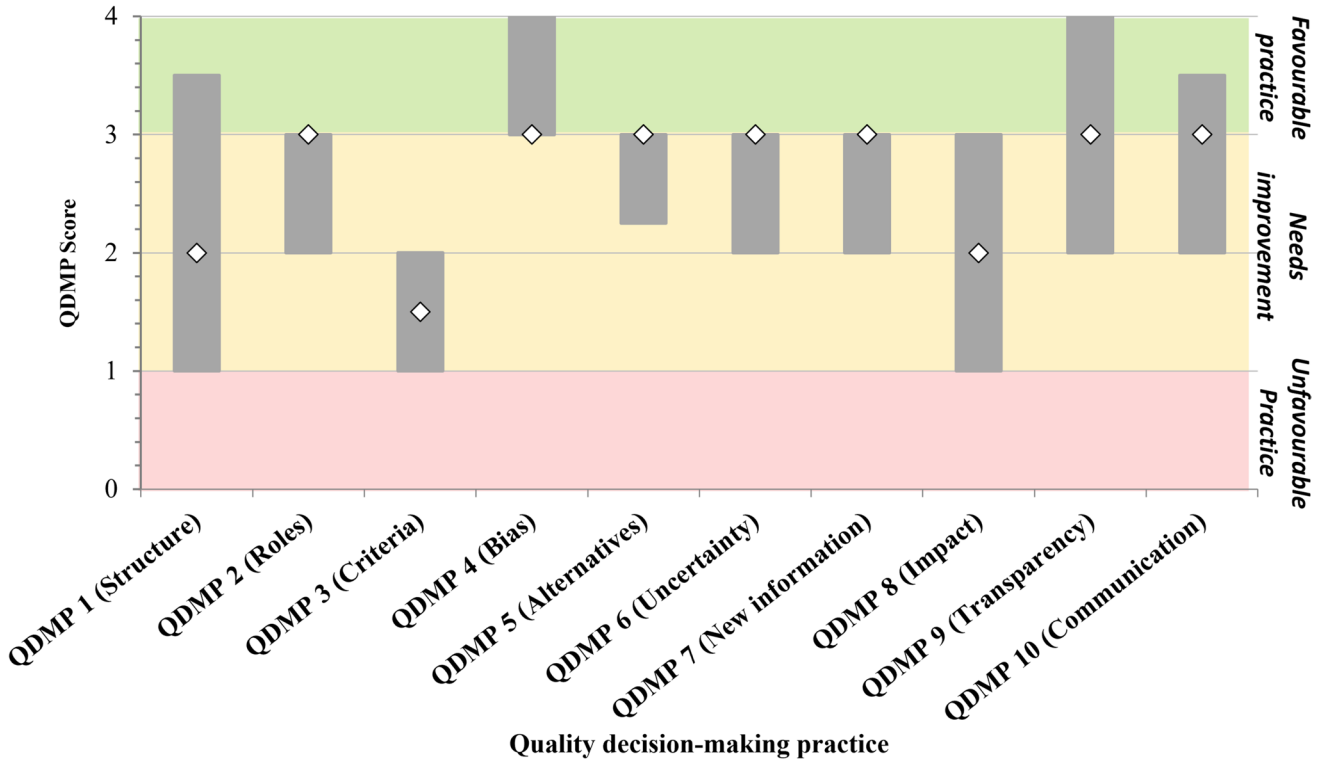

Fig. 6 Median and variance combined responses of the TCVM (n = 7): QoDoS *organizational* items mapped to the ten QDMPs. *Box* = 25th and 75th percentile; *diamond* = median. *QDMP* Quality Decision-Making Practice, *QoDoS* Quality of Decision-Making Orientation Scheme, *TCVM* Technical Committee for Veterinary Medicines

general recognition of the need for improvement and training in decision-making science [1, 21, 25]. One practice that the members from both committees felt needed improvement was impact analysis of the decisions made as it scored low from the individual's perspective. This is an important step in the review and approval process as it is related to present and past situations to ensure that the process is consistent and in most cases is not considered essential [2]. Research highlights the importance of consistency and transparency in decision-making processes [22]. Implementing QDMPs can lead to increased productivity, reduced uncertainty and more predictable outcomes in pharmaceutical development and regulation [1, 23]. Impact analysis can be improved by incorporating it in the decision-making framework by including the assessment of how similar medicines were reviewed within its jurisdiction or other NMRAs [5]. Even though the individual members had knowledge of the decision-making practices, most of them felt they needed more training in this area so as to ensure that they consistently make the right decisions based on the well-structured approach. Training has demonstrated to improve the quality of decisions that individuals make [20]. Therefore, there is a need for improvement in this area by the Authority to ensure that decisions are made consistently and transparently. This will also help reduce biases in the way the final decisions are made by the individual members of the committees. This will in turn standardize the process between the two committees, thereby ensuring consistency and transparency in the decision-making process.

The study has demonstrated that though the Authority has a framework, it is not well defined; hence, it needs to be improved upon. The QoDoS framework has been demonstrated to be a reliable tool that is well applicable to ZAMRA and can be adopted in its regulatory review and approval of medicines. The acceptability of the QoDoS framework within ZAMRA was demonstrated through high levels of participant engagement and willingness to reflect on and discuss the findings. Although acceptability was not measured using a formal quantitative scale, qualitative indicators such as participation in feedback sessions and receptiveness to recommendations suggest that the tool is feasible for routine use within the Authority. The findings from a study conducted by Burns and colleagues [24] on the adoption of real-world evidence in the regulatory decision-making process demonstrated that most regulatory agencies have defined their regulatory frameworks for the decision-making process. Having well-defined legal and regulatory frameworks is key in the regulation of medicines. Active and functioning committees form an important part of the quality decision-making process, thereby ensuring that good quality, safe

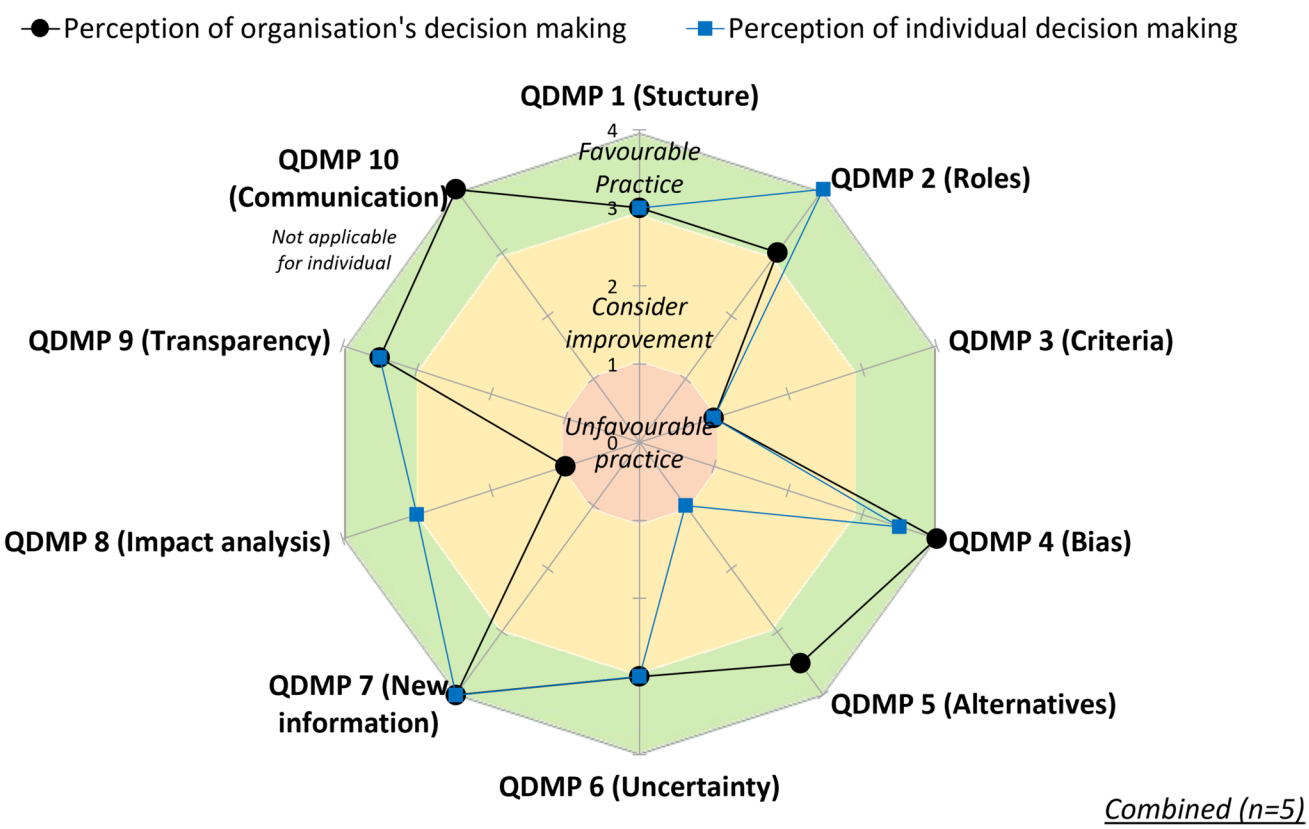

Fig. 7 Median combined responses of the TCVM ($n = 7$): Organizational vs individual QoDoS items mapped to the ten QDMPs. *QDMP* Quality Decision-Making Practice, *QoDoS* Quality of Decision-Making Orientation Scheme, *TCVM* Technical Committee for Veterinary Medicines

and efficacious medicines are made available to the market. Further assessments should be made to assess the QDMPs that scored low in this study to ensure that they are improved upon. Implementing QDMPs can increase transparency, consistency and efficiency in regulatory processes, ultimately benefiting patients and stakeholders [5]. It is important for the NMRAs to be more consistent and predictable in decision-making processes during the approval process of medicines. This is achieved through capacity building and encouraging utilization of validated decision-making frameworks within organizations [4]. Research indicates that QDMPs are crucial in the development, review and reimbursement of medicines. However, organizations rarely provide training in decision-making science [1]. Implementing structured decision-making processes is crucial for quality management and systematic planning in organizations [23]. Overall, formal evaluation of decision-making quality is essential for improving practices and outcomes in the pharmaceutical industry and regulatory bodies. From this study, it has been noted that there is a need to improve in the areas that scored low, so as to improve the quality of the decision-making process. There is a need to also clearly define the decision-making framework that is used in the review process. The technical committee members should be trained in the decision-making process, so as to reduce any biases.

The limitations of the study included the small sample size and that the study focused on the final stage of the entire regulatory review process. As participants were assessing the decision-making processes within committees of which they are members, responses may be subject to social desirability bias or self-assessment bias.

7 Conclusion

The assessment of individual and organizational decision-making practices within the TCHM reveals generally favourable perceptions of the ten QDMPs. This suggests a baseline confidence in existing decision-making structures. However, the observed variance in responses indicates that decision-making approaches are not entirely uniform across committee members, which could introduce inconsistencies in regulatory evaluations. These findings underscore the need for enhanced standardization and structured decision-making processes. The Authority should train the technical committee members in decision-making so that they are conversant with the decision-making practices that are in place. This

will in turn reduce individual biases and improve the perception they have of the Authority. Further impact analysis should be incorporated in the decision-making framework so as to improve the quality of the decision-making process. By addressing these areas, the organization can move towards greater consistency, efficiency and reliability in regulatory decision-making, ultimately enhancing the quality and impact of its evaluations. Having a defined QoDoS framework in place that links directly to the World Health Organization (WHO) Global Benchmarking Tool (GBT) indicators will strengthen the regulatory review process, which is important for ZAMRA as it aims to attain WHO GBT maturity level 3.

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Declarations

Conflict of interest SW is an Editorial Board member of *Pharmaceutical Medicine*. SW was not involved in the selection of peer reviewers nor in any editorial decisions regarding this manuscript. CSC, MS, SL and JL have no conflicts of interest relevant to the contents of the article.

Ethics approval Ethical approval for this study was granted by the Human Research Ethics Committee (Medical) of the University of Witwatersrand, Johannesburg, South Africa (Waiver number: R14/49 Chisha; registration number is H24/01/05). Permission was granted by the ZAMRA for the collection of data and for its subsequent publication.

Consent to participate Informed consent was obtained from all participants prior to participation.

Consent to publish Participants provided consent for anonymized data to be used in publication.

Availability of data and material The datasets generated and/or analysed during the current study are not publicly available due to confidentiality agreements but are available from the corresponding author on reasonable request, subject to institutional approval.

Code availability Not applicable.

Author contributions CSC devised the study, collected data, analysed the data and wrote the manuscript. MS supervised the study and critically reviewed the manuscript. SL devised and supervised the study, analysed data and critically reviewed the manuscript. JL analysed data and critically reviewed the manuscript. SW devised and supervised the study, analysed the data and critically reviewed the manuscript. All the authors confirm that they have read and approved the final manuscript.

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