Measuring transparency to improve good governance in the public pharmaceutical sector

PAKISTAN

World Health Organization
Regional Office for the Eastern Mediterranean

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Foreword

The health sector in Pakistan has undergone rapid advancements and developments in recent years. The Government of Pakistan is eager to expand its primary health care services and undertake innovative initiatives for the well-being of its growing population. The Ministry of National Health Services Regulations and Coordination is the principal health care provider and develops health policies and strategies, health programmes and plans for the health sector, while the Drug Regulatory Authority of Pakistan (DRAP) is responsible for regulating and overseeing the pharmaceutical industry of Pakistan.

As part of national efforts to ensure quality and safety of medicines in Pakistan, the Ministry of National Health Services Regulations and Coordination initiated the Good Governance for Medicines programme in Pakistan, with technical support from the World Health Organization (WHO). This assessment identifies areas to be addressed to ensure a comprehensively regulated system for the governance of pharmaceuticals. DRAP has taken the necessary measures to formulate new policies to rectify deficiencies and vulnerabilities in the effective regulation of the process of drug manufacturing in Pakistan, which will, in turn, increase exports.

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 Pakistan. 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 health sector to benefit from the lessons learnt from this assessment. I also hope the Pakistani experience in measuring and improving good governance in this critical sector contributes to the global learning process and struggle to ensure full and affordable access to quality essential medical products within the global goal of universal health coverage.

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Federal Government of Pakistan, Islamabad
December 2015

Preface

Corruption is a major obstacle to strengthening the pharmaceutical system and increasing access to quality medicine in countries such as Pakistan. In an effort to address this complex and multifaceted challenge, WHO launched the Good Governance of Medicines programme to address the need for transparency and to improve the situation of medicines regulation and supply. Guided by the WHO Medicines Strategy and launched in late 2004, the Good Governance of Medicines programme seeks to ensure that essential medicines reach the people who need them.

Medicines represent one of the largest components of health expenditures. The value of the pharmaceutical market is increasing steeply over time at a faster rate than total health expenditure and even more than the growth of gross domestic product worldwide. The sheer scale of the market makes it a very attractive target for abuse and greed is often reported as a main cause of corruption. There are other reasons for the vulnerability of this sector, including the existence of many stakeholders whose roles, responsibilities and accountability relationships are often not clearly defined. Information imbalance between health care providers and patients, and between pharmaceutical companies and regulators, is a critical factor. Finally, regulation of the health sector is poorly resourced or implemented.

The World Bank has identified corruption as the greatest obstacle to economic and social development. As the good governance project grows, more and more national medicine 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 introduced in some 30 countries around the world.

This report presents the findings of the first phase of the national Good Governance of Medicines programme in Pakistan. 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. The assessment looked at eight functions: registration of medicines, licensing of pharmaceutical establishments, inspection and market control of medicines, medicines promotion control, clinical trials of medicines, selection of medicines, procurement of medical products and distribution of medicines. The data on the eight functions was collected from the four provinces of the country through carefully selected key

informants (KIs) using a structured questionnaire by a team of national assessors.

The diagnostic framework and the methodology that this assessment introduces can help researchers, health specialists and government decision-makers to prioritize those areas in the pharmaceutical system that need the highest attention, investment and regulation. In this way, the framework helps to ensure that investments in the pharmaceutical system are maximized and that access to essential medicines by the public is enhanced.

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 change 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 to identify vulnerable aspects of the pharmaceutical system that 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 assessment of good governance in medicine in Pakistan was conducted by a team of four experts who were selected as the national assessors: Dr Azhar Hussain, Dr Tofeeq Ur-Rehman, Dr Nadeem Irfan Bukhari and Mr Muazzam Ali Khan. They were responsible for conducting the interviews using the transparency assessment tool developed by WHO. They collected, compiled and analysed the data from the interviews that were conducted in Pakistan between the third and fourth quarter of 2014. The data represent the opinions of key informants (KIs) knowledgeable about the pharmaceutical sector of Pakistan. WHO wishes to acknowledge their contribution.

WHO also acknowledges with appreciation the support of: Mrs Saira Afzal Tarar, Minister of State, National Health Services, Regulations and Coordination, Mr Mohammad Ayub Sheikh, Federal Secretary, and Mr Imtiaz Elahie, Former Federal Secretary, Ministry of National Health Services, Regulations and Coordination, and Dr Mohammad Aslam Khan, Chief Executive of Drug Regulatory Authority of Pakistan (DRAP) for their support during all phases of the planning, conducting and finalizing of this assessment. They provided strong support to the Assessment Team and to the study as a whole, demonstrating their eagerness to ensure transparency and accountability in the Ministry's pharmaceutical services.

WHO is grateful to the Chief Drug Inspectors of the four provinces who substantially assisted the study in identifying KIs for data collection. Thanks are also due to the KIs themselves, who provided their time and the required information.

Finally, WHO would like to thank its national counterparts, Dr Ayaz Ali Khan and Dr AQ Javed Iqbal, and the data collection facilitators Dr Ubaid Ali at Karachi, Abid Hayat at Peshawar and Dr Noman ul Haq at Quetta. The services of Mr Jamshaid ARH Qureshi are acknowledged for his coordination and the writing of this report.

Executive summary

This report presents the results of a transparency assessment of the public pharmaceutical sector in Pakistan. It gives a comprehensive assessment of the level of transparency and vulnerability to corruption within eight primary functions of the pharmaceutical sector: registration of medicines, licensing of pharmaceutical establishments, inspection and market control of medicines, medicines promotion control, clinical trials of medicines, selection of medicines, procurement of medical products and distribution of medicines.

The methodology, applied in accordance with the WHO assessment instrument, provides both qualitative and quantitative information. Two teams of national assessors, nominated from academia and the pharmaceutical regulatory authorities in Pakistan, collected the data through interviews with carefully selected key informants (KIs). The information collected was then converted using a quantification method into a zero to 10 scale to provide a score for each function in terms of vulnerability to corruption.

Medicines registration

The area of medicines registration has been determined to be moderately vulnerable to corruption. An up-to-date list of registered products is not available. However, data about registered medicines are available in the form of notifications circulated after meetings of the Registration Board. The applications forms, along with the procedure for submitting an application for registration of medicinal products, are comprehensive, published in the official gazette and available from the Registration Office. The procedure/forms are a reflection of the Drugs (Licensing, Registration and Advertisement) Rules 1976 framed under the Drugs Act 1976. Written procedures describing the process to be followed in assessing submissions are not available and there is no timeframe for processing applications. The principal weakness in the area of medicines registration is the absence of written conflict of interest guidelines. The members of registration committees are not required to sign any declaration of conflict of interest. A registration board for registration of medicinal products is functional in the country, but the criteria for the selection of members of the board and their terms of reference are not laid down. Although written guidelines on the decision-making process do not exist, the KIs believe that the registration committee follows consistent procedures developed over years of practice. Lack of transparency and illegal rewards were highlighted as the most unethical behaviours in this area of assessment.

Licensing of pharmaceutical establishments

It is mandatory in Pakistan to have a license in order to operate any pharmaceutical establishment. The granting of licenses for manufacturing drugs is regulated under the Drugs (Licensing, Regulation and Advertisement) Rules 1976. The Drug Regulatory Authority of Pakistan (DRAP) is responsible for issuing drug manufacturing licenses for formulations, basic manufacture, repacking and experiment. The licenses for sale, storage, stocking and distribution of drugs are issued by the provincial authorities, in accordance with the drugs sales rules of the province. The written procedure for submission of applications for manufacturing licenses is available at the DRAP website, which illustrates the criteria, requirements and procedures to be followed by applicants, along with the prescribed fee. However, the timeframe for processing the application is not stated. A comprehensive up-to-date list of all pharmaceutical establishments (manufacturers, retailers and distributers) is not available from any of the authorities. However, the list of manufacturing license holders is available from DRAP (611 at present). Sixty-five percent of KIs agreed or strongly agreed that the licensing of pharmaceutical establishments in Pakistan is systematically carried out according to the policies and procedures. The licensing of pharmaceutical establishments has been found to be marginally vulnerable to corruption.

Inspection and market control

The inspection and market control of medicine manufacturers and distributors was found to be marginally vulnerable to corruption. There is comprehensive provision in the medicines legislation covering the inspection of medicine manufacturers and distributors and there are written standard operating procedures for inspectors on how to conduct an inspection. These procedures are available in writing to the inspectors in the form of a checklist but are not publicly available. They include the requirements for pre- and post-inspection activities, a scheduling system that identifies companies due for inspection within a set timeframe, and the format and content of inspection reports. No written guidelines exist on conflicts of interest with regard to inspection activities, there are no written procedures to prevent regulatory capture and no external auditing of inspections is carried out by inspectors from another country. However, DRAP and the Provincial Quality Control Board have unwritten procedures to help to prevent regulatory capture, including the rotation of inspectors and visiting sites for inspection in teams with a team leader.

Medicines promotion control

The area of medicine promotion control has been assessed to be very vulnerable to

corruption. The legal provisions on promotion of medicines encompass advertisement to the public and professionals, packaging, labelling and package inserts. However, the provisions do not cover free samples, symposia and scientific meetings (in-country and abroad), post-marketing scientific studies, speaker and consultancy fees, promotion of exported medicines, and restrictions on gifts and other benefits. Any person in breach of any provision of the law is liable for imprisonment and fine, but this is generally not enforced satisfactorily. There is no formal procedure for reporting unethical promotional practices, no committee responsible for monitoring and enforcing the provisions on medicines promotion and no written guidelines on conflicts of interest with regards to control of advertisement. A number of unethical behaviours were identified in medicine promotion involving both health professionals and health institutions in general and the regulatory office staff and committee members responsible for controlling medicine promotion.

Clinical trials of medicines

The clinical trials of medicines function has been rated as very vulnerable to corruption. Clinical trials of medicines in Pakistan are regulated under Drug Research Rules 1978, amended in 2013. National guidelines on the principles of good clinical practice are available from the pharmacy services division of DRAP, although most of the KIs were unaware of them. Written guidelines on submission of applications to DRAP prior to conducting a clinical trial are not publically available, but a form for submission of a clinical trial proposal along with a checklist can be obtained from DRAP. There is no written policy or procedure for submission of a clinical trial application to the independent ethics committee that covers the acceptability of trial investigators, suitability of trial protocols, means of recruiting trial subjects, adequacy and completeness of information, provision of compensation in case of injury or death of subjects and form of payment or remuneration by the trial sponsor. The form for submission of a clinical trial proposal requires submitting prior approval from an ethics committee with the name and designation of its members. Conflict-of-interest guidelines on clinical trial activities have not been notified so far and there is no list or database of those clinical trial applications approved or rejected by the authority. For improvement in this function, the KIs highlighted issues and actions relating to ethics and good clinical practice.

Selection of medicines

The selection of medicines function was rated as very vulnerable to corruption. The government has officially adopted an essential medicines list that is available through the public health system and helps the government purchase appropriate drugs for the population. Health institutions in the public sector at various levels

(primary, secondary and tertiary) have also developed their own lists/formularies of drugs according to their needs and budgets. The essential medicines list, which seems to have been developed in consultation with interested parties and the government, has clear guidelines that specify what criteria have been applied for medicines to be included in or deleted from the list. However, it contains no reference to national standard treatment guidelines. A selection committee that includes physicians of different specializations and pharmacists has been appointed to provide technical advice on the revision and updating of the essential medicines list. There are no written conflict of interest guidelines or declaration form. Common unethical behaviours noted by the KIs include favouritism, gifts, political influence and misuse of authority.

Procurement of medical products

Procurement of medical products was found to be moderately vulnerable to corruption. The government has a document that describes the procurement process for pharmaceutical products under the Public Procurement Regulatory Act and the rules framed by it. The document is publicly available and requires: the use of generic names; the advertisement of tenders; making contract specification publicly available; including criteria for adjudication of tenders as part of the tender package; making information on the tender process and results publicly available; and a description of the internal process to be followed by procurement staff when processing bids. A formal appeal process is available for applicants who have had their bids rejected. The principal weaknesses are the absence of written conflict of interest guidelines with regard to the procurement process or a conflict of interest declaration for tender committee membership. The procurement office has to undergo external auditing through the Auditor General at least once a year and each drug shipment is physically inspected. The KIs noted the unethical practices of favouritism, illegal gifts, administrative and political pressure, and undue delay in payment of bills, with only 20% of KIs agreeing that the procurement system in Pakistan operates in a totally transparent manner.

Distribution of medicines

The distribution of medicines has been rated as marginally vulnerable to corruption. The government has transparent and explicit procedures that describe the distribution process for pharmaceutical products. A designated staff member is responsible for checking receipts against the packing list when supplies arrive at the warehouse. The responsible person prepares documentation through a receiving report on the basis of the invoice, specifying the types, quantities and condition of the supplies received. Government medicines can be identified by imprints on containers and external packaging in conspicuous ink reading "Government property – not for sale". At tertiary and secondary care hospitals there is systematic

and orderly shelving of products in warehouses. There are explicit standard operating procedures for stock management at each level of distribution that provide information regarding average working stock, amount of safety stock, frequency of reordering, quantity of reordering, average inventory and expiry date for each product. There are inventory records and procedures in warehouses at the various levels of the distributing system. The warehouses are subject to internal and external auditing. A computerized system provides information on medicines that have left a warehouse to specific health facilities. Products in warehouses are organized systemically by dosage forms: tablets and capsules, injections, syrups and suspensions, creams and ointments. The dosage forms are arranged according to therapeutic action. Sanctions are imposed on individuals for theft or corrupt practices. The principal weakness is the absence of effective security management for storage and distribution and the lack of a programme for monitoring and evaluating the performance of the medicines distribution system.

1. Introduction

The most important factor influencing good governance in medicine in any country is the level of priority and support accorded to tackling corruption in general. Where anti-corruption programmes and processes are already in place across many sectors, good governance in medicine is able to achieve significant progress more speedily. Additional momentum is achieved when support emanates from high political levels, especially from senior decision-makers.

This assessment has been conducted to provide a comprehensive picture of the level of transparency and potential vulnerability to corruption in the eight chosen functions in the pharmaceutical sector in Pakistan. The functions assessed and evaluated during the study include: registration of medicines, licensing of pharmaceutical establishments, inspection and market control of medicines, medicines promotion control, clinical trials of medicines, selection of medicines, procurement of medical products and distribution of medicines. The structures and processes involved in each of these functions must work optimally to ensure the availability of safe, effective and appropriate medicines of the required quantity and at reasonable cost.

Transparency means clarity, truthfulness and openness, and is the golden principle on which the duty of civil servants, managers and trustees to act openly, predictably and understandably rests. Those affected by administrative decisions should be informed of the process and the decisions taken. Transparency encompasses access, relevance, quality and reliability, and describes the increased flow of timely and reliable economic, social and political information. It facilitates institutions and the public to make informed political decisions, improves accountability in the public sector and reduces the scale of corruption. Transparency is also essential to the financial and economic system; it improves resource allocation, enhances efficiency and increases growth prospects. Absence of transparency in the pharmaceutical sector can dissipate resources, which in turn reduces the availability of essential medicines and so threatens the well-being of the population at large.

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 personal 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 the stakeholders and the provision of easy access to information at all levels.

This report summarizes the findings of the national transparency assessment in the public pharmaceutical sector that was carried out in Pakistan from July to December 2014 in accordance with the WHO assessment instrument. The 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 good governance for medicines programme in Pakistan.

The objectives of the assessment were to collect facts and perceptions on eight identified functions of the public pharmaceutical sector from policy-makers, industry, academia, national and international nongovernmental organizations, media and other stakeholders.

The specific objective of the study was to assess the level of transparency and vulnerability to corruption in the procedures and structures of the following eight functions of the pharmaceutical sector in Pakistan:

- medicines registration
- licensing of pharmaceutical establishments
- inspection and market control
- medicine promotion control
- clinical trials of medicine
- selection of medicines
- procurement of medical products
- distribution of medicines.

The findings of the study will be used to advance a national good governance for medicines framework and in the implementation of a national good governance for medicines programme.

2. Overview of the public health sector in Pakistan

2.1 Country information

Pakistan has a 1046 kilometre coastline along the Arabian Sea and is bordered by Afghanistan and Islamic Republic of Iran in the west, India in the east and China in the far north-east. It covers an area of 796 095 km^2 and is the thirty-sixth largest state by area. It is a federation of five provinces, a capital territory and a group of federally administered tribal areas. Pakistan's estimated population in 2014 was over 188 million, making it the world's sixth most populous country. During 1950–2011, Pakistan's urban population expanded more than sevenfold, while the total population increased more than fourfold. In the past, the country's population had a relatively high growth rate, but that has now been changed by a moderate birth rate. In 2014, the population growth rate stood 1.49%. Pakistan is a multicultural and multi-ethnic society and hosts one of the largest refugee populations in the world as well as a young population.

2.2 Public sector health facilities

Although health care services in Pakistan are provided by public and private providers, the government is considered by far the main provider of preventive care throughout the country and the major provider of curative services in most rural areas. In the public sector, health services are provided through a tiered referral system of health care facilities with increasing levels of complexity and coverage from primary to secondary and tertiary health facilities. Primary care facilities include basic health units, rural health centres, government rural dispensaries, mother and child health centres and tuberculosis centres. All these facilities provide outpatient services for preventive care and a limited number of curative services, while rural health centres provide a broader range of curative services. Primary care facilities also provide outreach preventive services to communities through vaccinators, sanitary inspectors and sanitary patrols. Tehsil and district headquarter hospitals provide increasingly specialized secondary health care, while teaching hospitals from the tertiary level tier.

2.3 Overall state of health in Pakistan

The health care system of Pakistan, though well structured, has problems similar to many other developing countries. The public sector, which is responsible for the health care of the majority of the population, is backed by government and private sector functions that take a commercial approach. Government spending on health care is about 1% of gross domestic product (GDP), which is less than the spending in other countries. Seventy-six per cent of health care expenditure in Pakistan is for out-of-pocket expenditure.

In the public sector, health care provision is decentralized and is principally the responsibility of government at the provincial level. The Federal Ministry of National Health Services, Regulations and Coordination looks after national policy, planning, coordination and implementation of the six national health programmes: immunization, family planning, tuberculosis, HIV/AIDS, malaria, tobacco control and nutrition.

Pakistan is among those countries with the highest share of out-of-pocket payments relative to total health expenditure. The landscape of public health service delivery presents an uneven distribution of resources between rural and urban areas: the rural poor are at a clear disadvantage in terms of primary and tertiary health services, and also fail to benefit fully from public programmes such as immunization of children. The poor state of public facilities overall has contributed to the diminished role of public health facilities, while the private sector's role in the provision of service delivery has increased enormously. Following the 18th amendment to the Constitution of Pakistan, the health sector has been devolved to the provinces, but the distribution of responsibilities and sources of revenue generation between the tiers remains unclear. A multipronged national health policy is needed that tackles the abysmal child and maternal health indicators, and reduces the burden of disease.

There is scarcity of qualified and trained staff, essential medicines, and medical and other supplies in most public health facilities. As a result, patients have to seek medical care in the private health sector. The health care system is urban-biased, with private sector health care facilities mainly concentrated in urban areas, making it difficult for the rural poor to access the facilities and meet the expenses of treatment. Patients have to seek health care in the private health sector or from alternative sources (herbalists/*hakeems*), as observed in the latest Pakistan Social and Living Standards Measurement Survey (Federal Bureau of Statistics).

2.4 Pharmaceutical sector

The pharmaceutical industry in Pakistan has grown during recent decades, almost entirely in pharmaceutical formulation. At the time of Pakistan's independence in 1947, there were few production units in the country. Currently, Pakistan has about 600 low technology large volume pharmaceutical formulation units, mainly run using Chinese equipment, including those operated by the 25 multinationals present in the country. The Pakistani pharmaceutical industry meets around 70% of the country's demand for finished dosage forms and 4% of its demand for active ingredients. Specialized finished dosage forms such as soft gelatine capsules, parenteral fat emulsions and metered-dose inhalers continue to be imported. There are only a few bulk drug active ingredient producers and the country largely depends on import of bulk drugs for its formulation needs, resulting in frequent drug shortages.

Pakistan has a growing pharmaceutical industry which has a market value of approximately US$ 2.3 billion. The pharmaceutical needs of the country are met through local manufacturing (80%) and imports (20%). Pakistan also exports pharmaceuticals regionally and worldwide. The number of currently registered pharmaceutical formulations exceeds over 65 000. The current pharmaceutical market share by value is 60% to multinational companies and 40% to local manufacturers, but the situation is the opposite in terms of share by volume, which is 60% to local manufacturers and 40% to multinational companies. The price of medicines plays a vital role in access to medicines and pricing has been an ongoing challenge for the country. The pharmaceutical market is a brand market with dozens of different brands for an individual molecule registered in the country. The value of pharmaceuticals sold nationwide exceeded US$ 1.4 billion in 2007 and US$ 2.3 billion in 2012, and is expected to exceed US$ 3.2 billion by 2014. As of 2013, the total export value of Pakistani-manufactured medicines stood at US$ 500 million.

2.5 National health policy

The national health policy is based on a vision of providing health care for all. The policy adopts a focused approach through recognized strategies for the health sector. A principal feature of the policy is health sector investment as an element of the government's poverty alleviation plan, with priority given to primary and secondary health care to reduce the load on tertiary care facilities. The policy envisions good governance as a milestone towards achieving quality health care. It identifies specific areas, with targets, including reducing the incidence of transmissible diseases, minimizing the malfunction of primary and secondary health care, eliminating administrative inefficiency at the district level, encouraging better gender equity, improving the population nutrition status, reducing the urban bias of the health system, implementing drug regulation of community pharmacies, creating mass

awareness on public health issues, improving the drug sector and enhancing the capacity to monitor health policy status and implementation.

2.6 National medicines policy

A national medicines policy is an integral part of the national health policy, which commits to ensuring equitable access to and rational use of safe and effective medicines. The Ministry of National Health Services, Regulations and Coordination drafted a national medicines policy in line with the recommendations of WHO's Drug Action Programme in 1997. The eight objectives of the policy promised to develop and promote essential medicines with regular and uninterrupted supply, promote the rational use of medicines use to safeguard public health from inappropriate medicines, attain self-sufficiency in medicines by encouraging local sources of raw materials, protect the public from substandard medicines, develop adequately trained human resources in medicines management, develop a research base in the country and develop the pharmaceutical industry. The policy has two broader domains: promotion of the pharmaceutical industry and the promotion and protection of public health. There is currently a need to review the national medicines policy and its implementation.

2.7 Drug regulation in Pakistan

Drugs and drug-related matters in Pakistan are regulated by the Drugs Act 1976 that replaced the Drugs Act 1940. There are more than 40 sets of rules framed under the provisions of the Drug Act 1976. The sale of drugs in Pakistan had been controlled by the Drug Act 1940 until the Generic Names Act 1972 that stipulated that drugs were to be prescribed, dispensed, sold, or distributed by their generic names only. This act was not put into practice due to pressure from multinational pharmaceutical companies. The Drugs Act 1976 and the rules framed by it regulate the registration, manufacturing, marketing, sales, import, export and quality assurance of medicines in Pakistan. However, as a result of the 18th amendment to the Constitution of Pakistan in 2010, health has been devolved to the provincial level, necessitating the formulation of new laws by the provincial governments.

2.8 Drug Regulatory Authority of Pakistan

The Drug Regulatory Authority of Pakistan (DRAP) at the Ministry of National Health Services, Regulations and Coordination is responsible for the regulation of the pharmaceutical sector in Pakistan. DRAP performs its functions in accordance

with the DRAP Act 2012 and the Drugs Act 1976 and the rules framed by it. The Authority has a full time chief executive officer and 13 directors to manage drug affairs in the country. The general direction, administration and monitoring of the authority is vested in the policy board, which consists of 15 members, including the Secretary of the National Health Services, Regulation and Coordination Division of Pakistan who serves as chairperson. The chief executive officer of DRAP is secretary of the policy board. Other members of the board include representatives from the Ministry of Law, the secretaries of all provincial health departments and six experts from the public and private sectors. There are field offices of DRAP located in the provincial headquarters and responsible for monitoring drug manufacturing licenses and good manufacturing practices. The sale of medicines and post-marketing surveillance is the responsibility of provincial governments who have inspectors for this purpose in all provinces at tehsil and district levels. At the provincial level, provincial quality control boards are responsible for reviewing complaints reported by inspectors and granting permission for prosecutions.

2.9 Health care providers

There are 116 298 physicians, 48 446 nurses, 7862 dentists, 21 000 pharmacists and 31 000 pharmacy assistants in Pakistan, a quite low number compared to the country's population. Medical doctors are dominant and hold the major health sector administrative and decision-making positions.

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 and four methods 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.

The Minister of National Health Services, Regulations and Coordination and the Chief Executive Officer of DRAP were informed about the assessment objectives, methodology and the process to be followed during the course of the study. DRAP accorded formal permission to WHO to undertake the study interviews using national assessors. DRAP provided administrative support for the assessment and a focal person for each team was nominated by the Government of Pakistan to facilitate the process.

To implement the study, DRAP, in consultation with WHO, nominated four national assessors, divided into two teams. Three of the national assessors were from academia and the one was a former senior health regulator. The teams were assigned to work independently: team 1 was responsible for the Islamabad Capital Territory (ICT), Khyber Pakhtunkhwa, Sindh and Baluchistan, while team 2 was responsible for Punjab province. The national assessors managed the whole assessment process after receiving training from WHO on the assessment methodology and the collection of related materials, laws and regulations relevant to each function for validating information on structural indicators and comparison with the evidence provided by the key informants (KIs). The questionnaires were administered by the national assessors during formal interviews with KIs chosen from across the different functions. The resulting data were compiled and analysed and a final report produced containing the study findings.

3.2 Selection of key informants

A qualitative approach for selection of KIs was used to allow a flexible interactive exploratory approach. In qualitative research, there are no adequate guidelines for estimating sample size; the sample size is estimated to reach saturation point by the assessors. Snowball sampling is particularly popular and is considered the best way to identify respondents with certain attributes or characteristics. Therefore, a snowball sampling technique was used for identifying the KIs for the study.

The KIs were identified with the assistance of DRAP through personal contacts, comprising provincial drug regulators, pharmaceutical companies, private entrepreneurs, nongovernmental organizations and the media. The selected KIs had direct involvement in the pharmaceutical sector and were apparently knowledgeable about the subject of the assessment. Inclusion of senior, mid-level and junior officers from all sectors added diversity. The KIs consisted of public officials including pharmacy staff at DRAP, staff from the central warehouse, the inspection department, the procurement office and the primary health care programme, members of the registration board and the tender committee, and representatives from large and small governmental hospitals. From the private sector, KIs included representatives from local manufacturers, and large and small pharmaceutical companies. Table 1 shows the distribution of KIs across the public and private sectors, nongovernmental organizations, international organizations and the media.

Table 1. Distribution of KIs across public and private sector, nongovernmental organizations, international organizations, academia and the media

Functions	Public sector	Private sector	NGOs	International organization	Academia	Media	Total KIs/function
Registration	6	20	0	0	1	0	27
Licensing	6	12	1	0	1	0	20
Inspection	16	10	0	0	0	0	26
Promotion	6	12	0	0	0	1	19
Clinical trial	6	8	0	0	1	0	15
Selection	13	7	0	0	0	0	20
Procurement	12	10	1	1	0	0	24
Distribution	5	10	1	0	0	0	16
Total KI/type	70	89	3	1	3	1	167

3.3 Conducting the interviews

The identified KIs were contacted in person or by telephone to set up an appointment for the interview. The interviews were conducted by the national assessors in person at a time and place of convenience for the KIs. Team 1 conducted interviews in ICT, Khyber Pakhtunkhwa, Sindh and Baluchistan provinces, while team 2 conducted the interviews in Punjab province.

3.4 Data collection and scoring

During the study period from July to December 2014, data collection involved utilizing the questionnaire forms provided in the WHO Good Governance for Medicines instrument to interview a total of 167 KIs: 27 KIs for the registration function, 20 KIs for the licensing function, 26 KIs for the inspection and market control function, 19 KIs for the promotion function, 15 KIs for the clinical trials function, 20 KIs for the selection function, 24 KIs for the procurement function and 16 KIs for the distribution function. Only answers under methods 1 and 2 were counted in the final score. Answers to methods 3 and 4 questions were of a qualitative nature and were noted by the assessors during the interview and summarized for the report.

Method 1 requires that each indicator gave a binary answer, either "yes" or "no". A "yes" was given a value of "1" and a "no" was assigned a value of "0", depending on the availability of supporting documentation. Method 2 involved questions with a series of sub-criteria. Each criterion is to be answered by "yes", "no" or "don't know". The total "yes" answers are 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.

Method 3 involved subjective questions that probe the perceptions of the KIs. The KIs were asked for each statement if they strongly agreed, agreed, were undecided, disagreed, strongly disagreed, found not applicable or did not know. Frequencies

were used to present the results. Method 4 used open questions. KIs could also provide additional input on the function in general.

3.5 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 the analyses and record keeping. The names and identities of the 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.

Table 2. Scale for degrees of vulnerability to corruption

0.0–2.0	2.1–4.0	4.1–6.0	6.1–8.0	8.1–10.0
Extremely vulnerable	Very vulnerable	Moderately vulnerable	Marginally vulnerable	Minimally vulnerable

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 167 KIs. The functions of selection of medicines, clinical trials and promotion of medicines were found to be very vulnerable to corruption, while licensing of pharmaceutical establishments and distribution of medicines were only marginally vulnerable. The functions that were moderately vulnerable were medicines registration, inspection and market control, and procurement of medical products. The scores given are an average of the scores for all the KIs for that indicator for a function.

4.1.1 Scales of vulnerability

The overall vulnerability scores for each of the eight functions are summarized in Table 3. The scores for the individual indicators for each function are presented in Annexes 1 and 2.

4.1.2 Perceptions of KIs

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

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

Indicator	Reg	Lic	Ins	Prom	CT	Sel	Proc	Dist
1	0.0	1	0.962	0.84	0.87	0.70	0.75	0.56
2	0.40	1	0.923	0.60	0.60	M3	0.38	M3
3	0.81	0.86	0.624	0.64	0.56	0.44	0.29	0.76
4	0.48	0.8	0.325	0.58	0.41	0.42	0.75	0.78
5	0.86	0.85	0.230	0.16	0.60	0.70	0.86	0.75
6	0.22	0.95	0.615	0.37	0.40	M3	M3	0.87
7	0.78	0.28	0.595	0.14	0.27	0.25	0.46	0.83
8	0.53	0.62	0.592	0.22	0.20	0.08	0.04	0.94
9	0.58	0.9	M3	0.32	0.41	0.18	M3	0.72
10	0.01	0.60	M3	0.20	0.27	0.31	0.30	0.85
11	M3	M3	M4	M3	0.14	M4	0.88	0.92
12	0.29	0.9	M4	M3	0.15	M4	0.44	0.81
13	0.96	M3	---	M3	M3	---	0.70	0.67
14	M3	M4	---	M3	M3	---	M3	0.89
15	M3	M4	---	M4	M3	---	M4	0.59
16	M4	---	---	M4	M4	---	M4	0.57
17	M4	---	---	---	M4	---	---	0.67
18	---	---	---	---	---	---	---	M3
19	---	---	---	---	---	---	---	M4
Total*	5.94	8.76	4.87	4.07	4.87	3.08	5.84	12.17
Final score**	4.94	7.96	6.08	4.07	4.05	3.85	5.31	7.6
Degree of vulnerability	Mod	Marg	Mod	Very	Very	Very	Mod	Marg

Note: Reg = Registration; Lic = Licensing; Ins = Inspection; Prom = Promotion; CT = Clinical trials; Sel = Selection; Proc = Procurement; Dist = Distribution; M3 = Method 3; M4 = Method 4; Mod = Moderate; Marg = Marginally.
The scores given are an average of scores for all KIs for that indicator for a function.
*Total = Sum of all average scores for Method 1 and Method 2 only indicators.
** Final score = Total divided by number of indicators and multiplied by 10.

4.2 Data presentation

The following section presents qualitative information collected through interviews for each indicator. The detailed scores are presented in tables in Annexes 1 and 2. Some indicators that are based on the opinion of KIs on the types of unethical

behaviour common in the registration system, in licensing, in the control of medicine promotion, in clinical trials, in inspection, in the selection process and in the procurement system could not be presented in the tables. The results of the indicators based on method 3 and 4 are not depicted in tables. A summary of qualitative indicators has been presented with the relevant indicator. The KIs were also asked for the first action that they would take to improve the quality and transparency of each service. Their responses have been listed at the conclusion of each of the eight functions. Their answers are summarized.

4.2.1 Medicine registration

In Pakistan, Section 7 of the Drugs Act 1976 regulates the registration of drugs. The applications for registration are decided by the Registration Board set up pursuant to Rule 24 of the Drugs (Licensing, Registration and Advertisement) Rules, 1976 (LRA 1976).

At present, the Registration Board is comprised of 14 members representing different specialties in pharmaceutics. The procedures for drug registration are laid down under Rules 26 and 29 of LRA 1976. A summary is available online. A separate application is required for each drug on forms 5/5-A/5-D/5-E for locally-manufactured/imported/new molecule/patent drugs, respectively. The assessment is carried out by registration office staff, the Dossier Evaluation Cell, inspection teams, reviewers and expert committees (Expert Committee on Biological Drugs for biological drugs and Veterinary Expert Committee for veterinary drugs) constituted under Section 10 of the Drugs Act 1976. Where the Registration Board is satisfied with the safety, efficacy, quality and economic value of the drug, the registration is approved and the certificate of registration is issued on Form 6. The Registration Board may reject the application/cancel the registration if it is not satisfied. The aggrieved party may appeal against such decisions to the Appellate Board set up under Section 9 of the Drugs Act 1976.

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

An up-to-date list of products registered in Pakistan is not available and the most recent version is not available online or in print form. Lists are sporadically available from the registration department of DRAP. All KIs were aware of this situation.

Indicator I.2: If such a list exists, does it provide a minimum level of information?

Data on registered medicines are available in the form of notifications circulated after meetings of the Registration Board, which is the competent authority to decide

on the registration and de-registration of medicinal products in Pakistan. These notifications only provide the registration number, name of product, name of manufacturer, authorized distributor in case of imported drugs and general conditions of registration. The notification does not include the site of manufacture. There is no specification for the medicine's status, such as prescription only or over the counter. With the exception of narcotics and psychotropic medicines, all medicines can be bought without prescription. This indicator scored 40%.

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

The applications forms and the procedure for submitting an application for registration of a medicinal product are lucid and comprehensive, published in the official gazette and available from the registration office, in addition to being available on the DRAP website. The procedures/forms reflect the Drugs (Licensing, Registration and Advertisement) Rules 1976, framed under the Drugs Act 1976. The form describes the process to be followed for submitting an application, the data to be submitted and the fee and criteria for drug registration. However, the form does not mention the timeframe for processing the application.

The fee for registration has been revised lately and there is a special procedure for fast track registration with additional fees. In the interviews with KIs, it was revealed that although there is a timeframe for meetings of the Registration Board, there is no timeframe for processing applications for registration. The decision on registration is delayed in most cases and one of the KIs reported that some applications submitted during 2010 had not been decided yet.

Most of the KIs were aware of this practice. This indicator scored 81%.

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

The assessment of submitted application falls under the domain of the Registration Board, pursuant to the Drugs Act 1976 and the rules framed thereunder. The assessment is assisted by the registration office staff, Dossier Evaluation Cell and co-opted evaluators (as approved by the Board in specific cases). A checklist is available from the Dossier Evaluation Cell, and has been posted on the DRAP website, which serves as a guideline for assessors and applicants. However, during the interviews it became clear that there is no specific procedure laid down for evaluators and the registration office staff. As such, there are neither written procedures available to describe the process to be followed in assessing submissions, nor any timeframe for processing. Specific guidance for report writing is also not available.

This indicator scored 48%.

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

An application form is available on the DRAP website and from the registration office, while form 5 of LRA 1976 is available in the manual of the drug laws. All KIs were aware that the form is publicly available. The application form requires information on the name of the product (brand and international nonproprietary name), composition per unit, a brief summary of method of manufacture, specification of pharmaceutical ingredients, summary of product characteristics, inserts and labelling information. However, it does not require specification of pharmaceutical excipients and packaging material.

This indicator scored 86%.

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

There are no guidelines on time limits for meetings between government officers and applicants, but there are prescribed official days of the week when such meetings can take place. However, government officials report that an office notification is in place which states the visiting hours to be followed for meetings with representatives of pharmaceutical companies. When documents are missing in the pharmaceutical dossier, or when clarification is needed, the applicant can seek a meeting with government officials. In practice, any company representative can meet any government official, depending on the official's availability and will.

The KI response for this indicator scored 0.21, confirming this.

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

There is a functional and operational Registration Board for registration of medicinal products in the country. The members of the Board have responsibility for making registration decisions on the agenda items placed before the Board by the registration office staff and vetted by the Dossier Evaluation Cell. The members may ask for specific clarification/information from the registration office staff or may refer to a specific evaluator, if required. Most KIs believed that the Registration Board is the committee responsible for assessing applications for registration; some said that the Dossier Evaluation Cell is responsible for providing an opinion to recommend or reject an application. This is the reason that the indicator received a high score.

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

The composition of the Registration Board and the expertise/timeframe for members, other than ex-officio members, is notified in the DRAP Act 2012/LRA 1976. This was indicated by the KIs for availability of written criteria; however, the requirement for declaration of conflicts of interest is not included. The members of the Board are designated by position as per LRA 1976 and comprise representatives of the registration office (secretary), academia, pharmacists and physicians. All members have appropriate professional qualifications and technical skills. Some KIs said that members with the requisite expertise and skills are proposed according to personal preference/contact. The Federal Government approves and notifies the composition of the Board.

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

The competent authority issues the notification for composition of the Registration Board, which is published in the official gazette available to the public. The notification includes the name and designation of members without referring to the duties/quorum/term (as per the Drug Act 1976). The specific responsibilities, obligations, accountability and financial benefits of members are not stated in the notification. For this reason, this indicator scored 58%.

Indicator I.10: Are there written guidelines on conflict of interest with regards to registration activities?

There are no requirements for declaration of conflict of interest by committee members or any others involved in the registration process. All KIs were aware of this situation.

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"?

Almost half of the KIs agreed or strongly agreed with the statement (see Fig.1).

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

There are no written guidelines on the decision-making process. However, the KIs reported that the registration committee follows consistent procedures developed over years of practice.

The Registration Board usually issues minutes of meetings regarding decisions on agenda items. The agenda may contain a summary report of hundreds of applications, containing: the name of the product, the manufacturer, the strength and dosage form, presentation, clinical data (summary of product characteristics, conditioning notice, clinical summary) and recommendations, if any. The registration certificate is issued at the end of the process and remains valid for five years. It can take several years before the Board evaluates a product application. It is noteworthy that nearly 99.99% of applications for registration are not new molecular entities that might require extensive evaluation and assessment. There is no guideline/policy regarding assessment of applications for renewal, specifically on recording post-marketing surveillance data.

Most KIs were aware of this practice. This indicator scored 29%.

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

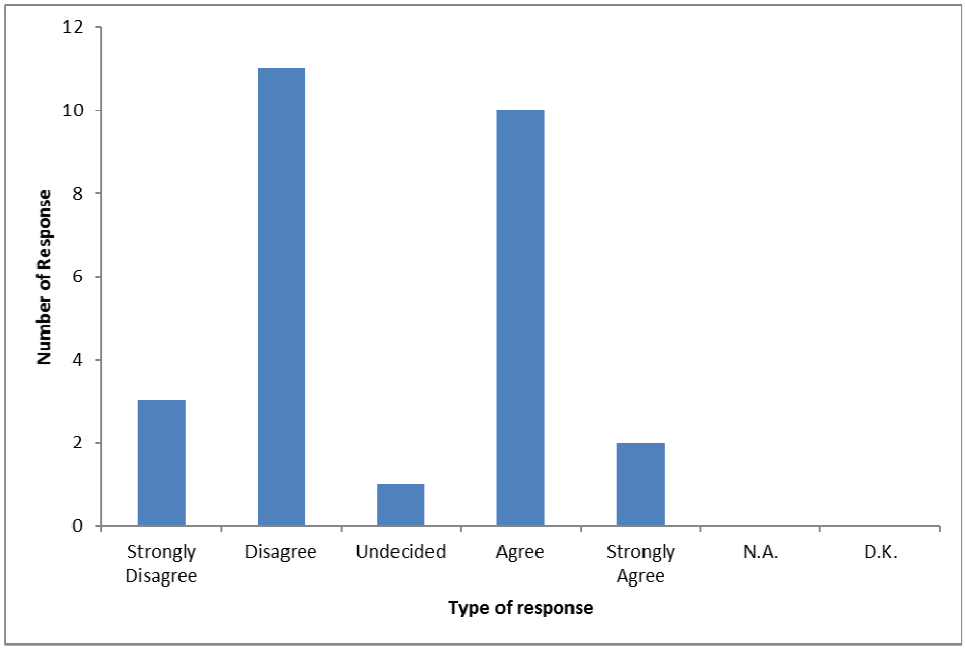

Fig. 1. KI perceptions that members of the registration committee are systematically and objectively selected based on the written criteria in force in Pakistan

As per Section 9 of the Drug Act 1976, the Appellate Board has been constituted for disposal of appeals by persons aggrieved by any decision of the Central Licensing Board or the Registration Board. The Secretary, Ministry of National Health Services, Regulations and Coordination, is Chairman of the Appellate Board, along with Provincial Health Secretaries and technical members. The Appellate Board has the power to suspend and reverse decisions of the Registration Board if it is convinced of the need to do so. A formal appeal from applicants who have had their application rejected can be submitted to the Appellate Board set up under the Drugs Act 1976. The Appellate Board Rules 1976 are publically available in the manual of the drug laws. All KIs agreed that a formal appeals system is in practice.

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

Most of the KIs disagreed with the statement, as shown in Fig. 2.

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

Most of the respondents agreed with the statement, as shown in Fig. 3.

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

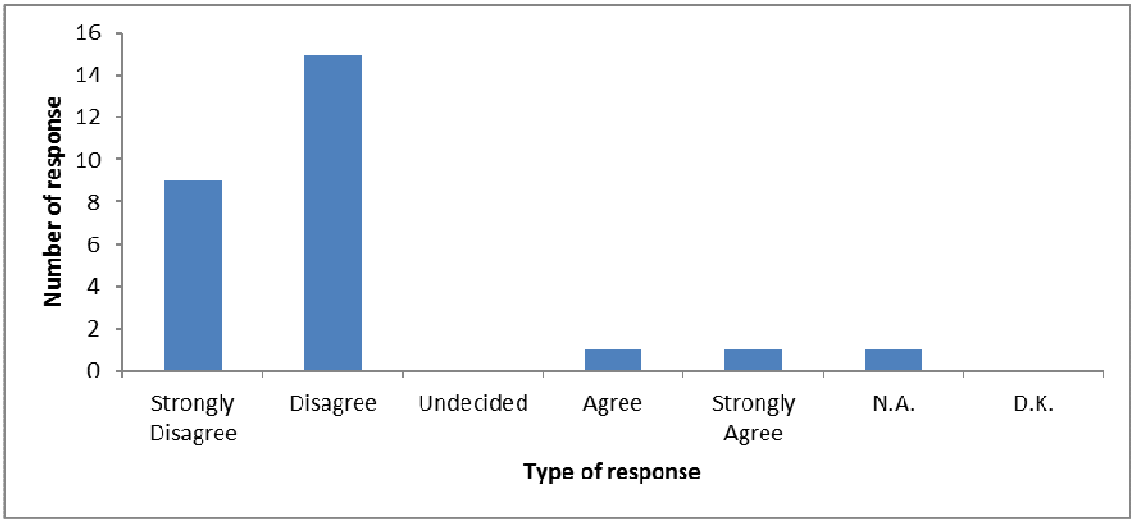

Fig. 2. KI perceptions of the influence on decisions of gifts and other benefits given to registration officials

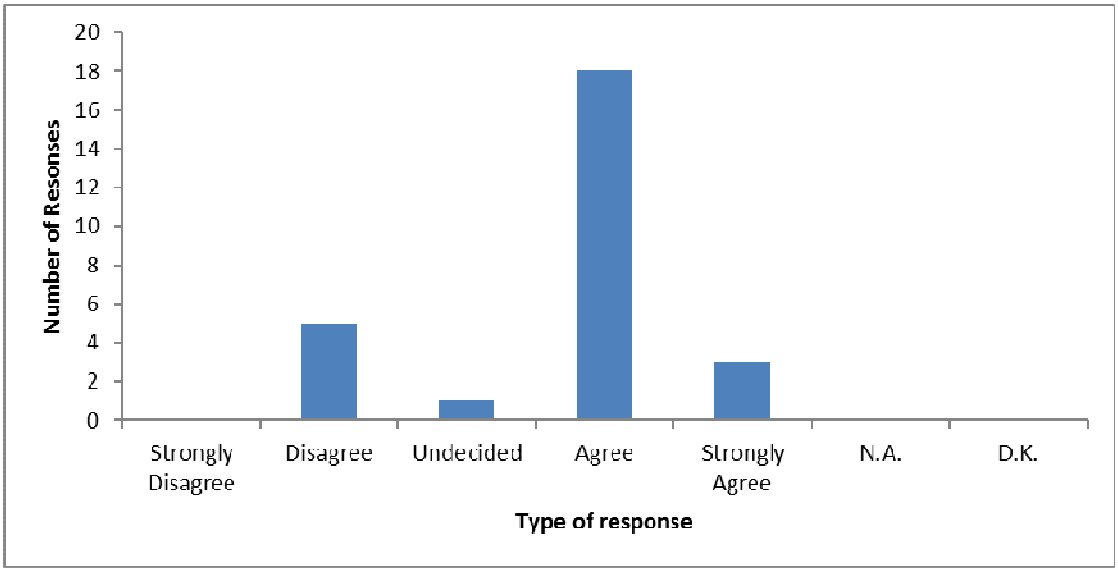

Fig. 3. KI perceptions of the registration committee meeting regularly and keeping its minutes

The common types of unethical behaviour in the registration system of Pakistan, as highlighted by KIs, are:

- unnecessary delay in processing registration applications;
- the influence of politicians and bureaucrats;
- lack of transparency;
- lack of in-depth study for price fixing;
- undue objections based on personal dislike;
- submission of fake data by applicants;
- lack of confidentiality/data protection;
- illegal rewards; and
- no declaration of conflicts of interest.

Indicator I.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 the KIs would take to improve the registration process in Pakistan would be to:

- address the lack of a proper system for evaluation of dossiers, insufficient staff and lack of adequate training by establishing an independent dossier evaluation cell with pre-defined expertise in DRAP;
- ensure that assessors are expert in their respective fields and that the pool of experts is developed with broad professional consultation and approval by the Registration Board;
- computerize the entire process of medicines registration to ensure the transparency of procedures and to accelerate the registration process, and make the pertinent information available to the public;
- make the facility for submission of applications available online through adoption of the Electronic Common Technical Document;
- provide applicants with the ability to know the status of their applications online, instead of through physically visiting the DRAP office;
- ensure that the timeframe for each step of processing the application is notified and in case of delay, a valid reason recorded;
- ensure only trained and qualified staff of sufficient number to guarantee the smooth functioning of the complex registration process;
- ensure a proper system for regular training of personnel for evaluation of relevant dossiers;
- strengthen the working of the registration office through the provision of proper infrastructure facilities, computer equipment and expertise, and secretarial support;
- only appoint competent and honest officials to the registration office, as the honesty and integrity of officials needs to be ensured to minimize unethical contact with the industry, and record all meetings using CCTV cameras;
- prepare a comprehensive list of medicinal products registered in Pakistan and make it available to all field staff and the public at large;
- publish the mandatory requirements, processes and standard operating procedures for assessment of medicine registration applications and make them publicly available for transparency;
- ensure that the decision-making process is merit-based, transparent and open to the public;
- put in place a well-defined conflict of interest policy and select staff and members of registration and evaluation committees strictly in accordance with the policy, with DRAP ensuring that all those responsible for medicines registration declare any conflicts of interest in writing;
- make WHO and International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guidelines regarding the registration of pharmaceutical products a guiding principle, implemented in their true spirit;

- make the interests and priorities of public health the overriding principle of registration for pharmaceutical products; and
- ensure price fixing is in uniformity with the international reference price, taking the socioeconomic indicators of Pakistan into consideration.

4.2.2 Licensing of pharmaceutical establishments

In Pakistan, a license is mandatory in order to operate a pharmaceutical establishment. The issuance of licenses for manufacturing medicines is regulated under the Drugs (Licensing, Regulation and Advertisement) Rules 1976 framed under the Drug Act 1976. The Central Licensing Board and the licensing section established at DRAP are responsible for issuing drug manufacturing licenses for: formulations, basic manufacture, repacking and experiments. The licenses for sale, storage, stocking and distribution of drugs are issued by the provincial authorities notified in accordance with the Drugs Sales Rules of the respective province after an inspection report from the relevant drug inspector.

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

In compliance with the Drugs Act 1976, it is mandatory to have a license in order to operate a pharmaceutical establishment. The issuance of licenses for manufacturing drugs is regulated by the Central Licensing Board set up under Section 5 of the Drugs Act 1976. However, the granting of drug sale licenses has now devolved to the provinces pursuant to a constitutional amendment. All KIs were aware of this practice.

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

DRAP is responsible for issuing drug manufacturing licenses through the licensing section in the Directorate of Licensing. As laid down under Rule 3 of the Drugs (Licensing, Registering and Advertising) Rules 1976 framed under the Drugs Act 1976, the following five types of license are issued depending upon the nature of the activity of pharmaceutical manufacturing: license to manufacture by way of formulation; license to manufacture by way of basic manufacture; license to manufacture by way of semi-basic manufacture; license to manufacture by way of repacking; and license to manufacture by way of experimental purpose.

The licenses for sale, storage and distribution of drugs and medicines are issued by the provincial governments. Authority has been delegated to the respective

executive district officer (health)/district health officer and licensing branches have been established in the respective offices. However, Baluchistan province is an exception where the Director-General of Health is the licensing authority and there is a centralized licensing branch for the entire province.

All KIs were aware of this practice.

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

The written procedure for submission of applications for manufacturing license is available at the DRAP website, which describes the criteria, requirements and procedures to be followed by applicants along with the prescribed fee. However, the timeframe for processing the application is not stated. While interviewing the KIs, it was revealed that it usually takes a long time to obtain a drug manufacturing license.

When an application is made to the Central Licensing Board for establishment of a pharmaceutical unit, it is examined for the required documents and after the fulfilment of the prerequisites the proposed site is inspected for site verification by the Federal Inspector of Drugs/Field Officer of DRAP. If the proposed site is recommended for establishment of a pharmaceutical unit under the requirements laid down under Schedule B of the Drugs (Licensing, Registering and Advertising) Rules 1976 framed under the Drugs Act 1976, the case is processed for approval by the competent authority. Afterwards, the site approval is communicated to the applicant if that is in conformity with the provisions of the rules. The application is rejected by the competent authority if the site does not meet the laid down criteria. Where the site is approved, the applicant is required to furnish the plan of its layout drawn in line with current good manufacturing practices requirements, for construction of the proposed unit. The guidelines following current good manufacturing practices requirements are specified in Schedule B-1 of the Rules. Once the layout plan is found to be in order, as per current good manufacturing practices requirements, it is processed for approval of the competent authority. The approval is communicated to the applicant for construction of the facility. The applicant, after completing the construction of the unit, submits an application for grant of a drug manufacturing license on the prescribed Form-I, along with the necessary documents/information. The application is scrutinized and if all code-related formalities are found to be met, a panel is constituted for inspection of the unit. The panel of experts/inspectors, including a member of the Central Licensing Board, inspects the premises to evaluate the facilities provided for production and quality control of the drugs to be manufactured, and submits its report accordingly. The inspection report is placed before the Central Licensing Board in its meeting for consideration and a decision is taken in the light of the recommendations of the panel and the provisions of the relevant law/rules.

The procedure for acquisition of a drug sale license is available in drug sale rules of the concerned province, including Punjab Drug Rules 2007, Sindh Drug Rules 1979, Baluchistan Drug Rules 1983, NWFP Drug Rules 1982 and Islamabad Capital Territory (ICT) Drug Rules 2013.

Most KIs were aware of this procedure. The indicator scored 85%.

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

Guidelines for assessing applications for the issuance of a manufacturing license are available and were approved by the Central Licensing Board in meeting number 232. The conditions for the grant of a drug sale license, as laid down in the Drug Sale Rules, are considered to be the guidelines for assessing the application.

Eighty per cent of KIs reported that written guidelines are available, while the remaining emphasized the need for a separate comprehensive guideline document.

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

The submission of pre-licensing inspection report is one of the requirements for making decisions on whether to issue a drug manufacturing/drug sale license or not. Most KIs were aware of this procedure.

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

The Central Licensing Board is responsible for assessing applications for a drug manufacturing license. In Punjab, Sindh and Khyber Pakhtunkhwa there are no formal committees to assess applications for a drug sale license. However, the Executive District Officer Health/District Officer Health has staff in charge of licensing who may be a senior drug inspector or a senior office assistant. In Baluchistan, a committee comprising the District Health Officer, Drug Inspector and another member nominated by the provincial government is responsible for assessing and recommending applications to the Director-General Health Services for the grant of a drug sale license.

The KIs involved in manufacturing affirmed the existence of formal committees in accordance with the Central Licensing Board.

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

In the Drugs Act 1976 and Drugs (Licensing, Registering and Advertising) Rules 1976, the composition of the Central Licensing Board and the expertise/timeframe for members other than the ex-officio members has been laid down. Accordingly, the KIs indicated that written criteria are available**.** However, some KIs reported that members of requisite expertise and skills are proposed according to personal contact/preference. The Federal Government approves and notifies the composition of the Central Licensing Board. The appointment does not require members to sign any conflict of interest form or be subject to any specific code of conduct. Most KIs were aware of this practice. The composition of Central Licensing Board is laid down in Rule 8 of the Drugs (Licensing, Registering and Advertising) Rules 1976 framed under the Drugs Act 1976. However, this does not specify that the Board is composed of all head of departments of DRAP. At present, the Director Licensing and Director Quality Assurance, provincial Drug Controller/Chief Drug Inspector, two experts with the requisite experience in manufacturing, quality control and teaching, one legal expert from the Ministry of Law, and the Deputy Director-General Licensing (the ex-officio secretary of Central Licensing Board) are members of the Central Licensing Board.

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

The members of the Central Licensing Board are notified by the Federal Government in the official gazette. The composition of the Board and the expertise of the current Board are available on the DRAP website, but it does not contain the roles and responsibilities, accountability and financial benefits of members.

This indicator scored 62%.

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

There is a requirement that at least two inspections (for cGMP, licensing, etc.) are conducted by the inspector and the team nominated by the Central Licensing Board/Registration Board. According to the Drug Sales Rules every provincial drug inspector is required to inspect license premises located in his/her area of jurisdiction at least twice a year. Most KIs were aware of this practice.

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

A comprehensive and up-to-date list of all pharmaceutical establishments (manufacturers, retailers and distributers) is not available with any authority.

However, a list of manufacturing license holders is available with DRAP (611 at present), which contains the name and address of premises, license number and type of license, but does not include the validity of the license, date of last inspection and name of the qualified/contact person. The provincial governments have also not compiled or made (publically) available the list of retailers/distributers. The KIs involved with the registration and manufacturing of drugs confirmed the presence of a list of licensed manufacturers. However, other KIs from the provinces involved in the sales/distribution of medicines reported that a list of retailers and distributors had not been compiled. This has been reflected in the response of the KIs.

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"?

Sixty-five per cent of KIs agreed or strongly agreed that the licensing of pharmaceutical establishments in Pakistan is systematically carried out according to the policies and procedures, while 30% did not agree with the statement (Fig. 4).

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

There is an appellate board established under the Drugs Act 1976 where applicants may appeal against the decision of the Central Licensing Board. In the provinces, there is an appellate authority headed by the Additional Chief Secretary or the Secretary Health to whom the appeal against the decision of the licensing authority may be made. Almost all KIs were aware of this procedure.

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

70% of KIs agreed or strongly agreed with the statement, while 30% did not agree (Fig. 5).

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

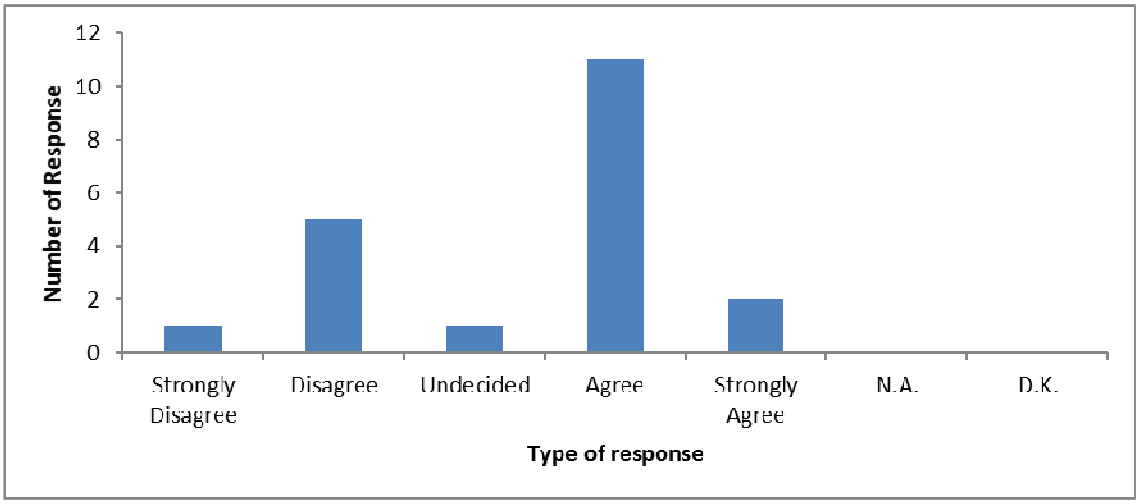

Fig. 4. KI perceptions of the licensing of pharmaceutical establishments being systematically carried out according to policies and procedures

The respondents highlighted the following common unethical practices in the process of licensing of pharmaceutical establishments in the country:

- undue delay in accepting and processing of applications based upon personal preference;
- political and administrative influence on the licensing process;
- baseless, bad faith and invented objections to delay the renewal process;
- demands for undue favours in terms of personal gifts, travel tickets, employment, medicines and other kickbacks;
- many medical practitioners, in addition to their practices, illegally running medical stores without a drug sales license;
- duplication of qualified persons due to the lack of a centralized licensing system for granting drug sales licenses;
- lack of declaration and implementation of a conflict of interest policy; and
- lack of transparency in selection of Central Licensing Board members.

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?

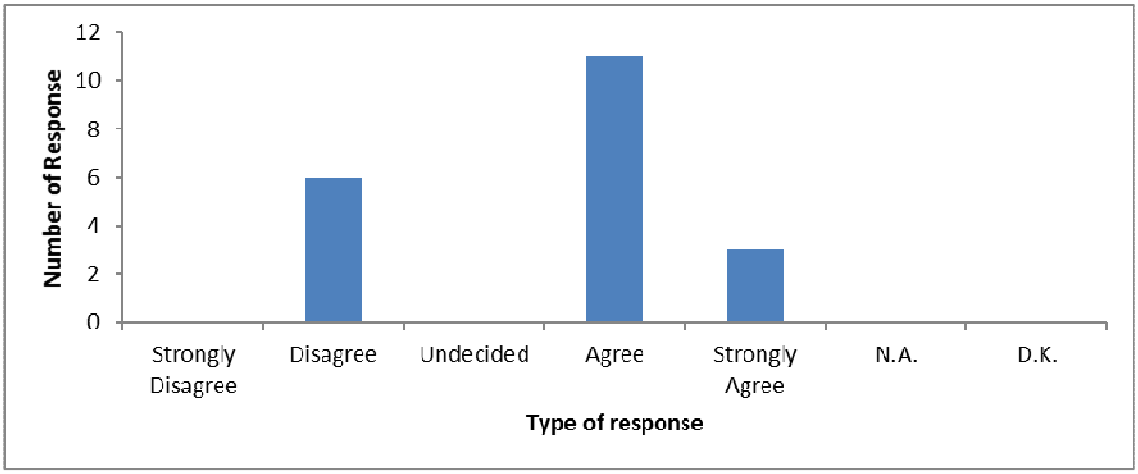

Fig. 5. KI perceptions that the formal committee that assesses applications for licensing of pharmaceutical establishments is fully operational and meets on a regular basis

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

- ensure that all regulations, procedures and guidelines covering the licensing process for pharmaceutical establishments are posted online;
- provide comprehensive training for all the inspectors regarding accountability, professional conduct and cGMP inspection;
- increase the number of inspectors and develop and implement a clear rotation system mechanism;
- encourage regular training of inspectors.

4.2.3 Inspection and market control

Inspection of pharmaceutical manufacturing units and sales outlets is governed under the provisions of the Drugs Act 1976 and the Rules framed thereunder are available on the DRAP website. Detailed regulations for appointment and powers of inspectors, and procedures and forms for federal and provincial inspectors, are publicly available. Provincial drug testing laboratories and a central drug testing laboratory are available for testing and analysis of samples sent by provincial and federal inspectors. Federal inspectors submit their reports to the Central Licensing Board/Registration Board and Quality Control Board, whereas the provincial inspectors submit their reports to the concerned provincial quality control board for further legal advice/actions. Any person aggrieved with the test report from the drug testing laboratory has the right to appeal to the concerned board which may refer the sample to the appellate laboratory under section 22 of the Drugs Act 1976.

Indicator III.1: Is there a provision in the medicines legislation/regulation covering inspection of medicines manufacturers and distributors?

Provisions exist in the medicines legislation covering the inspection of medicines manufacturers and distributors. These are contained in the DRAP Act 2012 and the drug sale rules in the Drugs Act 1976 contain sections pertaining to inspections at the provincial level.

Almost all KIs were aware of the legal position.

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

The provisions of inspection empower the inspectors to inspect the premises and the pharmaceutical activities. The law authorizes the inspectors to enter at any reasonable time at any place where medicinal products are produced, packaged, stored, distributed or tested in order to carry out an inspection. The law also outlines duties of the inspectors, responsibilities and powers to take action in case of violations of provisions of the medicines legislation and/or regulation. The law also stipulates that a copy of the provision is made available to the companies that are inspected. All KIs were aware of the provisions on inspection.

The indicator scored 92%.

Indicator III.3: Are there written guidelines on 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?

There are written guidelines on the classification of good manufacturing practices. The document is called Drugs (Licensing, Registration and Advertisement) Rules, framed under the Drugs Act 1976. There are written guidelines on the classification of good distribution and storage practices. Guidelines on good manufacturing practices and good distribution and storage practices are available in writing and accessible to all stakeholders. The guidelines provide classification of good manufacturing practices deficiencies and the measures to be taken in case of non-compliance. There are written appeal mechanisms for companies: the Drug Appellate Board at the federal level and the provincial quality control boards at the provincial level.

This indicator scored 62%.

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 to prevent regulatory capture between inspectors and the companies inspected. However, DRAP and the provincial quality control boards have unwritten procedures that help to prevent regulatory capture between inspectors and manufacturers/distributors inspected. These include the rotation of inspectors and the requirement for inspectors to visit sites in teams with a team leader. There is no external auditing of inspection performed by inspectors from another country. Most of the KIs were aware of this.

This indicator scored 32%.

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

There are no written guidelines on conflicts of interest with regards to inspection activities. However, the DRAP Act 2012 and the Punjab Drug Rules 2007 framed under the Drug Act, 1976 stipulate that no person will be appointed as an inspector who has a financial interest in the pharmaceutical trade. However, these provisions are not being implemented. Most of the KIs were aware of the legal position and current practice.

This indicator scored 23%.

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

Inspection findings and conclusions, in the form of complaints, are subject to internal review by the Central Licensing Board at the federal level and by the provincial quality control boards at the provincial level. Most KIs were aware of this practice.

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

The drug inspectors have written standard operating procedures to guide them in performing their duties. These standard operating procedures are available in writing (to the inspectors) in the form of a checklist. The guidelines include requirements for pre- and post-inspection activities, the scheduling system that identifies companies due for inspections within a set timeframe, and the format and content of inspection reports. The standard operating procedures are not publicly available. Most KIs were aware of this practice.

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

The criteria for selection and recruitment of inspectors only include the professional qualifications required (being a pharmacist). Recruitment of inspectors requires a minimum one year of work experience in the area and is not based on recommendations from former employers. Most KIs were aware of this requirement and practice.

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

Only 15% agreed or strongly agreed with the statement (Fig. 6).

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)"?

Only 38% agreed or strongly agreed with the statement (Fig. 7).

Indicator III.11: In your opinion, what types of unethical behaviour are common in the inspection area in your country? These can include bribery, material gifts, favouritism (towards family or friends), conflicts of interest (e.g. investments in pharmaceutical companies) and so on.

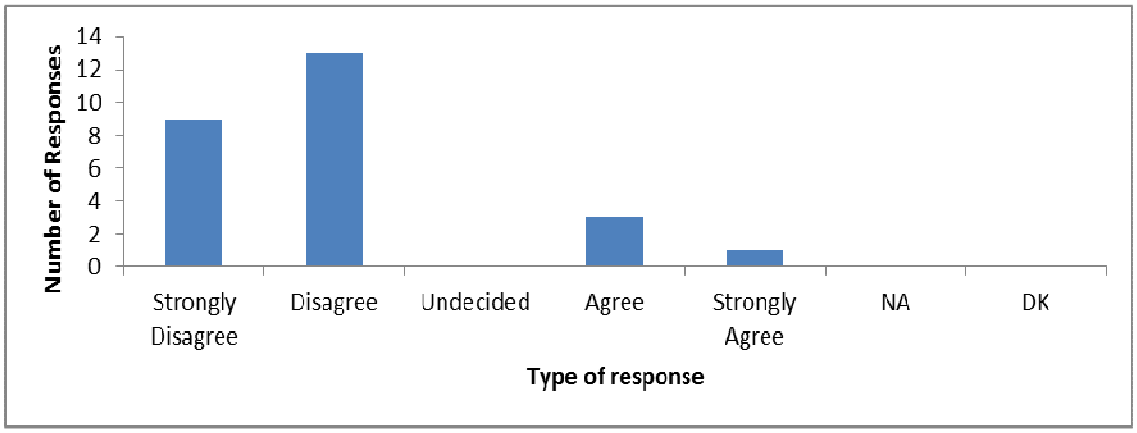

Fig. 6. KI perceptions of the integrity of inspectors being not at all influenced by personal gains, such as bribes, gifts, material or other benefits

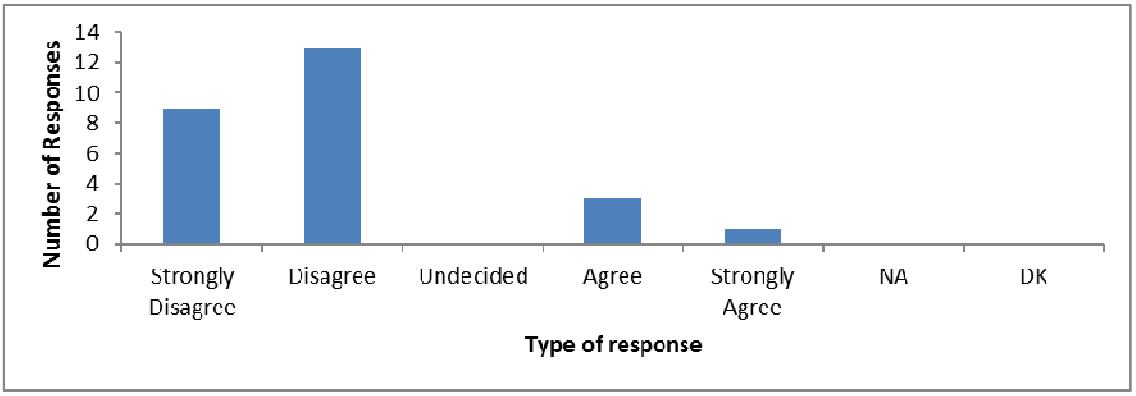

Fig. 7. KI perceptions of inspection activities being systematically carried out in accordance with the guidelines and procedures to prevent biases

The KIs reported that common types of unethical behaviour in the inspection area include:

- favouritism
- conflicts of interest
- material gifts
- political influence
- misuse of power
- unnecessary harassment
- blackmail.

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 actions that KIs would take to improve the inspection process in Pakistan would be to:

- post all regulations covering inspection of medicines and all guidelines and procedures regarding the inspection activity online;
- ensure a comprehensive training programme for all the inspectors regarding accountability, professional conduct and current good manufacturing practices inspection;
- develop and publish written guidelines on the conflict of interest policy with regard to inspection activities and establish a mechanism for monitoring, including sanctions in cases where the guidelines are breached;

- implement a clear system and schedule for the inspection of companies and publish the inspection reports;
- increase the number of inspectors and develop and implement a clear rotation system mechanism;
- improve the salary structure and logistic support for the inspectors;
- encourage regular training of inspectors for capacity-building;
- advise inspectors on how to avoid harassment during inspections; and
- ensure strict accountability of the conduct of inspectors.

4.2.4 Control of medicine promotion

The advertisement of medicines is controlled and regulated under Section 24 of the Drugs Act 1976 and the rules that have been framed pursuant to that law. The legal provisions on promotion of medicines only encompass the areas of advertisement to the public and professionals, packaging, labelling and package inserts. Any person in breach of any provision of the law is liable to imprisonment and fine which is usually not enforced satisfactorily. There is no formal procedure for complaints to report unethical promotional practices or any forum responsible for monitoring and enforcing the provisions on medicines promotion. No guidelines exist on conflicts of interest with regards to control of advertisement activity. The KIs assessed the area of control of medicine promotion to be very vulnerable.

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

Section 24 of the Drugs Act 1976 stipulates that "no person shall himself or by any other person on his behalf advertise except in accordance with such conditions as may be prescribed". Chapter IV of the LRA 1976 further outlines the procedure and conditions for advertisements. Most KIs reported that that there is a provision in the law.

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

Legal provisions on promotion of medicines encompass the following areas: advertisement to the public and professionals, packaging, labelling and package inserts. However, the provisions do not cover the qualifications and training of medical representatives, restriction and monitoring of free samples, symposia and scientific meetings, post-marketing scientific studies, speaker and consultancy fees, promotion of exported medicines, and restrictions and limits on gifts and gimmicks.

Most KIs were aware of the legal position and current practice. The indicator scored

60%, representing KIs' responses to the available sub-elements (1 to 4 and 8) for this indicator, which are to some extent mentioned in the advertisement rules. The rest of the sub-elements are not explicitly mentioned in the advertisement rules.

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

Pre-approval of promotional and advertising materials aimed at the public is mandatory but not officially required if aimed at health providers. In practice, only advertisements directed to consumers for prescription and non-prescription medicines are subject to pre-approval from the advertisement committee established under DRAP. Application for pre-approval requires the provision of information on the generic name, brand name, company name, major indications and contraindications, and adverse effects. However, information on drug interactions and cost of advertisement is not required.

This indicator scored 64%.

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

As per Section 27(4) of the Drugs Act 1976, any person in breach of any provision of the Act (including Section 24 on control on advertisement) is liable to imprisonment and fine which may extend up to five years and a 50 000 Rupees fine. In practice, enforcement of the law is less than satisfactory. Although 58% of KIs reported that the provisions foresee an enforcement mechanism on promotion of medicines, few examples exist of sanctions for violations.

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

There is no formal complaints procedure to report unethical promotional practices. In practice, the provincial and federal drug inspectors are authorized to launch a complaint in the drug courts. The process is long and mostly results in acquittal or meagre financial penalties.

Most KIs reported no formal complaints procedure.

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

There is no special committee responsible for monitoring and enforcing the

provisions on medicines promotion. However, a committee has been notified by the Federal Government which approves the contents of the advertisements to the public. The monitoring of all contraventions is the responsibility of the drugs inspectors and concerned boards (Quality Control Board and Registration Board). However, the monitoring and enforcement system for advertisement is undermined by the other functions of the boards and inspectors.

Most KIs reported that there is no service or committee responsible for monitoring and this is reflected by the low score for this indicator.

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

There are no publically available criteria that outline professional qualifications, technical skills and work experience required for members of the committee, including real and perceived conflicts of interest.

Most KIs were aware of the current situation.

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

There are no written documents available that describe the composition and terms of reference of the service/committee.

Most KIs were aware of this situation, except a few who reported otherwise.

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

There are no publically-available written standard operating procedures that guide the services responsible for pre-approving or monitoring medicine promotion and advertising.

Most KIs reported that no written standard operating procedures are available on this subject.

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

There are no written guidelines on the conflicts of interest with regards to control of advertisement.

Most KIs reported that there are no guidelines available on conflicts of interest.

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"?

A majority of the KIs did not agree with the statement. There is no organization outside the Ministry of National Health Services, Regulations and Coordination involved in reviewing, assessing and monitoring the promotion of medicines in Pakistan. In addition, there is no mechanism for reporting unethical practices in the control of medicine promotion function (Fig. 8).

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

More than half of the KIs disagreed with the statement, although 30% expressed their approval of the existing system (Fig. 9).

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"?

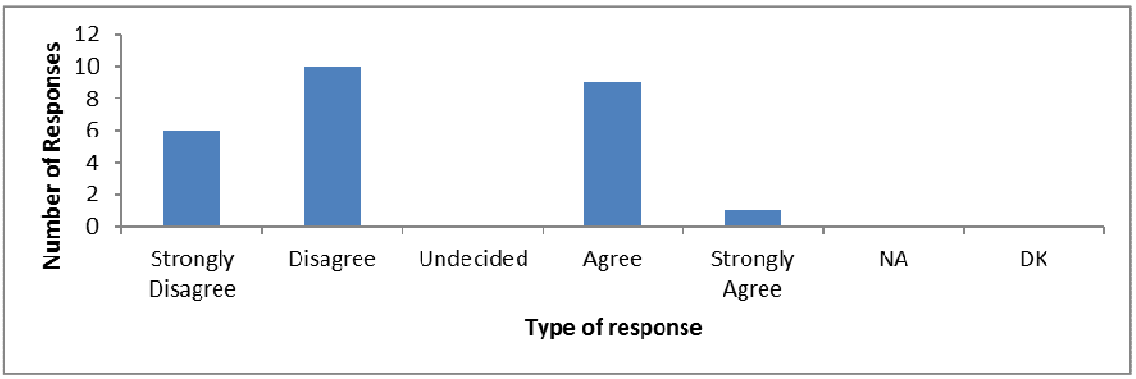

Fig. 8. KI perceptions of legal provisions on medicine promotion having been developed in broad consultation with all interested parties

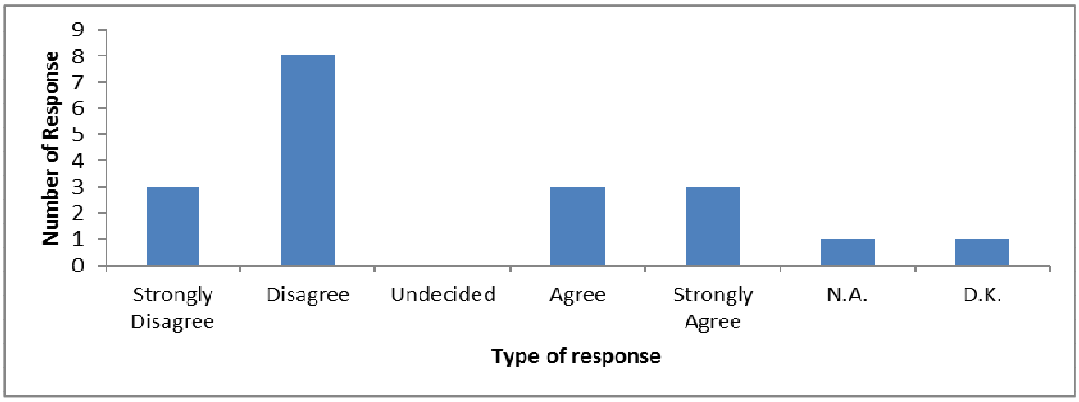

Fig. 9. KI perceptions of pre-approval of promotional and advertising material being systematically obtained before they are made public

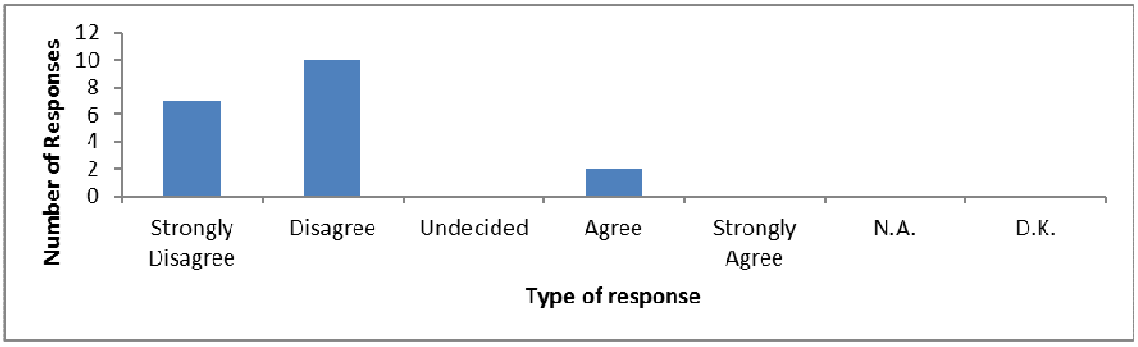

Fig. 10. KI perceptions of whether civil society/nongovernmental organizations have a great influence on improving the control of medicine promotion in Pakistan

Approximately 90% of KIs disagreed or strongly disagreed with the statement (Fig.10).

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"?

Almost 70% of KIs did not agree or strongly disagreed with the statement (Fig. 11).

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

1) Involving health professionals and health institutions in general.

Common unethical behaviours reported are:

- a great appetite among health professionals for personal, practice/hospital and business development, including kickbacks, share of sale, international travel support, payment of utility bills, clinic renovation, foreign trips, cash, transport, and arranging events such as birthday parties, weddings, funerals and social events;
- franchisers providing deceitful information and being involved in false bio-equivalence studies, and no regular check/system on promotion control; and
- unethical prescription of pharmaceuticals and medical devices under the influence of illegal marketing.

2) Involving regulatory office staff and the committee members responsible for controlling medicine promotion.

Common unethical behaviours reported are:

- no regular monitoring;
- committee members are not selected from civil society;
- cases brought for violation of legal provisions on promotion are scarce and the officers involved do not fulfil their legal obligations;
- incidents of undue favour for granting of notice of compliance for public advertisement;
- no conflict of interest policy;
- considerable favouritism; and
- no dedicated section in DRAP or the provincial drug control administrations to manage issues relating to illegal promotional activity.

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 in Pakistan would be to:

- promulgate and publish special laws regarding marketing and promotion of health care products and pharmaceuticals, such as the Foreign Corrupt Practices Act, for the awareness of the general public;
- review and develop the legislation covering medicine promotion in line with the international standards in consultation with all stakeholders;

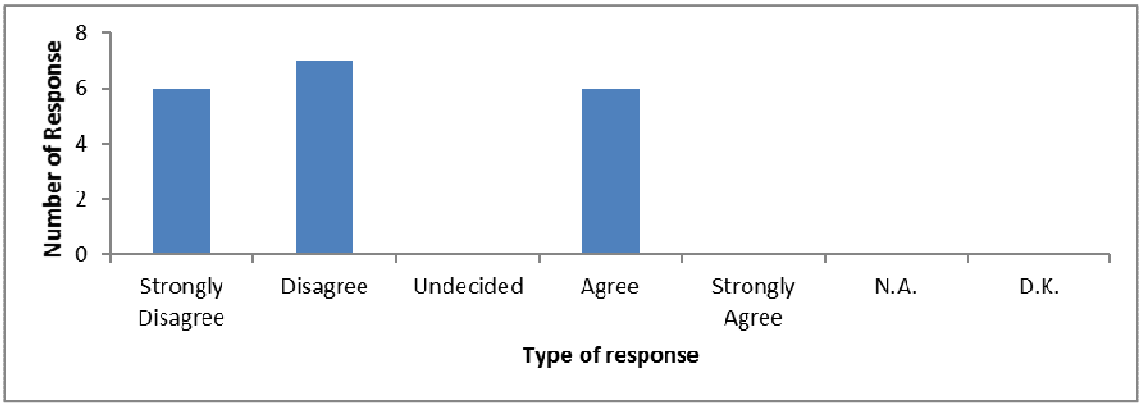

Fig. 11. KI perceptions of whether sanctions in the provisions on medicine promotion are systematically applied when there is a breach

- devise and disseminate standard operating procedures guiding the services responsible for pre-approving and monitoring medicine promotion;
- monitor the promotion of health care products by pharmaceutical companies;
- develop specific regulations for the classification of sponsorship, with notification of an upper limit;
- enact a complete ban on financial support to health care professionals for clinic renovation, gifts, bribery, and encourage all pharmaceutical companies to develop a voluntary code as part of their corporate social responsibility with strict implementation;
- introduce and enforce policies that establish and monitor ethical standards for pharmaceutical company promotion to prescribers;
- set up a dedicated monitoring cell at DRAP to ensure documentation of all types of expense incurred on promotion of pharmaceuticals and publish the data for public review;
- ask the government to ensure that medicine promotion is only based on sound scientific practice;
- make recommendations the PMDC and PPC for a training programme for health care professionals on good prescribing practices;
- introduce a comprehensive programme of education for practitioners and consumers on the impact of unethical medicine promotion;
- frame and enforce a law to monitor and punish unethical practices by medicine promotion companies;
- authorize field officers to impose fines for off-label promotions and other malpractices;
- ensure violations of provisions regarding promotion are rapidly tried in the courts of law;

- solicit the opinion of the Registration Board on restriction of the number of brands for the same molecule, to avoid unhealthy competition in sale and promotion; and
- put in place a well-defined conflict of interest policy and strictly select the staff/members of the medicine promotion control committee in accordance with the policy; DRAP should be required to ensure that all concerned committees responsible for control of advertisement of pharmaceutical products submit conflict of interest declarations in writing.

4.2.5 Control of clinical trials

The clinical trial of medicines in Pakistan is regulated under the Drug Research Rules 1978 which were amended in 2013. The national guidelines on the principles of good clinical practices, the Pakistan Good Clinical Practices Guidelines, based on ICH and WHO guidelines, are available with the division of pharmacy services of DRAP. However, most KIs were unaware of the presence/implementation of the guidelines. Written guidelines for submission of application to DRAP prior to conducting clinical trials are not publically available. Nevertheless, a pro forma for submission of a clinical trial proposal along with a checklist can be obtained from DRAP. Apart from the Pakistan Good Clinical Practices Guidelines, there are no documented policies/rules or procedures for submission of clinical trial applications to the independent ethics committee that cover acceptability of the investigators for the trials, suitability of the protocols, means of recruiting trial subjects, adequacy and completeness of the information, provision of compensation in case of injury or death of subjects and the form of payment for remuneration by the sponsor. The pro forma for submission of a clinical trial proposal requires submitting prior approval from any ethical committee with the name and designation of its members. No list/database of clinical trial applications approved or rejected by the authorities in Pakistan is available. In this assessment, the clinical trial of medicines has been rated as being very vulnerable.

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

Clinical trials in Pakistan are regulated under the Drug Research Rules 1978 which were amended in 2013. The Pakistan Good Clinical Practices Guidelines (2008) are available for the design, conduct, recording and reporting of trials. This document has been adopted from the ICH good clinical practices guidelines.

Most KIs were aware of the guidelines.

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

National guidelines on the principles of good clinical practices, the Pakistan Good Clinical Practices Guidelines 2008, are available with the division of pharmacy services of the DRAP, but are not available on the DRAP website.

Some of the KIs were unaware of these guidelines.

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

There are no written guidelines available publically for submission of applications to DRAP prior to conducting clinical trials. However, a pro forma for submission of a clinical trial proposal along with a checklist can be obtained from DRAP. The pro forma includes the trial objective and purpose, and the criteria for inclusion and exclusion of a trial subject, but does not cover trial design, the means of obtaining informed consent and the timeframe required for assessing the application.

This indicator scored 56%.

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

A documented policy or procedure is available for submission of clinical trial applications to the independent ethics committee as per the Pakistan Good Clinical Practices Guidelines. It covers the acceptability of investigators for trials, suitability of the protocols, means of recruiting trial subjects, adequacy and completeness of information, provision of compensation in case of injury or death of subjects and form of payment of remuneration by the sponsor. The pro forma for submission of the clinical trial proposal requires submitting prior approval from any ethical committee, along with the name and designation of its members.

This indicator scored 41%.

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

A requirement exists for pre-approval for the manufacture, import, export and use of investigational products. 60% of KIs reported that the requirement exists.

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

There is a formal review committee at DRAP, working under the Director of Pharmacy Services, which is responsible for reviewing applications at the central level. The applications are reviewed by a panel of experts notified on a case-to-case basis.

Sixty per cent of KIs were unaware of the composition of the current formal review 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?

The experts involved in review of clinical trial applications are nominated through personal recommendation and there is no pool of pre-identified experts which could be referred to for reviewing of clinical trial applications.

Most KIs reported that no mechanism is in place to ensure appropriate review of applications by experts and that clinical trial results are not reviewed by those possessing sufficient and current expertise.

Indicator V.8: Is there a clinical trials inspection system established and operational?

Apparently, there is no established and operational clinical trial inspection system and most KIs affirmed this to be the case.

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

An independent ethics committee/independent review board is officially established, consisting of members with the required qualifications and procedures for compliance with good clinical practices as described in the Pakistan Good Clinical Practices Guidelines (2008). Although the guidelines require the establishment of an independent ethics committee, most KIs were unaware of the requirement because it is not publically available. As such, this indicator resulted in a low score.

The indicator scored 41%.

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

There is no timeframe outlined for the review committee to assess applications for clinical trials. Most KI=s were aware of this situation and current practice.

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

The guidelines on conflicts of interest regarding clinical trial activities have not been notified yet. All KIs were aware of this situation.

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

There is no list/database of clinical trial applications approved or rejected by the authorities. Almost all KIs reported that no such list was available.

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

Only a quarter of KIs agreed or strongly agreed that the selection of institutional ethics committee members is based on the written selection criteria (Fig. 12).

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

Seventy-five per cent of KIs did not agree that selection of the review committee members was based on the written selection criteria (Fig. 13).

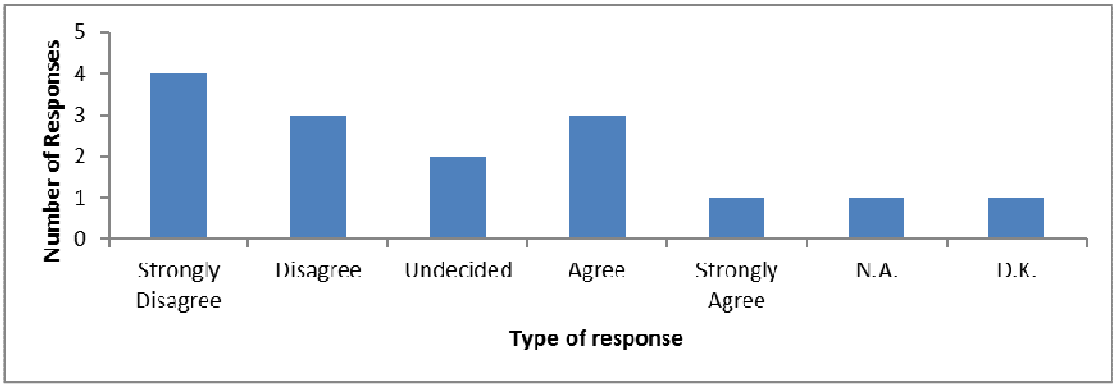

Fig.12. KI perceptions that institutional ethics committee members are systematically selected based on the written selection criteria

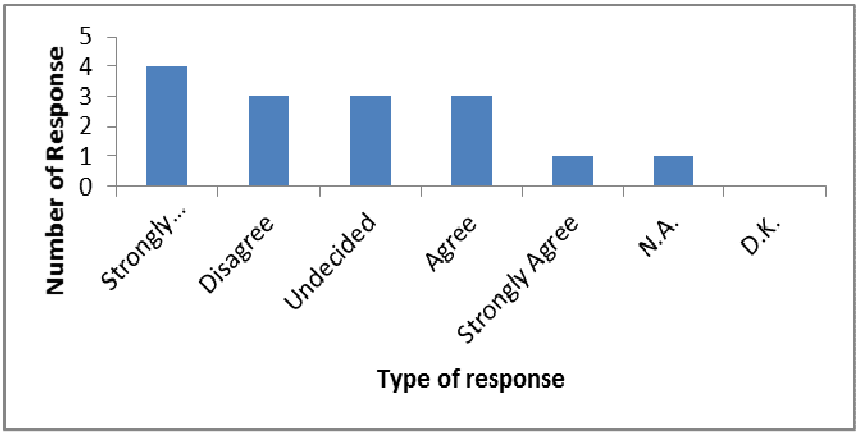

Fig. 13. KI perceptions medicine regulatory authority review committee members are selected systematically based on written selection criteria

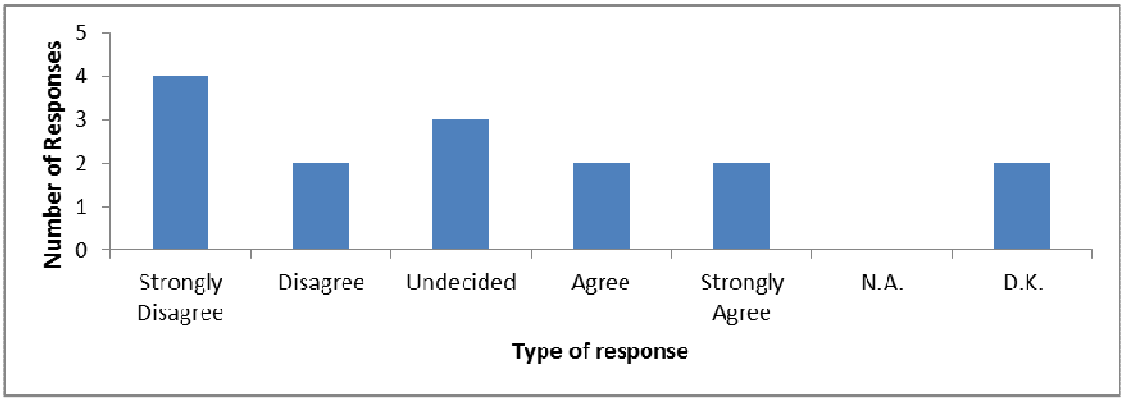

Fig. 14. KI perceptions that the medicine regulatory authority is ensuring that clinical trials conducted in Pakistan are done in accordance with the regulations and good clinical practices principles

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

Seventy-five per cent of KIs did not agree with the statement (Fig. 14).

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

The KIs reported the following common types of unethical behaviour:

- all stakeholders take undue advantage due to the absence of proper regulations, guidelines and accountability checks, and DRAP lacks capacity in terms of technical expertise and staffing to monitor clinical trials so that clinical trials are not properly regulated by DRAP;
- unapproved/hidden clinical trials are being conducted in some areas without the consent/knowledge of the regulatory authority;
- selection of trial subjects is not random but is mostly based upon the convenience of researchers;
- the rights of patients/subjects are compromised and subjects are misinformed regarding the hazards and expected outcomes of the trials, and compensation to subjects is delayed/not made;
- the principal investigators do not follow the good clinical practice guidelines in letter or spirit; and
- the principal investigators are only interested in monetary benefits and selection of principal investigators by sponsors is purely based upon marketing strategy, with sponsors and funding not disclosed and no public access to data regarding the agreement.

Indicator V.17: If you were in a position of highest authority, what would be the first actions 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 Pakistan would be to:

- publish and disseminate the national guidelines on good clinical practices to all concerned;
- notify a pool of experts in particular areas of clinical research and select the members of the clinical trial assessment committee from this pool based on transparent and well-defined criteria;
- establish an operational clinical trials inspection system to ensure that proper checks on unethical practices in clinical trials;
- carry out on-site inspection of clinical trials by a team of experts;
- constitute an independent national bio-ethics committee which should liaise with institutional ethics committees and ensure publication and implementation of coherent ethical guidelines throughout the country;
- monitor the workings of the institutional review board and the institutional ethics committee;

- appoint officers in the clinical trial section on the basis of prior training/expertise in the area, and for a specific time period only;
- train and educate DRAP officials in the clinical trial unit in line with international regulatory bodies;
- allocate and ensure a timeframe for the processing of applications;
- ensure the protection of patients' rights in clinical trials;
- develop guidelines on conflict of interest policy with regard to clinical trials;
- improve interaction and sharing of information between researchers and DRAP; and
- ensure implementation of good clinical practices and ethical regulations for clinical trials.

4.2.6 Selection of medicines

Prior to the 18th amendment to the Constitution of Pakistan, there was a committee notified by the now defunct Ministry of Health for development of a national essential medicines list. Copies of the National Essential Medicines List 2007 were distributed among the provinces to ensure public sector purchases were in accordance with the national essential medicines list. Now, all provinces have their own selection committees under different names at different levels which have been devolved for the procurement of medical products, even to district level in some provinces. The essential medicines list has been officially adopted in Pakistan and has been updated with the help of relevant experts. In addition, primary, secondary and tertiary hospitals have developed their formularies according to their needs and budgets. For example, a list of medicines has been prepared by the Punjab Health Department for procurement of secondary level health institutions. A list of medicines for tertiary level hospitals has also been prepared by the concerned hospitals. A committee comprising physicians and pharmacists is responsible for revising and updating the list of medicines. However, the essential medicines list has no reference to national standard treatment guidelines. Written guidelines have not been prepared and implemented regarding conflicts of interest of the members of the committee responsible for revision and updating of the essential medicines list.

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

The government officially adopted the National Essential Drugs List, which was published in 2007 and is available online for the public health system, and helps the government to purchase appropriate medicines for the population. From 2013 onwards, the WHO Model List of Essential Medicines has been adapted. However, notification has not yet been circulated to health institutions, as indicated by the

response of the KIs who mostly did not have a copy of the essential medicines list even though they confirmed its publication and availability online. Health institutions in the public sector at various levels (primary, secondary and tertiary) have also developed their own lists/formularies of drugs according to their needs and budgets. These lists are prepared in consultation with senior professionals of different specialties and end users. Seventy per cent of KIs were aware of the existence of the National Essential Drugs List.

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

Forty per cent agreed or strongly agreed with the statement (Fig. 15).

Indicator VI.3: Are there clearly written and transparent rules/criteria for the selection process for including or deleting medicines from the national essential medicines list?

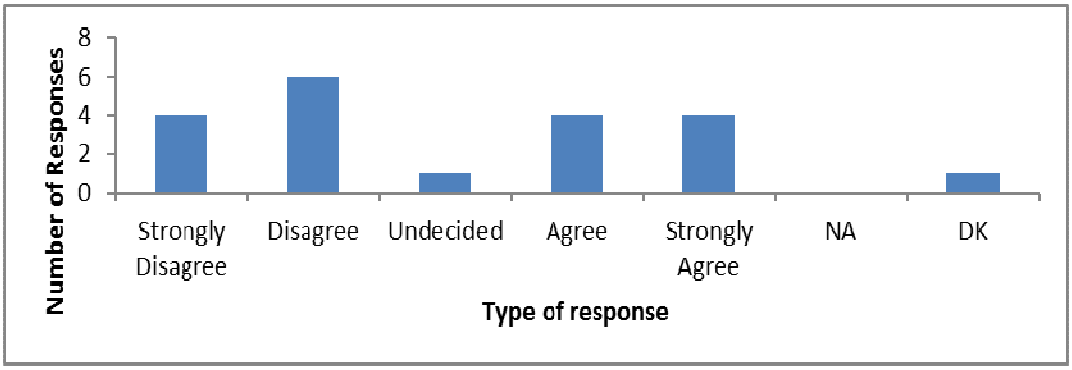

Fig. 15. KI perceptions that a national essential medicines list has been developed in consultation with, and considering the opinion of, all interested parties and using an evidence-based approach

The government has adopted WHO guidelines which have criteria for the medicines to be included in the list or deleted/rejected from the essential medicines list. The selection of medicines is based on their safety, efficacy, cost–effectiveness and the health needs of the country. The provincial committees make decisions regarding inclusion/deletion of the medicines in the list that serves as the guideline for provincial procurement. Most of the tertiary care hospitals have their own lists. The inclusion of new medicines is generally based on studies confirming that the medicine is necessary for the health needs of the population and is cost-effective, while the deletion of a medicine from the essential medicines list is based on the evidence that the medicines is inappropriate or no longer cost-effective for the population's health needs.

The indicator scored 44%.

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

Although Pakistan has adopted the WHO essential medicines list as such, it is not publically available and disseminated to the relevant health professionals. The products are listed in the essential medicines list by generic name, pharmacological category and by level of health care. There are no national treatment guidelines for all common diseases in Pakistan, so the essential drug list is not linked to national standard treatment guidelines. The essential medicines list is not regularly revised or published.

This indicator scored 42%.

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

A selection committee is in place to give technical advice on the revision and updating of the essential medicines list which includes physicians of different specializations and pharmacists.

Seventy per cent of KIs were aware of the committee.

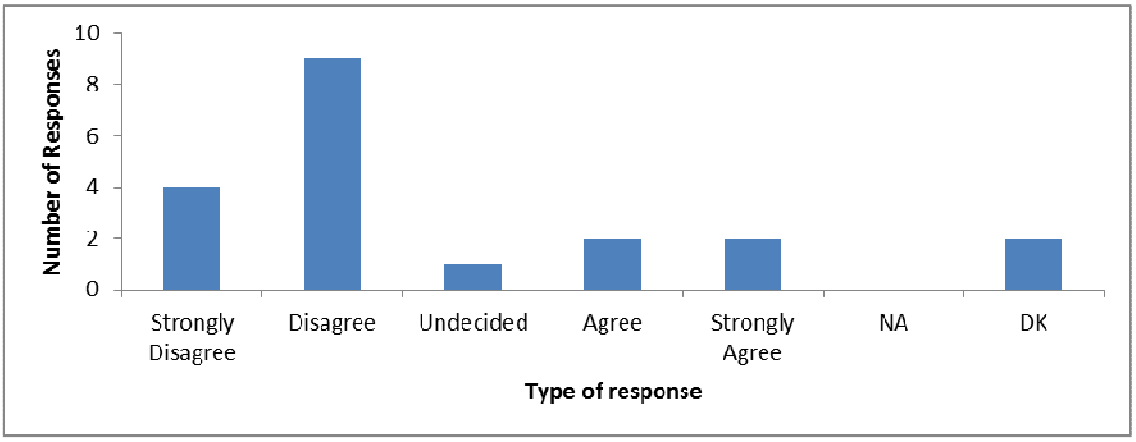

Fig. 16. KI perceptions that the committee responsible for the selection of the national essential medicines list is operating free from external influence

Indicator VI.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"?

Twenty per cent of KIs agreed or strongly agreed with the statement (Fig. 16).

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

No clear criteria for selection of members of the selection committee are available publically. However, a notification outlines professional requirements of being from the fields of medicine and pharmacy. The criteria do not require declaration of conflicts of interest and membership of the committee is not time-limited.

This indicator scored 25%.

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

There are no written guidelines on conflicts of interest and a conflict of interest declaration form does not exist.

Almost all KIs were aware of this situation.

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

There are no clear and publicly available standard operating procedures that describe the role and responsibilities of the selection committee.

Most KIs answered that there are no standard operating procedures which describe the role and responsibilities of the selection committee.

Indicator VI.10: Are the rules for decision-making clear and transparent in the standard operating procedures?

Decisions are made by all the members in a democratic manner, minutes of the meetings are produced and approved by the members and final decisions for selection of medicines are taken independently. However, consultations are seldom held with interested parties, and the decisions are not disseminated widely until publication of the decision.

This indicator scored 31% and 40% of KIs stated that standard operating procedures for the decision-making process did not exist.

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 common types of unethical behaviour in the selection process:

- material gifts
- favouritism
- conflicts of interest
- administrative/political influence
- misuse of power
- lack of proper training of staff.

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?

The first actions that KIs would take to improve medicine selection in Pakistan would be to:

- carry out all public sector procurement in accordance with the national essential medicines list;
- adopt appropriate measures to promote prescribing from the national essential medicines list in the public and private sector;

- develop prescribing guidelines for particular disease patterns and circulated to all concerned for adherence;
- base the essential medicines list on WHO guidelines and develop national prescribing guidelines in keeping with the morbidity and mortality data for Pakistan;
- ensure members of the committee for selection/deletion of pharmaceutical products in the national essential medicines list are representative of all the stakeholders geographically and professionally;
- ensure the selection process of the committees is transparent and the criteria are publically available.
- develop and disseminate guidelines for the selection process for inclusion/deletion of medicines, along with the guidelines for the decision-making process for preparation of the essential medicines list, to all concerned.
- train essential medicines list committee members on all parameters/criteria, including public health priority, effectiveness, cost–effectiveness, safety concerns and disease prevalence.
- develop and enforce a standard form for the conflict of interest policy along with the guidelines for the relationship between members of the medicine selection committee and the pharmaceutical industry;
- establish provincial and district committees to ensure the implementation of the essential medicines list in their areas and authorize them to take decisions in special circumstances;
- prohibit gifts and others illegal rewards through stringent provisions of law;
- avoid the selection of pharmaceutical monopoly formulations as much as possible;
- disseminate the scientific information pertaining to the reasons for choosing and deleting medicines;
- change the members of the selection committees every year;
- train the members to review matters on a cost–effectiveness basis; and
- make the decision-making process on the rules and the standard operating procedures clear and transparent, and accessible to the public.

4.2.7 Procurement of medical products

In Pakistan, pharmaceuticals are procured under the Public Procurement Regularity Act and the rules framed thereunder which are accessible for the public online. Procurement is made using the generic name and by a double envelope system consisting of technical and financial bids. Financial bids are opened from only those bidders who qualify for the technical bids. The provinces have prepared procurement guidelines and constituted committees for various stages of

procurement; for instance, in Punjab, there is a purchase committee, technical bid evaluation committee, grievance committee and inspection committee. Any party aggrieved by the tender committee's decision has the right to appeal before the grievance committee. Internal and external audits are carried out after the supply of procurement goods.

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

The government has a document that describes the procurement process for pharmaceutical products under the Public Procurement Regulatory Authority Act, and the rules framed thereunder. This document is publicly available and requires: the use of generic names; advertisement of tenders with contract specification; criteria for adjudication of tenders; and that decisions are made by the tender and bid processing committee. In practice, Public Procurement Regularity Act rules are applicable to all types of the procurement at federal and the provincial level, which does not require the procurement of medicines in accordance with the national essential drugs list. The decisions of the tender process are required be published.

This indicator scored 75%.

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

There are written guidelines in the Public Procurement Regularity Act rules/purchase manual for procurement office staff on the types of procurement methods to use for purchasing different types of products, including medicine. There are several types of procurement methods used to purchase pharmaceutical products, which fall into one of the four basic categories: open tender, restricted tender, competitive negotiations and direct procurement. The procurement method chosen for each product aims to obtain the lowest possible purchase price for assured quality products. However, there are no specific guidelines for purchase of medicines using open tender, restricted tender, competitive negotiations and direct procurement.

Only 38% of KIs were aware of the legal situation and current practice.

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

Medicines procurement is based on expected health needs and budget availability to

reduce the risk of over-supply, under-supply, or unnecessary supply of pharmaceuticals. However, morbidity data, adjusted consumption in cases of disaster and service level projections are seldom taken into consideration. This is the reason for the low score for this indicator.

Twenty-nine per cent of KIs reported that procurement is done with an objective of quantification method to determine the quantity of pharmaceuticals to be purchased.

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

The appeal mechanism works in the following way: if a firm is unsuccessful in its bid for a tender, a representative from the firm can file a protest based on the firm's view that the tender process was flawed. The appeals are mostly addressed to the Chief Purchase Officer who may constitute a committee to probe the matter.

Seventy-five per cent of KIs reported that a formal appeals process exists.

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?

There are purchase committees at the federal, provincial, district and institutional levels which are responsible for contract decisions and selection of suppliers for restricted tenders. The respective procurement staff calls for, receives and processes the bids for the decision of the respective purchase committee. Most of KIs were aware of the current practice.

The indicator scored 86%.

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"?

Eighty-seven per cent of KIs agreed or strongly agreed with the statement (Fig. 17).

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

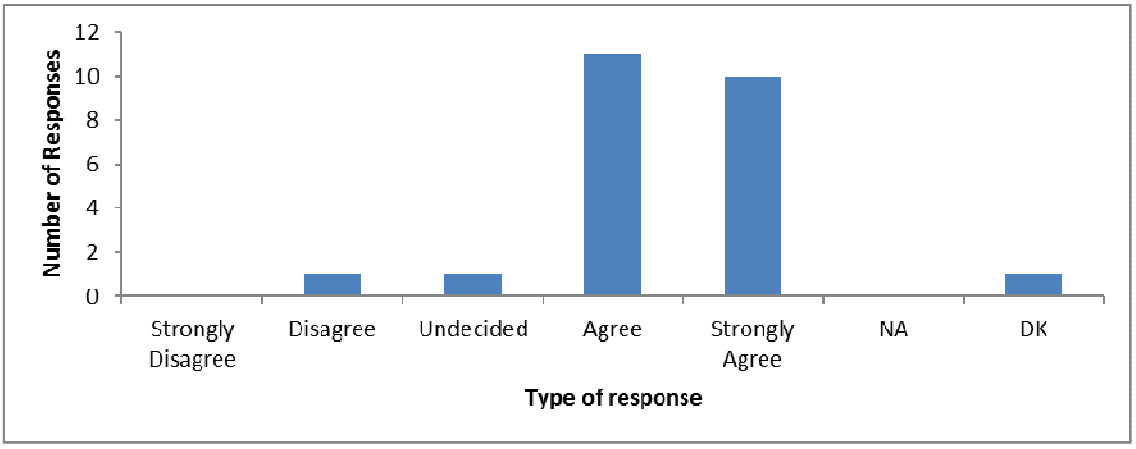

Fig. 17. KI perceptions of the decisions of the tender committee always being taken into account in the procurement process

A purchase committee has been composed and notified pursuant to the Public Procurement Regularity Act rules/purchase manual/Devolution Rules 2001, consisting of ex-officio administrative members, technical members from medical/pharmaceutical specialities and representative of end-users. The criteria do not require that members declare conflicts of interest or the regular rotation of membership. The criteria for committee membership are publicly available and are framed pursuant to the rules referred to above. Some KIs felt that the criteria should include experience in procurement or professional/clinical experience/skills, besides their specialities.

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

There are no written guidelines on conflicts of interest with regard to the procurement process. Almost all KIs were aware of the lack of 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)"?

Twenty-five per cent of KIs agreed or strongly agreed with the statement (Fig. 18).

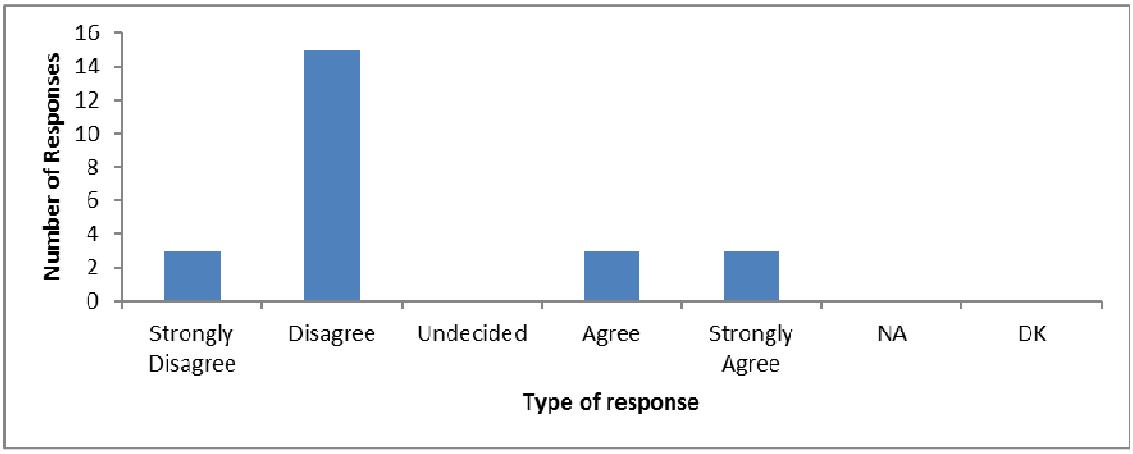

Fig. 18. KI perceptions of the members of the tender committee being systematically selected based on specific criteria

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

The management information system is computerized, includes product availability records and monitors facility performance. However, the system does not include comparison of estimates and purchase quantities, feedback from facilities, supplier performance and tracking the status of purchase orders. The system is only available in centrally-managed health programmes, such as the tuberculosis control programme, national programme for family planning and primary health, and the Prime Minister's programme for lady health workers, and occasionally in provincial headquarters and tertiary care hospitals. In other hospitals, procurement is managed manually to monitor the supplier in terms of quality control reports, status of order and quantity purchased.

This indicator scored 30%.

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

In Pakistan, each drug shipment is required to be physically inspected which involves checking adherence to the contract specifications. In addition, it is required that batch samples should be sent to the quality control laboratories using systematic sampling. All documents, including inspection reports and laboratory testing results, should be archived in the procurement office. The payment of bills is linked with satisfactory/position test/analysis reports.

Most KIs were aware of this requirement and current practice. The indicator scored 88%.

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

The procurement office monitors supplier performance and compliance with the contract terms. The monitoring system tracks the supplier's lead time, delivery status, shelf-life and packaging of products. Product quality is also tracked. The suppliers with poor performance are blacklisted for a certain period of time. A record of procurements for the preceding five years is maintained for auditing purposes. This record contains the names of suppliers along with other information.

This indicator scored 44%.

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

The procurement office has to undergo external auditing through the Auditor General at least once a year, and the results are made publicly available in the Public Accounts Committee of the Parliament/Provincial Assembly. The annual audit should report on the operating costs of the procurement office, pharmaceutical products tendered, quantities of products procured, and the contracts awarded. The results of the tenders are available online. Most KIs reported that the procurement office undergoes regular audits of procurement.

This indicator scored 70%.

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"?

Twenty per cent of KIs agreed or strongly agreed with the statement (Fig. 19).

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

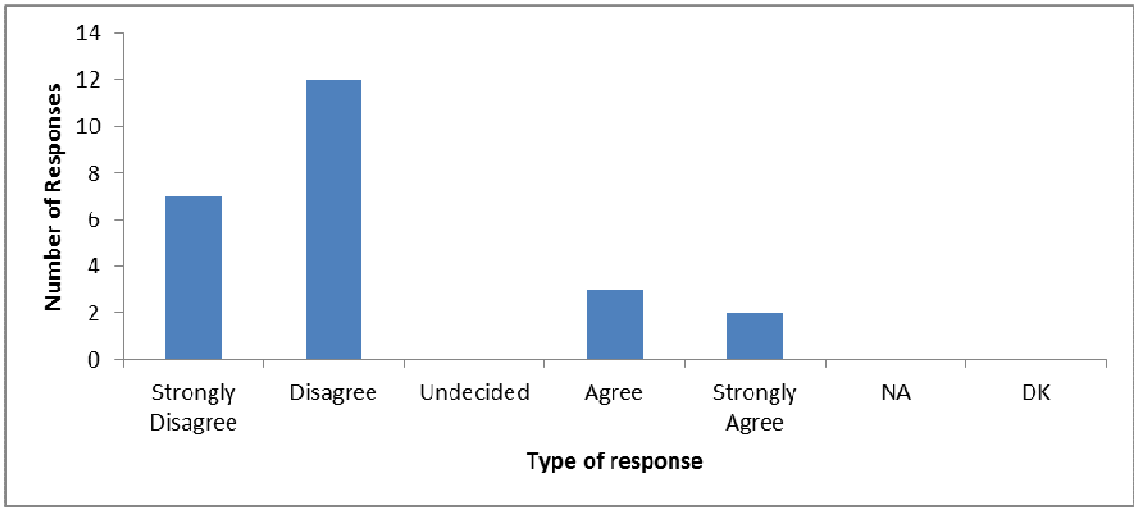

Fig. 19. KI perceptions that the procurement system in Pakistan is operating in a totally transparent manner

The KIs reported that common types of unethical behaviour in the procurement system in Pakistan are:

- material gifts
- bribery
- favouritism
- administrative or political pressure
- conflicts of interest
- undue delay in payment of bills .

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 Pakistan would be to:

- require members of the tender committee to declare conflicts of interest;
- establish a well-coordinated procurement department in every provincial headquarters which should provide the necessary documents and guidelines to all institutions and district heads for the procurement process;
- provide support to the procurement department including having dedicated specification, account and audit, quality assurance, receipt, and information technology sections;

- restrict bulk purchase to the national essential medicines list and according to the level of care (primary, secondary or tertiary);
- take all measures to ensure that the procurement function is independent and there is no interference at a political or senior bureaucratic level;
- coordinate the procurement process with the selection and distribution of medicines process;
- make a management information system available at district level (at least) to monitor and report the performance of particular suppliers and products;
- review procurement procedures to ensure that prospective suppliers are pre-qualified and their performance is monitored for product quality, service reliability, delivery time and financial viability; all information should be appropriately recorded in a retrievable database;
- update the status of companies in connection with their performance regularly and blacklist suppliers according to well-defined publically-available criteria;
- shift the current procurement process to a needs-based procurement system;
- give all categories of staff involved in the procurement process appropriate training on a regular basis to build their capacity to adhering to Public Procurement Regularity Act rules;
- appoint the right people in the right positions to ensure transparency in the procurement process;
- limit the maximum tenure of staff involved in the procurement process to three years;
- develop an online system for submission of tenders online and make the results available online;
- organize a new procurement department around key functions to include specification, accountancy, quality assurance (including audit), procurement, receiving and checking, and information technology sections;
- restrict public sector tender procurement to the rational drug list;
- Review procurement procedures to ensure that prospective suppliers are pre-qualified and their performance monitored for product quality, service reliability, delivery time and financial viability; appropriately record information and retain in a retrievable database;
- regularly update the blacklist of non-performing or poor-performing suppliers and forward a copy of the list to the procurement department; and
- simplify the procurement process to improve the system and its effectiveness by requiring a more evidence-based approach to medicine selection for procurement and rationalization of medicine requirements (by reducing the chemical entity in each therapeutic group, for instance, to two beta blockers, two proton pump inhibitors, and so on).

4.1.8 Distribution of medicines

As most medicines required for public procurement and distribution are manufactured locally, the distribution system does not entail port clearance. Distribution of medicines in public sector health institutions in Pakistan is carried out through a transparent and explicit system. Supplies are received and warehoused with proper inventory control, which is computerized in the major warehouses. Stocks are checked by designated staff. A computerized record of incoming and outgoing consignments is maintained at tertiary and secondary level hospitals. Pilferage and theft of supplied medicines is controlled through special colour scheme for medicines packaging with conspicuous printing of the phrase: "Government property: not for sale", as provided in Drugs (Labelling and Packing) Rules 1986, framed under the Drugs Act 1976. In Punjab, written guidelines for distribution have been introduced in line with WHO standards in the form of "good storage and distribution practices", contained in schedule H of the Punjab Drugs Rules 2007, framed under the Drugs Act 1976. Internal and external auditing of distribution of supplies is regularly conducted. Security arrangements are in place to oversee storage and distribution, along with a lock and controlled key distribution system.

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

The importers designate and retain a person responsible for port clearing and there is a computerized system to monitor port clearing activities. However, public sector hospitals and institutions are not directly involved in importation/port clearance. KIs from both private and public sectors reported the hiring of the services of clearance agents to expedite clearance from ports.

Fifty-six per cent of KIs reported that there is a system in place.

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"?

Very few products are imported compared to the bulk of medicines being manufactured and distributed locally. As a result, 44% of KIs were unaware of the implications of this question.

Only 11% agreed with the statement (Fig. 20).

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

The designated staff is responsible for checking the receipts against the packing list when supplies arrive at the warehouse. The responsible person prepares documentation through a receiving report on the basis of the invoice specifying the types, quantities and condition of the supplies received.

Most KIs were aware of this practice. Usually there is an allocated space for keeping the consignments in quarantine until the inspection report is formulated. An oversight system is in place whereby, in some instances, there are stock verifiers who cross-check these and other types of stocks.

This indicator scored 76%.

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

Government medicines can be identified by imprints on the containers and external packaging. A system including special colour packing is in use, which signifies in conspicuous ink "Government Property – Not for Sale".

Seventy-eight per cent of KIs reported that there is a coding system in use for identification of government medicines.

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

Products in warehouses are organized systemically by dosage forms: tablets and capsules, injections, syrups and suspensions, creams and ointments, and so on.

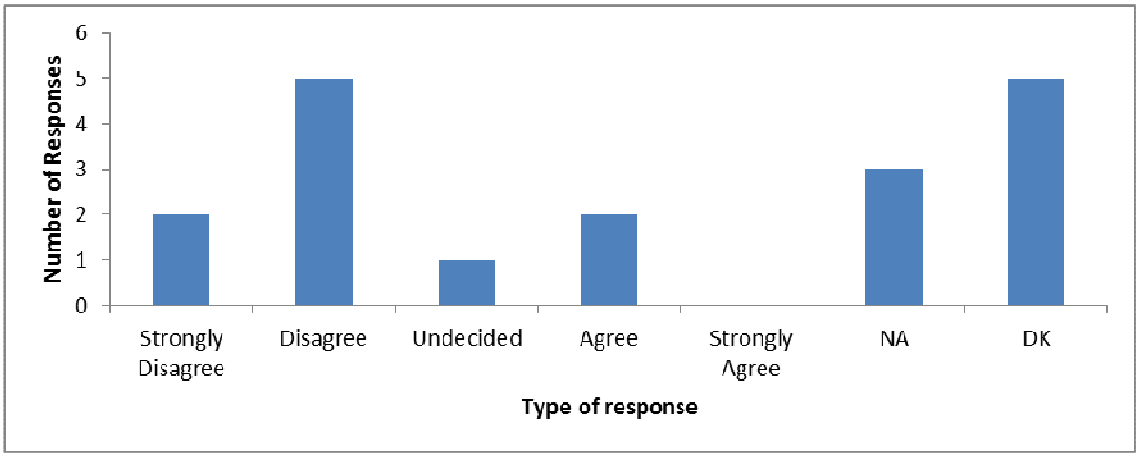

Fig. 20. KI perceptions that port clearing is done smoothly and there is no need for bribery or gift-giving to expedite the process

These dosage forms are arranged according to therapeutic actions. The layout of the location of medicines is available/applied in some tertiary care hospitals and in provincial and central warehouses. There are bin cards, maintained manually and, in some instances, a computerized inventory system which takes into account the quantity and expiry date.

Most KIs were aware of current practice and this indicator scored 75%.

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

A conventional security system to oversee storage and distribution exists on entry and exit to monitor the warehouses. In provincial warehouses, the system requires the sealing/de-sealing of the locks and keys by the concerned staff, which may be bypassed under special circumstances by the committee/officer in charge after recording the reasons for doing so. Limited access by unauthorized persons is ensured and controlled substances (narcotics) are separated and secured by locks. Nevertheless, neither there is no alarm system for security breaches nor any requirement for physical searches of those leaving the warehouse.

Most KIs were aware of the current conditions. This indicator scored 87%.

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

There are standard operating procedures available for stock management at each level of distribution system that provide information regarding average working

stock, amount of safety stock, frequency of reordering, quantity of reordering, average inventory and expiry date for each product. However, this practice does not exist at primary health care facilities. A management information system exists at district level which has methodical standard operating procedures for reporting the stock out situation.

Eighty-three per cent of KIs reported that there are standard operating procedures available for stock management.

Indicator VIII.8: Is there an inventory management system that is used in the warehouse at each level of the distribution system?

There are inventory records and procedures at various levels of the distribution system in the central warehouse and at tertiary and secondary health care facilities. The inventory control system provides information on the following components: the average working stock; the amount of safety stock; the frequency of reordering; the quantity of reordering; the average inventory; the lead time; and the expiry date. Mostly, the store in charge is directed to convey the situation of near-expiry stock in quarterly reports. Inventory control at tertiary and secondary care hospitals is computerized, but the system at the primary health care level is manual.

Almost all KIs were aware of the current practice. The indicator scored 94%.

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

Warehouse staff continuously monitor and produce up-to-date records of current stock levels reconciled with the physical count of the selected medicines.

Seventy-two per cent of KIs were aware of current practice.

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

The warehouses are subject to external auditing by the Auditor General on a yearly basis and random auditing by health authorities that is confined to purchase auditing. The warehouse supervisor is able to provide the date of the last audit and can show a report of the warehouse audit indicating that the audit has been carried out at least once a year by an independent audit party. The KIs reported this purchase auditing as “stock auditing”.

Almost all KIs were aware of this practice and this indicator scored 85%.

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?

A computerized system provides the requisite information about the medicines that have left the central warehouse or have been received by health facilities. This information also includes: the type of medicines that have left the warehouse; quantity of medicines that have left the central warehouse; the person who verified the amounts; and the intended recipients of the medicines. However, most warehouses do not have a computerized system. The date of arrival of drug is recorded manually, while short/excess/damage/incorrect shipments are rarely recorded.

Most KIs reported that there is a system in place and the indicator scored 92%.

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

Health facilities have a procedure in place for requesting medicines which includes the medicines to be supplied, dosage form, strength and quantity. The requisition is checked by the person in charge of the facility.

Most KIs were aware of this practice and the indicator scored 81%.

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

Schedule H of the Punjab Drug Rules 2007 contains the WHO guidelines on good storage and distribution practices. These address adverse transportation conditions, methods of protection/theft and mechanisms to prevent swapping of stock during transportation and the requests being signed by a responsible person.

This indicator scored 67%.

Indicator VIII.14: Is there a well-functioning communication system between distribution points?

The communication system between distributions points includes: a manual/document exchange system at all levels; telephone contact between all levels; and fax contact between all levels. However, a computerized system does not exist.

Eighty-nine per cent of KIs reported that there is a well-functioning communication system in place.

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

A loose monitoring and evaluation programme exists and is carried out by the Auditor General of Pakistan (an independent authority). The auditors of the Health Department and the Office of the Auditor General of Pakistan audit procurements, distribution and stocks at least once a year. The reports of these audits identify the weakness and flaws of the procurement and distribution system, along with allied issues. Although such audit reports are not posted publically online, they are discussed in the Public Accounts Committee, a forum comprising elected public representatives.

This indicator scored 59%.

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

Sanctions are imposed on individuals for theft or corrupt practices. Procedures are in place for the application of sanctions for corrupt behaviour. The sanctions depend on the nature and gravity of the act of corruption. There is evidence that individuals have been punished for corrupt behaviour in the past. KIs were aware of the system under the Pakistan Penal Code 1860, the Drug Act 1976, the Punjab Employees Efficiency, Discipline and Accountability Act, the Anti-Corruption Act, and the National Accountability Bureau Act, but were concerned about their implementation and execution.

This indicator scored 57%.

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

Appropriate procedures are available with the person in charge of the health facility for disposal of expired and/or spoiled medicines through a committee of responsible persons under notification to the higher authorities, not necessarily DRAP. After completion of destruction of expired and/or spoiled medicine, the minutes of proceedings, giving the details of medicines destructed, are recorded for circulation to all concerned.

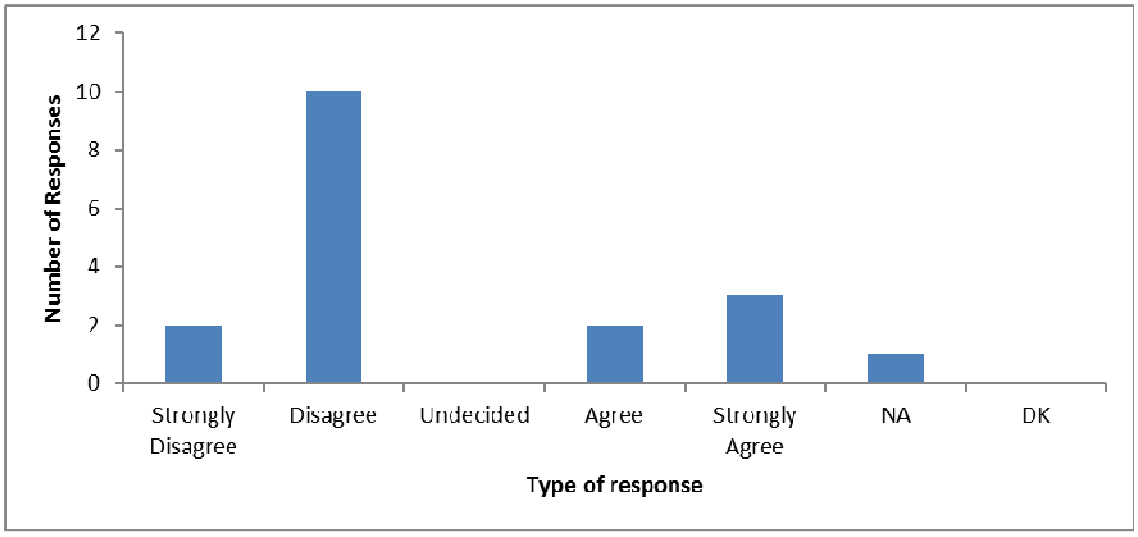

Fig. 21. KI perceptions that there are very rarely leakages in the medicine distribution system in Pakistan

This indicator scored 67%.

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".

Twenty-seven per cent of KIs agreed or strongly agreed with the statement (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 Pakistan would be to:

- ensure the distribution system continues, with an uninterrupted supply of essential medicines throughout the year;
- make concerted attempts to keep drugs in good condition throughout the distribution process (receipt, transport and storage); temperature control is of vital importance;
- establish a medicine management system to control the inventory level of essential medicines at each facility and ensure provincial/district headquarters are able to mobilize slow moving items from one facility to another well before expiry of the medicines;

- establish a uniform coding system to identify public sector procurement at all levels; the manufacturers/importers should be made to keep records of all supplies with batch numbers that could be matched in cases of stolen medicine;
- carry out independent audit of warehouses by external third party inspectors/auditors;
- develop written guidelines on the transportation and delivery of medicines from manufacturers to warehouses and points of consumption; this is critical for preserving the efficacy of medicines;
- put a programme in place to monitor and evaluate the performance of the medicine distribution system on regular or occasional basis;
- put a proper system in place for handling of expired and spoiled medicines in accordance with internationally accepted standards;
- request government to invest in capacity-building through training of staff, providing adequate storage facilities and equipping warehouses with necessary equipment so that storage and distribution practices are in line with WHO guidelines;
- permit only authorised distributors/suppliers to supply medicines directly to health facilities;
- devise a system to ascertain reports identifying the weaknesses of the distribution system, and give the public reasonable access to the reports;
- give due importance to making security management adequate to overseeing storage facilities and distribution; and
- introduce a computerized system for communication between distribution points to manage the distribution of medicines system.

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, inspection and market control, medicine promotion control, clinical trials of medicines, selection of medicines, procurement of medical products and distribution of medicines.

5.1 Medicines registration

Upon comparing method 2 indicators (I.8 and I.9) with method 3 indicators (I.11) it was observed that the evidence of written criteria for selection of committee members exists and there is a document available that describes the composition or terms of reference of the concerned technical committee, excepting that the document lacks a few sub-functions of this parameter. Half the KIs disagreed with the statement: "The members of the registration committee are systematically and objectively selected based on the written criteria in force in your country". This affirms the need to develop more robust mechanisms for the selection of members and the operation of committees.

The evidence obtained from the answers to method 2 Indicator I.10 affirms that there are no written guidelines on conflict of interest. Most KIs disagreed or strongly disagreed with the statement: "Gifts and other benefits given to officials in charge of medicines registration have no influence at all on the final decision". This highlights a need to address the issue of conflicts of interest management.

5.1.1 Strengths of the medicines registration function

The strengths of the medicines registration function are as follows.

The application forms and procedures for submitting an application for registration of medicinal products are comprehensive, published in the official gazette, available online and can be obtained from the registration office.

The meetings of the Registration Board are held regularly and the agenda/minutes of the meeting of the Board are available online.

Applicants aggrieved with the decisions of the Registration Board have the right to launch an appeal to the Appellate Board. The appeals are decided, generally, within a reasonable timeframe.

5.1.2 Weaknesses of the medicines registration function

The weaknesses of the medicines registration function are as follows.

- An up-to-date list of the registered products is not available.
- Written procedures describing the process to be followed in assessing submissions are not available except as a checklist.
- No timeframe is notified for the processing of applications.
- The absence of written guidelines on conflicts of interest.
- Criteria for the selection of members of the Registration Board and their terms of reference are not laid down.
- Members of the Registration Board/Committee/Dossier Evaluation Cell are not required to issue any declaration of conflicts of interest.
- Written guidelines on the decision-making process of the Registration Board do not exist. Similarly, written guidelines explaining the protocol for meetings of officers with applicants do not exist.
- No procedures are in place to regulate the receiving of gifts and benefits by officials working in the registration sections or by members of the Registration Board.

5.2 Licensing of pharmaceutical establishments

The evidence obtained from method 2 indicators (II.3 and II.4) shows the existence of procedures for submission of applications for licensing and the existence of specific guidelines for assessing applications for a license. For the method 3 indicator (II.11), most KIs agreed or strongly agreed with the statement: "The licensing of pharmaceutical establishments is systematically carried out according to policies and procedures".

Upon comparing method 2 indicators II.6 and method 3 indicators II.13, it was found that the answers were compatible and both confirmed the existence of a formal committee that assesses applications for the licensing of pharmaceutical establishments and that is fully operational and meets on a regular basis.

5.2.1 Strengths of the licensing of pharmaceutical establishments function

The strengths of the licensing of pharmaceutical establishments function are as follows.

- The Drugs Act 1976, and the Rules framed thereunder, contain comprehensive provisions that prohibit any pharmaceutical establishment without a valid license.
- The licensing section of DRAP and offices of the Executive District Officer (Health) have been mandated to deal with the applications for drug manufacturing and drug sale licenses, respectively. Written procedures for submission of applications for manufacturing licenses are available to the public (at the DRAP website), which illustrate the criteria, requirements and procedures to be followed by applicants, along with the prescribed fee.
- The application forms, along with the requirement for issuance of drug manufacturing and drug sale licenses, are available in the Drugs (Licensing, Registration and Advertisement) Rules 1976 and the respective provincial drug sale rules.
- Inspection of pharmaceutical establishments (for manufacturing, sale or distribution) is mandatory prior to issuance of a license.
- The right to appeal against the decisions of the licensing board or licensing authority has been ensured in the Drugs Act 1976.
- The list of licensed manufacturing units is available on the DRAP website.

5.2.2 Weaknesses of the licensing of pharmaceutical establishments function

The weaknesses of the licensing of pharmaceutical establishments function are as follows.

- A complete and up-to-date list of all pharmaceutical establishments (manufacturers, retailers and distributers) is not available with any of the authorities.
- The rules for selection of members of the Central Licensing Board do not describe unambiguous areas of expertise required of members.
- The timeframe for processing applications is not stated.
- In absence of clear guidelines for disposal of applications for licensing, unnecessary delays are apparent.
- Sales outlets operating under the umbrella of "general practitioners" are not regulated.

5.3 Inspection and market control

The evidence obtained from method 2 indicators (III.5 and III.6) shows the absence of written mechanisms to prevent regulatory capture between inspectors and the manufacturers that they inspect (although unwritten procedures do exist) and there are no written guidelines on conflicts of interest with regard to inspection activities. For method 3 indicator (III.10), most KIs disagreed or strongly disagreed with the statement: "The integrity of inspectors is in no way influenced by personal gain, such as bribes, gifts, or any other benefits".

5.3.1 Strengths of the inspection and market control function

The strengths of the inspection and market control function are as follows.

- The regulations covering the inspection of pharmaceutical establishments in Pakistan as per the Drugs Act 1976, and the rules framed thereunder, are effective.
- The powers, duties and procedures to be followed by inspectors are clearly laid down.
- The inspectors are not allowed to prosecute accused persons directly in the court of law.
- The complaints of inspectors are reviewed by the concerned authority/board and the permission of the concerned board is mandatory to lodge prosecution in the drug courts.
- Check lists for good manufacturing practices inspection and inspection of sale outlets are available.
- Written guidelines on good manufacturing practices and good distribution and storage practices are available.

5.3.2 Weaknesses of the inspection and market control function

The weaknesses of the inspection and market control function are as follows.

- The required guidelines with regard to conflicts of interest are not available to inspectors.
- Although a person having financial interest in the pharmaceutical trade may not be appointed as inspector according to section 17 of the Drugs Act 1976, no declaration of conflicts of interest is issued by inspectors.
- The mechanism to prevent regulatory capture between inspectors and manufacturers/sellers is very weak.

- KIs complained of the acceptance of illegal rewards and misuse of authority by inspectors, which are not properly addressed due to lack of an effective monitoring mechanism.

5.4 Control of medicines promotion

Upon comparing method 2 indicator IV.1 and method 3 indicator IV.11, the evidence was found of provision in the medicines legislation covering medicine promotion. However, most KIs disagreed or strongly disagreed with the statement: "The legal provisions on medicine promotion have been developed in broad consultation with all interested parties".

Upon comparing method 2 indicator IV.3 and method 3 indicator IV.12, it was confirmed that pre-approval of promotional and advertising materials is required. However, most KIs disagreed with the statement: "pre-approval of promotional and advertising materials is systemically being obtained before they are made public".

The evidence obtained from both method 2 indicator IV.4 and method 3 indicator IV.14 confirms that legal provisions for sanctions on medicines promotion do exist. However, the legal provisions are not systemically enforced for breach of conduct.

5.4.1 Strengths of the control of medicine promotion function

The strengths of the control of medicine promotion function are as follows.

- There are legal provisions under the Drug Act 1976/ Drugs (Licensing, Registration and Advertisement) Rules 1976 which cover the regulation of medicines advertisement.
- Pre-approval of advertising material regarding registered drugs is mandatory, pursuant to the provisions of Drug Act 1976, before it is released to print and electronic media.

5.4.2 Weaknesses of the control of medicine promotion function

The weaknesses of the control of medicine promotion function are as follows.

- The legal provisions do not contain restrictions or monitoring of free samples, symposia and scientific meetings in country and abroad, post-marketing scientific studies, speaker and consultancy fees, promotion of exported medicines, and restriction and limits on gifts and gimmicks of all kinds.

- Proper procedures do not exist to report unethical practices and to launch a complaint.
- A dedicated and exclusive forum responsible for the monitoring and enforcement of the provision on medicine advertisement does not exist. No guidelines have been developed by the federal/provincial governments regarding composition of the advertisement committee and selection of its members.
- There is no publically-available comprehensive document describing the services responsible for pre-approving or monitoring medicines promotion.
- Guidelines on conflicts of interest with regards to officials involved in the control of advertisement activities either at federal level or at provincial level have not been framed.
- It is widely perceived that the legal provisions on medicines promotion are inadequate and have not been developed with the consultation of the relevant stakeholders.
- There is no evident role given to civil society/nongovernmental organizations in improving the control on medicines promotion in the country.
- For the existing provisions on medicine promotion, the enforcement mechanism is too weak.

5.5 Clinical trials of medicines

Upon comparing method 2 indicator V.9 and method 3 indicator V.13, it was confirmed that national guidelines require the establishment of an independent ethics committee. However, most KIs were unaware of the requirement and answered that they disagreed/were undecided with the statement: "The independent ethics committee members are systematically selected based on the written selection criteria".

The evidence obtained for method 2 indicator V.6 and method 3 indicator V.14 confirms that there is a non-functional formal review committee in the medicine regulatory authority which is responsible for reviewing applications and clinical trial results.

5.5.1 Strengths of the clinical trials of medicines function

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

- There exists statutory provision in the DRAP Act 2012 and the Drug Research Rules 1978, framed under the Drugs Act 1976, which regulates clinical trials in Pakistan.
- National guidelines on the principles of good clinical practices based on ICH and WHO guidelines have been developed (the Pakistan Good Clinical Practices Guidelines 2008).
- A license is required for the manufacture, import and export of investigational products.

5.5.2 Weaknesses of the clinical trials of medicines function

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

- There is no independent section/directorate for monitoring clinical trials in Pakistan.
- Only a few aspects of clinical trials are regulated through Director Pharmacy Services of DRAP, supported by an assistant drug controller.
- A committee is responsible for the review of clinical trial applications. However, the composition of the committee is not available on the DRAP website. Most KIs were ignorant of this committee. A mechanism to ensure that officials/members of the review committee have sufficient expertise in the required areas does not exist.
- There is no operational system for clinical trial inspection. However, the committee/Director Pharmacy Services can inspect the site.
- There is no timeframe for assessment of clinical trial applications and no policy guidelines have been formulated for declaration of conflicts of interest by persons involved in the review process.
- The list of approved/rejected applications for clinical trials in Pakistan is not publically available.
- KIs had strong reservations about the selection and working of the review committee and role of the DRAP in ensuring the conduct of clinical trials in accordance with good clinical practices guidelines.

5.6 Selection of medicines

The evidence obtained from method 2 indicator VI.10 and method 3 indicator VI.2 confirms that there are no standard operating procedures for the decision-making process of the committee and half of the KIs disagreed with the following statement: "The national essential medicines list has been developed in consultation with all interested parties and using an evidence-based approach".

Upon comparison between method 2 indicators VI.8 and VI.10 and method 3 indicator VI.6, it was confirmed that there are no written guidelines on conflicts of interest with regard to selection of medicines, but there are standard operating procedures available for the decision-making process of the committee. In addition, most disagreed with the statement: "The committee responsible for the selection of the national essential medicines list is operating free from external influence".

5.6.1 Strengths of the selection of medicines function

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

- The Federal Government of Pakistan officially developed the National Essential Medicines List 2007 and later on the WHO Model List of Essential Medicines was adopted.
- The criteria for inclusion/deletion of medicine in the National Essential Medicines List are transparent and rational.
- The National Essential Medicines List 2007 was disseminated to the provinces, so that public sector purchases are made according to the list.
- The lists of medicines are prepared by local experts at tertiary, secondary and primary health facilities according to their needs and budget.
- At present, the provinces have developed their own essential drugs lists which serve as guidelines for public procurement.

5.6.2 Weaknesses of the selection of medicines function

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

- The criteria for selection of members of the National Essential Medicines List committee and provincial committees are questionable because the committees lack rules of business.
- The terms of reference of members are also not available.
- There are no written guidelines to address possible conflicts of interest by officials and members of the selection committees. In practice, no declarations are signed by the experts engaged in the selection process at the federal or provincial level.
- Complaints of favouritism, material gifts, vested interests and misuse of authority were made by KIs.
- The decision-making process of the committee responsible for revision of the National Essential Medicines List, and finalization of list of medicines to be

procured, is random and does not follow any set of standard operating procedures.
- No criteria are publicly available for the selection process for including or deleting medicines in the indented medicine list.

5.7 Procurement of medical products

The evidence obtained from method 2 indicator VII.7 shows that there exist specific criteria for tender committee membership. However, most KIs disagreed with the statement: "Members of the tender committee are systemically selected based on specific criteria" (method 3 indicator VII.9).

Upon reviewing method 2 indicator VII.1, it was evident that the government uses transparent and explicit procedures for the procurement of pharmaceutical products and there are no written guidelines on conflicts of interest with regard to the procurement process (method 2 indicator VII.8). On the other hand, for method 3 indicator VII.14, most KIs disagreed or strongly disagreed with the statement: "The procurement system in your country is operating in a totally transparent manner".

5.7.1 Strengths of the procurement of medical products function

The strengths of the procurement of medical products function are as follows.

- An explicit document that serves as the official procedure is publically available for public procurement namely, Public Procurement Regularity Act and the rules framed thereunder.
- An appeal system exists for aggrieved parties.
- Purchase committees at federal, provincial, district and institutional level are responsible for contract decisions and selection of suppliers.
- A system for routine inspection of consignments of medicines procured is in place.
- The procurement has to undergo external auditing through the Auditor General at least once a year, and its results are made publically available in the public accounts committee of the Parliament/Provincial Assemblies.

5.7.2 Weaknesses of the procurement of medical products function

The weaknesses of the procurement of medical products function are as follows.

- The Public Procurement Regularity Act that regulates public procurement imposes no condition that all medicine purchases for the public sector should be procured in accordance with national essential medicines list.
- There are no written criteria for selection of experts for the purchase committee.
- Tenders are not accepted online.
- There are no written guidelines on conflicts of interest of procurement staff nor is there any declaration required regarding conflicts of interest by procurement staff.
- Complaints of favouritism are rampant.
- A computerized management information system to monitor product problems is not available at all administrative levels.
- The system of monitoring the quality of medicines after procurement and supply is fairly weak.

5.8 Distribution of medicines

Upon comparing method 1 indicator VIII.1 with method 3 indicator VIII.2, it was revealed that a system is in place to expedite port clearance. However, most KIs were undecided/did not know if port clearing is done smoothly or if there is no need for bribery or gift-offering to expedite the process.

The evidence from most of the method 2 indicators (VIII.8, VIII.6, VIII.11 and VIII.16) shows that there is no security management system in place to oversee storage and distribution. An inventory management system exists at each level of distribution that provides the minimum information required. The evidence also confirmed that there is either a computerized or manual system to track the movement of pharmaceuticals from a warehouse to a particular health facility and that punishments are imposed for theft or other corrupt practices associated with the maldistribution. However, most KIs disagreed or strongly disagreed with the statement "There are very rarely leakages in the medicine distribution system in your country".

5.8.1 Strengths of the distribution of medicines function

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

- Medicines are received and distributed in special packaging/colour scheme of labelling with the phrase "Government property—not for sale" printed in

conspicuous ink, pursuant to the provisions of the law to prevent pilferage of distributed medicines.
- Written guidelines regarding good storage and distribution practices, in line with WHO guidelines, are followed in the process of distribution of medicines.
- Designated staff/inspection committees are responsible for checking receipts against the packing list when supplies arrive at warehouses.
- Inventory records and procedures can be readily examined at various levels of the distribution system in the central warehouse and in tertiary and secondary health care facilities.
- An appropriate procedure is practised by health facilities for requesting supplies of medicines.

5.8.2 Weaknesses of the distribution of medicines function

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

- The distribution of medicines is not computerized at the primary or secondary health care levels and there is no effective security management to administer storage and distribution at the hospital level.
- No programme exists for regular monitoring and evaluation of the performance of medicine distribution system. KIs reported that complaints of leakages in medicine distribution are widespread in the system.

6. Recommendations

6.1 General recommendations

The following are recommendations that are common to all functions in the assessment.

- The entire process of decision-making should be based on merit and be made open to the public for transparency.
- All rules, regulations, standard operating procedures and guidelines should be posted online.
- A well-defined conflict of interest policy should be put in place for the selection of staff and members of the various committees.
- The entire process of registration should be computerized to ensure transparency and to accelerate the registration process.
- Qualified staff with integrity and of sufficient number should be made available to the agencies working in the management of the pharmaceutical sector for the proper and prompt disposal of the work.
- List of registered medicines, licensed manufacturers and distributors should be available online and updated regularly.
- Pharmaceutical companies should be monitored during the process of promotion of health care products to ensure that medicines promotion is only done on a sound scientific basis. A law should be published and enforced to monitor and punish any unethical practices by pharmaceutical companies in the promotion of their products.
- Investment should be made in training for capacity-building. The officials deputized in the clinical trials unit should be trained and educated in line with international regulatory standards and appointment of officers in the clinical trial section should be made on the basis of their prior training/expertise in the area and for a specific time only. Special attention should also be given to the development of infrastructure, including storage facilities and warehouse equipment.
- Guidelines for the selection process for inclusion/deletion of medicines, along with the decision-making process for the preparation of National Essential Medicines List, should be developed and disseminated to all concerned.

- There should be a distinct programme to monitor and evaluate the performance of the medicines distribution system. A computerized medicine management system to control the inventory level of essential medicines at each facility/district headquarters should be able to mobilize slow moving items from one facility to another well before the expiry of the medicines. Effective security management to oversee storage and distribution of medicines should be put in place.

6.2 Medicines registration

The following are recommendations to improve the transparency of the medicines registration function in Pakistan.

- The registration process should be strengthened through the provision of qualified staff in sufficient number and regular training for evaluation of relevant dossiers.
- A comprehensive list of medicinal products registered in Pakistan should be prepared and made available to all field staff and the public at large.
- The entire process of registration should be computerized to ensure transparency and accelerate the registration process. The submission of applications should be online through adoption of the electronic common technical document. The status of the application should be available online.
- Publication of all required processes and standard operating procedures for assessment of medicines registration applications should be mandatory to ensure transparency. WHO and ICH guidelines regarding registration of pharmaceutical products should be the guiding principle and should be implemented according to its true spirit.
- A timeframe should be notified for each step in processing applications and a valid reason should be recorded for any delays. The overriding principle of registration of pharmaceutical products should be the public health interest and priorities.
- The price fixed should be in uniformity with the international reference price, given the socioeconomic indicators of Pakistan.
- Only competent and honest officials should be appointed to the registration branch. The honesty and integrity of officials should be observed to minimize unethical contact with the industry. All meetings should be recorded by CCTV camera. There should be transparency in the decision-making process and an adherence to merit in processing/decision-making, which should be open to the public.

- A well-defined conflict of interest policy should be put in place, and the selection of staff and members of registration and evaluation committees should be strictly in accordance with the conflict of interest policy. DRAP should ensure that all those responsible for medicines registration should declare conflicts of interest in writing.

6.3 Licensing of pharmaceutical establishments

The following are recommendations to improve the governance in the area of licensing of pharmaceutical establishments function in Pakistan.

- The entire system of issuance of drug manufacturing licenses should be computerized with all relevant standard operating procedures available online. A complete list of licensed manufacturing units with available sections, products and qualified personnel should be available in the public domain. A computerized licensing cell should be established through deployment of sufficient skilled staff to evaluate applications and monitor existing licensed units.
- The system of issuance of drug sales licenses should be computerized and all relevant standard operating procedures made publically available, preferably through a central website.
- The training by international experts of the officers in the licensing section on current good manufacturing practice, current good laboratory practices should be regular practice.
- The Drugs Act 1976 should be reviewed to make it more stringent towards the manufacturing and sale of spurious drugs in line with international norms. The existing laws and regulations regarding establishment of manufacturing units should be reviewed and implemented without discrimination. An in-built accountability system for all those involved in the licensing process should be introduced and implemented.
- A complete list of distributers with the name of the foreign principals/local manufacturers should be made available online. The list of licensed retail pharmacies should be updated on a monthly basis with the name of the proprietor and qualified personal placed on a central website.
- The officers posted in the licensing sections should be offered market-based incentives and their integrity should be monitored. Selection of the members of the Central Licensing Board and assessors should be based upon transparent and pre-defined criteria. Adequate training should take place of assessors,

members of inspection teams and members of the Central Licensing Board on current good manufacturing practices.

- A well-defined conflict of interest policy should be put in place and the selection of staff of the licensing section, evaluation cell and members of the Central Licensing Board should be strictly in accordance with the policy. DRAP should ensure that all concerned committees responsible for the licensing of pharmaceutical establishments should submit conflict of interest declarations in writing.

6.4 Inspection and marketing control

The following are recommendations to improve the transparency of the inspection and marketing control function in Pakistan.

- All regulations covering the inspection of medicines and all guidelines and procedures regarding inspection activity should be posted online. A clear system for the inspection schedule and publication of inspection reports should be devised and published.
- The number of inspectors should be increased and a clear rotation mechanism implemented. The salary structure should be improved and logistical support provided. A comprehensive training programme should be ensured for all inspectors regarding accountability, professional conduct and current good manufacturing practices inspection.
- Written guidelines on conflicts of interest with regard to inspection activities and the mechanism of monitoring, including sanctions in case of breach of the guidelines, should be developed and published.
- A code of conduct should be devised for inspectors to avoid unnecessary harassment during inspections and their accountability ensured.

6.5 Control of medicines promotion

The following are recommendations to improve the transparency of the medicine promotion control function in Pakistan.

- Standard operating procedures to guide services for pre-approving and monitoring medicines promotion should be developed and published. The legislation covering medicine promotion should be reviewed and developed in line with international standards in consultation with all stakeholders. This should include framing special laws regarding the marketing and promotion of

health care products and pharmaceuticals in line with the Foreign Corrupt Practices Act and their publication for public awareness. Comprehensive regulations should be made regarding classification of sponsorship with detail of an upper limit that should be notified.

- There should be monitoring of pharmaceutical companies during the process of promotion of health care products to ensure that their medicines promotion is based only on sound scientific studies. There should be enforcement of a law to monitor and punish unethical practices by pharmaceutical companies.
- A complete ban should be imposed on financial reward to health care professionals under the cover of "promotion", such as for clinic renovation, gifts and bribes. All pharmaceutical companies should be encouraged to develop a voluntary code of ethics as part of their corporate social responsibility and for strict compliance. Policies should be established and enforced that establish and monitor ethical standards with respect to pharmaceutical company medicines promotion to prescribers.
- There should be a dedicated monitoring cell at DRAP to ensure the documentation of all types of expenses incurred in the promotion of pharmaceuticals. The data should be published for public review.
- A comprehensive practitioner and consumer education programme should be introduced on the impact of unethical medicines promotion. Recommendations should be made to the Pakistan Medical and Dental Council and the Pharmacy Council of Pakistan for training of health care professionals on how to adopt good prescribing practices.
- Field officers should be authorized to impose spot fines for off-label promotions and other malpractices.
- Trials for cases of violation of provisions regarding medicines promotion should be expedited.
- The opinion of the Registration Board should be solicited regarding restriction on the number of brands for the same molecule to avoid unethical competition for sale and promotion.
- A well-defined conflict of interest policy should be put in place and staff/members of the medicines promotion control committee should be selected in accordance with the policy. DRAP should ensure that all those concerned/committees responsible for control of advertisements of pharmaceutical products submit a conflict of interest declaration in writing.

6.6 Control of clinical trials of medicines

The following are recommendations to improve the transparency of the clinical trials of medicines function in Pakistan.

- The national guidelines on good clinical practices should be published and disseminated to all concerned. A pool of experts in particular areas of clinical research should be notified and the members of the clinical trial assessment committee should be selected from that pool based on transparent and well-defined criteria. An operational clinical trials inspection system should be established so that a proper check on unethical practices in clinical trials is ensured. On-site inspection of clinical trials should be carried out by a team of experts.
- An independent national bio-ethics committee should be constituted that could ensure publication and implementation of coherent ethical guidelines throughout the country and liaise with institutional ethics committees. The workings of the Institution Review Board and the Intuitional Ethics Committee should be monitored.
- DRAP officials deputized to the clinical trial unit should be trained and educated in line with international regulatory standards. The appointment of officers in the clinical trial section should be made on the basis of their prior training/expertise in this area and for a specific time only.
- The timeframe for processing an application should be allocated and ensured, along with the protection of patients' rights.
- Interaction and sharing of information between researchers and DRAP should be improved and conflict of interest guidelines with regard to clinical trial-related activities should be developed.

6.7 Selection of medicines

The following are recommendations to improve the transparency of the selection of medicines function in Pakistan.

- Guidelines for the selection process for inclusion/deletion of medicines, along with guidelines for the decision-making process for the National Essential Medicines List, should be developed and disseminated to all concerned. All public sector procurement should be carried out in accordance with the National Essential Medicines List. Appropriate measures should be adopted to promote prescribing from the list in the public and private sectors. The List should be based on WHO principles and national prescribing guidelines, while

keeping in mind the mortality data of Pakistan and ensuring that the standard operating procedures for decision-making are clear and transparent to the public. All scientific information pertaining to the reasons for choosing and deleting medicines should be published.

- The members of the committee for selection/deletion of pharmaceutical products in the National Essential Medicines List should be representative of all stakeholders geographically and professionally. The selection process for the committee should be transparent and publically available, and committee members should be rotated periodically. National Essential Medicines List committee members should be trained on all parameters/criteria, including public health priorities, effectiveness, cost–effectiveness, safety concerns and disease prevalence. There should be provincial and district committees to ensure the implementation of the National Essential Medicines List in their area that are authorized to take decisions under special circumstances.
- Guidelines for particular disease patterns should be developed and circulated to all concerned for adherence. A standard form for conflicts of interest and guidelines for the relationship between members of the medicine selection committee and pharmaceutical companies should be develop and enforced.
- The selection of pharmaceutical monopoly formulations should be avoided as much as possible. The committee members should be trained to assess and weigh cost–effectiveness.
- Gifts and other illegal rewards should be prohibited for doctors and other prescribers/professionals through implementation of a code of ethics prescribed for doctors by the Pakistan Medical and Dental Council.

6.8 Procurement of medical products

The following are recommendations to improve the transparency of the procurement of medical products function in Pakistan.

- A well-coordinated procurement department should be established in every provincial headquarters, capable of providing the necessary documents and guidelines to all institutions and district heads for the procurement process. The following key functions/sections should be included in the structure of the procurement department: specification, accountancy, quality assurance, audit, procurement, receiving and checking, and management information system support to monitor and report the performance of particular suppliers and

products. Ensure that the process for submissions of tender is available online and results are posted online.

- The written guidelines on conflicts of interest with regard to the procurement process should be implemented and members of the tender committee should declare any conflicts of interest.
- The procurement process should be simplified to improve the system and its effectiveness. This can be achieved by requiring a more evidence-based approach to medicine selection for procurement and rationalization of medicine requirements by reducing the chemical entity in each therapeutic group (for instance, having two beta blockers, two proton pump inhibitors, and so on).
- The process of submission of tenders should be online and the results posted on the website. Bulk purchase should be restricted only to the National Essential Drugs List and according to the level of care (primary, secondary or tertiary health care). All measures should be taken to ensure that the procurement function is independent and free from political interference.
- Procurement procedures should be reviewed to ensure that prospective suppliers are pre-qualified and their performance is monitored for product quality, service reliability, delivery time and financial viability. All information must be appropriately recorded in a retrievable database. The status of firms in connection with their performance should be updated regularly and blacklisting of suppliers should be done according to well-defined criteria that are made public. Training of procurement staff should be carried out to build up their capacity for adhering to Public Procurement Regularity Act rules. Proper training of staff involved in the procurement process should be ensured.

6.9 Distribution of medicines

The following are recommendations to improve the transparency of the distribution of medicines function in Pakistan.

- There should be a dedicated programme to monitor and evaluate the performance of the medicines distribution system. The medicines management system to control the inventory level of essential medicines at each facility/district headquarters should be able to mobilize slow moving items from one facility to another, well before the expiry of the medicines. The distribution system should ensure a continuous, uninterrupted supply of essential medicines throughout the year and the medicines should be kept in

good condition throughout the distribution process (receipt, transport and storage).

- There should be an independent audit of warehouses by external inspectors/auditors. There should be written guidelines on transportation and delivery of medicines from manufacturers to warehouses and to the point of consumption.
- Ensure good storage and distribution practices in line with WHO guidelines.
- A more effective security management system should be put in place to oversee storage and distribution.
- A uniform coding system should be established to identify public sector procurement at all levels. Manufacturers/importers should be required to keep records of all supplies with their batch numbers, to be used for matching in cases of stolen medicine.
- Written guidelines should be developed for the handling of expired and spoiled medicines.
- Investment should be made in capacity-building through staff training, equipping warehouses and provision of proper storage facilities.
- Only authorized distributors/suppliers should be allowed to supply medicines directly to health facilities.
- Reports should be submitted identifying the weakness of the distribution system and made publicly available.
- A computerized system for communication between distribution points should be introduced.

7. Conclusions

The results of the assessment have been presented in tables and diagrams classifying them into the categories of: very vulnerable, moderately vulnerable or marginally vulnerable. The functions of selection of medicines, clinical trials of medicines and medicine promotion control were found to be very vulnerable to corruption, while the licensing and distribution functions were only marginally vulnerable. The functions that were moderately vulnerable were medicines registration, inspection and market control, and procurement of medical products. The scores given are an average of the scores of all KIs for that indicator in a function.

Efforts to promote good governance show that arrangements to address corruption require legislative reform, and establishing the legal and administrative structures and processes to establish a transparent medicines regulation and procurement system, along with defining the legal sanctions system for those not complying with the law. In addition, promotion of institutional integrity through promotion of moral value and ethical principles is critically significant. A coordinated approach, integrating all components, should be adopted for significant impact.

The result of this assessment will help the system regulators of Pakistan to apply the "discipline measures" and "institutional measures" needed to adjust the laws, administrative structures and procedures regarding medicines regulations and procurement. All actions recommended by the KIs should be finalized after broad-based consultation with all stakeholders to promote good governance in medicines regulations and procurement.

The implementation of good governance for medicines in the public sector is a developmental process. Quick results are not possible in conditions where vulnerability is fairly high, but satisfying results are possible in the short term. As a way forward, Pakistan will have to develop its own strategy unique to its own needs and realities. The process will adjust to the context over time.

Recently, Pakistan has taken far-reaching steps towards improving its management structures for medicines. The establishment of DRAP is a progressive step, backed and supported by the professional and political leadership. The agency is endeavouring to improve the transparency of medicines governance and decrease the vulnerability of the system to corruption.

Enormous efforts are needed to improve the system, particularly in the area of medicine promotion control, which requires the enforcement of new regulations that

cover all medicines promotion activities and the establishment of a committee that will be responsible for controlling and monitoring medicines promotion.

Further to improving the pharmaceuticals management system, efforts are needed to promote a culture of transparency across the different professions in the pharmaceutical domain. An ethical infrastructure document could be a useful tool in achieving this. However, such a document would need to be established in wide collaboration with various stakeholders. Even if the ethical infrastructure were in place for the public sector, the involvement of other actors who are users of the system would be beneficial to the process.

8. Resource documents

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Annex 1. KI perceptions of the transparency of each function

Function	Question	KI perceptions
Registration of medicines	The members of the registration committee are systematically and objectively selected based on the written criteria in force in your country	7.4% strongly agree 37.0% agree 40.7% disagree 11.1% strongly disagree
	Gifts and other benefits given to the officials in charge of medicines registration have no influence at all on their final decisions	3.7% strongly agree 3.7% agree 55.5% disagree 33.3% strongly disagree
	The registration committee meets on regular basis and keeps minutes for its meetings	7.4% strongly agree 37.0% agree 40.7% disagree 11.1% strongly disagree
Licensing of pharmaceutical establishment	The licensing of pharmaceutical establishments is systematically carried out according to policies and procedures	10% strongly agree 55% agree 25% disagree 5% strongly disagree
	The formal committee that assesses applications for licensing of pharmaceutical establishment is fully operational and meets on a regular basis	15% strongly agree 55% agree 30% disagree
Inspection and market control	The integrity of inspectors is not at all influenced by personal gains, such as bribes, gifts, material or other benefits, etc.	3.8% strongly agree 11.8% agree 50 % disagree 34.61% strongly disagree
	Inspection activities are systematically carried out in accordance with the guidelines and procedures to prevent biases (e.g. peer review or rotation)	3.8% strongly agree 34.6% agree 38.4% disagree 23% strongly disagree

Function	Question	KI perceptions
Medicine promotion control	The legal provisions on medicine promotion have been Developed in broad consultation with all interested parties	10.5% strongly agree 15.78% agree 21.5% disagree 42.1% strongly disagree
	Pre-approval of promotional and advertising material is systematically obtained before they are made public	15.7% strongly agree 15.7% agree 42.1% disagree 15.7% strongly disagree
	Civil society/nongovernmental organizations have a great influence on improving the control of medicine promotion in your country	10.5% agree 52.6% disagree 36.8% strongly disagree
	Sanctions foreseen in the provisions on medicine promotion are systematically applied when there is a breach	31.57% agree 36.8% disagree 31.5% strongly disagree
Clinical trials of medicines	The institutional ethics committee members are systematically selected based on the written selection criteria	6.6% strongly agree 20% agree 20% disagree 26.6% strongly disagree
	The medicine regulatory authority review committee members are selected systematically based on the written selection criteria	6.6% strongly 20% agree 20% disagree 26.6% strongly disagree
	The medicine regulatory authority is ensuring that clinical trials conducted in the country are done in accordance with the regulation and good clinical practice principles	13.3% strongly agree 13.3% agree 13.3% disagree 26.6% strongly disagree
Selection of medicines	The national essential medicines list has been developed in consultation with, and considering the opinion of all interested parties and using an evidence-based approach	20% strongly agree 20% agree 30% disagree

Function	Question	KI perceptions
		20% strongly disagree
	The committee responsible for the selection of the national essential medicines list is operating free from external influence	10% strongly agree 10% agree 45% disagree 20% strongly disagree
Procurement of medical products	Decisions of the tender committee are always taken into account in the procurement process	41.6% strongly agree 45.8% agree 4.1% disagree
	The members of the tender committee are systematically selected based on specific criteria	12.5% strongly agree 12.5% agree 62.5% disagree 12.5% strongly disagree
	The procurement system in your country is operating in a totally transparent manner	8.3% strongly agree 12.5% agree 50% disagree 29.1% strongly disagree
Distribution of medicines	Port clearing is done smoothly and there is no need for bribery or gift-giving to expedite the process	11.1% agree 27.7% disagree 11.1% strongly disagree
	There are very rarely leakages in the medicine distribution system in your country	16.6% strongly agree 11.1% agree 55.5% disagree 11.1% strongly disagree

Annex 2. Score sheets for functions

Table A1. Medicine registration vulnerability scale points

Country Name:				Period assessment Carried out										Registration																
PAKISTAN				JULY to DECEMBER 2014																										
	Method	RG 101	RG 102	RG 103	RG 104	RG 105	RG 106	RG 107	RG 108	RG 209	RG 310	RG 311	RG 312	RG 313	RG 314	RG 315	RG 316	RG 417	RG 418	RG 519	RG 520	RG 521	RG 522	RG 523	RG 524	RG 525	RG 526	RG 527	Total	Average per question
Profession	-----	P	G	P	P	P	G	P	P	G	P	P	P	P	P	P	G	AC	G	P	P	P	P	P	P	G	P	P		
Indicator I.1	M1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.00	0.00
Indicator I.2	M2	0.87	0.5	0	0.62	0	0.75	0.62	0	0.37	0.37	0	0	0	0.62	0	0	0	0	0.63	0	0.63	0.87	0.87	0.87	1	0.62	0.62	10.83	0.40
Indicator I.3	M2	0.71	0.85	0.85	0.71	0.85	0.85	0.85	0.85	1	0.71	0.71	0.57	0.71	0.85	0.5	1	1	0.71	0.86	0.86	0.86	0.85	0.85	0.85	0.85	0.85	0.85	21.96	0.81
Indicator I.4	M2	0.66	0.66	0.66	0	0.83	0.83	0.83	0.16	1	0	0.33	0	0	0.5	0	1	0	0.66	0.5	0.8	0.5	0.66	0.66	0.66	0	0.5	0.5	12.90	0.48
Indicator I.5	M2	0.87	1	0.75	0.87	1	1	1	0.75	1	1	1	1	1	1	1	1	1	1	0	0	0	1	1	1	1	1	1	23.24	0.86
Indicator I.6	M1	0	1	0	1	1	1	0	0	0	1	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	6.00	0.22
Indicator I.7	M1	0	0	1	1	1	1	1	1	1	1	0	0	1	1	1	1	0	0	1	1	1	1	1	1	1	1	1	21.00	0.78
Indicator I.8	M2	0.16	0	0	0	0.6	0.83	0.83	0	1	0	0	1	0.16	0.83	0.5	0.16	0.33	0	0.83	0.83	0.83	1	1	1	0.83	0.83	0.83	14.39	0.53
Indicator I.9	M2	0.75	0	0	0.25	0.62	0.75	0.5	0.42	0.87	0	0.25	0.5	0.5	0.87	0.57	0	0.63	0.63	0.75	0.88	0.75	1	1	1	0.75	0.75	0.75	15.73	0.58
Indicator I.10	M2	0	0	0	0	0	0	0.14	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.16	0	0	0.30	0.01
Indicator I.11	M3	DI	SA	AG	AG	DI	SA	AG	AG	DI	DI	SD	DI	SD	AG	DI	DI	SD	UD	DI	AG	DI	AG	AG	AG	AG	DI	DI		
Indicator I.12	M2	0.75	0.75	0.12	0.12	0.57	0.75	0.62	0	0.87	0	0.12	0.62	0	0	0.42	0	0.12	0	0	0	0	0.71	0.71	0.71	0	0	0	7.96	0.29
Indicator I.13	M1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	26.00	0.96
Indicator I.14	M3	DI	DI	DI	DI	SA	DI	SD	DI	DI	DI	SD	DI	SD	DI	SD	DI	SD	SD	AG	NA	DI	SD	SD	SD	DI	DI	DI		
Indicator I.15	M3	AG	SA	AG	AG	AG	SA	DI	DI	SA	AG	UD	AG	AG	AG	DI	AG	AG	AG	AG	AG	DI	AG	AG	AG	AG	AG	DI		
Indicator I.16	M4	See text in narrative report																												
Indicator I.17	M4	See text in narrative report																												
																												Total	5.94
																												**Final Score Registration	4.94

G= Government or private official

P= Private sector (national or international)

Table A2. Licensing of pharmaceutical establishments vulnerability scale points

Country Name:					Period assessment Carried out							Licensing											
PAKISTAN					JULY to DECEMBER 2014																		
	Method	LIC 101	LIC 102	LIC 103	LIC 104	LIC 205	LIC 306	LIC 307	LIC 308	LIC 309	LIC 310	LIC 411	LIC 412	LIC 513	LIC 514	LIC 515	LIC 516	LIC 517	LIC 518	LIC 519	LIC 520	Total	Average per question
Profession	-----	G	P	AC	P	G	G	P	P	P	P	G	G	P	P	N	P	P	G	P	P		
Indicator II.1	M1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	20	1.00
Indicator II.2	M1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	20.00	1.00
Indicator II.3	M2	1	0.83	1	0.83	0.83	1	0.83	0.83	0.83	0.8	0.83	1	0.83	0.83	0.83	0.67	0.83	0.83	0.83	0.83	17.09	0.85
Indicator II.4	M1	1	1	1	1	1	1	1	1	0	0	1	1	1	1	1	1	1	0	0	1	16.00	0.80
Indicator II.5	M2	1	1	1	1	1	1	0	0	1	0	1	1	1	1	1	1	1	1	1	1	17	0.85
Indicator II.6	M2	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	19	0.95
Indicator II.7	M2	0.25	0	0.5	0	0	0	0	0.25	0	0	1	0	0.25	0.5	0.5	0	0.75	1	0.25	0.5	5.75	0.29
Indicator II.8	M2	1	0.75	0.75	0.5	0	0	0.5	1	0.25	0	1	0.5	0.75	1	1	0.4	0.75	0.5	0.75	1	12.4	0.62
Indicator II.9	M1	1	1	1	1	1	1	0	1	1	0	1	1	1	1	1	1	1	1	1	1	18	0.90
Indicator II.10	M2	0.4	1	1	1	0.6	0.8	0	1	0.6	0	0.6	1	0.4	0.67	0.4	0.4	0.4	1	0.4	0.4	12.07	0.60
Indicator II.11	M3	AG	AG	AG	UD	AG	AG	SD	AG	DI	AG	SA	SA	DI	AG	AG	DI	AG	AG	DI	DI		
Indicator II.12	M1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0	18	0.90
Indicator II.13	M3	SA	AG	AG	AG	DI	DI	DI	AG	SA	DI	SA	AG	AG	AG	AG	DI	AG	AG	AG	DI		
Indicator II.14	M4	See text in narrative report																					
Indicator II.15	M4	See text in narrative report																					
																					Total	8.76	
																					***Final Score Licensing*	7.96	

Table A3. Inspection of pharmaceutical establishments vulnerability scale points

Country Name:				Period assessment Carried out											Inspection																			
PAKISTAN				JULY to DECEMBER 2014																															
	Method	INS 101	INS 102	INS 103	INS 204	INS 205	INS 206	INS 307	INS 308	INS 309	INS 310	INS 311	INS 312	INS 413	INS 414	INS 415	INS 516	INS 517	INS 518	INS 519	INS 520	INS 521	INS 522	INS 523	INS 524	INS 525	INS 526	Total	Average per question					
Profession	-----	G	G	G	P	G	G	P	G	G	G	G	P	G	G	G	P	P	G	G	P	P	P	P	G	G	P						
Indicator III.1	M1	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1	25.00	0.96				
Indicator III.2	M2	0.8	0.8	0.8	1	1	1	1	1	0.8	1	1	1	1	0.6	0.8	1	1	0.8	0.8	0.8	1	1	1	1	1	1	24.00	0.92				
Indicator III.3	M2	0.33	0.83	0	0	0.5	1	0	0.16	0.16	0.66	1	1	0	0.66	0	0.8	1	1	0.67	0.83	1	1	0.83	1	1	0.8	16.23	0.62				
Indicator III.4	M2	0.4	0	0	0.25	0.5	0.4	0	0	0	0	0.83	0.83	0	0.5	0	0.17	0.17	1	0	0.17	0.4	0.67	0.33	0.83	0.83	0.17	8.44	0.32				
Indicator III.5	M2	0	0	0.14	0.2	0	0	0	0	0	0.14	0.28	0	0	0	0.42	0.43	0	0.29	0.5	0	0.6	0.86	0.43	0.57	0.71	0.43	5.99	0.23				
Indicator III.6	M1	0	1	1	1	1	1	0	0	1	1	0	1	0	1	0	0	0	0	1	1	1	1	1	1	1	0	16.00	0.62				
Indicator III.7	M2	1	0	0	0.5	0.75	1	0	0.4	0.6	0.6	0.4	1	0.4	0.4	0.6	0.4	0.8	0.8	0.75	0.2	0.67	1	0.8	1	1	0.4	15.47	0.59				
Indicator III.8	M2	0.6	0.8	0.2	0	0.6	0.6	0.4	0.6	0.6	0.8	0.8	0.8	0.6	0.4	0.6	0.4	0.4	1	0.8	0.8	0.8	0.6	0.4	0.6	0.8	0.4	15.40	0.59				
Indicator III.9	M3	SD	DI	DI	AG	SA	DI	SD	SD	DI	AG	DI	AG	DI	DI	DI	SD	SD	DI	DI	SD	DI	SD	SD	DI	DI	SD						
Indicator III.10	M3	DI	DI	DI	AG	AG	AG	SD	SD	AG	AG	AG	AG	DI	AG	DI	DI	SD	AG	SA	SD	DI	SD	SD	DI	DI	DI						
Indicator III.11	M4	See text in narrative report																															
Indicator III.12	M4	See text in narrative report																															
																											Total	4.87					
																											**Final Score Inspection*	6.08					

Table A4. Control of medicine promotion vulnerability scale points

Country Name:		Period assessment Carried out		Promotion																		
PAKISTAN		JULY to DECEMBER 2014																				
	Method	PRM 101	PRM 102	PRM 103	PRM 304	PRM 305	PRM 306	PRM 307	PRM 408	PRM 409	PRM 510	PRM 511	PRM 512	PRM 513	PRM 514	PRM 515	PRM 516	PRM 517	PRM 518	PRM 519	Total	Average per question
Profession	----	G	G	P	M	P	P	P	P	P	G	P	P	P	P	G	G	P	G	P		
Indicator IV.1	M1	1	1	1	1	1	1	1	1	1	1	1	1	1	0	0	0	1	1	1	16.00	0.84
Indicator IV.2	M2	0.9	0.4	0.6	0.7	0.3	0.2	0.6	0.3	0.4	0.7	0.5	1	0.7	0.7	0.8	0.5	1	0.9	0.23	11.43	0.60
Indicator IV.3	M2	1	0.62	0	0.87	0	0.5	0	0.37	0.5	0.88	0	0.88	1	1	1	1	1	1	0.62	12.24	0.64
Indicator IV.4	M1	1	1	1	1	0	0	0	0	1	1	0	1	1	0	0	1	1	1	0	11.00	0.58
Indicator IV.5	M2	0.75	0	0	0	0	0	0	0	0	0	0.5	0.25	0.5	0	0	0	0	0.5	0.5	3.00	0.16
Indicator IV.6	M1	1	1	1	0	0	0	0	0	0	0	0	0	1	0	0	1	1	1	0	7.00	0.37
Indicator IV.7	M2	0	0	0.2	0	0	0	0	0	0	0.8	0		0.6	0	0	0	0.75	0.4	0	2.75	0.14
Indicator IV.8	M2	1	0.6	0	0	0	0	0	0	0	0.4	0		0.8	0	0	0.67	0	0.8	0	4.27	0.22
Indicator IV.9	M2	1	0.66	0	0	0	0	0	0	0	0	1	0	1	0.67	0.33	0	0.67	0.67	0	6.00	0.32
Indicator IV.10	M2	0	0	0	0	0	0	0	0	0	0.43	0.29	0	0.57	1	0		0.5	1	0	3.79	0.20
Indicator IV.11	M3	SA	AG	SD	SD	DI	SD	DI	SD	SD	SD	SD	SA	AG	DI	DI	UD	SD	AG	DK		
Indicator IV.12	M3	AG	SA	DI	SD	DI	DI	DI	SD	SD	DI	NA	DI	SA	DK	DI	AG	AG	SA	DI		
Indicator IV.13	M3	DI	DI	AG	DI	DI	SD	DI	SD	SD	DI	DI	SD	DI	SD	SD	DI	DI	AG	SD		
Indicator IV.14	M3	AG	AG	SD	SD	DI	SD	DI	SD	SD	AG	DI	AG	DI	SD	DI	DI	AG	AG	DI		
Indicator IV.15	M4	See text in narrative report																				
Indicator IV.16	M4	See text in narrative report																				
																					Total	4.07
																					***Final Score Promotion*	4.07

Table A5. Control of clinical trials vulnerability scale points

Country Name:				Period assessment Carried out				Clinical Trials									
PAKISTAN				JULY to DECEMBER 2014													
	Method	CT 101	CT 102	CT 303	CT 304	CT 305	CT 306	CT 307	CT 408	CT 509	CT 510	CT 511	CT 512	CT 513	CT 514	CT 515	Total	Average per question
Profession	----	G	G	P	P	G	P	P	AC	G	G	G	P	P	P	P		
Indicator V.1	M1	1	1	1	1	1	1	1	0	0	1	1	1	1	1	1	13.00	0.87
Indicator V.2	M1	1	1	1	1	0	1	1	0	0	1	0	0	1	0	1	9.00	0.60
Indicator V.3	M2	0.83	0.8	0.8	0.8	0.8	0	0.8	0	0	0	0	1	1	0.6	1	8.43	0.56
Indicator V.4	M2	0.66	0.83	0	0.5	0.83	0	0.5	0	0	0	0	0.83	1	1	0	6.15	0.41
Indicator V.5	M2	1	1	1	1	1	1	1	0	0	0	0	1	1	0	0	9.00	0.60
Indicator V.6	M1	1	1	1	0	0	0	0	0	0	1	0	0	1	1	0	6.00	0.40
Indicator V.7	M2	0.75	0	0.25	0	0	1	0	0	0	0	0	1	1	0	0	4.00	0.27
Indicator V.8	M1	0	1	0	0	0	0	0	0	0	0	0	1	1	0	0	3.00	0.20
Indicator V.9	M2	1	0.5	0.75	0.33	1	0.5	0	0	0	0	0	1	1	0	0	6.08	0.41
Indicator V.10	M1	0	0	0	0	0	1	1	0	0	0	0	1	1	0	0	4.00	0.27
Indicator V.11	M2	0.33	0	0.16	0	0	0	0.16	0	0	0	0	0.83	0.67	0	0	2.15	0.14
Indicator V.12	M2	0.75	0.75	0	0	0	0	0	0	0	0	0	0	0.75	0	0	2.25	0.15
Indicator V.13	M3	SD	AG	SD	SD	DI	DI	DI	SD	UD	AG	NA	AG	SA	UD	DK		
Indicator V.14	M3	SD	AG	SD	SD	DI	DI	DI	SD	UD	AG	NA	AG	SA	UD	UD		
Indicator V.15	M3	SA	SA	SD	SD	SD	DI	DI	SD	UD	DK	DK	AG	AG	UD	UD		
Indicator V.16	M4	See text in narrative report																
Indicator V.17	M4	See text in narrative report																
																	Total	4.87
																	***Final Score Clinical Trials*	4.06

Table A6. Medicine selection vulnerability scale points

Country Name:	Period assessment Carried out	Selection
PAKISTAN	JULY to DECEMBER 2014	

	Method	SEL 101	SEL 202	SEL 203	SEL 204	SEL 205	SEL 206	SEL 307	SEL 308	SEL 409	SEL 410	SEL 411	SEL 512	SEL 513	SEL 514	SEL 515	SEL 516	SEL 517	SEL 518	SEL 519	SEL 520	Total	Average per question
Profession	-----	G	P	P	P	G	G	P	P	G	G	G	G	G	G	G	P	G	G	G	P		
Indicator VI.1	M1	1	1	0	1	1	1	1	0	0	1	0	1	1	1	1	1	1	0	0	1	14.00	0.70
Indicator VI.2	M3	AG	SA	SD	SD	DI	DI	DI	SD	DI	SA	DK	DI	UD	DI	AG	AG	SA	SA	SD	AG		
Indicator VI.3	M2	0	0.83	0	0.28	0	0.28	0	0	0.43	0.66	0	0.86	0.75	0	1	1	0.71	1	0	1	8.80	0.44
Indicator VI.4	M2	0.33	0.83	0	0.6	0.6	0.5	0.33	0	0.17	0.5	0	0.6	0.4	0.33	0.5	0.5	0.83	0.83	0	0.5	8.36	0.42
Indicator VI.5	M1	1	0	1	1	1	1	0	1	0	1	1	1	1	0	1	1	0	1	0	1	14.00	0.70
Indicator VI.6	M3	DK	NA	DI	DI	DI	DI	SD	DI	DI	SA	SA	DI	DI	DK	AG	SD	SD	DI	SD	AG		
Indicator VI.7	M2	0.33	0	0	0	0	0	0	0	0.14	0.86	1	0.5	0.2	0	0.5	0.57	0.43	0	0	0.5	5.03	0.25
Indicator VI.8	M2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.43	0.43	0.8	0	0	1.66	0.08
Indicator VI.9	M2	0.66	0	0	0	0	0	0	0	0	0.33	0	0	0	0	0.5	0	1	0.67	0	0.5	3.66	0.18
Indicator VI.10	M2	0.83	0	0	0	0.33	0.5	0	0	0.33	1	0	0.25	0.33	0	0.6	0.4	0.67	0.33	0	0.6	6.17	0.31
Indicator VI.11	M4	See text in narrative report																					
Indicator VI.12	M4	See text in narrative report																					
																					Total	3.08	
																					***Final Score Selection*	3.85	

Table A7. Medicine procurement vulnerability scale points

Country Name:	Period assessment Carried out	Procurement
PAKISTAN	JULY to DECEMBER 2014	

	Method	PRC 101	PRC 202	PRC 203	PRC 204	PRC 205	PRC 206	PRC 307	PRC 308	PRC 309	PRC 310	PRC 311	PRC 112	PRC 413	PRC 414	PRC 515	PRC 516	PRC 517	PRC 518	PRC 519	PRC 520	PRC 521	PRC 522	PRC 523	PRC 524	Total	Average per question
Profession	-----	G	G	P	G	P	P	P	P	G	G	P	IO	G	G	N	G	G	P	G	P	P	G	G	P		
Indicator VII.1	M2	0.7	0.9	0.9	0.9	0.9	0	0	0.8	1	0.4	0.2	1	0.4	1	0.9	0.9	0.9	0.9	0.9	1	0.9	0.9	0.9	0.89	18.03	0.75
Indicator VII.2	M1	0	1	0	0	1	0	0	0	1	1	0	1	1	1	1	1	0	0	0	0	0	0	0	0	9.00	0.38
Indicator VII.3	M1	0	0	0	0	0	0	0	1	1	0	1	1	1	1	1	0	0	0	0	0	0	0	0	0	7.00	0.29
Indicator VII.4	M1	0	1	0	0	1	0	1	0	1	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	18.00	0.75
Indicator VII.5	M2	1	1	0.3	1	0.7	1	0	1	1	0	1	1	1	0.6	1	1	1	1	1	1	1	1	1	1	20.59	0.86
Indicator VII.6	M3	SA	SA	AG	SA	SA	DK	DI	AG	SA	UD	SA	SA	SA	SA	SA	AG	AG	AG	AG	AG	AG	AG	AG	AG		
Indicator VII.7	M2	0.4	0.6	0.6	0.6	0.7	0.3	0.6	0	0.4	0	0	1	0	0.3	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.57	11.13	0.46
Indicator VII.8	M2	0	0	0	0	0	0	0	0	0	0	0	0.4	0	0	0.1	0	0	0	0.2	0	0	0.2	0	0	1.01	0.04
Indicator VII.9	M3	DI	DI	AG	AG	AG	SD	DI	DI	DI	SA	SD	SA	SD	SA	DI	DI	DI	DI	DI	DI	DI	DI	DI	DI		
Indicator VII.10	M2	0.9	0.1	0	0	0	0	0	0	1	0	1	0.7	0	0.1	0	0.3	0.3	0.3	0.3	0.3	1	0.3	0.3	0.29	7.08	0.30
Indicator VII.11	M2	0.3	1	1	1	1	0.5	0	1	0.8	1	1	1	0.5	1	1	1	1	1	1	1	1	1	1	1	21.00	0.88
Indicator VII.12	M2	0.3	1	1	0.8	0.5	0	0	0.2	0.3	0	0	1	0	1	0	0.3	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	10.48	0.44
Indicator VII.13	M2	0.9	0.6	0.4	0.8	0.8	0.8	0.6	0.4	0.5	0	0.9	1	0.8	1	0.8	0.8	0.8	0.8	0.8	0.8	1	0.8	0.8	0.75	16.91	0.70
Indicator VII.14	M3	DI	SA	AG	SD	AG	SD	SD	SD	DI	SD	SD	AG	SD	SA	DI	DI	DI	DI	DI	DI	DI	DI	DI	DI		
Indicator VII.15	M4	See text in narrative report																									
Indicator VII.16	M4	See text in narrative report																									
																									Total	5.84
																									***Final Score Procurement*	5.31

Table A8. Medicine distribution vulnerability scale points

Country Name:		Period assessment Carried out																			
PAKISTAN		JULY to DECEMBER 2014																			
	Method	DIS 101	DIS 102	DIS 303	DIS 304	DIS 305	DIS 306	DIS 107	DIS 408	DIS 409	DIS 510	DIS 511	DIS 512	DIS 513	DIS 514	DIS 515	DIS 516	DIS 517	DIS 518	Total	Average per question
Profession	-----	P	P	G	P	P	G	IO	G	G	P	P	P	P	P	P	P	G	P		
Indicator VIII.1	M1	0	0	1	1	0	1	1	1	0	1	0	0	1	1	0	1	1	0	10.00	0.56
Indicator VIII.2	M3	DK	NA	UD	DI	AG	DI	SD	AG	DK	SD	NA	NA	DI	DI	DK	DK	DI	DK		
Indicator VIII.3	M2	0	1	0.33	1	1	1	1	1	1	1	0.67	1	1	1	1	0	1	0	13.67	0.76
Indicator VIII.4	M1	1	1	1	0	0	1	1	0	1	1	1	1	1	1	1	0	1	1	14.00	0.78
Indicator VIII.5	M2	0.66	1	1	1	0	0.66	1	0.66	0	0.67	1	1	0.67	1	1	0.7	1	0.5	13.47	0.75
Indicator VIII.6	M2	0.83	0.66	1	0.83	1	1	1	1	0	0.83	1	1	1	1	0.83	1	1	0.6	15.59	0.87
Indicator VIII.7	M1	1	1	1	1	0	1	1	1	0	1	1	1		1	1	1	1	1	15.00	0.83
Indicator VIII.8	M2	1	0.86	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	16.86	0.94
Indicator VIII.9	M1	1	0	0	1	1	1	1	1	0	1	0	0	1	1	1	1	1	1	13.00	0.72
Indicator VIII.10	M2	1	1	1	1	0.66	1	1	1	0	1	0.67	0.67	1	1	0.67	1	1	0.67	15.33	0.85
Indicator VIII.11	M2	1	0.83	0.8	1	1	1	1	1	0.83	1	0.83	0.83	1	1	0.83	1	1	0.67	16.63	0.92
Indicator VIII.12	M2	0.8	0	0	0	1	1	1	1	0.8	1	1	1	1	1	1	1	1	1	14.60	0.81
Indicator VIII.13	M2	0.75	0.5	0	1	0.25	0	0.75	0.75	0.5	1	0.75	0.75	1	1	1	1	1	0	12.00	0.67
Indicator VIII.14	M1	1	1	0	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	16.00	0.89
Indicator VIII.15	M2	0.57	0.66	0	0.83	0	0.71	1	0	0	0.86	0.75	0.75	1	1	0.5	0.6	1	0.33	10.53	0.59
Indicator VIII.16	M2	1	0.5	1	1	0	1	1	0	0	1	0	0	0.33	1	0.5	1	1	0	10.33	0.57
Indicator VIII.17	M2	0.5	0.25	1	1	0	1	1	1	0.25	0.75	1	1	0.8	0.75	1	0	0.8	0	12.00	0.67
Indicator VIII.18	M3	DI	SA	DI	DI	DI	SA	SA	DI	AG	DI	SD	DI	AG	DI	DI	NA	DI	SD		
Indicator VIII.19	M4	See text in narrative report																			
																				Total	12.17
																				***Final Score Distribution*	*7.60*

Annex 3. List of evidence obtained

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

Registration of medicines

- Procedure for registration of medicines
- Application form for registration of locally manufactured medicines
- Application form for registration of imported medicines
- Guidelines for licensing and registration of biological medicines 2009
- Application form for renewal of registration of medicines (Form 5-B)
- Documents required for post-registration variation
- Checklist for scrutiny of registration application/dossiers
- Notification for amendment of Rule 8 and 24 of LRA 1976 regarding composition of Central Licensing Board and Registration Board (SRO 684[I] 2013)
- Composition of medicines Registration Board as on 18 March 2015
- Minutes of the recent meetings of the Registration Board

Licensing of pharmaceutical establishments

- Composition of Central Licensing Board as of 18 March 2015
- Procedure for grant of medicine manufacturing license
- Procedure for medicines sale license Punjab
- Application form for grant of medicine manufacturing license (Form-1)
- Application form for renewal of medicine manufacturing license (Form 1-A)
- Updated list of pharmaceuticals manufacturers of Pakistan
- Standard operating procedures for licensing section of DRAP, minutes of 232nd meeting of Central Licensing Board, Agenda item XVI
- Current good manufacturing practices
- Minutes of recent meetings of Central Licensing Board

Inspection and market control

- Intimation to person from whom sample is taken
- Form of receipt for stock of medicines seized under section 8 (f) of the Drugs Act
- Certificate of test or analysis by the Federal Drugs Laboratory/government analyst
- Government of Khyber Pakhtunkhwa inspection pro forma for medicines inspectors

Medicine promotion control

- Section 24 of the Drugs Act 1976 and Rule 31/35 of LRA 1976
- Ethical criteria for medicinal drug promotion, schedule G of LRA 1976
- Application form for approval to advertise a medicine

Clinical trials of medicines

- Notification for amendment in The Drugs Research Rules 1978 regarding guidance for conduct of clinical trial (SRO 272[I] 2013)
- Pakistan good clinical practices guidelines 2008
- Pro forma for submission of clinical trial proposal
- Checklist for clinical trials

Selection of medicines

- National Essential Medicines List of Pakistan, Ministry of Health, Government of Pakistan, Islamabad, 2007
- List of drugs/medicines, surgical and disposable items etc., along with their bill of quantities and technical specifications
- Essential Drug List of Khyber Pakhtunkhwa for primary and secondary health care facilities
- Government of Khyber Pakhtunkhwa Medicine Coordination Cell formulary of medicines/surgical disposables for 2014–2015
- Government of Baluchistan, list of medicines for 2014–2015 issued by Additional Director, Government Medical Stores Depot, Quetta

Procurement of medicines

- Notification of the Purchase Committee Punjab
- Notification SO(D)H/7–1/2014/MCC regarding constitution of medicines committee for selection and purchase of medicines
- Approved list of the medicines and surgical and disposable items for procurement in Punjab
- Seventh formulary of Jinnah Hospital, Allama Iqbal Medical College, Lahore
- Bidding documents for procurement of drugs, Punjab
- Technical Bid Evaluation Committee, Punjab

Distribution of medicines

- Good storage and distribution practices to be followed by the licensee and a public sector institution or a private organization, Schedule H
- Keys record book, Government Medical Stores Depot, Government of Punjab
- Notification for audit of the accounts

Annex 4. Organizational structure and staffing of the Drug Regulatory Authority of Pakistan

Chief Executive Officer												
Director Pharmaceutical evaluations and registration	Director Drug Licensing	Director Quality Assurance and laboratory testing	Director Medical devices and medicated cosmetics	Director Biologicals	Director Controlled Drugs	Director Pharmacy Services	Director Health and OTC products (non-drugs)	Director Costing and Pricing	Director Budget and accounts	Director Administration Human resource and Logistics	Director Legal Affairs	Director management information services
Deputy Director General (2)	Deputy Director General (1)	Chairman Quality Control (1)		Deputy Director General (1)	Deputy Director General (1)	Deputy Director General (1)						
Deputy Drugs Controller (6)		Deputy Drugs Controller(2)		Deputy Drugs Controller (1)	Deputy Drugs Controller (1)	Deputy Drugs Controller (1)	Deputy Drugs Controller (1)	Deputy Drugs Controller (1)	Drawing and Disbursing Officer		Deputy Drugs Controller (1)	
Assistant Drugs Controller (5)	Assistant Drugs Controller (1)		Assistant Drugs Controller (1)					Assistant Drugs Controller (1)		Section officers (2)		

This report presents the results of an assessment to measure transparency in the pharmaceutical sector in Pakistan. National transparency assessment is the beginning of a process aimed at bringing about desirable and sustainable changes in the governance of the sector. It provides a comprehensive picture of the level of transparency and the potential vulnerability to corruption of the eight essential functions of the pharmaceutical sector, namely: Registration of Medicines, Licensing of Pharmaceutical Establishments, Inspection and Market Control of Medicines, Medicines Promotion Control, Control of Clinical Trials, Selection of Medicines, Procurement of Medicines and Distribution of Medicines. The results of this assessment will inform the development and implementation of a national good governance for medicines programme in Pakistan.

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