

Measuring transparency to improve good governance in the public pharmaceutical sector

OMAN



**World Health
Organization**

Regional Office for the Eastern Mediterranean

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Foreword

The health sector in Oman has experienced rapid development in recent years. The Ministry of Health is the principle health care provider and develops health policies and strategies, health programmes and plans for the health sector. Health services are almost universally accessible based on the primary health care approach. The health transition, demand for better quality care and the ever-increasing costs of health services calls for a health road map. The Ministry of Health has developed a vision for 2050 to address these concerns.

As part of national efforts to ensure the quality and safety of medicines in Oman, the Ministry of Health initiated the Good Governance for Medicines programme, with technical support from the World Health Organization (WHO). This assessment identifies areas that need to be addressed to ensure a comprehensive system for the governance of pharmaceuticals. Much work has been undertaken since conducting the assessment to address the vulnerabilities in the Omani pharmaceutical system.

The publication of this report comes hand-in-hand with the finalization of a comprehensive national framework for good governance in the pharmaceutical sector in Oman. The framework outlines the major components of a national integrity system and lays the foundation for continuous efforts to increase transparency and accountability in the regulation and supply of medicines.

It is with great pleasure that I release this report and encourage practitioners in the Omani health sector to benefit from the lessons learnt from this assessment. I also hope the Omani experience in measuring and improving good governance in this critical sector contributes to the global learning process and the struggle to ensure full and affordable access to quality essential medical products within the global goal of universal health coverage.



Dr. Ahmed Mohammed Al Saidi
Minister of Health

Preface

The goal of the WHO Good Governance for Medicines programme is to improve the situation of medicines regulation and supply. Guided by the WHO Medicines Strategy, and launched in late 2004, the programme seeks to ensure that essential medicines reach the people who need them. The World Bank has identified corruption as the single greatest obstacle to economic and social development. As the Good Governance project increases in momentum, more and more national medicines regulatory authorities are taking up the challenge to address it.

The Good Governance of Medicines programme offers a three-step technical support package that involves: national transparency assessment; development of a national framework on good governance for medicines; and implementation of a national programme. The global programme is being successfully implemented in some 30 countries around the world.

This report presents the findings of the first phase of the national Good Governance for Medicines programme in Oman, the national assessment. The assessment aims to obtain a picture of the level of transparency and potential vulnerability to corruption in the public pharmaceutical sector using WHO's assessment instrument. In Oman, the assessment looked at eight functions: medicines registration, licensing and inspection of pharmaceutical establishments, promotion, clinical trials, selection, procurement and distribution.

This national assessment represents a baseline from which to monitor the country's progress over time in terms of transparency. However, by dealing with unethical practices, transparency and accountability, the assessment raises sensitive issues and it was imperative that it should be conducted in a constructive manner. The goal of the project was not to measure corruption but to examine how resistant or vulnerable the system is towards unethical practices.

The assessment is an entry point for the development and promotion of a national programme on good governance for medicines and should not be seen as an end in itself. It is the beginning of a process aimed at bringing about desirable and sustainable changes in the governance of the pharmaceutical sector. This exciting challenge has already been accepted by an increasing number of countries.

The assessment findings will help a country to identify vulnerable aspects that could lead to corruption and unethical practices. They will also determine what can be done to increase system transparency and accountability with the goal of improving access to medicines for people, especially vulnerable and marginalized groups.

Acknowledgements

This report was prepared by Qasim Al-Riyami, Dr Ibrahim Al-Zakwani, Sawsan Ja'afar and Anisa Rasool. The authors were responsible for conducting the interviews using the transparency assessment tool developed by WHO. The authors also collected and analysed the data. The assessment was conducted in Oman in February and March 2011. The views in this document were collected through a wide range of key informants (KIs) whose experience and knowledge within the pharmaceutical sector in Oman provides the basis for this assessment and its recommendations. WHO acknowledges the input of all contributors with thanks.

The Minister for Health, H.E. Dr Ahmed bin Mohamed bin Obaid Al Saidi and the Under-Secretary for Health Affairs, Dr Mohammed Al Hosni provided support to the study demonstrating their commitment to ensuring transparency and accountability in the regulation and supply of medicines. The Ministry of Health provided additional information and support during the assessment process.

Executive summary

This report presents the results of a transparency assessment carried out in Oman. It gives a comprehensive assessment of the level of transparency and the level of vulnerability to corruption within the eight primary functions of the pharmaceutical sector – registration, licensing, inspection, promotion, clinical trials, selection, procurement and distribution of medicines.

The methodology provides both qualitative and quantitative information. Two national investigators, selected by the Ministry of Health, collected data by conducting a series of interviews with 94 carefully selected key informants (KIs). The information collected was then converted using a rough quantification method into a zero to 10 scale to provide a score for each function in terms of vulnerability to corruption (minimal to extreme). The scoring indicates the vulnerability in terms of the policy, the regulatory and administrative structures, and the procedures at the time of the survey.

The quantitative data reveal that of the different functions: medicine distribution is minimally vulnerable to corruption; licensing and procurement are marginally vulnerable to corruption; medicine registration and selection are moderately vulnerable to corruption; the inspection process is very vulnerable to corruption; and medicine promotion and clinical trials are extremely vulnerable to corruption.

The results indicate the vulnerabilities of the policy, structures and procedures in place at the time of the survey. They do not reveal in any way the level of possible existing corruption in the country.

Oman has laws controlling the different activities within the domestic pharmaceutical sector. Various decrees, sub-decrees, regulations and circulars have been published by the Ministry of Health. A website has been developed in order to disseminate information, which in the future should provide access to all procedures and the criteria for any decision-making within the Ministry of Health.

Each area of the public pharmaceutical sector has an operational and functional committee responsible for decision-making that is made up of all relevant stakeholders in the country and not only by Ministry of Health staff.

Registration of medicines

There is a standard application form for applications for medicine registration, which is available for download from the Ministry of Health website and all registered pharmaceutical products are listed according to a defined minimum level of information. A formally established technical committee is responsible for

registration decisions and the committee comprises sufficiently qualified members and meets regularly. However, there is no detailed document describing composition and terms of reference of the registration committee, no written criteria for membership selection, no conflict-of-interest guidelines and no clear written guidelines on the committees' decision-making process. There is an appeals process for rejected applications; however, the process is not an independent one.

Licensing of pharmaceutical establishments

There exist a directorate responsible for licensing and a licensing committee as well as standard written criteria for submission of an application for a license, including fees. There are also regular post-licensing inspections of all licensed establishments. However, there is no detailed document describing composition and terms of reference of the licensing committee, no criteria for membership selection, no conflict-of-interest guidelines and no clear written guidelines on the committees' decision-making process. There is no independent appeals system for license rejection and no timeframe for approval of a license.

Inspection of pharmaceutical establishments

In the area of inspections, there is a provision covering the inspection of medicine distributors in the pharmacy law and an active unit for the inspection of pharmacies. However, there are no mechanisms to prevent regulatory capture, no independent appeals system for rejected applicants, no selection criteria for the recruitment of inspectors and inadequate numbers of inspectors. There is also no provision for the declaration of conflicts of interest by the parties involved in inspection activities.

Control of medicine promotion

Regulation of the promotion of medicines does not exist except for regulation restricting direct-to-consumer advertising. However, at the time of writing, regulations were being developed. Advertisement to professionals is not controlled. There is no control of published medical information given to health professionals, no committee for approving or monitoring medicine promotion and advertisement, no restrictions on providing free goods and samples to private pharmacies and clinicians, and the ethical criteria for medicine promotion are not adequate or sufficient to enhance good prescribing and dispensing practices.

Control of clinical trials

There is legal provision for conducting clinical trials and written guidelines on the principles of good clinical practice. There is also a research committee that reviews applications. However, there are no clear written regulations or conflict-of-interest guidelines for the conduct of clinical trials. There is also no inspection of clinical trial progress and sites.

Selection of medicines

The recently revised national formulary is in line with the WHO essential medicines list. A central drug committee exists within the Ministry of Health that is responsible for the selection of medicines, but there are no written selection criteria for membership of the committee, no publicly available guidelines on the process for the selection of medicines, no publicly available terms of reference for the committee, no conflict-of-interest guidelines and the committee does not involve all stakeholders.

Procurement of medicines

Procurement of medicines in Oman varies depending on the type of pharmaceutical product. There are publicly available written procedures for the procurement of medicines through tenders and bids. There is a tender committee, which follows written guidelines concerning the process of the bid. However, there are no written criteria for committee membership selection, no conflict-of-interest guidelines and a long lead time of almost 10–11 months. There is also no independent appeal system in the procurement process. There are constant shortages of medicines, especially in rural areas. At the time of writing, new regulation had been enacted to monitor medication supply to referral patients in peripheral polyclinics and hospitals.

Distribution of medicines

There is systematic and orderly shelving of products in the central medicine warehouse and a computerized system is employed for the inventory and to track the movement of pharmaceuticals from the central medicine warehouse to end beneficiaries. Medicines are coded and stored in compliance with international and WHO regulations. An external audit is carried out annually by an independent central auditors unit and a physical stock-take is done regularly on all items in the central medicine warehouse by internal staff. At the time of writing, the distribution function had received British Standards Institution/International Organization for Standardization certification. There is no security management system, especially in regional stores, and security systems at all medical stores do not include cameras to monitor entrances and exits.

Recommendations

In order to increase openness and transparency, Oman should develop written procedures for all activities of the eight core functions of the pharmaceutical sector. In addition, information such as the terms of reference of the various committees and the roles, responsibilities and professional qualifications of their members, could be added to the document describing the composition of the committees.

All law enforcement processes should be clearly defined, as well as the roles and power of officials and committees to enforce the law. All laws and regulations should also be made easily accessible to the public.

Declaration of conflicts of interest should be required for the members of committees and government officials. An independent appeal mechanism to manage concerns and complaints from the private sector should be developed.

The diagnostic framework and methodology that this assessment study introduces aims to provide health specialists and government decision-makers with the information needed to prioritize those functions of the pharmaceutical system that need the highest investment and regulation. In turn, this helps to ensure that investments in the pharmaceutical system are maximized and that access to essential medicines is improved.

A good system with transparent procedures and strong ethical structures is needed to improve good governance. Some legislative and administrative reforms will be needed to establish a transparent system. Evidence from this assessment will help policy-makers to revise and adjust existing policies and procedures.

This assessment is the first step of the WHO programme on Good Governance for Medicines. The next steps are the implementation of recommendations and the development of a national ethical framework based on core values and ethical principles.

1. Introduction

This assessment is designed to provide Oman with a comprehensive picture of the level of transparency and potential vulnerability to corruption of eight functions of the pharmaceutical sector at the public level. The assessed functions include: registration of medicines, licensing of pharmaceutical establishments, inspection of pharmaceutical establishments, control of medicine promotion, control of clinical trials, selection of medicines, procurement of medicines and distribution of medicines.

The World Bank defines corruption as “behaviour on the part of officials in the public and private sectors, in which they improperly and unlawfully enrich themselves and/or those close to them, or induce others to do so, by misusing the position in which they are placed,” in other words it is “the abuse of entrusted power for private gain”. Transparency involves defining policies and procedures in print and publishing the printed documentation, giving reasons for decisions to the parties concerned and giving reasons for rejection of applications. It should be present at all levels of decision-making. Transparency encompasses the development of clear work plans and operating procedures. It should be encouraged through open systems of communication with stakeholders and the provision of easy access to information.

This report summarizes the findings of the national transparency assessment in the pharmaceutical public sector that was carried out in Oman between February and March 2011. This assessment marks the first step in an effort to increase the transparency and accountability of the pharmaceutical sector. The results of the assessment will inform the development and implementation of a national officially adopted Good Governance for Medicines programme in Oman.

2. Overview of the public pharmaceutical sector in Oman

2.1 Country information

Oman is located in the south-eastern corner of the Arabian Peninsula. It borders United Arab Emirates on the north-west, Saudi Arabia on the west and Yemen on the south-west. The total population is estimated at 3 174 000, of which 1 156 000 are expatriates. Oman is classified as an upper-middle income country, with a GDP in 2009 of 17 731 million Omani rials (approximately US\$ 45 746 million). Over 90% of national income is from crude oil. Agriculture is limited, while industrial activity is beginning to develop. Expenditure on health in 2009 was 299.6 million Omani rials (approximately US\$ 773 million).

2.2 Health system

The Ministry of Health is the principal provider of health care and provides free services to all Omani citizens and expatriates working in government institutions. The Ministry of Health operates 50 hospitals and 172 health centres. Other providers of health care include the Sultan Qaboos University Hospital, Royal Oman Police Hospital and Ministry of Defence Hospital.

The Directorate-General of Medical Supplies is responsible for the procurement, storage and distribution of all supplies of medicines, and surgical and laboratory consumable items, for all Ministry of Health units. The procurement mechanism includes direct negotiation with manufacturers, Gulf Cooperation Council joint tenders, and open international and local tenders with the participation of other government institutions. Emphasis is given to the procurement of generic items.

The central medical store is located in Muscat and there are regional stores in Nizwa and Salalah. A strategic reserve store is located at Bausher in Muscat, where vital items are stocked as a precautionary measure in case of emergencies and natural disasters.

A central drug committee oversees medicine policy and maintains vigilance on developments. A national formulary for the Ministry of Health includes medicines approved by the central drug committee and covers the Ministry of Health's needs for medicines to tackle major health problems in a cost-effective manner. Since 2002, an efficient medicines quality surveillance and reporting system has been implemented for medicines purchased by the Ministry of Health through local and Gulf Cooperation Council tenders. This is undertaken with the active participation of health care professionals in various Ministry of Health units with the aim of

monitoring and improving the efficacy and safety of medicines used in Ministry of Health institutions.

The Department of Rational Use of Medicine is an independent body in the Ministry of Health established to monitor the rational use of medicines in Oman. Its goal is to ensure that patients receive the appropriate medicine or treatment in the correct dose at the correct period of time, with the appropriate advice and follow-up, and with regards to safety, efficacy, suitability and cost.

2.3 Pharmaceuticals market

The majority of registered medicines in Oman are imported, mostly from other Arab countries, Europe, India and United States of America. There are three local manufacturers producing medicines and one of these only produces raw materials. Oman has around 406 private pharmacies and 47 drug stores, and 931 pharmacists and 461 assistant pharmacists. The total medicines bought by government institutions and the private sector in 2009 amounted to 105.2 million Omani rials.

Despite the rapid growth of the private health sector, patients mainly attend government, particularly Ministry of Health, institutions for treatment and medicines. This is likely to be due to the high cost of medicines and treatment in the private sector.

2.4 Pharmaceuticals regulation

Since 1996, the law that governs the pharmaceutical sector is Royal Decree 41/96. The law controls the import, distribution and sale of medicines in the country.

The Directorate-General of Pharmaceutical Affairs and Drug Control is responsible for the licensing of pharmacists and assistant pharmacists, as well as their premises. The Directorate is also responsible for the registration of pharmaceutical companies and their products, the pricing of those products, the clearance of medicines being imported into the country, psychotropic and narcotic medicines approval and granting licences. The Directorate is additionally responsible for analysing all medicines that enter the country to check their specification and efficacy against what has been registered.

The Directorate is responsible for implementing and monitoring Royal Decree 41/96 and the following ministerial decisions:

- Ministerial Decision 73/2000: pharmacist and assistant pharmacist licensing terms and conditions
- Ministerial Decision 74/2000: regulations for pharmaceutical establishments

- Ministerial Decision 84/2000: import and export of drugs
- Ministerial Decision 86/2000: registration of drug company products and pricing of those products.

In addition, a number of committees have been formed to monitor different activities including:

- Committee for registration of pharmaceutical companies and their products as well as pricing of medicines
- Committee for registration of herbal companies and their products
- Committee for licensing of pharmaceutical establishments
- Committee for licensing of pharmacists and assistant pharmacists
- Committee to look into the issues concerned with the good manufacturing practices of manufacturers
- Committee for inspection and monitoring of narcotic and psychotropic medicines
- Committee for destruction of expired and unused medicines.

Pharmacovigilance activity begun in 1995 and Oman is a member of the WHO Collaborating Centre for International Drug Monitoring in Uppsala, Sweden. The programme addresses drug-related problems and ensuring the quality and safety of medicines. A national pharmacovigilance centre is located within the Directorate and there are focal points in the regions. In 2010, there were 1062 reports of adverse drug reactions.

3. Methodology

3.1 Study design

The WHO Good Governance for Medicines instrument for measuring transparency in the public pharmaceutical sector was used for the study. A different questionnaire was designed for each function being assessed, where four methods were used to determine the level of transparency of the practice. The methodology used was intended primarily to collect qualitative information on selected indicators and then to quantify the vulnerability to corruption by giving a final score (Methods 1 and 2), along with capturing the perceptions of relevant health professionals in the public and private sectors (Method 3). Method 4 was used to capture additional information by using open-ended questions.

To implement the study, the Ministry of Health established a four-member national team. This included two national assessors with long experience in the pharmaceutical sector in Oman, one from academia and one from academia and services, and two counterparts from the Ministry of Health, one from regulatory affairs and one from medicine supplies.

The national assessors managed the whole assessment process and the national team received training from WHO. The national assessors were provided with dedicated fully-equipped offices, away from the pharmaceutical services area. The Ministry of Health counterparts provided all the necessary laws, regulations, ministerial circulars and other documents required. The national assessors were responsible for the selection of KIs, compiling lists of KIs across the different functions, and arranging and conducting interviews with the informants. They also compiled and analysed the results and wrote the report in consultation with their Ministry of Health counterparts. The questionnaires were administered during formal interviews conducted in the presence of both national assessors. No one else was allowed to be present during the interviews.

3.2 Selection of key informants

KIs were selected based on their direct involvement in the pharmaceutical sector. They were selected to include both senior and junior professionals from the public and private sectors. From the public sector they included government officials such as pharmacy staff at the Ministry of Health, the central warehouse, the inspection department, the procurement office and from primary health care services, members of the Ministry of Health registration committee and the tender committee, and representatives from scientific offices. From the private sector they included representatives from local manufacturers and from large and small pharmaceutical companies. Table 1 shows the distribution of KIs across the public and private sectors. The KIs were distributed across almost all 11 regions of Oman. There were no KIs from nongovernmental or international organizations.

Table 1. Distribution of KIs across public and private sectors

Function	Public sector	Private sector	Total KIs/function
1. Registration	8	7	15
2. Licensing	4	6	10
3. Inspection	3	11	14
4. Promotion	2	8	10
5. Clinical trials	2	8	10
6. Selection	5	5	10
7. Procurement	6	5	11
8. Distribution	12	2	14

Note: Total KIs interviewed = 94.

3.3 Data collection and scoring

During the study period from February to March 2011, data collection involved utilizing the questionnaire forms provided in the WHO Good Governance for Medicines instrument to interview a total of 94 KIs: 15 KIs for the registration function, 14 KIs for the inspection function, 10 KIs for the licensing function, 10 KIs for the clinical trials function, 10 KIs for the selection function, 11 KIs for the procurement function, and 14 KIs for the distribution function. Only answers under Methods 1 and 2 were counted in the final score. Answers to Method 3 and 4 questions were of a qualitative nature and were noted by the assessors during the interviews and summarized for the report.

Method 1 required that each indicator was a binary answer, either “yes” or “no”. A “yes” was given a value of “1” and a “no” was given a value of “0”, depending on the availability of a supporting document. Method 2 involved questions with a series of sub-criteria. Each criterion was answered by “yes”, “no” or “don’t know”. The total “yes” answers were counted and divided by the total number of valid answers.

“Don’t know” answers were not considered valid answers and were subtracted from the total answers to give the total number of valid answers. Each question was scored between “1” and “0”. For each function, an average rating was calculated and the results were converted to a zero to 10 scale.

All individual scores for Methods 1 and 2 were entered into the consolidation template and used to calculate the final score for each section for the transparency assessment. The results were interpreted according to a scale of degrees of vulnerability to corruption as shown in Table 2 below.

Table 2. Scale for degrees of vulnerability to corruption

0.0-2.0	2.1-4.1	4.1-6.0	6.1-8.0	8.1-10.0
Extremely vulnerable	Very vulnerable	Moderately vulnerable	Marginally vulnerable	Minimally vulnerable

Method 3 involved subjective questions that probed the perceptions of the KIs. The KIs were asked whether they strongly agreed, agreed, were undecided, disagreed, or strongly disagreed with each statement. Frequencies and percentages were used to present the results. Method 4 used open questions. KIs could also provide additional input on the function in general.

3.4 Ethical considerations

Confidentiality is an important part of the assessment methodology. To ensure the anonymity of KIs and the confidentiality of their answers, each KI was designated a code number which was used for all analyses and record keeping. The names and identities of KIs were not recorded in any way that would lead to their identification. Each KI was asked to give their verbal consent to participate in the assessment. Two KIs from the private sector decided not to participate.

4. Results and data presentations

4.1 Summary

This section of the report presents the results of the questionnaires that were filled in by the national assessors during the interviews with the 94 KIs.

4.1.1 Scales of vulnerability

The overall vulnerability scores for each of the eight functions are presented in Table 3. The scores for the individual indicators for each function are presented in Annex 1.

Table 3. Vulnerability scale scores in the eight different functions in Oman

	Reg	Lic	Ins	Prom	CT	Sel	Proc	Distr
Final score*	5.38**	6.18	3.86	0.32	1.69	4.35	6.24	8.15
Degree of vulnerability	Mod	Marg	Very	Extr	Extr	Mod	Marg	Min

Note: Reg = Registration; Lic = Licensing; Ins = Inspection; Prom = Promotion; CT = Clinical trials; Sel = Selection; Proc = Procurement; Distr = Distribution; Mod = Moderate; Marg = Marginal; Extr = Extreme; Min = Minimal.

* Final scores: total average/number of indicators x 10.

** The numbers represent average score per question, which was calculated only based on valid responses, while all "Don't know" and "Not applicable" answers were discarded.

4.1.2 Perceptions of KIs

KIs were asked to give their opinions on a series of statements. The responses are described, and represented as graphs where relevant, in the following data presentation and are also discussed in section 5.

4.2 Data presentation

4.2.1 Medicine registration

Pharmaceutical products that are imported, manufactured or used in Oman are required by law to be registered with the Ministry of Health. The law governing registration is Royal Decree 41/96 and its amendments.

The Technical Committee for Registration and Pricing is responsible for registration and determining prices. Forms A and B are used in submitting an application for registration. Form A is for the registration of a manufacturer and form B is for the registration of a product. The manufacturer must be registered in Oman before its products are submitted for registration. The price for registering a manufacturer is 100 Omani rials and 50 Omani rials for each product (each Omani rial is equivalent

to US\$ 2.58). The forms are detailed enough, are available at the Ministry of Health website and can be collected from the Ministry of Health. The time for registration is specified to be a maximum of four months. The composition of the Technical Committee for Registration and Pricing is determined according to Ministerial Decision 5/2001 which appoints members according to positions occupied in the Ministry of Health. The members remain as members as long as they occupy the positions. All are pharmacists. The Committee meets as often as necessary and the members do not get any additional financial remuneration. Members of the Committee do not have to sign or declare conflict-of-interest forms.

Indicator I.1: Is there an up-to-date list of all registered pharmaceutical products in your country?

There is an up-to-date list of products registered in Oman. The latest version is published on the website and updated every year. Hard copies are also available free of charge at Ministry of Health offices. All KIs were aware of the lists' existence.

Indicator I.2: Does it provide a minimum level of information?

The list provides product description, name and country of manufacturer, date of registration, validity of registration and conditions for registration. The list does not include the site of manufacturer, but that information is provided in the dossier. There is specification for prescription-only medicines, pharmacist-only medicines, over-the-counter medicines, controlled psychotropic medicines, controlled non-psychotropic medicines and controlled narcotics. Many medications for chronic diseases can be purchased without prescription. 76% of the KIs were fully aware of the level of information provided in the list.

Indicator I.3: Are there written procedures for applicants on how to submit an application for registration of medical products?

Written procedures for applicants on how to submit an application are available. They describe the process to follow and documents to submit for registration. Distributors and companies can get these procedures directly from the Registration of Pharmaceuticals Department. However, six out of 15 KIs commented that the procedures were not publicly available.

Data to be submitted and criteria for registration are presented in guidelines for the submission of pharmaceutical products. The fees for registration are clearly presented, but the current laws do not mention the timeframe for processing.

Indicator I.4: Are there written procedures for assessors on how to assess applications submitted for registration of medicinal products?

Evaluators at the Registration of Pharmaceuticals Department are provided with a checklist which guides them in the assessment of a pharmaceutical dossier. The

checklist enumerates items that should be included in the pharmaceutical dossier. There is no mention of the timeframe for processing an application as it depends on the complexity of each individual application. The checklist provides a method of report writing. Nine out of 15 KIs did not know of the existence of written procedures to assess an application.

Indicator I.5: Is there a standard application form publicly available for submission of applications for registration of medicinal products?

The application form is available at the Registration of Pharmaceuticals Department. All KIs were aware that it was publicly accessible (companies wanting to get the form can also come to the Department and ask for it). The application form covers all important information; 90% of KIs were aware of the form.

Indicator I.6: Are there guidelines setting limits on how and where medicine registration officers meet with applicants?

When documents are missing in the pharmaceutical dossier or when clarification is needed, an applicant can meet with government officials. There are guidelines setting limits on meetings between government officers and applicants and there are official days of the week when such meetings can take place. Half of the KIs were aware of the guidelines.

Indicator I.7: Is there a functioning formal committee responsible for assessing applications for registration of pharmaceutical products?

There is a functional and operational committee for registration. Members have responsibility for examining the dossiers and making decisions on registration. All KIs confirmed their awareness of the existence of the registration committee.

Indicator I.8: Are there clear written criteria for selecting the members of the committee?

No written criteria were found during the assessment; 14 KIs said that there were no clear written criteria for membership selection and one KI did not know if there were.

Indicator I.9: Is there a written document that describes the composition and terms of reference of the committee?

Ministerial Decision 5/2001 of 9 January 2001 describes the composition and terms of reference of the committee.

Nearly all KIs responded that there were no written documents describing the composition and terms of reference of the registration committee.

Indicator I.10: Is there a conflict of interest form that members of the committee and public officials are obliged to complete?

No such form exists and all KIs responded negatively.

Indicator I.11: To what extent do you agree with the following statement: “The members of the registration committee are systematically and objectively selected based on the written criteria in force in your country”?

Because there were no written criteria for the selection of committee members, 73% disagreed or strongly disagreed with this question (11/15). Two agreed and two felt it was not applicable (Fig. 1).

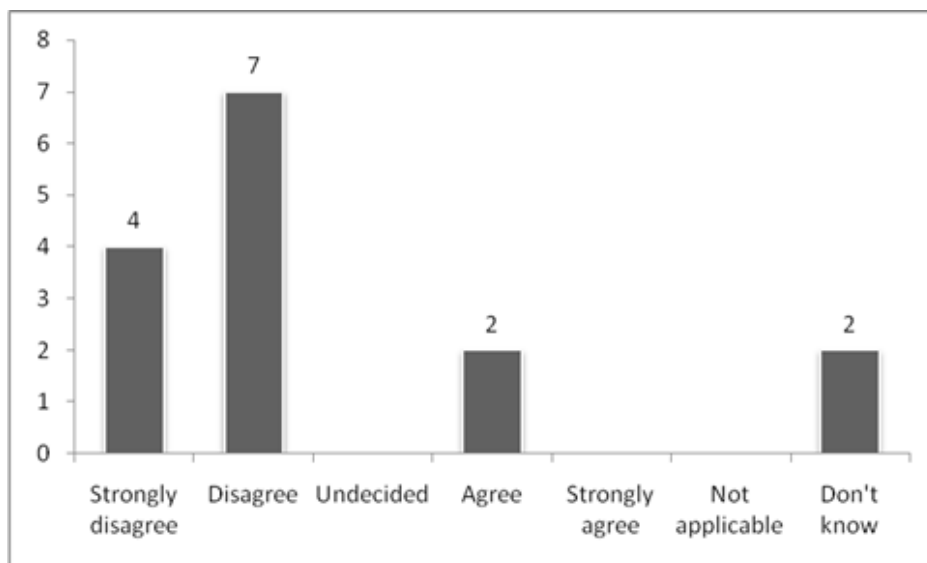


Fig. 1. KI perceptions of systematic and objective membership selection for the registration committee

Indicator I.12: Are there clear and comprehensive guidelines for the committee’s decision-making process?

Ministerial Decision 5/2001 dated 9 January 2001 includes guidance on the decision-making process.

Seven of the 15 KIs responded negatively (that there were no comprehensive guidelines for the committee to follow) and one KI did not know if there were any.

The remaining KIs acknowledged that the committee met regularly, submitted a report to the Undersecretary for Health Affairs and communicated with the company whose application had been denied.

Indicator I.13: Is there a formal appeals system for applicants who have their medicine applications rejected?

All KIs, except one, acknowledged that there was a formal appeals system, but indicated that it was the same registration committee which had rejected the application that reviewed the applicant’s appeal.

Indicator I.14: To what extent do you agree with the following statement: “Gifts and other benefits given to officials in charge of medicines registration have no influence at all on their final decisions”?

66% of KIs (10/15) agreed or strongly agreed with the statement (Fig. 2).

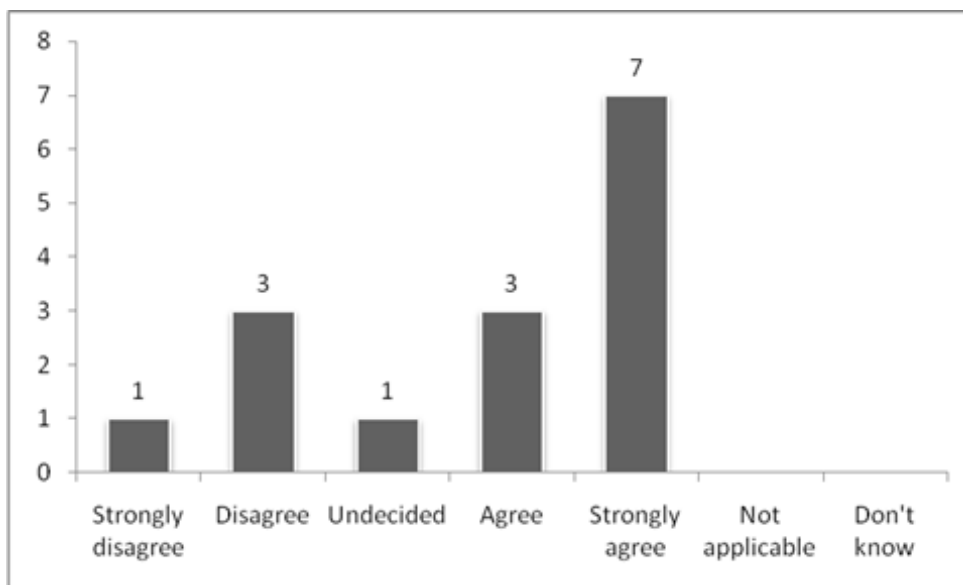


Fig. 2. KI perceptions of the influence on decisions of gifts and benefits given to registration officials

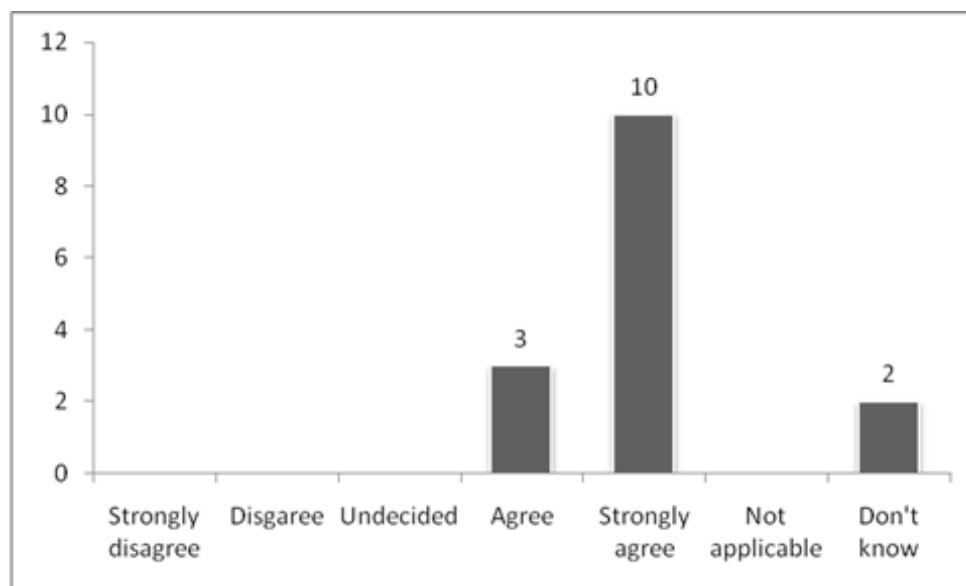


Fig. 3. KI perceptions of the registration committee meeting regularly and keeping its minutes

Indicator I.15: To what extent do you agree with the following statement: “The registration committee meets on a regular basis and keeps minutes of its meetings”?

Thirteen out of 15 KIs agreed or strongly agreed with the statement, while the remaining two KIs did not know (Fig. 3).

Indicator I.16: In your opinion, what types of unethical behaviour are common in the registration system in your country?

Eleven of the KIs indicated that there were no unethical behaviours known to them. The other four KIs mentioned that requests to attend conferences and expensive gifts could lead to bias towards registering some pharmaceutical companies. Some of those who felt there were no unethical behaviours observed that the committee tended to be influenced by the decisions of Gulf Cooperation Council (GCC) meetings and the absence of clear guidelines for the committee and a clear statement on conflicts of interest. Some felt that having the registration committee composed of members drawn only from the Ministry of Health could constitute unethical behaviour.

Indicator 1.17: If you were in a position of highest authority, what would be the first action that you would take to improve the registration process in your country?

The first actions that KIs would take to improve the registration process in Oman would be to:

- make the registration process electronic, transparent and time-bound;
- increase the numbers of trained and competent human resources;
- create criteria for the selection of committee members to reflect all stakeholders;
- increase the amount of space and equipment in the Directorate given the increasing number of products being registered;
- make the registration and medicine authority an independent entity.

4.2.2 Licensing of pharmaceutical establishments

Royal Decree 41/96 also governs the licensing of pharmaceutical establishments. The Decree and ministerial decisions differentiate the various types of pharmaceutical establishment as pharmaceutical manufacturer, wholesaler or medical store, public pharmacy, in-house pharmacy and pharmaceutical office. The Decree defines these establishments, the functions they can and cannot perform, their space and staff requirements, and the licensing process. The requirements for licensing and fees are available at the licensing directorate. There is a committee responsible for licensing pharmaceutical establishments. The committee is fully aware of good manufacturing practice.

Indicator II.1: Is it a requirement by law to have a license in order to operate a pharmaceutical establishment?

Royal Decree 41/1996 issued on 8 June 1996 and Ministerial Decision 74/2000 dated 2 September 2000 require establishments to have a license before operating a pharmaceutical establishment and all KIs confirmed this to be the case.

Indicator II.2: Does the medicines regulatory authority have a unit responsible for issuing pharmaceutical establishment license?

A unit exists within the Directorate-General of Pharmaceutical Affairs and Drug Control and all KIs were aware of its presence.

Indicator II.3: Are there written criteria for submission of applications for licensing?

Ministerial Decision 74/2000 contains criteria for submission of applications for licensing. Nine KIs confirmed the presence of written criteria for submission of an application, while one KI responded negatively. However, some KIs indicated the absence of a timeframe and some indicated that application forms were not publicly available.

Indicator II.4: Are there written guidelines for assessing applications for licensing?

Ministerial Decision 74/2000 contains the guidelines. Four out of 10 KIs answered yes, five KIs answered no and one KI did not know.

Indicator II.5: Is the submission of a pre-license inspection report one of the requirements for making decisions on whether to issue a license or not?

Ministerial Decision 74/2000 makes the submission of a pre-license inspection report one of the requirements for making decisions. All KIs, except one, confirmed that a pre-license inspection report was one of the requirements for making decisions on whether to issue a license. One KI did not know.

Indicator II.6: Is there a functioning formal committee that assesses applications for the licensing of pharmaceutical establishments?

A committee exists and seven KIs confirmed the presence of a functioning formal committee that assesses applications for licensing. Two KIs responded negatively and one KI did not know.

Indicator II.7: Are there clear written criteria for selecting the members of the committee?

There are no clear written criteria for selecting the members of the committee and all KIs confirmed this.

Indicator II.8: Is there a written document that describes the composition and terms of reference of the committee?

Ministerial Decision 74/2000 describes the composition and terms of reference of the committee. Six KIs responded that there was no written document, two KIs did not know and two KIs answered that there was a written document, but that it was not publicly available.

Indicator II.9: Does the medicine regulatory authority carry out regular (at least every two years) post-licensing inspection of all licensed pharmaceutical establishments?

All KIs confirmed that the medicine regulatory authority carried out regular inspections of licensed establishments more than once every year.

Indicator II.10: Is there an up-to-date list of all licensed pharmaceutical establishments available in the country?

A list is available on the website, although two KIs did not know of the presence of an up-to-date list. Three KIs, who confirmed presence of the list, stated that the date of last inspection was not stated in the list.

Indicator II.11: To what extent do you agree with the following statement: “The licensing of pharmaceutical establishments is systematically carried out according to policies and procedures”?

Eight out of 10 KIs agreed or strongly agreed with the statement. Two KIs disagreed (Fig. 4).

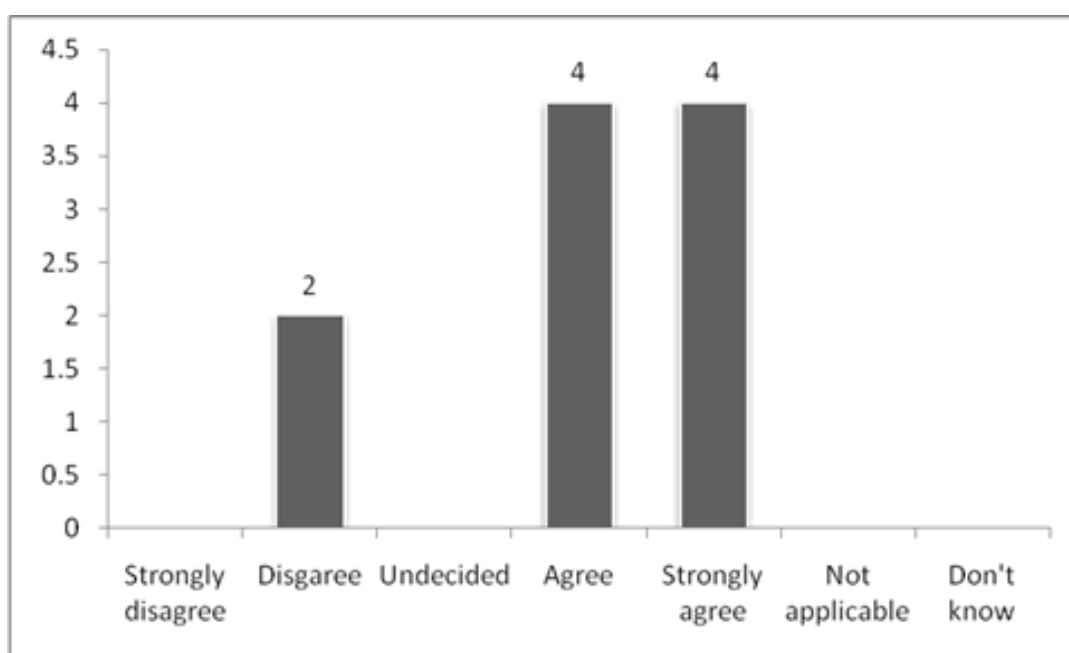


Fig. 4. KI perceptions of the licensing of pharmaceutical establishments being systematically carried out according to policies and procedures

Indicator II.12: Is there an independent appeals system for applicants that have had their applications for licensing rejected?

An appeal system does not exist. Appeals are sent to the same committee issuing the decisions and then on to the Minister of Health if the Minister is not satisfied with the outcome. Nine KIs indicated that there was no appeals system in place. One KI did not know.

Indicator II.13: To what extent do you agree with the following statement: “The formal committee that assesses applications for the licensing of pharmaceutical establishments is fully operational and meets on a regular basis”?

Five KIs agreed or strongly agreed with the statement, three KIs disagreed or strongly disagreed and two KIs did not know (Fig. 5).

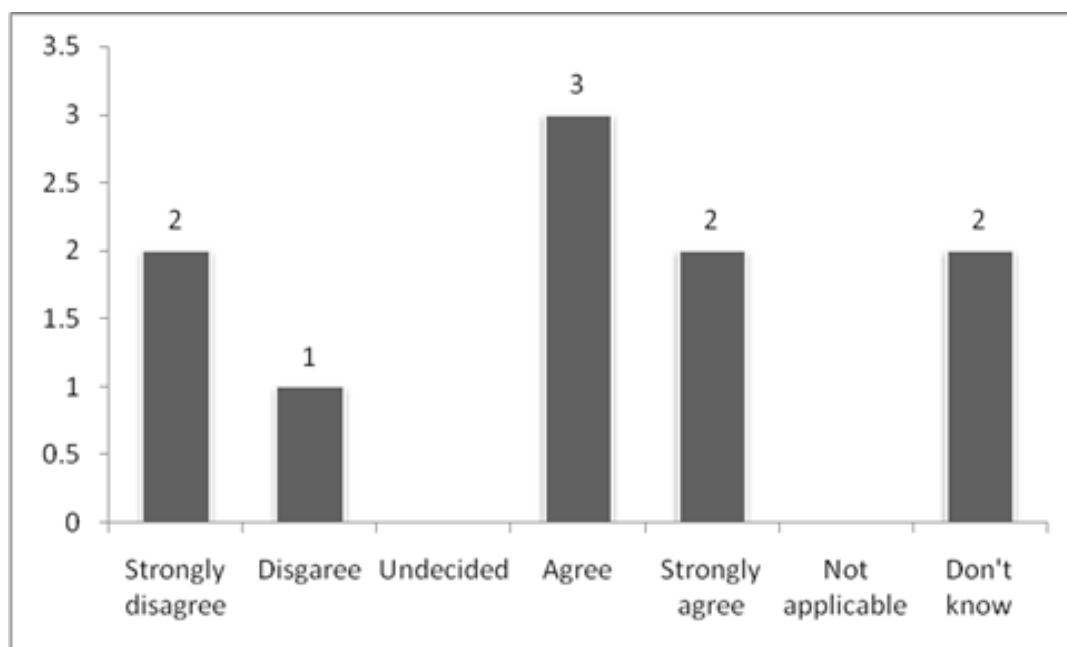


Fig. 5. KI perceptions of the formal committee that assesses applications for licensing of pharmaceutical establishments being fully operational and meeting on a regular basis

Indicator II.14: In your opinion, what types of unethical practices commonly occur in the process of licensing pharmaceutical establishments in your country?

Nine KIs answered that there were no unethical practices associated with licensing pharmaceutical establishments. Only one KI felt that requests for expensive gifts and sponsorship to attend conferences were unethical.

Indicator II.15: If you were in a position of highest authority, what would be the first action that you would take to improve the licensing process for pharmaceutical establishments in your country?

The first actions that KIs would take to improve the licensing process for pharmaceutical establishments in Oman would be to:

- improve knowledge of administrative procedures;
- increase the number of qualified and fully trained personnel, expand space and improve the information technology system in the unit;
- improve transparency and the ability to update information regularly;
- establish a separate licensing department with qualified personnel;
- establish clearly written guidelines for licensing;
- update the rules and regulations to reflect the current situation;
- establish longer distances between pharmacies;
- allow equitable licensing opportunities for all applicants, without denying large- and medium-size chain pharmacies the opportunity to expand.

4.2.3 Inspection of pharmaceutical establishments

There is a provision in the pharmacy law and ministerial decisions related to the inspection of all pharmaceutical establishments. The inspection directorate in the Ministry of Health is very active, visiting pharmacies, manufacturing units and medical stores. There is provision for visiting manufacturing units outside Oman before companies are registered in the country. On some occasions, the inspector(s) from Oman join inspectors from other GCC countries to form a GCC inspection team. Inspectors are not posted at border posts, sea ports or at air ports. Oman has adopted internationally recognized good manufacturing practices and requires manufacturers to be aware of the most current updated version. Pharmacies and medical stores are inspected regularly, but almost always by the same inspectors. The reports are peer reviewed within the Ministry before being sent to the concerned pharmacy for the necessary action.

Indicator III.1: Is there a provision in the medicines legislation/regulation covering inspection of pharmaceutical establishments?

Royal Decree 41/96 issued on 8 June 1996 and Ministerial Decision 74/2000 issued on 2 September 2000 cover the inspection of pharmaceutical establishments. All KIs confirmed the presence of the provision in the pharmacy law regarding inspection of pharmaceutical establishments.

Indicator III.2: Is the provision on inspection comprehensive enough?

The legislation was found to cover the minimum criteria. Three KIs confirmed that the provision on inspection was comprehensive enough, and the other KIs felt that there were deficiencies in that the duties of inspectors were not defined and inspectors were not provided with identifying badges.

Indicator III.3: Are there written guidelines on the classification of good manufacturing practices non-compliance that describe the types of deficiencies and the corresponding measures to be taken by the medicine regulatory authority?

The legislation refers to WHO and GCC guidelines on good manufacturing practices that contain classification of non-compliance issues. No guidelines were found describing the corresponding measures. Six of the 14 KIs felt that the question was not applicable to them because they were in retail pharmacy practice. Those that were aware of the guidelines felt that they were not easily accessible to all stakeholders. There is no independent appeals mechanism.

Indicator III.4: Are there written procedures/mechanisms to prevent regulatory capture between inspectors and the manufacturers or distributors that he/she inspects?

There are no written procedures. Six of the 14 KIs replied that there were no written procedures to prevent regulatory capture between inspectors and those being inspected. Those KIs who answered positively indicated that inspectors conducted their inspections independently without peer review, but that there was no geographical area rotation and no auditing of inspection.

Indicator III.5: Are there written guidelines on conflicts of interest with regard to inspection activities?

None were found. Twelve KIs confirmed the absence of guidelines on conflicts of interest and two KIs did not know.

Indicator III.6: Are inspection findings and conclusions subject to an internal review?

There is an internal review process. Seven KIs confirmed that inspection findings and conclusions were subject to internal review. These KIs were mainly from the Ministry of Health and manufacturing sites. Those from the private pharmacy sector felt the findings and conclusions were not subject to internal review.

Indicator III.7: Are there written standard operating procedures for inspectors on how to conduct inspections?

Standard operating procedures for inspectors were observed during the assessment. Six KIs answered that there were no written standard operating procedures for inspectors. These KIs were from the private pharmacy sector. Those who responded positively observed that there was no detailed information regarding pre-inspection and/or post-inspection procedures, and no scheduling system for inspecting pharmaceutical establishments (private retail pharmacies).

Indicator III.8: Are there written criteria for the selection and recruitment of inspectors?

No written criteria exist. Twelve KIs answered that there were no written criteria for selection of inspectors. Two KIs did not know.

Indicator III.9: To what extent do you agree with the following statement: “The integrity of inspectors is not at all influenced by personal gain, such as bribes, gifts, material or other benefits”?

Eleven KIs agreed or strongly agreed with the statement. Two KIs disagreed and one KI did not know (Fig. 6).

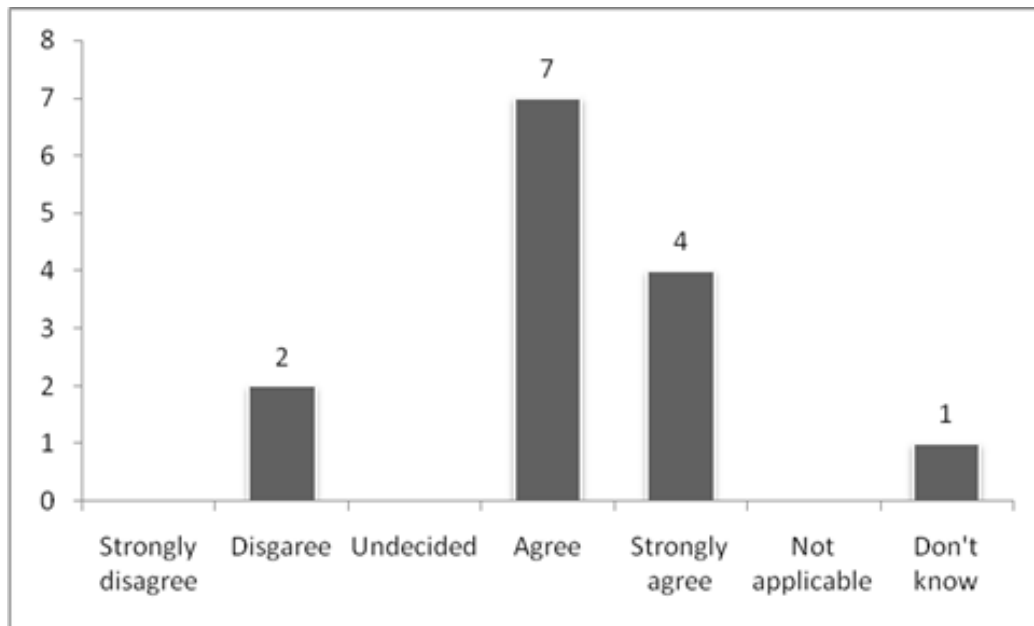


Fig. 6. KI perceptions of the integrity of inspectors being not at all influenced by personal gain, such as bribes, gifts, material or other benefits

Indicator III.10: To what extent do you agree with the following statement: “Inspection activities are systematically carried out in accordance with the guidelines and procedures to prevent biases (e.g. peer review or rotation)”?

Eleven KIs agreed or strongly agreed with the statement. One KI each was undecided, disagreed and strongly disagreed (Fig. 7).

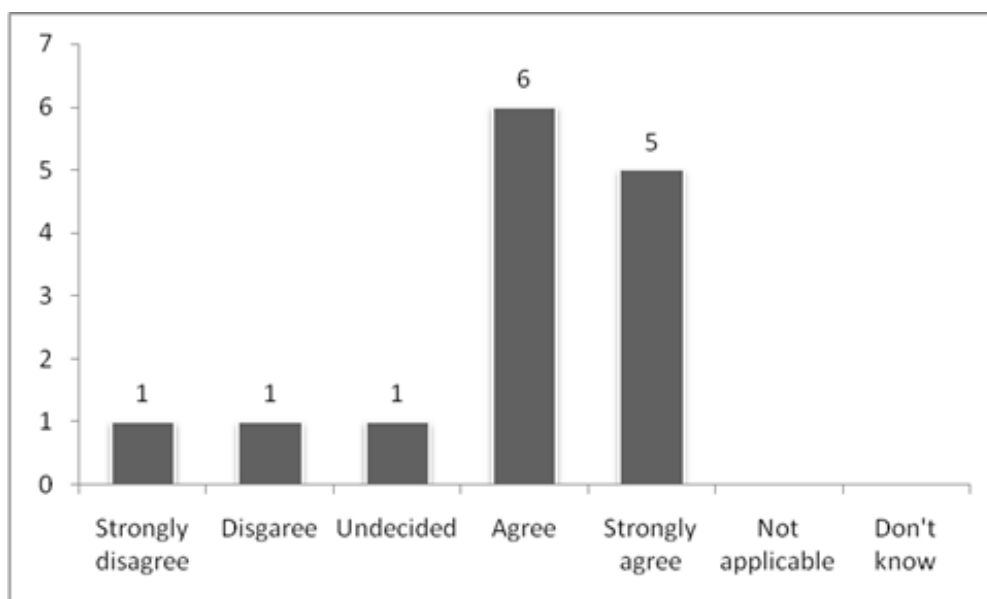


Fig. 7. KI perceptions of inspection activities being systematically carried out in accordance with the guidelines and procedures to prevent biases

Indicator III.11: In your opinion, what types of unethical behaviour are common in the inspection area in your country?

All KI, except one, answered that there was no unethical behaviour in the inspection function. The KI who felt there was unethical behaviour described this as a lack of transparency in the inspection process.

Indicator III.12: If you were in a position of highest authority, what would be the first action that you would take to improve the inspection process in your country?

The first action that KIs would take to improve the inspection process in Oman would be to:

- provide appropriate training to the inspection team;
- ensure that inspectors were peer reviewed;
- establish geographical rotation of inspectors;
- establish a clear and transparent inspection process;
- develop a training process for inspectors of international standards.

4.2.4 Control of medicine promotion

The law in Oman instructs manufacturers and distributors to promote their products to health care professionals and forbids direct-to-consumer advertising through public media. There are no restrictions on promotion of pharmaceuticals to health care professionals. However, most of the originator companies have their own promotion “code of ethics” which they strictly adhere to.

Ten KIs agreed to respond to the interview, but one KI replied “did not know” to all questions asked and his responses are not included in the calculation of the vulnerability score.

Indicator IV.1: Is there a provision in the medicines legislation/regulations covering medicine promotion and advertising?

Ministerial Decision 74/2000 covers medicine promotion and advertising. Five KIs confirmed the presence of legislation covering medicine promotion control, but such guidelines do not appear in any medicines legislation. There are plans to introduce regulations. Some ministerial announcements have been circulated, but all respondents agreed that these were not strictly followed.

Indicator IV.2: Do the provisions on medicine promotion and advertising include explicit mention of the following forms of promotion?

Provisions on the promotion of medicines are restricted to: advertisement to the public; restrictions on and monitoring of free samples; and packaging, labelling and package inserts. There are no restrictions on: advertisements to professionals; symposia and studies; speakers’ fees and consultancies; and gifts and gimmicks. Most multinationals enforce their own restrictions following the rules and regulations enacted by their companies.

Five KIs were aware to varying extent of the provisions, four KIs were not aware and one KI did not know.

Indicator IV.3: Is pre-approval of promotional and advertising materials officially required?

Pre-approval of promotional and advertising materials is officially required. However, nine KIs responded negatively to this question and stated that the regulations are not always strictly followed, while one KI did not know.

Indicator IV.4: Do the provisions foresee an enforcement mechanism on promotion and advertisement of medicines, stating the sanctions in cases of violation?

No enforcement mechanism is present. Seven KIs said that there were no enforcement mechanisms and three did not know.

Indicator IV.5: Is there a formal complaints procedure to report unethical promotional practices?

There is no formal complaints procedure. Seven KIs reported that there was no formal complaint procedure and three KIs did not know.

Indicator IV.6: Is there a service or committee responsible for monitoring and enforcing the provisions on medicine promotion?

There is no committee responsible for monitoring and enforcing the provisions on medicine promotion. Seven KIs were aware that there was no committee and three KIs did not know.

Indicator IV.7: Are there clear criteria for selecting the members of the service/committee?

There is no committee and therefore no criteria for selecting committee members. Three KIs did not know this.

Indicator IV.8: Is there a written document that describes the composition and terms of reference of the service/committee?

There is no document because there is no committee. Eight KIs did not know this.

Indicator IV.9: Are there written or publicly-available standard operating procedures guiding the services responsible for pre-approving or monitoring medicine promotion and advertising?

There are no written standard operating procedures guiding the services responsible for pre-approving or monitoring medicine promotion and advertising. Nine KIs knew this and one KI did not know.

Indicator IV.10: Are there written guidelines on conflicts of interest with regard to control of medicine promotion activities?

There are no guidelines on conflicts of interest. Nine KIs knew this and one KI did not know.

Indicator IV.11: To what extent do you agree with the following statement: "The legal provisions on medicine promotion have been developed in broad consultation with all interested parties"?

Six KIs felt that either the question was not applicable or they did not know and four KIs disagreed or strongly disagreed with the statement (see Fig. 8).

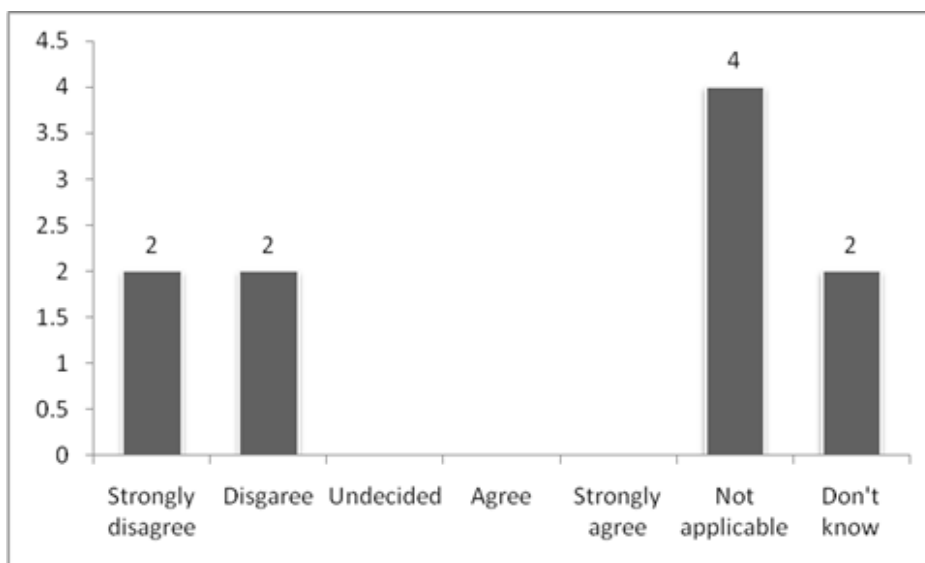


Fig. 8. KI perceptions of legal provisions on medicine promotion having been developed in broad consultation with all interested parties

Indicator IV.12: To what extent do you agree with the following statement: “Pre-approval of promotional and advertising materials is systematically obtained before they are made public”?

Six KIs responded that the statement was either not applicable or that they did not know and four KIs either disagreed or strongly disagreed with the statement (see Fig. 9).

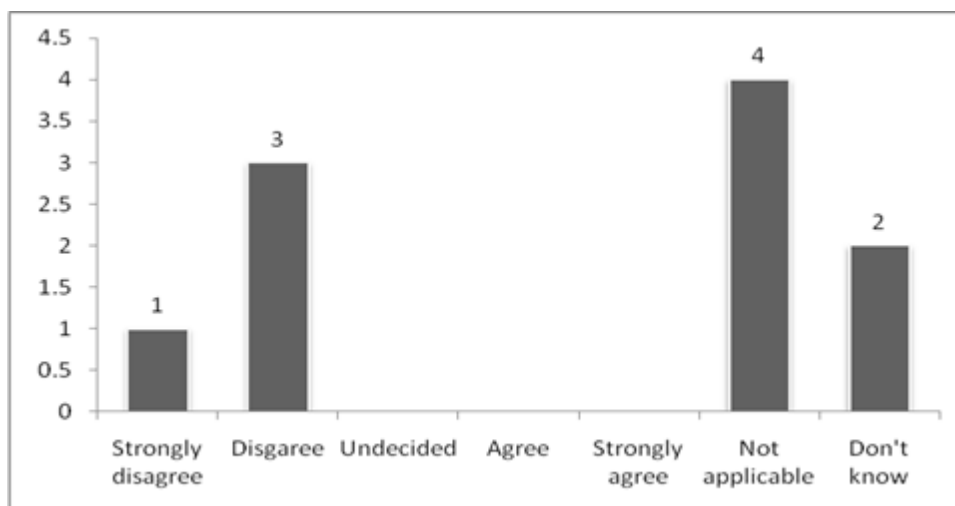


Fig. 9. KI perceptions of pre-approval of promotional and advertising materials being systematically obtained before they are made public

Indicator IV.13: To what extent do you agree with the following statement: “Civil society/nongovernmental organizations have a great influence on improving the control of medicine promotion in your country”?

Civil society presence in the country is limited and the nongovernmental organizations that exist have not been active in the pharmaceutical field. This may be because all medicines are provided free of charge for nationals and expatriates working in the public sector. Five KIs felt that the statement was not applicable or did not know, four KIs disagreed and one KI strongly disagreed (see Fig. 10).

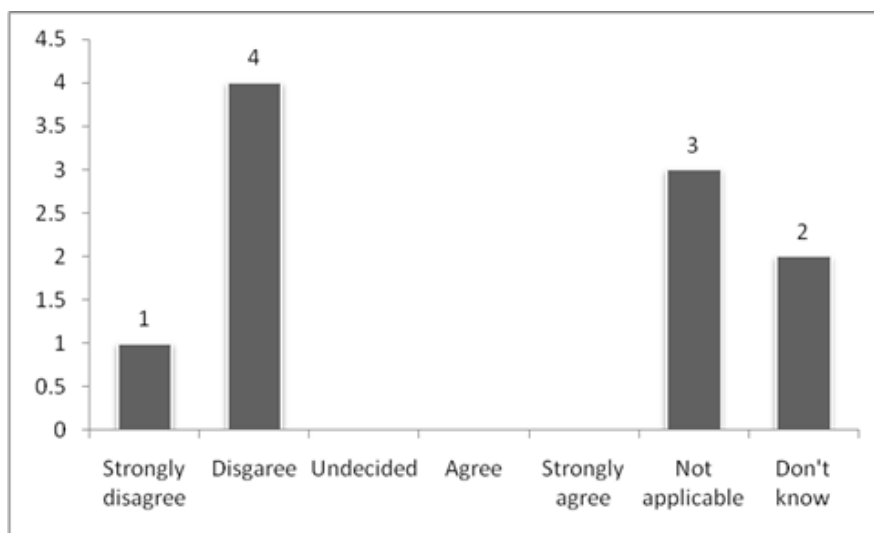


Fig. 10. KI perceptions of whether civil society/nongovernmental organizations have a great influence on improving the control of medicine promotion in Oman

Indicator IV.14: To what extent do you agree with the following statement: “Sanctions foreseen in the provisions on medicine promotion are systematically applied when there is a breach”?

Three KIs felt the statement was not applicable, three KIs did not know, two KIs disagreed with the statement, one KI strongly disagreed and one KI agreed (see Fig. 11).

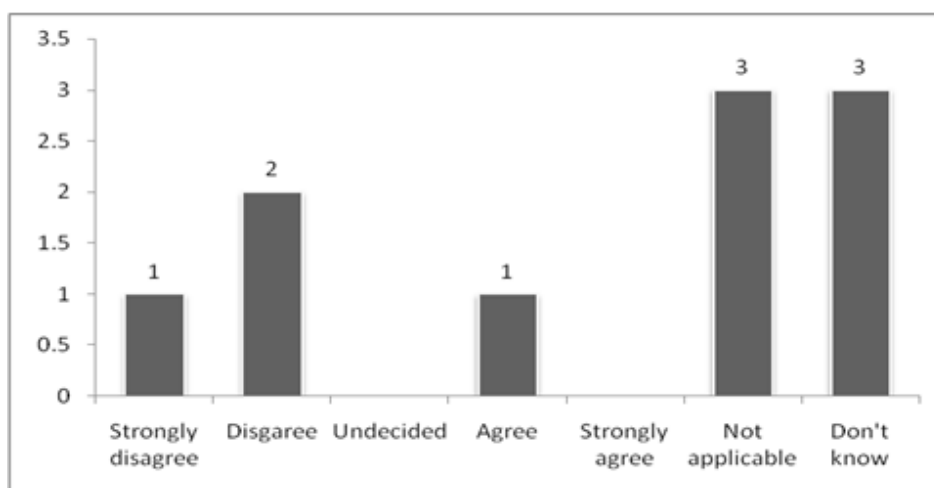


Fig. 11. KI perceptions of whether sanctions in the provisions on medicine promotion are systematically applied when there is a breach

Indicator IV.15: In your opinion, what types of unethical behaviour are common in the medicine promotion area in your country?

a) Involving health professionals and health institutions in general

The types of unethical behaviour that are common in the medicine promotion area in Oman regarding health professionals and health institutions in general are:

- samples and gifts offered to prescribers in return for increased prescribing of company products;
- free-of-charge sales packs given to retail pharmacies which facilitate increased sales of such products;
- free-of-charge sales packs/bonuses offered to private clinics to influence increased prescribing/sales;
- the possibility that links exist between service/educational support and promotion;
- direct cash payments to the private sector.

b) Involving regulatory office staff and committee members responsible for controlling medicine promotion

Nine KIs responded that there was no unethical behaviour on the part of regulatory office staff with regards to promotion of medicines and on KI did not know.

Indicator IV.16: If you were in a position of highest authority, what would be the first action that you would take to improve the medicine promotion process in your country?

The first actions that KIs would take to improve the medicine promotion process in Oman would be to:

- establish a law/regulations, as soon as possible, to control promotion of medicines, including free samples;
- establish a properly equipped department to oversee and standardize promotion guidelines;
- establish promotion guidelines that are transparent and involve all stakeholders;
- monitor the “kickbacks” that generic manufacturers are in the habit of offering;
- liaise with multinational companies and/or international organizations and adopt their regulations after appropriate modification; for example, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) code.

4.2.5 Control of clinical trials

There is a department and a committee responsible for research within the Ministry of Health. However, the committee does not fully regulate clinical trials. Some of the

KIs responded to the questions on clinical trials in light of the general provisions for research. The positive responses for this function relate mainly to the provision and regulations of the research committee.

Indicator V.1: Is there legal provision requiring the regulation of clinical trials?

Ministerial Decision 108/2007 regulates research. Although clinical trials are not mentioned explicitly in the document, approvals are sought from the Ministry of Health for specific studies.

Five KIs confirmed the presence of legal provision regulating clinical trials, two KIs did not know and three KIs said there were none. No document was received to confirm the existence of legal provision.

Indicator V.2: Are there written national guidelines on the principles of good clinical practice?

One KI confirmed the presence of written national guidelines on principles of good clinical practice, but this document was not submitted; eight KIs said that there were no written guidelines and one KI did not know.

Indicator V.3: Are there written and publicly available guidelines on submission of applications to the medicines regulatory authority to conduct clinical trials?

Six KIs said that there were no written and publicly available guidelines on submission of an application to conduct clinical trials and three KIs did not know. One KI confirmed the presence of guidelines; the document presented by the KI related more to patient-centred research (trials).

Indicator V.4: Is there a documented policy or procedure for submission of clinical trial applications to an independent ethics committee?

One KI said there was a documented policy for submission of clinical trial applications to an independent ethics committee; however, the document was more related to patient-oriented research. Seven KIs said there was not and two KIs did not know.

Indicator V.5: Are there requirements for the manufacture, importation, exportation and use of investigational products?

The procedures for importation require that the applicant seeks Ministry of Health approval for investigational products. Four KIs responded confirming the presence of requirements for manufacture, importation, exportation and use of investigational products. Five KIs responded negatively and one KI did not know. KIs may have equated this indicator with phase 3B/IV of clinical trials.

Indicator V.6: Is there a formal review committee in the medicines regulatory authority responsible for reviewing applications and clinical trial results?

Four KIs confirmed the presence of a formal review committee in the medicines regulatory authority responsible for reviewing applications and clinical trial results, three KIs did not know and three KIs said there was no such committee.

Indicator V.7: Are there mechanisms in place to ensure that those involved in the review of applications and clinical trial results have sufficient and current expertise in all required areas?

Only one KI confirmed the presence of mechanisms to ensure expert knowledge amongst those reviewing clinical trials. The expertise resided in technical qualification and research experience. Five KIs felt that there were no mechanisms and four KIs did not know.

Indicator V.8: Is there a clinical trial inspection system that is established and operational?

Six KIs said that there was no inspection system for clinical trials in place and four KIs did not know.

Indicator V.9: Do the national guidelines require the establishment of an independent ethics committee?

There are no national guidelines requiring the establishment of an independent ethics committee in the Ministry of Health. Seven KIs confirmed their absence and three KIs did not know.

Indicator V.10: Is there a timeframe for the review committee for assessing applications for clinical trials?

Seven KIs said that there was no timeframe for assessing applications and three KIs did not know.

Indicator V.11: Are there written guidelines on conflicts of interest with regard to clinical trial activities?

There are no guidelines on conflicts of interest with regard to clinical trials. Seven KIs said there were no guidelines and three KIs did not know.

Indicator V.12: Is there a public list/database of all approved and rejected clinical trial applications and is the list published?

Six KIs said there was no publicly available list/database of all approved and rejected clinical trial applications and four KIs did not know.

Indicator V.13: To what extent do you agree with the following statement: “The independent ethics committee members are systematically selected based on written selection criteria”?

Seven KIs felt the statement was not applicable, two KIs did not know and one KI strongly disagreed (Fig. 12).

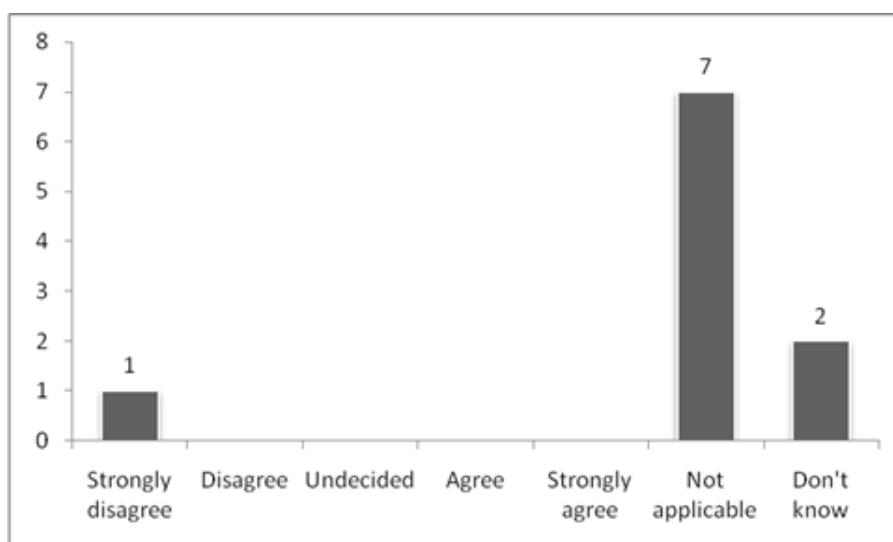


Fig. 12. KI perceptions that independent ethics committee members are systematically selected based on written selection criteria

Indicator V.14: To what extent do you agree with the following statement: “The medicines regulatory authority review committee members are selected systematically based on written selection criteria”?

Five KIs felt that the statement was not applicable, two KIs did not know, two KIs disagreed and one KI strongly disagreed (Fig. 13).

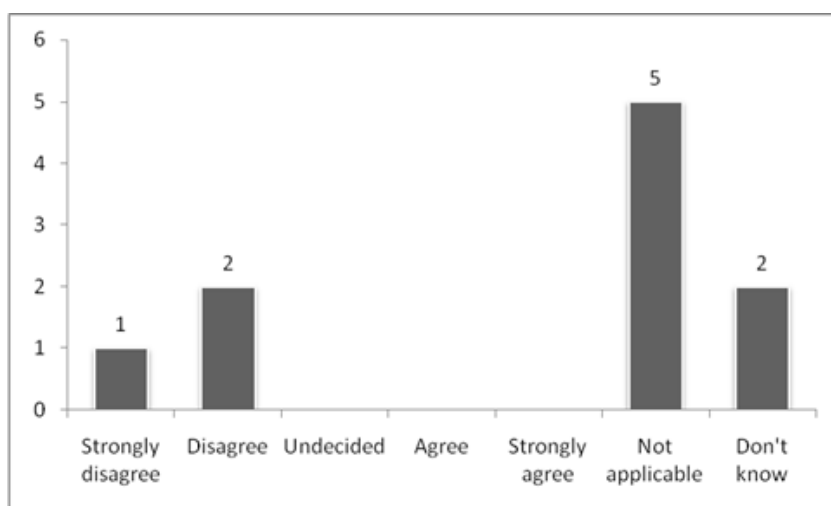


Fig. 13. KI perceptions that independent ethics committee members are systematically selected based on written selection criteria

Indicator V.15: To what extent do you agree with the following statement: “The medicines regulatory authority is ensuring that clinical trials conducted in the country are done in accordance with the regulations and good clinical practice principles”?

Four KIs felt the statement was not applicable, two KIs did not know, three KIs agreed and one KI disagreed (Fig. 14).

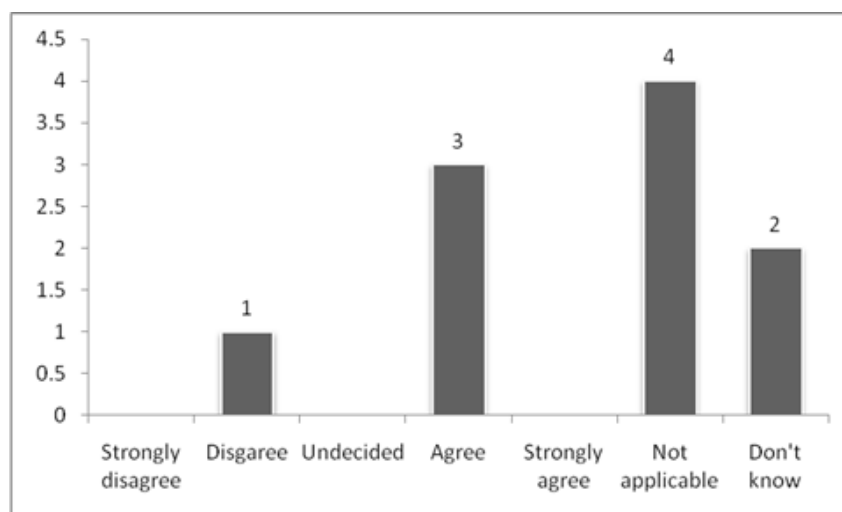


Fig. 14. KI perceptions that the medicines regulatory authority is ensuring that clinical trials conducted in the country are being done in accordance with the regulations and good clinical practice principles

Indicator V.16: In your opinion, what types of unethical behaviour are common in the clinical trials area in your country?

The majority of KIs responded that there was no unethical behaviour or not to their knowledge. One KI felt the statement was not applicable because the clinical trial function was not regulated. One KI confirmed that clinical trials had been done without official authorization and one KI felt that the informed consent form was not explained sufficiently enough to the participants and that this constituted unethical behaviour.

Indicator V.17: If you were in a position of highest authority, what would be the first action that you would take to improve the way clinical trials are carried out in your country?

The first actions that KIs would take to improve the way clinical trials are carried out in Oman would be to:

- establish an appropriate committee and regulations for clinical trials;
- establish an appropriate national independent ethics committee;
- ensure transparency in clinical trials;
- define the type/amount of honorarium to be offered to those involved in clinical trials;
- ensure that members of the independent ethics committee are technically competent;
- consider establishing a Food and Drugs Administration-type of organization;
- liaise closely with multinational companies, but avoid “medico-marketing” (pharmaceutical marketing);
- ensure that independent ethics committee members are remunerated appropriately;
- appoint independent ethics committee members in accordance with international regulations.

4.2.6 Selection of medicines

The Ministry of Health, with the help of WHO, developed and adopted a national drug policy in 2000. In 2003, the first edition of the Oman national formulary was published. It is modelled on the WHO essential medicines list. The Oman national formulary has been extensively revised and medicines are classified according to pharmacological classification. They are also restricted according to location of practice. The national formulary was developed by experts from different specialties, though all from the Ministry of Health. The national formulary is now widely distributed and used in some teaching institutions.

There is a central drug committee in the Ministry of Health which is responsible for the selection of medicines for use in Ministry of Health hospitals. The committee members are all from the Ministry of Health.

Indicator VI.1: Does the government have an officially adopted national essential medicines list that is publicly available?

All KIs, except one, confirmed that the Ministry of Health has an officially adopted national essential medicines list (the Oman national formulary). The KI who responded negatively was not aware of it.

Indicator VI.2: To what extent do you agree with the following statement: “The national essential medicines list has been developed in consultation with all interested parties and using an evidence-based approach”?

Seven KIs either agreed or strongly agreed with the statement, while three KIs disagreed; their reservation was on the wording, “in consultation with all interested parties” (Fig. 15).

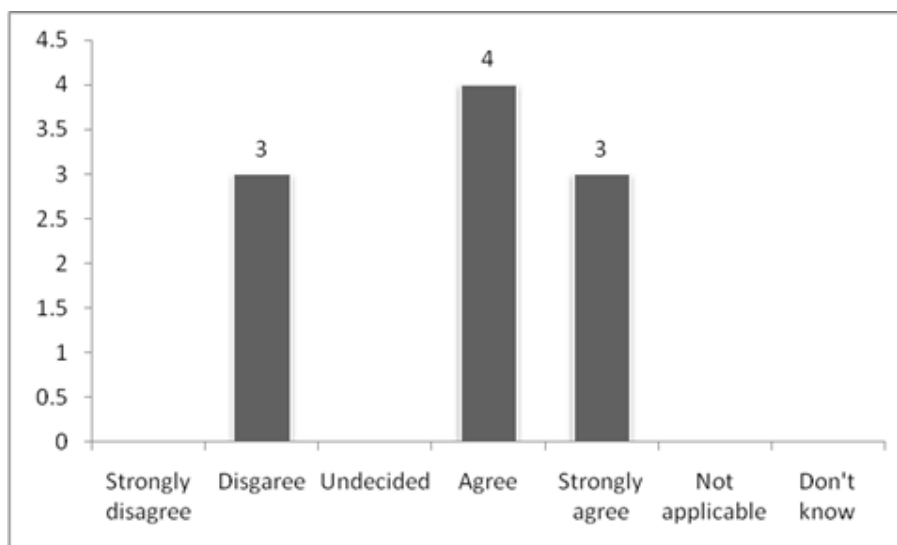


Fig. 15. KI perceptions that the national essential medicines list has been developed in consultation with all interested parties and using an evidence-based approach

Indicator VI.3: Are there clearly written and publicly available guidelines for the selection process for including or deleting medicines from the national essential medicines list?

No guidelines are available. Eight KIs said there were no such guidelines. Two KIs said that there were clearly written guidelines for the selection process, but confirmed that the guidelines were not publicly available.

Indicator VI.4: Is the essential medicines list in line with WHO procedures?

Eight KIs confirmed that the essential medicines list is in line with WHO procedures, and two KIs said it was not. Three of those KIs who responded positively observed that the essential medicines list is not published and hence not publicly available. They commented that the list is not made according to the level of health care (primary, tertiary and so on) and not linked to standard treatment guidelines.

Indicator VI.5: Is there a committee responsible for the selection of the national essential medicines list?

A committee is available for the selection of the national essential medicines list. All KIs answered positively and confirmed the presence of the committee responsible.

Indicator VI.6: To what extent do you agree with the following statement: “The committee responsible for the selection of the national essential medicines list is operating free from external influence”?

Five KIs either agreed or strongly agreed with the statement, one did not know and four either disagreed or strongly disagreed with it (Fig. 16).

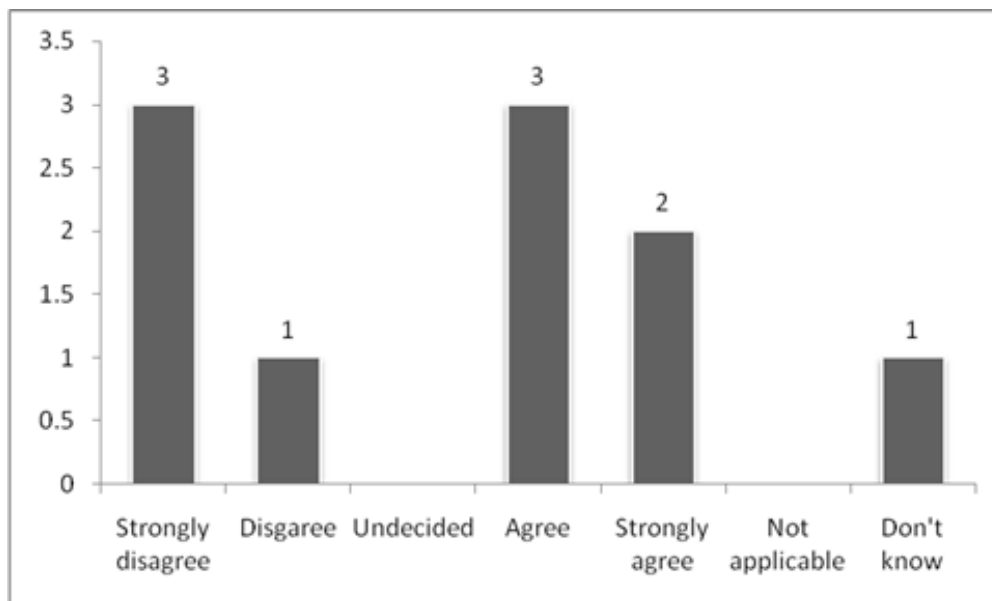


Fig. 16. KI perceptions that the committee responsible for the selection of the national essential medicines list is operating free from external influence

Indicator VI.7: Are there clear criteria for the selection of members of the selection committee?

There are no criteria for selection available. Nine KIs said there were no clear criteria for the selection of members of the selection committee, and one KI did not know.

Indicator VI.8: Are there written guidelines on conflicts of interest with regard to selection of essential medicines?

Eight KIs said there were no written guidelines on conflicts of interest with regards to the committee, one KI did not know and one KI confirmed the presence of such guidelines, though the guidelines could not be produced, but reference was made to generic government regulations that refer to conflicts of interest.

Indicator VI.9: Are there clear and publicly available terms of reference that describe the role and responsibilities of the selection committee?

Terms of reference for the selection committee are present in the Ministerial Decision. Four KIs confirmed the presence of clear and publicly available terms of reference that describe the role and responsibilities of the selection committee. Some felt that they were not publicly available. Five KIs felt such terms of reference were not available and one KI did not know.

Indicator VI.10: Are there written standard operating procedures for the decision-making process of the committee?

There are no standard operating procedures available. Four KIs answered that there were none, two KIs did not know and four KIs responded that there were some. The four KIs who responded that there were standard operating procedures commented that either decisions on the selection process were not publicly available or that decisions were not disseminated widely. Some said that the rules for the decision-making process were not described in official documents.

Indicator VI.11: In your opinion, what types of unethical behaviour are common in the selection process in your country?

The KIs gave these examples of unethical behaviour in the selection process:

- decisions may be influenced by personalities;
- pharmaceutical manufacturers have great influence on the decision-making process of the committee;
- absence of conflict of interest guidelines, meaning members may have stakes, either directly or indirectly, in the pharmaceutical industry;
- unethical promotion/marketing of branded products;
- members tend to be influenced indirectly by professional colleagues (lobbying).

Indicator VI.12: If you were in a position of highest authority, what would be the first action that you would take to improve medicine selection in your country?

The first action that KIs would take to improve medicine selection in Oman would be to:

- involve all appropriate stakeholders in the selection committee;
- establish criteria for selection of committee members that are transparent;
- ensure that the selection committee is an independent entity;
- establish an open discussion forum and a closed discussion forum for the selection process;
- rotate members of the selection committee at specified intervals;
- ensure that there is a clear, well written and transparent process of selection;
- link the selection process to budget availability/approval;
- ensure that committee members are of different specializations;
- establish enforceable conflict of interest guidelines for members of the selection committee;
- ensure that members of the selection committee are well versed in evidence-based practice;
- ensure members of the selection committee have knowledge of pharmacoeconomics.

4.2.7 Procurement of medicines

The Ministry of Health, through the Directorate-General of Medical Supplies, is responsible for the procurement of all pharmaceuticals, vaccines and biologicals required for use in all its health care facilities: primary health centres (172), secondary and regional hospitals (57) and tertiary hospitals (12). All prescribed medicines are dispensed to Omani patients and government employees free of charge. The annual budget for medicines in 2010 was Omani rials 24 million (US\$ 62.34 million). All medicines are purchased centrally through the Directorate-General of Medical Supplies. The process of tendering is done through the Central Tender Board. The listing of medicines in tender documents uses approved, generic names. The supplies are purchased through local and international tenders and through the joint purchasing system with other Gulf Cooperation Council member countries. The tendering process is centred in Riyadh, Saudi Arabia. Within the Ministry of Health there is a committee that evaluates and makes recommendations which are then submitted to the Central Tender Board for the final decision and announcement to the tenderers.

Indicator VII.1: Does the government use transparent and explicit procedures for procurement of pharmaceutical products?

Royal Decree 47/98 and the financial bylaw issued by Ministerial Decision 118/2008 regulate procurement in the public sector. In addition, Royal Decree 36/2008 regulates tender boards. Contract specifications and criteria for the adjudication of tenders are announced in local newspapers prior to the tender but are not available on the Ministry of Health website. Full results of the tender are available on request on compact disc at a nominal cost and summary information is posted on the website.

Although 10 KIs confirmed the presence of procedures for procurement, they mentioned that contract specifications are not publicly available, criteria for the adjudication of tenders are not included in the tender package and neither the results nor the tender process are made public. One KI felt that the Ministry of Health was not using transparent procedures for the procurement of pharmaceuticals.

Indicator VII.2: Is there written guidance for procurement office staff on the type of procurement method to be used for different types of product?

Written guidance is available and nearly all KIs agreed that there was written guidance for staff in the procurement office to follow, except for two KIs who said there was none.

Indicator VII.3: Is procurement done with an objective quantification method to determine the quantity of pharmaceuticals to be purchased?

Procurement is done with an objective quantification method to determine the quantity of pharmaceuticals to be purchased. Ten KIs were aware of this and one KI did not know.

Indicator VII.4: Is there a formal appeals process for applicants who have their bids rejected?

No formal appeals system is available. All KIs agreed that there was no formal appeals process for applicants who have had their bids rejected.

Indicator VII.5: Is there a tender committee? If so, are the key functions of the procurement office and those of the tender committee clearly separated?

All KIs agreed that there was a tender committee; however, eight KIs said that the tender committee was not responsible for restricted tenders (direct purchases). The value of direct purchases is regulated as per the financial regulations.

Indicator VII.6: To what extent do you agree with the following statement: "Decisions of the tender committee are always taken into account in the procurement process"?

All KIs either agreed or strongly agreed with the statement (Fig. 17).

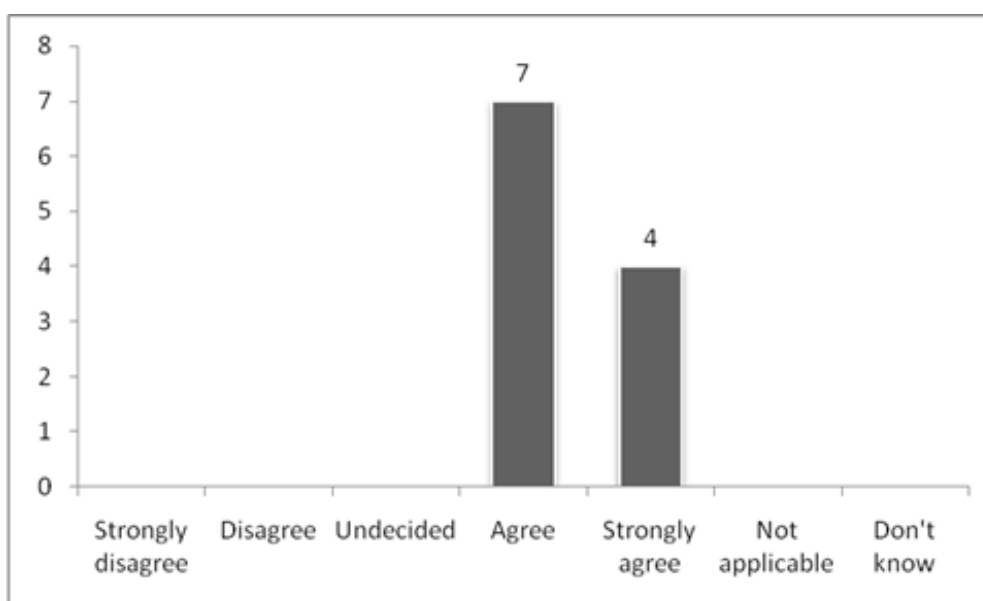


Fig. 17. KI perceptions of the decisions of the tender committee always being taken into account in the procurement process

Indicator VII.7: Are there specific criteria for tender committee membership?

There are no specific criteria for tender committee membership. Ten KIs answered negatively to the question and one KI did not know.

Indicator VII.8: Are there written guidelines on conflicts of interest with regard to the procurement process?

All 11 KIs agreed that there were no written guidelines on conflicts of interest.

Indicator VII.9: To what extent do you agree with the following statement: “The members of the tender committee are systematically selected based on specific criteria (see question VII.7)”?

One KI was undecided, two KIs did not know, one KI agreed and seven KIs either disagreed or strongly disagreed with the statement (Fig. 18).

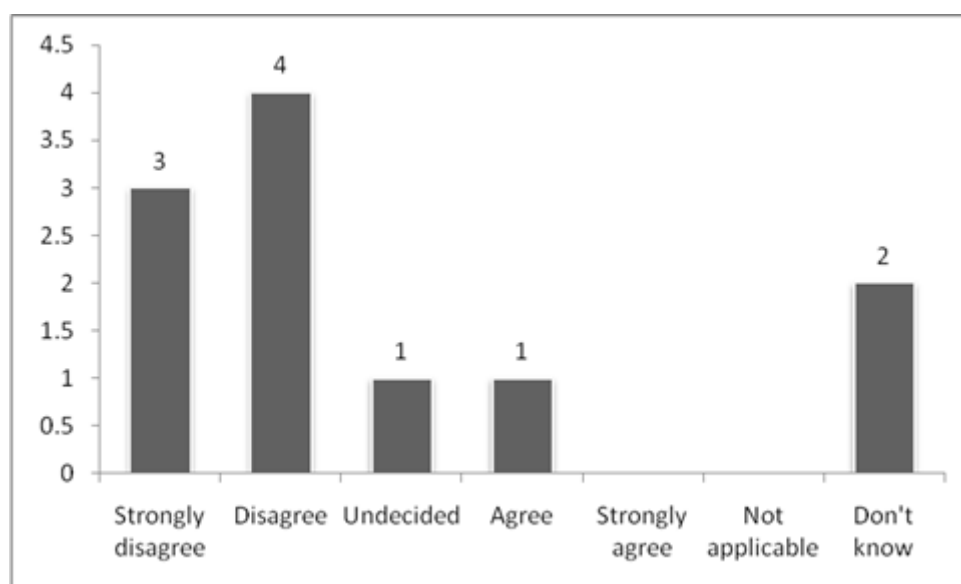


Fig. 18. KI perceptions of the members of the tender committee being systematically selected based on specific criteria

Indicator VII.10: Is there a computerized management information system used to report product problems in procurement?

Ten KIs said that the Ministry of Health had a computerized management information system and one KI answered that there was no such system. Those who responded positively felt that the management information system did not monitor client’s performance and did not record quality assurance information.

Indicator VII.11: Are there standard operating procedures for routine inspection of consignments?

Eight KIs said that there were standard operating procedures for routine inspection of consignments. The remaining three KIs did not know.

Indicator VII.12: Is there an efficient post-tender system in place to monitor and report on suppliers’ performance to the tender committee?

All KIs confirmed the presence of an efficient system to monitor and report suppliers' performance after the tender award. The KIs observed that suppliers who defaulted were not always blacklisted.

Indicator VII.13: Does the procurement office undergo regular audits?

The procurement office undergoes regular audits. Nine KIs agreed that the procurement office was audited regularly by central government and two KIs said they did not know. However, the audits are not available to the public; some KIs mentioned that operating costs are not reported.

Indicator VII.14: To what extent do you agree with the following statement: "The procurement system in your country is operating in a totally transparent manner"?

One KI disagreed with the statement, while 10 KIs either agreed or strongly agreed that the procurement system in Oman is operating in a totally transparent manner (Fig. 19).

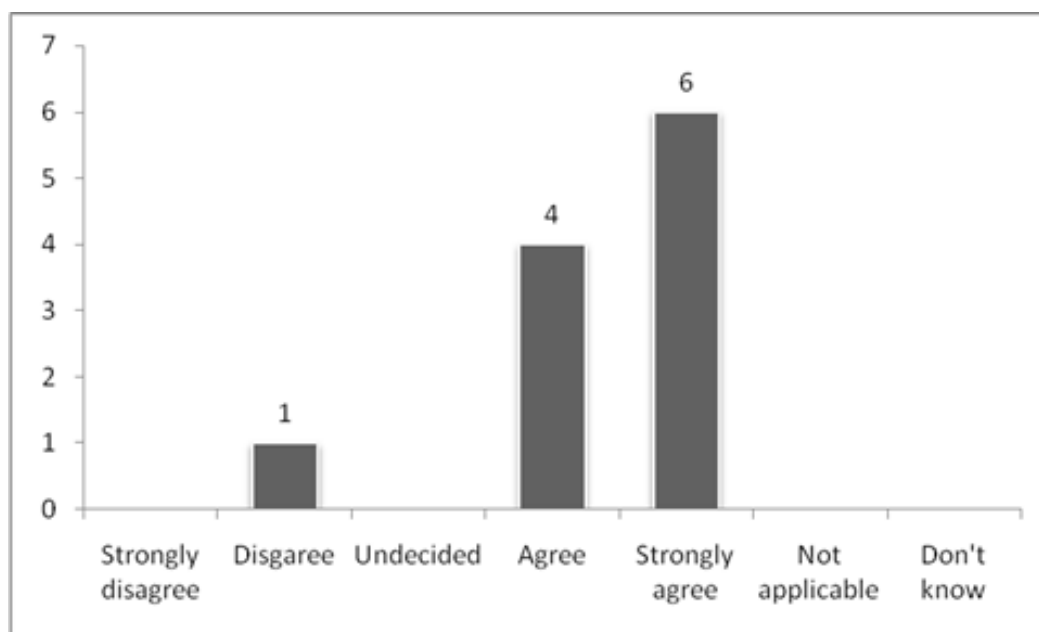


Fig. 19. KI perceptions that the procurement system in Oman is operating in a totally transparent manner

Indicator VII.15: In your opinion, what types of unethical behaviour are common in the procurement system in your country?

The KIs gave this example of unethical behaviour in the procurement system in Oman:

- Absence of conflict of interest guidelines.

Indicator VII.16: If you were in a position of highest authority, what would be the first action that you would take to improve the systems and processes of procurement?

The first actions that KIs would take to improve the systems and processes of procurement in Oman would be to:

- introduce health insurance, which will lead to outsourcing of outpatient medicine dispensing;
- improve the quality and quantity of staff in procurement;
- increase storage space;
- ensure payments are made according to agreed tender conditions;
- improve transparency;
- improve the procurement system to reduce time lag;
- introduce conflict of interest regulations;
- introduce computer linkage between purchasing/procurement and stores (including stock position in wards);
- increase the pharmaceutical budget.

4.2.8 Distribution of medicines

An efficient electronic management information system exists which links the central medical stores with all regional and hospital stores. This ensures a very effective inventory control system. The Ministry of Health has well-defined policies and procedures detailing the delivery of medicines to its warehouse, undertakes inspection on arrival and has allocated a space for holding newly received consignments. Delivery to the central medical stores is the responsibility of suppliers (as part of the tender condition: warehouse to warehouse).

The Ministry of Health stocks supplies sufficient to last 15 months for all the Omani population attending its health establishments. The central medical stores distribute medicines to its regional stores located in Salalah and Nizwa to serve nearby regional health care facilities. All tertiary and regional referral hospitals are supplied directly from the central medical stores. Supplies to different medical stores and health care facilities are contracted out, but the contractors are strictly monitored for compliance with temperature and humidity conditions and delivery time schedules.

Indicator VIII.1: Is there a system in place that can expedite port clearing?

No system for expediting port clearance is in place. Eight KIs thought that there was a system to expedite port clearance, two KIs said there was none and four KIs did not know.

Indicator VIII.2: To what extent do you agree with the following statement: “Port clearing is done smoothly and there is no need for bribery or gift-giving to expedite the process”?

Seven KIs said they agreed or strongly agreed with the statement, while seven KIs said they did not know anything about port clearing (Fig. 20).

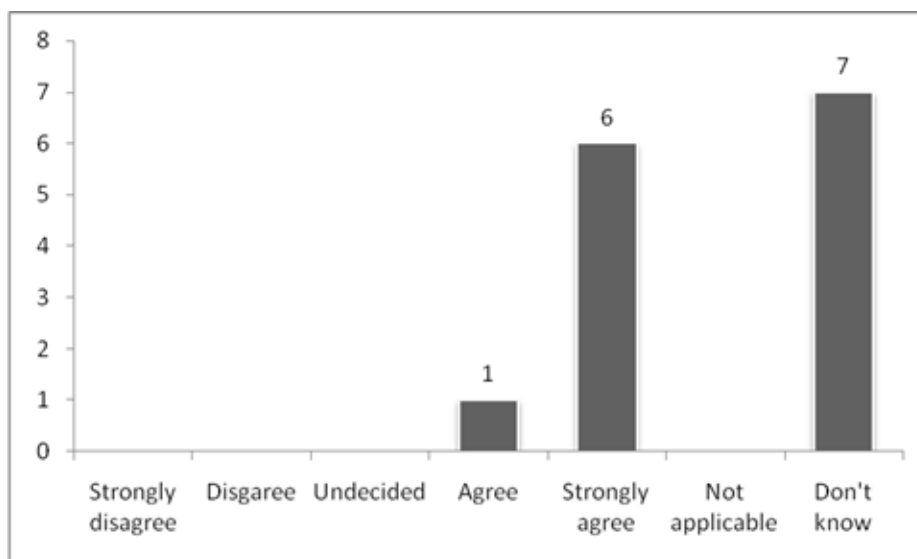


Fig. 20. KI perceptions that port clearing is done smoothly and there is no need for bribery or gift-giving to expedite the process

Indicator VIII.3: Is there any inspection system to verify that the medicines delivered from the port or directly from a supplier match those that were shipped from the supplier?

There is an inspection system to verify delivery of ordered products. This was confirmed by 13 KIs, while one KI said there was not a system. In smaller regional stores, due to the lack of space, there is no separate location for inspection.

Indicator VIII.4: Is there a coding system used to identify government medicines?

All KIs agreed that there was a computer coding system.

Indicator VIII.5: Is there systematic and orderly shelving of products in warehouses or storerooms?

There is systematic and orderly shelving of products in Ministry of Health warehouses. All KIs answered that there was orderly shelving of products in stores. In some smaller regional stores, due to the lack of sufficient space, there are no strict arrangements.

Indicator VIII.6: Is there a security management system in place to oversee storage and distribution?

A security management system is in place to oversee storage and distribution. All KIs confirmed its presence. However, there is no strict monitoring of entry or exit of non-stores personnel, no CCTV cameras and no searches done by security personnel. The controlled substances stores are under strict control.

Indicator VIII.7: Are there standard operating procedures for stock management at each level of the distribution system?

There are standard operating procedures for stock management at each level of the distribution system. Eleven KIs confirmed the presence of standard operating procedures, while three KIs said there were none.

Indicator VIII.8: Is there an inventory management system at each level of the distribution system and which provides information?

There is an inventory management system at each level of the distribution system which provides information. Only one KI said there was none, while the remaining 13 KIs confirmed the presence of an inventory management system, which was kept up to date and exceeded the minimum requirements.

Indicator VIII.9: Are stock records reconciled with physical counts at least every three months by internal staff?

All KIs confirmed that the reconciliation process is being followed. It is implemented every time a new order is placed. There is also electronic monitoring.

Indicator VIII.10: Are there independent audits of warehouses by external inspectors or auditors?

All KIs confirmed that there is auditing by independent external auditors.

Indicator VIII.11: Is there a system (computerized or manual, historical or current) in place to track the movement of pharmaceuticals from a warehouse to a health facility?

All KIs confirmed the presence of a system to track the movements of pharmaceuticals.

Indicator VIII.12: Do health facilities have an appropriate procedure for requesting medicines?

Health facilities have an appropriate procedure for requesting medicines. All KIs confirmed this, except one KI who did not know.

Indicator VIII.13: Are there appropriate written guidelines on transportation and delivery of the medicines from/to the warehouses?

The Ministry of Health has a contract with a transportation company and all contract details are held in the transport section. Two KIs did not know, five KIs said there were none and seven KIs agreed that there were appropriate guidelines on transportation and delivery of medicines.

Indicator VIII.14: Is there a well-functioning communication system for ordering, re-ordering and complaints between the suppliers and the end-users?

All KIs confirmed the presence of a well-functioning communication system for ordering, re-ordering and complaints between supplies and end-users. This is included in the inventory management system.

Indicator VIII.15: Does a programme exist for monitoring and evaluating the performance of the medicine distribution system?

There is a programme for monitoring and evaluating the performance of the medicine distribution system. One KI answered that there was none, one KI did not know and the remaining 12 KIs confirmed its presence. However, all 12 KIs who confirmed its presence identified programme limitations; for example, monitoring is not regular or systematic, reports identifying weaknesses and their recommendations are not made public, and overall reports are not available to the public.

Indicator VIII.16: Are sanctions imposed on individuals or agencies/companies for theft or corrupt practices associated with distribution?

No theft or corruption cases were reported up to the time of the assessment. Ten KIs answered that they were not aware of any sanctions imposed on any individuals or companies for theft or corruption, one KI did not know and three KIs assumed that the general government regulations on theft covered the distribution function as well.

Indicator VIII.17: Does the Ministry of Health have appropriate procedures for disposal of expired and/or spoiled medicines?

The Ministry of Health has appropriate procedures for disposal of expired or spoiled medicines and all KIs agreed with this.

Indicator VIII.18: To what extent do you agree with the following statement: "There are very rarely leakages in the medicine distribution system in your country"?

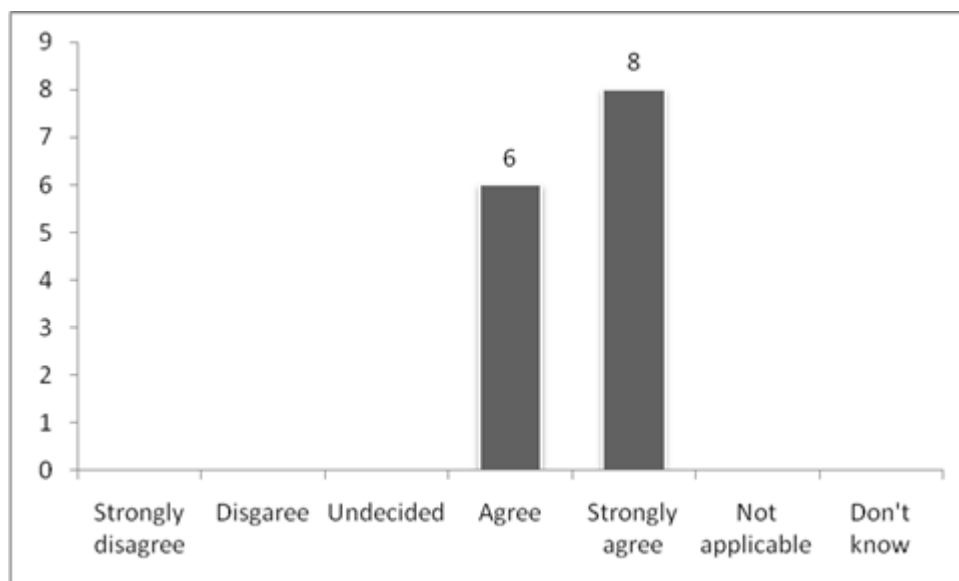


Fig. 21. KI perceptions that there are very rarely leakages in the medicine distribution system in Oman

All KIs agreed or strongly agreed with the statement that there are very rarely leakages in the medicine distribution system (Fig. 21).

Indicator VIII.19: If you were in a position of highest authority, what would be the first action that you would take to improve the systems and processes of public sector medicine distribution in your country?

The first actions that KIs would take to improve the systems and processes of public sector medicine distribution in Oman would be to:

- ensure sufficient stock in regional stores;
- centralize uniform instructions on pharmacy services to avoid overlapping of information from different directorates;
- ensure staff are properly trained in administration and supplies management;
- consult regional stores/hospitals before withdrawing products;
- establish a countrywide unit dose system;
- avoid shortages of medicines;
- ensure procedures are publicly available;
- establish buffer stocks of specialized medicines;
- decentralize the pharmaceutical budget;
- improve communication;
- increase storage space;
- computerize and link all health care facilities, including wards, with the central medical stores.

5. Data analysis and discussion

The following section provides a function-specific analysis of the results obtained during the interviews with the KIs. The analysis offers a strength–weakness analysis for each function, based on the responses of the KIs and summarizes their main perceptions. The information covers the following eight functions: medicine registration, licensing of pharmaceutical establishments, inspections, control of medicines promotion, control of clinical trials, selection of medicines, procurement of medicines and distribution of medicines.

5.1 Medicine registration

The vulnerability to corruption score shows that the medicine registration function is moderately vulnerable to corruption.

5.1.1 *Strengths of the registration function*

The strengths of the registration function are as follows.

- There is a formally-appointed technical committee responsible for registration of manufacturers, products and setting of prices.
- The committee is composed of technically qualified and competent personnel within the Ministry of Health.
- The committee members are selected according to the position occupied.
- The applicant receives an acceptance or rejection letter documenting additional information/data required.
- Applications which are rejected can appeal to the Minister’s office, though such an appeal is referred back again to the same committee that made the initial decision.
- There is a list of all registered pharmaceutical products, available on the Ministry of Health website. The list includes the approved name, the trade name, the manufacturer, country of origin, dosage form, strength, presentation and registration number.
- The list clearly classifies the products as over the counter, controlled or prescription-only, and so on.
- There is a standard application form for submission of application, publicly available on the Ministry of Health website.
- The application form gives detailed registration requirements, publicly available on the Ministry of Health website.

- The registration department has established a rotation list for all prospective applicants, detailing the dates and times, and whom to meet to submit registration applications.
- The application form requires information on approved and trade names, packet insert, and inner and outer containers.
- The submission of a good manufacturing practice certificate, certificate of analysis, pharmacodynamic and pharmacokinetic data, clinical trial or bioequivalence studies must also be submitted.
- Staff of the registration department review the documents submitted using the approved checklist in the presence of the applicant.

5.1.2 Weaknesses of the registration function

The weaknesses of the registration function are as follows.

- Though there are documented standard operating procedures for the registration process, they are only available for internal use.
- There are no detailed duties and responsibilities of committee members and therefore no accountability of members.
- Committee members are not required to declare any conflict of interests.
- Committee members are all from the Ministry of Health and remain in the committee as long as they occupy their positions.
- There is no independent appeal mechanism for rejected applications.

5.1.3 Perceptions of KIs

73% of KIs interviewed believed that members of the registration committee are selected unsystematically and without objectivity. Two-thirds of KIs believed that gifts and other benefits do not affect their decisions. The majority of KIs (87%) believed there is no unethical behaviour in Oman as far as the registration of pharmaceutical products is concerned.

5.2 Licensing of pharmaceutical establishments

The licensing function scored better in terms of vulnerability to corruption score, with a score of 6.18 (marginally vulnerable).

5.2.1 Strengths of the licensing function

The strengths of the licensing function are as follows.

- There is a licensing directorate and a committee responsible for licensing.
- There are written criteria for submission of an application including fees.

- There are written guidelines and a pre-licensing inspection report is a requirement.
- There are regular post-licensing inspections of all licensed establishments.

5.2.2 Weaknesses of licensing function

The weaknesses of the licensing function are as follows.

- The application for licensing is not publicly available.
- The licensing committee members are selected without specified criteria.
- Committee members are not expected to declare any conflicts of interest.
- The licensing committee does not have terms of reference and hence accountability.
- There is no appeal system when a license application is rejected.
- There is no timeframe for approval of a license.

5.2.3 Perceptions of KIs.

80% of KIs interviewed believed that licensing is systematically carried out according to policies and procedures and 50% believed the committee's meetings were held regularly. The majority of KIs (90%) believed that there is no unethical behaviour in the licensing of pharmaceutical establishments.

5.3 Inspection of pharmaceutical establishments

The score is low, indicating that the inspection function is very vulnerable to corruption. This is because there is an absence of transparency in the inspection process in retail pharmacies and medical stores, the directorate is understaffed, with the same inspectors visiting establishments, and there is potential for conflicts of interest.

5.3.1 Strengths of the inspection function

The strengths of the inspection function are as follows.

- There are provisions in the law covering inspection of pharmaceutical establishments.
- The inspectors are given the power they require to carry out their activities.
- There is a checklist for what to do, and how, during an inspection visit.
- Internal review of inspection reports is carried out for each report.
- Current good manufacturing practice is used in inspecting manufacturers.

5.3.2 Weaknesses of the inspection function

The weaknesses of the inspection function are as follows.

- Inspections are carried out individually through inspectors even though the inspectors visit as a team.
- There is no mechanism to prevent regulatory capture.
- There are no written guidelines with regards to conflicts of interest.
- There is no appeal system.
- There are no criteria for the selection and recruitment of inspectors.

5.3.3 Perceptions of KIs

Nearly 80% of KIs believed that inspectors are not influenced by personal gain, and a similar percentage of KIs believed that inspection activities are carried out systematically in accordance with the guidelines. Nearly all KIs believed that there is no unethical behaviour in the inspection process.

5.4 Control of medicine promotion

This function scored very low and is extremely vulnerable to corruption. The absence of an appropriate committee and enforceable procedures/regulations led to this low score.

5.4.1 Strengths of the promotion function

The strengths of the promotion function are as follows.

- There is growing concern over promotion ethics.
- Regulations for promotion are currently been formulated and will be released in the near future.
- There is strict regulation restricting direct-to-consumer advertising.

5.4.2 Weaknesses of the promotion function

The weaknesses of the promotion function are as follows.

- There is a lack of control of published medical information.
- There is no regulatory body/committee to supervise medicine promotion activities.
- There are no restrictions in line with WHO criteria for medicine promotion which would facilitate good prescribing and dispensing practices.

- There are no restrictions on free goods and samples passed on to retail pharmacies or private clinicians.
- The absence of regulations governing medicine promotions is the major weakness in this function.

5.4.3 Perceptions of KIs

All responding KIs believed that there is unethical behaviour on the part of regulatory office staff with regards to medicine promotion. They believed that there is misuse of promotion of free goods, free samples and bonuses offered to health professionals and pharmacies in the private sector. They could not comment on other indicators because these do not exist in Oman.

5.5 Control of clinical trials

The control of clinical trials function scored 1.69/10 and is extremely vulnerable to corruption.

5.5.1 Strengths of the control of clinical trials function

The strengths of the control of clinical trials function are as follows.

- There is legal provision covering the conduct of clinical trials.
- There are written guidelines on the principles of good clinical practice.
- There is a committee (the research committee) which reviews applications, for which members have technical knowledge.

5.5.2 Weaknesses of the control of clinical trials function

The weaknesses of the control of clinical trials function are as follows.

- The absence of a clear, well written document guiding the conduct of clinical trials.
- The absence of an independent ethics committee.
- The absence of procedures for declaring conflicts of interest.

5.5.3 Perceptions of KIs

Nearly all KIs did not comment on this function due to the absence of clear regulations and procedures. The most significant comment made concerned informed consent forms and the amount of information given to participant subjects.

5.6 Selection of medicines

The selection of medicines function scored as moderately vulnerable to corruption. This is due to the absence of publicly available information about central drug committee activities, membership selection criteria and conflict of interest guidelines.

5.6.1 Strengths of the selection of medicines function

The strengths of the selection of medicines function are as follows.

- There is an essential medicines list (Oman national formulary) which is widely distributed.
- There is a central drug committee responsible for selection of medicines.
- The Oman national formulary has already gone through its first revision (the second edition is available).
- The Oman national formulary is in line with WHO recommendations: medicines are listed by generic name, arranged pharmacologically and classified by level of health care.

5.6.2 Weaknesses of the selection of medicines function

The weaknesses of the selection of medicines function are as follows.

- There are no publicly available guidelines on selection of medicines.
- There are no criteria for selection of members of the central drug committee.
- The central drug committee does not involve all stakeholders.
- There are no written guidelines on declaration of conflicts of interest.
- There are no publicly available terms of reference for the central drug committee.
- There are no standard operating procedures for its decision-making process.

5.6.3 Perceptions of KIs

The majority of KIs believed that the Oman national formulary was developed after wide consultation and 50% of KIs believed that the central drug committee is free from external influence. There were reports of unethical behaviour in the selection process, such as decisions being influenced by personalities, the absence of conflict of interest guidelines and lobbying of central drug committee members by professional colleagues.

5.7 Procurement of medicines

The procurement of medicines function scored high and is considered to be marginally vulnerable to corruption.

5.7.1 Strengths of the procurement of medicines function

The strengths of the procurement of medicines function are as follows.

- There are written procedures for the procurement of medicines through the government's central tender board.
- The list of medicines in tenders is by generic or approved name.
- The Directorate-General of Medical Supplies is responsible for the central procurement of all medicines required for use in health centres, polyclinics and hospitals.
- There is an approved national medicine policy and national formulary guidance on medicines to be purchased.
- There is a committee responsible for estimating annual requirements.
- Auditing of procurement is conducted regularly by the Ministry's own audit department and by the external audit department of the Ministry of Finance.
- The management information system is an important tool in procurement management and all tender processes are carried out electronically.
- There is an efficient post-tender system to monitor and report on suppliers' performance.
- There is an efficient medicine quality reporting system.

5.7.2 Weaknesses of the procurement of medicines function

The weaknesses of the procurement of medicines function are as follows.

- Members of the tender committee are selected without specific criteria.
- Committee members do not have to declare conflicts of interest.
- There is no appeal system in the procurement process.
- There is a long lead time, of almost 10 to 11 months, for procurement.
- There are constant shortages of medicines, especially in rural areas.
- There is insufficient storage space in the central and regional medical stores.

5.7.3 Perceptions of KIs

All KIs believed that the decisions of the tender committee are always accepted in the procurement process. Nearly 90% of KIs believed that the procurement system is transparent and that there are no ethical behaviours except for the absence of conflict of interest guidelines.

5.8 Distribution of medicines

This function had the highest score and is classified as minimally vulnerable to corruption.

5.8.1 Strengths of the distribution of medicines function

The strengths of the distribution of medicines function are as follows.

- An efficient inventory control system exists.
- Detailed procedures on receipt, inspection and quality control of supplies exist.
- A detailed procedure for the collection of expired medicines is available.
- Physical inventory control, compared with electronic data, is done at least twice annually.
- Medicines are stocked pharmacologically and alphabetically, and separated out according to their formulation and storage conditions.
- Controlled medicines are stored in compliance with international and WHO regulations.
- All medicines are coded.
- There are standard operating procedures for stock management at each level of distribution.
- All medical stores are audited at least once annually by external auditors.
- Electronic prescribing using generic/approved medicine names in all health care facilities improves the monitoring of consumption.
- As of writing, the Directorate-General of Medical Supplies has been granted ISO certification.

5.8.2 Weaknesses of the distribution of medicines function

The weaknesses of the distribution of medicines function are as follows.

- The security system at all medical stores does not include monitoring by camera.
- Agents of suppliers are sometimes allowed in the central medical stores.
- Restrictions as to who can enter are not always enforced in regional stores.

5.8.3 Perceptions of KIs

50% of KIs believed that port clearance is smooth and there is no need for bribery, while 50% did not know because they were not routinely involved with suppliers. All KIs believed that there are no leakages in the medicine distribution system.

6. Recommendations

6.1 General recommendations

Lack of declaration on conflicts of interest by committee members, lack of selection criteria for committee members and the absence of all relevant stakeholders in committees, all contributed towards lowering the vulnerability to corruption scores for some functions. Many aspects of the various committees and their processes are not disseminated publicly; the use of information technology would go a long way in enhancing transparency.

6.2 Registration of medicines

The following are recommendations to improve the transparency of the registration function in Oman:

- Develop a clearly written document for the public explaining how registration decisions are taken by the committee.
- Develop written guidelines to be followed by the registration committee in the registration process.
- Establish a separate committee, other than the original committee, which is responsible for receiving appeals.
- Develop conflict of interest guidelines which every member must sign and adhere to.
- Ensure that all applicants access the application forms online from the Ministry of Health's website.
- Provide technical support by linking the registration committee with international sources of information.
- Consider establishing a semi-autonomous body to be responsible for registration.

6.3 Licensing of pharmaceutical establishments

The following are recommendations to improve the transparency of the licensing function in Oman:

- Increase human, technical (information technology) and space resources for the department.
- Establish criteria for selection of committee members.

- Establish conflict of interest guidelines which each member must sign and adhere to.
- Ensure that rules and regulations governing licensing are current and that all concerned are made aware of them.
- Ensure that committee members reflect the stakeholders.
- Establish a separate committee, other than the one that provides licenses, to review appeals.
- Consider establishing a semi-autonomous body for licensing.
- Review the distance between retail pharmacies.
- Consider offering temporary licenses to graduate pharmacists while they are processing their registration.

6.4 Inspection of pharmaceutical establishments

The following are recommendations to improve the transparency of the inspection of pharmaceutical establishments function in Oman:

- Introduce procedures for the selection and training of inspectors.
- Increase the number of inspectors to avoid the same individual inspecting the same establishments every time, with the potential for regulatory capture.
- Enforce peer review site inspection with publicly-available procedures.
- Better equip inspectors with transportation and computers.

6.5 Control of medicine promotion

The following are recommendations to improve the transparency of the medicine promotion function in Oman:

- Establish clear regulations for the promotion of medicines.
- Establish a committee responsible for regulating and monitoring medicine promotion.
- Ensure that the committee has clear guidelines on its membership and terms of reference.
- Ensure that committee members sign a conflict of interest form and adhere to it.
- Establish regulations on the amount and type of free samples and goods that can be given to health professionals.
- Establish an independent committee to review appeals regarding medicine promotion.

6.6 Control of clinical trials

The following are recommendations to improve the transparency of the clinical trial function in Oman:

- Establish clear regulations on the conduct of clinical trials in Oman.
- Establish a semi-autonomous committee/body to be responsible for regulating the conduct of clinical trials.
- Establish an ethics committee to review the ethical issues regarding clinical trials.
- Establish criteria for the selection of committee members and make it publicly available.
- Ensure that all committee members adhere to conflict of interest guidelines.
- Identify appropriate remuneration for those involved in committees.
- Ensure that committee membership reflects the different stakeholders.

6.7 Selection of medicines

The following are recommendations to improve the transparency of the medicine selection function in Oman:

- Establish a committee with representatives from the relevant stakeholders.
- Establish criteria for the selection of committee members.
- Ensure that committee members are rotated on a regular basis.
- Ensure that the committee has clear guidelines on the process of selection of medicines (using evidence-based and pharmacoeconomic principles).
- Establish a committee to review appeals regarding non-selected products.
- Ensure committee members strictly adhere to conflict of interest guidelines.

6.8 Procurement of medicines

The following are recommendations to improve the transparency of the medicine procurement function in Oman:

- Establish criteria for the selection of tender committee members.
- Establish clear terms of reference for the committee.
- Ensure that committee members adhere strictly to conflict of interest guidelines.
- Establish an independent committee or mechanism for resolving appeals.
- Establish a mechanism to reduce the long lead time in the procurement process.
- Encourage the establishment of a health insurance system to reduce the holding of large stocks in stores.

6.9 Distribution of medicines

The following are recommendations to improve the transparency of the distribution of medicines function in Oman:

- Improve the security system in medical stores by introducing CCTV.
- Improve the space capacity of medical stores.
- Ensure the continuous training of staff in stock management.
- Consider establishing a centralized unit dose system for the countrywide distribution of medicines.

7. Conclusions

This study reviewed the transparency of pharmaceutical services in Oman across eight functions: registration of medicines; licensing of pharmaceutical establishments; inspection of pharmaceutical establishments; control of medicine promotion; control of clinical trials; selection of medicines; procurement of medicines; and distribution of medicines.

The study has identified the strengths and weaknesses of various processes across these eight functions. It is anticipated that in the second and third phases of the project, the Ministry of Health will enhance the identified strengths and rectify the weaknesses through additional legislation and the relevant action.

The study identified the control of medicine promotion and the control of clinical trials in Oman to be extremely vulnerable to corruption. These two functions need to be looked into as soon as possible and the necessary regulations introduced to address this vulnerability. Where other functions have suboptimal vulnerability scores, this is mainly due to the absence of transparency.

Pharmaceutical services in Oman have generally been developed in a systematic manner and are very well organized within a good legal framework. There has been systematic collaboration with WHO during services development.

The study has assisted the Ministry of Health to identify the level of vulnerability to corruption and unethical behaviour within its pharmaceutical sector. It provides recommendations on how to improve and consolidate transparency and accountability in the pharmaceutical system. Efforts are being made to implement these recommendations, and policies and procedures are being updated and changed as a result.

It is anticipated that before the start of Phase III of the project, a follow-up assessment will be implemented to monitor the progress that has been achieved and to identify remaining challenges. This follow-up exercise should further improve the perceptions of those directly involved in utilizing the Ministry's pharmaceutical services.

It is heartening to observe that the observations recorded in the study relate mainly to processes; almost all those interviewed spoke very highly of the ethical behaviour and absence of corrupt practices amongst staff working in pharmaceutical services.

8. Resource documents

Royal Decree no. 41/1996: Pharmacy practice law.

Ministry of Health approved medicines list. Muscat: Ministry of Health; 2009 (http://www.who.int/selection_medicines/country_lists/omn_EDL_2009.pdf?ua=1, accessed 22 November 2015).

Measuring transparency to improve good governance in the public pharmaceutical sector: Jordan. Cairo: WHO Regional Office for the Eastern Mediterranean; 2009 (<http://applications.emro.who.int/dsaf/dsa968.pdf>, accessed 22 November 2015).

Measuring transparency to improve good governance in the public pharmaceutical sector: Lebanon. Cairo: WHO Regional Office for the Eastern Mediterranean; 2009 (<http://applications.emro.who.int/dsaf/dsa1005.pdf> accessed 22 November 2015).

Measuring transparency in the public pharmaceutical sector: assessment instrument. Geneva: World Health Organization; 2009 (<http://www.who.int/medicines/areas/policy/goodgovernance/AssessmentInstrumentM easterspENG.PDF>, accessed 22 November 2015).

Oman Annual Health Report 2009. Muscat: Ministry of Health; 2009.

Royal Decree no. 36/2008: Issuing the tender law (<https://www.paew.gov.om/TendersLaw/Tender-Law-38-2008>, accessed 22 November 2015).

Ministerial Decision no. 118/2008 issued for executive financial laws as per Royal Decree no. 47/98.

Managing medical supplies, January 2011 first edition. Muscat: Directorate-General of Medical Supplies, Ministry of Health; 2011 (<https://www.moh.gov.om/documents/71477/121151/Managing+Supplies/281f72a1-6496-416b-8e80-d4dfcdea94c8>, accessed 22 November 2015).

Annex 1. Score sheets for functions

Table A1. Medicine registration vulnerability scale points

Table A2. Licensing of pharmaceutical establishments vulnerability scale points

Table A3. Inspection of pharmaceutical establishments vulnerability scale points

Table A4. Control of medicine promotion vulnerability scale points

Table A5. Control of clinical trials vulnerability scale points

Table A6. Medicine selection vulnerability scale points

Table A7. Medicine procurement vulnerability scale points

Table A8. Medicine distribution vulnerability scale points

Table A1. Medicine registration vulnerability scale points

	Method	KI 1	KI 2	KI 3	KI 4	KI 5	KI 6	KI 7	KI 8	KI 9	KI 10	KI 11	KI 12	KI 13	KI 14	KI 15	Total	Average per question**
Profession *	---	G	G	G	G	G	G	G	P	P	P	P	P	P	P	G		
Indicator I.1	M1	1	1	1	1	1	1	1		1	1	1	1	1	1	1	14	1.00
Indicator I.2	M2	0.5	1	0.38	1	0.88	1	0.25		1	0.88	1	0.38	0.63	0.75	1	10.65	0.76
Indicator I.3	M2	0.57	1	1	0.71	1	1	1	0.57	0	1	1	0.71	0.86	0.71	0	11.13	0.74
Indicator I.4	M2	0.33	0.67	0.67	0	0.83			0	0	0.33	0	0	0	0	0	2.83	0.22
Indicator I.5	M2	1	0.88	1	0.88	1	0.88	0.75	0.88	0.75	0.88	0.88	0.88	1	1	0.86	13.52	0.90
Indicator I.6	M1	1	1	1	1	1	1	1	0	0	1	0	0	0	0	0	8	0.53
Indicator I.7	M1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	15	1.00
Indicator I.8	M2	0	0	0	0	0	0	0	0	0	0	0		0	0	0	0	0.00
Indicator I.9	M2	0	0.25	0.25	0.25	0	0.25	0.25	0	0	0.29	0	0	0	0	0	1.54	0.10
Indicator I.10	M2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.00

Indicator I.11	M3																		
Indicator I.12	M2	0.75	0.75	0.5	0	0.88	0	0.38	0	0	0		0	0.29	0	0.13	3.68	0.26	
Indicator I.13	M1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	14	0.93	
Indicator I.14	M3																		
Indicator I.15	M3																		
Indicator I.16	M4	see text in narrative report																	
Indicator I.17	M4	see text in narrative report																	
																	Total	6.45	
																	***Final score: Registration	5.38	

* G = Government or public official.

P = Private sector (national or international)

Table A2. Licensing of pharmaceutical establishments vulnerability scale points

	Method	KI 1	KI 2	KI 3	KI 4	KI 5	KI 6	KI 7	KI 8	KI 9	KI 10	KI 11	KI 12	KI 13	KI 14	KI 15	Total	Average per question**
Profession*	---	G	G	G	P	P	P	G	P	P	P							
Indicator II.1	M1	1	1	1	1	1	1	1	1	1	1						10	1.00
Indicator II.2	M1	1	1	1	1	1	1	1	1	1	1						10	1.00
Indicator II.3	M2	0.38	0.83	1	0.17	0.17	0.83	1	0.33	0.83	0						5.54	0.55
Indicator II.4	M1	0	1	1	0	1	0	1	0		0						4	0.44
Indicator II.5	M2	1	1	1	1	1	1	1	1		1						9	1.00
Indicator II.6	M2	1	1	1	0	0	1	1	1	1							7	0.78
Indicator II.7	M2	0	0	0	0	0	0	0	0								0	0.00
Indicator II.8	M2	0	0.75	0	0	0	0	0.75	0								1.5	0.19
Indicator II.9	M1	1	1	1	1	1	1	1	1	1	1						10	1.00
Indicator II.10	M2	1	0.75	0.75		1	1	1	1		0.2						6.7	0.84

	Method	KI 1	KI 2	KI 3	KI 4	KI 5	KI 6	KI 7	KI 8	KI 9	KI 10	KI 11	KI 12	KI 13	KI 14	KI 15	Total	Average per question**
Indicator II.11	M3																	
Indicator II.12	M1	0	0	0	0	0	0	0	0		0						0	0.00
Indicator II.13	M3																	
Indicator II.14	M4	see text in narrative report																
Indicator II.15	M4	see text in narrative report																
																	Total	6.80
																	***Final score: Licensing	6.18

Table A3. Inspection of pharmaceutical establishments vulnerability scale points

	Method	KI 1	KI 2	KI 3	KI 4	KI 5	KI 6	KI 7	KI 8	KI 9	KI 10	KI 11	KI 12	KI 13	KI 14	KI 15	Total	Average per question**
Profession*	---	G	G	P	P	P	P	P	P	G	P	P	P	P	P			
Indicator III.1	M1	1	1	1	1	1	1	1	1	1	1	1	1	1	1		14	1.00
Indicator III.2	M2	1	1	0.5	0.25	0.4	1	0.5	0.4	0.75	0.4	0.5	0.8	0.6	0.4		8.5	0.61
Indicator III.3	M2	0.5	0.5	0			0.83	0.83	0.5	0.6	0						3.76	0.47
Indicator III.4	M2	0	0	0.2	0.17	0	0.17	0.33	0	0	0	0.2	0.17	0.17	0.25		1.66	0.12
Indicator III.5	M2	0	0	0	0	0	0	0	0	0	0			0	0		0	0.00
Indicator III.6	M1	1	1	0	0	0	0	0	1	1	0	1	1	1	0		7	0.50
Indicator III.7	M2	0.33	0		0	0	1	0.6	0	1	0	0.6	0.75	0.8	0		5.08	0.39
Indicator III.8	M2	0	0	0	0	0	0	0	0	0	0			0	0		0	0.00
Indicator III.9	M3																	
Indicator III.10	M3																	
Indicator III.11	M4	see text in narrative report																
Indicator III.12	M4	see text in narrative report																
																	Total	3.09
																	***Final score: Inspection	3.86

Table A4. Control of medicine promotion vulnerability scale points

	Method	KI 1	KI 2	KI 3	KI 4	KI 5	KI 6	KI 7	KI 8	KI 9	KI 10	KI 11	KI 12	KI 13	KI 14	KI 15	Total	Average per question**
Profession*	---	G	P	P	P	G	P	P	P	P	P							
Indicator IV.1	M1	1	0		1	0	0	0	0	0	0						2	0.22
Indicator IV.2	M2	0.2	0		0.11	0	0	0.2	0.2	0.2	0						0.91	0.10
Indicator IV.3	M2	0	0		0	0	0	0	0	0	0						0	0.00
Indicator IV.4	M1	0			0	0	0	0		0	0						0	0.00
Indicator IV.5	M2	0	0			0	0	0	0	0	0						0	0.00
Indicator IV.6	M1	0	0			0	0	0	0	0	0						0	0.00
Indicator IV.7	M2	0	0			0	0	0	0	0	0						0	0.00
Indicator IV.8	M2	0	0			0	0	0	0	0	0						0	0.00
Indicator IV.9	M2	0	0		0	0	0	0	0	0	0						0	0.00
Indicator IV.10	M2	0	0		0	0	0	0	0	0	0						0	0.00

Indicator IV.11	M3																		
Indicator IV.12	M3																		
Indicator IV.13	M3																		
Indicator IV.14	M3																		
Indicator IV.15	M4	see text in narrative report																	
Indicator IV.16	M4	see text in narrative report																	
																	Total	0.32	
																	***Final score: Promotion	0.32	

Table A5. Control of clinical trials vulnerability scale points

	Method	KI 1	KI 2	KI 3	KI 4	KI 5	KI 6	KI 7	KI 8	KI 9	KI 10	KI 11	KI 12	KI 13	KI 14	KI 15	Total	Average per question**
Profession*	---	G	P	P	P	P	P	P	P	P	G							
Indicator V.1	M1	1	1	1	1	1	0		0		0						5	0.63
Indicator V.2	M1	1	0	0	0	0	0		0	0	0						1	0.11
Indicator V.3	M2		0		0	0	0		0	0	0.8						0.8	0.11
Indicator V.4	M2	0	0	0	0	0			0	0	0.67						0.67	0.08
Indicator V.5	M2	0	0	1	0	1		1	1	0	0						4	0.44
Indicator V.6	M1	1	0		0	0		1	1		1						4	0.57
Indicator V.7	M2	0	0		0	0			0		0.5						0.5	0.08
Indicator V.8	M1	0	0		0	0			0		0						0	0.00
Indicator V.9	M2	0	0	0	0	0			0		0						0	0.00
Indicator V.10	M1	0	0		0	0			0	0	0						0	0.00

Indicator V.11	M2	0	0		0	0			0	0	0						0	0.00
Indicator V.12	M2	0	0		0	0			0		0						0	0.00
Indicator V.13	M3																	
Indicator V.14	M3																	
Indicator V.15	M3																	
Indicator V.16	M4	see text in narrative report																
Indicator V.17	M4	see text in narrative report																
																	Total	2.03
																	***Final score: Clinical trials	1.69

Table A6. Medicine selection vulnerability scale points

	Method	KI 1	KI 2	KI 3	KI 4	KI 5	KI 6	KI 7	KI 8	KI 9	KI 10	KI 11	KI 12	KI 13	KI 14	KI 15	Total	Average per question**
Profession*	---	G	G	P	P	P	G	G	G	P	P							
Indicator VI.1	M1	1	1	0	1	1	1	1	1	1	1						9	0.90
Indicator VI.2	M3																	
Indicator VI.3	M2	0.86	0	0	0	0	0	0.71	0	0	0						1.57	0.16
Indicator VI.4	M2	1	1	0	1	0.6	1	0.5	1	0.83	0						6.93	0.69
Indicator VI.5	M1	1	1	1	1	1	1	1	1	1	1						10	1.00
Indicator VI.6	M3																	
Indicator VI.7	M2	0	0	0		0	0	0	0	0	0						0	0.00
Indicator VI.8	M2	0	0	0	0		0.29	0	0	0	0						0.29	0.03
Indicator VI.9	M2	0.67	0.67	0	0		0.67	0.67	0	0	0						2.68	0.30
Indicator VI.10	M2	0	1	0	0.67		0.67	0.83	0	0							3.17	0.40
Indicator VI.11	M4	see text in narrative report																
Indicator VI.12	M4	see text in narrative report																
																	Total	3.48
																	***Final score: Selection	4.35

Table A7. Medicine procurement vulnerability scale points

	Method	KI 1	KI 2	KI 3	KI 4	KI 5	KI 6	KI 7	KI 8	KI 9	KI 10	KI 11	KI 12	KI 13	KI 14	KI 15	Total	Average per question**
Profession*	---	G	G	G	G	G	P	P	P	P	P	G						
Indicator VII.1	M2	1	0.89	0.78	0.88	1	0	0.78	0.63	0.63	0.38	1					7.97	0.72
Indicator VII.2	M1	1	1	1	1	1	0	1	1	1	0	1					9	0.82
Indicator VII.3	M1	1	1	1	1	1	1	1	1	1		1					10	1.00
Indicator VII.4	M1	0	0	0	0	0	0	0	0	0	0	0					0	0.00
Indicator VII.5	M2	0.67	0.67	0.67	0.67	0.67	1	1	0.67	0.67	1	0.33					8.02	0.73
Indicator VII.6	M3																	
Indicator VII.7	M2	0	0	0	0	0	0		0	0	0	0					0	0.00
Indicator VII.8	M2	0	0	0	0	0	0	0	0	0	0	0					0	0.00
Indicator VII.9	M3																	
Indicator VII.10	M2	0.71	0.86	0.86	0	1	0.86	1	0.71	1	0.86	1					8.86	0.81

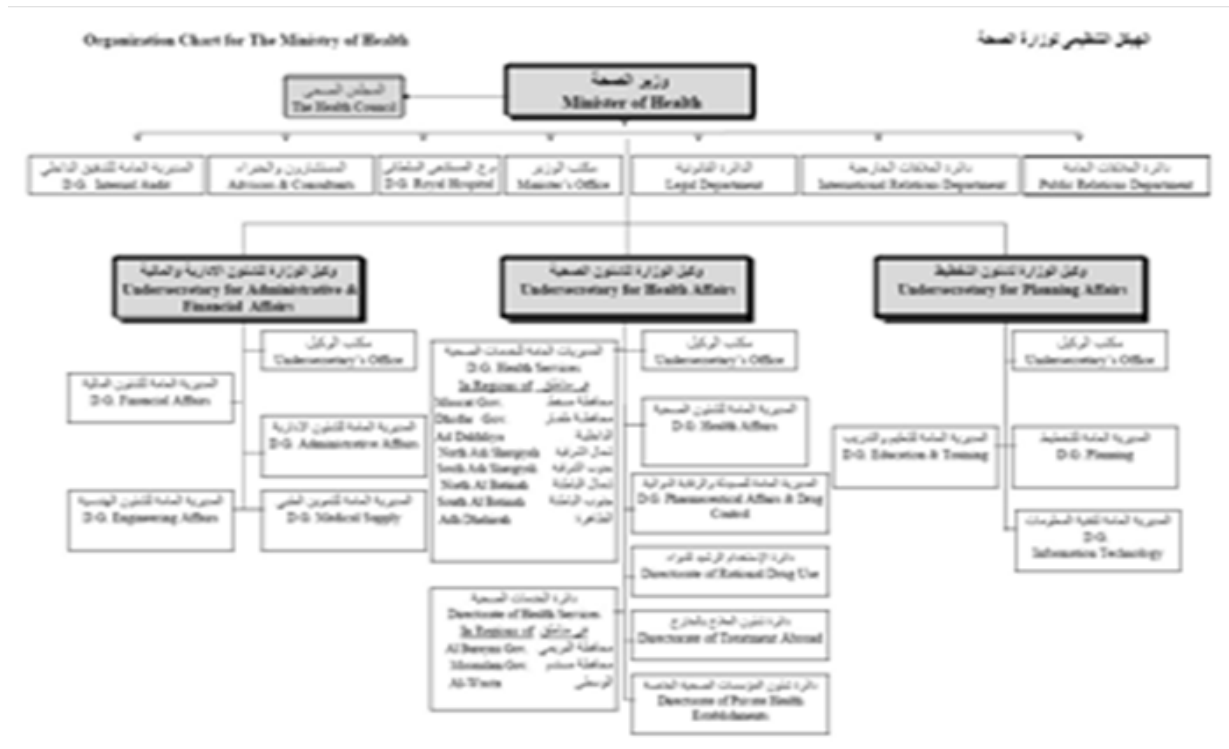
Indicator VII.11	M2	1	1			1	1	1	1	1	1	1					9	1.00
Indicator VII.12	M2	0.83	0.83	1	1	1	1	1	0.83	1	1	1					10.49	0.95
Indicator VII.13	M2	0.75	0.75	1	0.86	0.88	0.71	0.86			0.86	0.86					7.53	0.84
Indicator VII.14	M3																	
Indicator VII.15	M4	see text in narrative report																
Indicator VII.16	M4	see text in narrative report																
																	Total	6.87
																	***Final score: Procurement	6.24

Table A8. Medicine distribution vulnerability scale points

	Method	KI 1	KI 2	KI 3	KI 4	KI 5	KI 6	KI 7	KI 8	KI 9	KI 10	KI 11	KI 12	KI 13	KI 14	KI 15	Total	Average per question**
Profession*	---	G	G	G	G	G	G	G	P	P	G	G	G	G	G			
Indicator VIII.1	M1	1		0	1	1	1		1	1	1	0		1			8	0.80
Indicator VIII.2	M3																	
Indicator VIII.3	M2	1	1	1	1	1	0.75		1	1	1	0.75	1	0.75	1		12.25	0.94
Indicator VIII.4	M1	1	1	1	1	1	1	1	1	1	1	1	1	1	1		14	1.00
Indicator VIII.5	M2	1	1	1	1	1	0.67	0.33	0.67	1	1	1	1	1	1		12.67	0.91
Indicator VIII.6	M2	0.83	0.83	0.83	0.83	0.5	0.67	0.67	1	0.86	0.5	0.33	0.67	0.5	0.67		9.69	0.69
Indicator VIII.7	M1	1	1	1	1	1	1	1	1	1	0	1	1	0	0		11	0.79
Indicator VIII.8	M2	1	1	1	1	1	1	0	1	1	1	1	1	1	1		13	0.93
Indicator VIII.9	M1	1	1	1	1	1	1	1	1	1	1	1	1	1	1		14	1.00
Indicator VIII.10	M2	1	1	1	1	1	0.67	0.67	1	1	1	1	1	1	1		13.34	0.95

Indicator VIII.11	M2	1	1	1	1	1	1	1	1	1	1	0.67	1	1	1		13.67	0.98
Indicator VIII.12	M2	1	1	1	1	1	1	1	1		1	1	1	1	1		13	1.00
Indicator VIII.13	M2	1	1		0.75	0	1	0	1	1		0	0	0	0.5		6.25	0.52
Indicator VIII.14	M1	1	1	1	1	1	1	1	1	1	1	1	1	1	1		14	1.00
Indicator VIII.15	M2	0.57	0.43	0.57	0.57	0.71	0.71	0.86	0	0.57		0.71	0.71	0.71	0		7.12	0.55
Indicator VIII.16	M2	0	0.67		0.67	0	0	0	0	0	0	0	0.33	0	0		1.67	0.13
Indicator VIII.17	M2	1	1	1	1	0	1	1	1	1	0.5	1	1	1	0.5		12	0.86
Indicator VIII.18	M3																	
Indicator VIII.19	M4	see text in narrative report																
																	Total	13.04
																	***Final score: Distribution	8.15

Annex 2. Organizational structure and staffing at the Ministry of Health



Annex 3. List of evidence obtained

The following documents were gathered from various sources including government bodies and organizations and used in the assessment.

Registration of medicines

- Royal Decree no. 41/96: Law of pharmacy practice.
- Sample of list of pharmaceutical products on website.
- Application form for registration placed on website.
- Hard copy application form for registration available at the Ministry of Health.
- Checklist of registration requirements.
- Ministerial Decision no. 86/2000 on forming a technical committee for registration.
- Regulations on submission of application process.

Control of medicine promotion

- Royal Decree no. 41/96: Law of pharmacy practice.
- Article no. 4 of Ministerial Decision no. 74/2000 for organization of pharmaceutical establishments.
- Reminder for need of pre-approval of Ministry of Health for promotion material.

Control of clinical trials

- Ministerial Decision no. 108/2007 and updated with ministerial Decision no. 22/2011 on formation of committee to review and approve research studies and clinical trials from a scientific and ethical point of view.

Inspection of pharmaceutical establishments

- Royal Decree no. 41/96: Law of pharmacy practice.
- Ministerial Decision no. 74/2000.
- Instructions placed on website on inspection process.

Licensing of pharmaceutical establishments

- Royal Decree no. 41/96: Law of pharmacy practice.
- Ministerial Decision no. 7/2001 on formation of committee for licensing of pharmaceutical establishments.

Selection of medicines

- Oman National Formulary 2009 (list of essential medicines available at Ministry of Health health centres and hospitals).
- Ministerial Decision no. 99/2010 on formation of a new committee for the selection of essential medicines for Ministry of Health

Procurement of medicines

- Ministerial Decision no. 8/2000 to form an official tender committee.
- Tender conditions for the bidding process.
- Procurement process details available in Managing medical supplies, January 2011 first edition (Directorate-General of Medical Supplies, Ministry of Health, 2011).

Distribution of medicines

- Distribution process description available in Managing medical supplies, January 2011 first edition (Directorate-General of Medical Supplies, Ministry of Health, 2011).

This report presents the findings of the first phase of the national Good Governance for Medicines programme. In recent years, countries of the WHO Eastern Mediterranean Region have made significant achievements in the provision of health services. In the pharmaceutical field, countries have been striving to improve the structures and regulations pertaining to medicines and have progressed in many ways. However, there are still important challenges. The goal of the WHO Good Governance for Medicines programme is to improve the situation of medicines regulation and supply. National transparency assessment is the beginning of a process aimed at bringing about desirable and sustainable changes in the governance of the pharmaceutical sector.