THE REPUBLIC OF TURKEY

BAHCESEHİR UNIVERSITY

COMPLAINT MANAGEMENT (PHARMACOVIGILANCE) IN PHARMACEUTICAL INDUSTRY

Master's Thesis

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THE REPUBLIC OF TURKEY

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GRADUATE SCHOOL OF SOCİAL SCİENCES

MARKETİNG

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ABSTRACT

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Complaint management (Pharmacovigilance) in pharmaceutical industryis an essential area that any pharmacology student would like to pursue. It involved a depth in the study of the general discipline of complaint management and how it relates to pharmacovigilance in the pharmaceutical industry. Complaint management requires customer feedback, response from the manufacturer, and a follow-up to find out if the client was satisfied. Once the various characteristics of complaint management system are laid out, pharmacovigilance was investigated from literature to find out if it behaves like the normal system. Since pharmacovigilance deals with the health industry, complaints management is compulsory and physicians are legally required to report any event to the pharmacovigilance center.

This thesis was carried out to find out about complaints management in the pharmaceutical industry. The question that this thesis tried to answer is if how complaint management system is done will be how pharmacovigilance is done in the pharmaceutical industry. This information about pharmacovigilance was found in literature, internets, reports, and academic journals.

Pharmacovigilance is not only a complaint management system to manage customer complaints but it is a requirement by regulatory authorities to report every serious and non-serious cases that occur with the use of medical products or drugs. Pharmacovigilance is also done on medical devices and the standards offer reporting forms for filling out every case.

Pharmacovigilance matters because it provides information that will allow a company to be licensed to market its product or not. It also provides the information necessary to profile and label a drug product before it is sent to the market. Pharmacovigilance also provide the information necessary to show the implications of the medicinal product where used in special circumstances.

Keywords: Complaint Management, Pharmacovigilance, Pharmaceutical Sector,

ÖZET

İLAÇ SEKTÖRÜNDE ŞİKAYET YÖNETİMİ(FARMAKOVİJİLANS)

Aghasaf Osmanlı

Pazarlama

Tez Danışmanı: .Hakan Arı

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İlaç sektöründe şikayet yönetimi konusu eczacılık bilimi öğrencilerinin ilgi alanı olduğu gibi pazarlama, iletişim, müşteri ilişkileri konularıyla ilgilenen öğrenciler için de özel bir alandır.

Bu tezde, şikayet yönetiminin genel disiplini incelenmekle birlikte ilaç endüstrisi özelinde şikayetlerin (Farmakovijilans) nasıl sistematize edildiği ve çözülmeye çalışıldığı incelenmiştir.

Tüm dünyada, farmakovijilans, sağlık sektörü özelinde yasal olarak zorunludur. Bu bağlamda doktorların karşılaştıkları sıra dışı her olayı farmakovijilans merkezine rapor etmeleri gerekmektedir.

Bu çalışmanın cevap aradığı konu, farmakovijilansın diğer sektörlerde uygulanan şikayet yönetimi sistemlerinden ayrıştığı konulardır.

Çalışmada internet, internet dışı litaretür, resmi raporlar ve akademik makaleler taranmış,ilaç sektörü yetkilileriyle derinlemesine görüşmeler gerçekleştirilmiştir.

Anahtar Kelimeler: Şikayet Yönetimi, Farmakovijilans, İlaç Sektörü

CONTENTS

1: INTRODUCTION 1
1.1 PHARMACOVIGILANCE IN PHARMACEUTICAL INDUSTRY 1
1.2 OUTCOME MEASURES 2
1.3 RELEVANCE 2
1.4 OBJECTIVES AND HYPOTHESIS 3
2: ANALYSIS OF A BUSINESS DISCIPLINE 5
2.1 COMPLAINT MANAGEMENT 5
2.2 EFFECTIVE COMPLAINT HANDLING 8
2.2.1 The Solution 8
2.2.2 Further Exploration Of The System 10
2.2.3 How The Solution Works 13
2.3 BENEFITS OF COMPLAINT MANAGEMENT 13
2.4. PHARMACOVIGILANCE 14
2.4.1 DEFINATION OF PHARMACOVIGILANCE 14
2.4.2 TERMS USED IN PHARMACOVIGILANCE 14
3: AN ANALYSIS OF THE SECTOR 17
3.1 THE PHARMACEUTICAL SECTOR IN TURKEY 19
3.2 THE ADVANCEMENTS IN THE SECTOR 25
3.3 THE DOWNFALLS IN THE SECTOR 26
3.4 PHARMACOVIGILANCE IN TURKEY 27
3.5 ALTERNATIVES IN THE INDUSTRY 28
3.6 PROBLEMS FACING THE SECTOR 30
3.7 DEVELOPMENTS IN THE SECTOR 30
4: THE SECOND AND THIRD DEPARTMENT CONSOLIDATION 31
4.1.INTERNATIONAL COLLABORATION IN PHARMACOVIGILANCE 31
4.1.1 Cıoms 31
4.1.2 Ich 31
4.1.3 Who 32
4.2 NATIONAL AND REGIONAL DRUG REGULATORY AUTHORITIES 33

5: RESEARCH **34**

5.1. COMPLAINT MANAGEMENT AND REPORTING IN THE PHARMACEUTICAL INDUSTRY **34**

5.1.1 Adverse Event Reporting……..……..……**34**

5.1.2 The Four Elements Of An Adverse Event Case……..…**34**

5.1.3 Adverse Events Coding……..…**35**

5.1.4 Seriousness Determination…….....**35**

5.1.5 Expedited Reporting……..…….....**36**

5.1.6 Clinical Trial Reporting ……..…….….**36**

5.1.7 Spontaneous Reporting ……**36**

5.1.8 Aggregate Reporting……..**37**

5.1.9 Other Reporting Methods……..**37**

5.2. RISK MANAGEMENT……..**38**

5.2.1 Causality Assessment……**38**

5.2.2 Signal Detection……..**39**

5.2.3 Risk Management Plans……**39**

5.2.4 Risk/Benefit Profile Of Drugs……**39**

5.3 PHARMACOENVIRONMENTOLOGY **40**

5.4 PHARMACOVIGILANCE OF MEDICAL DEVICES **40**

5.5 PHARMACOVIGILANCE OF HERBAL MEDICINES **41**

6: CONCLUSIONS AND RECOMMENDATIONS **42**

6.1 RECOMMENDATIONS **42**

6.2 CONCLUSIONS **43**

REFERENCES **44**

APPENDICES

Exhibit I: Adverse reaction report form **50**

Exhibit 2. A typical complaint management system **54**

Exhibit 3 Turkey's statistics **55**

FIGURES

Figure 2.1: Showing the process of complaint management…….5

Figure 2.2: Showing a sample complaint management system…….6

Figure 2.3: A correspondent management cycle in complaint management……...7

Figure 2.4: An effective solution for complaint management system …….12

Figure 3.1: Turkey's life expectancy……..18

Figure 3.2: Turkey's health data……19

Figure 3.3 Turkey's World Rankings in Clinical Trials 21

Figure 3.4 Turkish Pharma industry world Ranking 22

Figure 3.5 Turkey's World ranking in import and export 233

Figure 3.6 Turkey's Pharmaceutical production 24

Figure 3.7 Showing the total Research and Development Expense for global pharma industry 26

Figure 3.8 Various Serious Adverse Events 28

Figure 4.1. Showing the organizational structure of ICH 32

TABLES

Table 3.1 Turkey's World Rankings in Pharma Industry market's size……20

Table 3.2 Turkey's Ranking in exports and imports of pharmaceutical products….25

1. INTRODUCTION

1.1 PHARMACOVIGILANCE IN PHARMACEUTICAL INDUSTRY

Effective companies take care of the customers and manage their complaints in time. Among the best-managed industries is the pharmaceutical industry, which lays down procedures to report any effect of the product. Medicinal products undergo lots of processing, studies, and trials before they are released to the market.One of the most difficult thing in this sector is management of consumers' complaints. National regulatory bodies have set standards that must be followed before any product is allowed to the market. The world Health organization (WHO) has also set its standards that all pharmaceutical products must follow if they want to enjoy the world market(WHO Guidelines, 2004). Pharmacovigilance is not clearly developed and many pharmaceutical companies do not have enough skilled labor to manage this department. Safety measures of the medicinal products areimportant because they reduce serious and non-serious events that occur during use of the product. The importance of pharmacovigilance cannot be underestimated by the industry thus this paper seeks to research on pharmacovigilance in pharmaceutical industry.

Turkey is among the leading Pharma producers in the world. It has more than 130 pharmaceutical companies leading in exports in the region. The country has guidelines on pharmacovigilance procedures for this company, but they have not been harmonized with those of the European Union or the World Health Organization. The sector requires being more vigilance and using technology to enhance their market in the world. Having this in mind, we tackle different world complaint management systems and how they can be applied to the pharmaceutical industry so that it can be more competitive and tap the local and international markets (Biwas & Chougule, 2009). The question that remains is can complaints management in the pharmaceutical industry be effective and consistent?

1.2 OUTCOME MEASURES

The regulatory bodies have laid out regulations that doctor and other healthcare professionals have reluctance in applying. The world health care standards require all health professionals to reports all cases serious and non-serious. This will ensure that all drug related deaths are reduced hence reducing the premature deaths caused by adverse reaction of drugs.

Every company is required to have a specialized pharmacovigilance officer who monitors and reports all adverse reaction and captures all reports so that they are all included in the product profile.

Clear labeling of products with warning for special parameters is essential improvement that this paper seeks to address. When drugs are labeled with adverse events clearly recorded consumers will have high alertness and report any effect to healthcare professional.

Laying out of efficient and effective corrective measures for fatal use of the medicinal product. This requires an antidote that will treat serious adverse events thus saving lives. This reduces suicidal cases where medicinal products are used to induce death.

Another outcome measure is an achieved consistency in the use of technology in management of pharmaceutical complaints and reporting.

1.3 RELEVANCE

This paper has covered complaint management in general than applied in pharmacovigilance. It has brought out the various effective complaint management system and how they can be applied in the pharmacovigilance that is solving the conflicts in the pharmaceutical industry.

These various guidelines used in the world for management of the pharmaceutical sector have been studied checking those of World health organization, the Food and Drugs authority in America, and those of the European Union.

The Pharmaceutical sector in Turkey is growing rapidly and there is need to have an effective way of managing complaints apart from those applied by the regulatory body. The analysis, advancement, and challenges facing the sector needs a clear guideline that is fast, consistent and effective in tackling the challenges of the industry. Reporting where cases are ignored has occurred in the past and lack of adequate reporting has crippled pharmacovigilance in the country (BMI, 2012).

Health care professional are better placed to access the relevance of a customer complaint before the case is forwarded for further investigation. Healthcare professional have also been reported of being reluctant in reporting adverse events. Also sometimes individuals would want to taint the image of a certain company and reduce the market of its products. These are important to be resolved and produce a system that will manage all the stakeholders thereby reporting and verifying all the complaints before taking action. This will reduce cost and overheads experienced by companies, which have large amount of reports data that cannot be effectively managed (CIOMS, 2001).

The pharmaceutical sector has applied technology in treatment of its patients but not in managing its complaints. Use of technology provides an efficient, consistent, and transparent means of dealing with the pharmacovigilance cases and data. Others sectors have successfully developed system to manage customer complaints that helps them to manage reputation and increase customer loyalty. This calls for application of systems that will manage adverse event reporting, categorizing complaints, and storing data in a retrievable form where all the stakeholders can retrieve information that is only relevant to them. Pharmacovigilance requires such a system so that follow-up and other procedures can be applied to ensure that the sector remains competitive in the economy (Ilac gibi geleck, 2012).

1.4 OBJECTIVES AND HYPOTHESIS

The objectives of this study were three. The first was to evaluate the general complaints management system and that of Turkey pharmaceutical sector. It was hypothesized that Turkey's Pharmaceutical sector has poor management system. It was also hypothesized

that the general discipline of complaints management has better system that effectively manage customer complaints.

The second objective was to evaluate the world system of pharmacovigilance and the standards used. It was hypothesized that the world system has efficient and effective standards that deal with pharmacovigilance in pharmaceutical sector. It was also hypothesized that the effective pharmacovigilance units use technology to manage complaints in the sector.

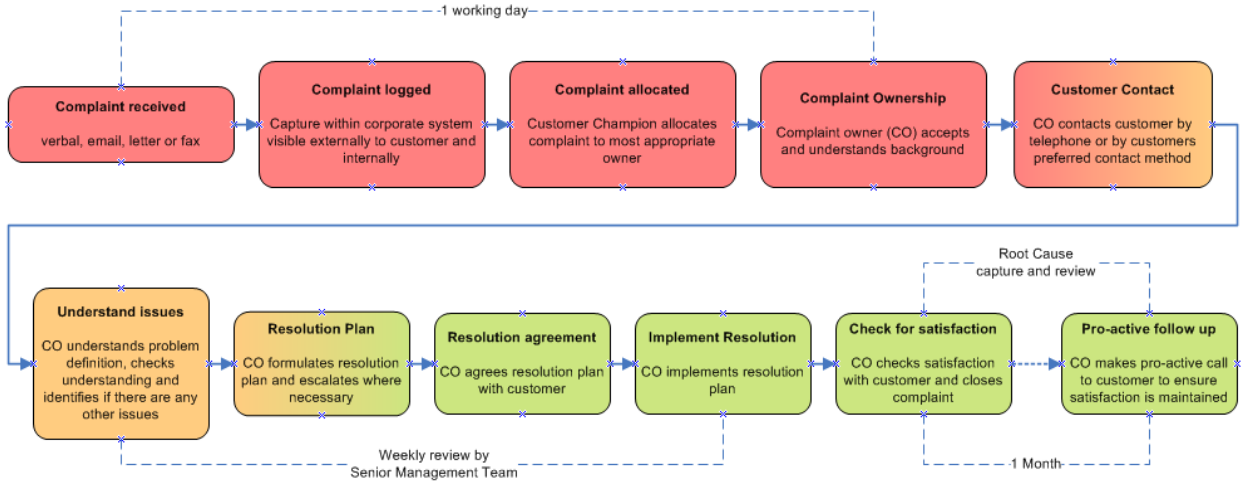
The third objective was to evaluate how the general complaints management system can be integrated with the pharmacovigilance to enhance the pharmaceutical sector consumer management. It was hypothesized that applying the general principles of complaint management will improve that pharmacovigilant unit of the pharmaceutical industry. It was also hypothesized that the general pharmacovigilant principles are difficult to integrate because of the details and huge data requirement of the sector. It was also hypothesized that the pharmaceutical sector does not have enough skilled personnel to solve the problems associated with pharmacovigilance. It was also hypothesized that Turkey's pharmaceutical sector has pharmacovigilance regulations that have not been harmonized with the international regulations.

2. ANALYSIS OF A BUSINESS DISCIPLINE

Complaint management is a discipline in every business involved in offering of goods or services to customers. Companies that handle seriously the complaints in the business have the capacity to satisfy and retain their customers.

The figure below shows a complaint management process that involves both customers and staff of an organization

Figure 2.1: Showing the process of complaint management



2.1 COMPLAINT MANAGEMENT

This is the process receiving, monitoring, giving feedback, and tracking the complaint issued by the customer. The aim of complaint management is to provide the customer with quality services and products. Complaints are an effective way of measuring and assessing customer satisfaction and a way of improving services. The system of handling complaints for a company affects its reputation. Companies and businesses should ensure that they do not handle complaints poorly because it gives the company a bad image and lacks improvement on defective areas (Ombudsman, 2008). Ignoring the complaints of the customer will risks public exposure when the customer seeks to address their problem in other arena. A company will lose more than it can gain by

ignoring customer complaints. When a company implements an effective complaints process, it gains the following:

i. Easier handling of internal complaints
ii. Gets knowledge on how to eliminate recurring complaints
iii. Improvement of standards of service to customers
iv. Makes better decisions

The figure below shows a sample system of complaints management:

The process starts when the customer creates a complaint either through an online system or through normal channels of communication like email, telephone call, face-to-face among others. The complaint is then processed by a service professional who receives it and creates a credit note for the complaint. The credit note created is one a receipt to the customer containing information that his/her complaint will be addressed. Once the complaint has been addressed, the service professional tracks the customer to respond to the complaint. This is an effective system because the company addresses the customer's complaints. The sample system below uses third party tools, such as web-based system tools that help to respond to customer complaints.

Figure 2.2: Showing a sample complaint management system

2.1.1 The Correspondent Management Cycle

The picture diagram below shows the correspondent management a sample of complaint management system.

Figure 2.3: A correspondent management cycle in complaint management

Like the sample system above, the correspondent management, cycle is a complaint management system. In stage 1, the customer sends the correspondent to the call center. The call center in stage 2 logs the details onto the central database. The database sends an automated email confirming that there is a new complaint. The resolution is located and the customer is informed of the resolution. This is the process for every correspondent logged into the system.

2.2 EFFECTIVE COMPLAINT HANDLING

Complaints management is a significant process in the perspective of compliance and regulations. It is key, to immediately respond to customers' complaints; some products can cause death to customers and court cases for manufacturers. This call for effective procedures for managing complaints right from the start of production to the end, when it is sold and consumed by customers.

For pharmaceutical companies, managing complaints is less of customer relationship and more of managing the consumer. An efficient complaint management system helps to reduce cost, increase revenue, and give the company ability to track customer and product trend in the market. This is useful because it helps to predict the future trends in the market.

One of the areas where management of complaints is difficult to achieve is the Pharma industry. The industry deals with patients with varying physiological needs and regulatory bodies that are difficult to comply. The reasons for having an effective complaints management system is: Warnings from regulatory bodies such as FDA to ensure that products complaints are handled; this is still a warning from regulatory bodies to pharmaceutical industry. There is also pressure from regulatory bodies and competing companies to have an efficient and effective complaints management system. Another need for effective complaints management system is the nature of the regulatory landscape, it is a requirement for all companies to execute and report every complaint associated with their products to assure safety and quality of the product. This also involves having events and activities that ensure no repetition of the complaint.

2.2.1 The Solution

The vital features of an effective complaint management system are as shown below:

1. Functional capabilities:

    a) A web system connected with workflow

b) Extreme case management capabilities

c) Ability to produce multiple processes (Such as parents and child notifying abilities)

d) Reminder

e) Reporting capabilities

f) Ability to show the processing of the complaints and closure forms

g) Multilingual abilities

h) Ability to manage documents enables to record all complaints

ı) Ability to produce identity of the complainant

i) Ability to integrate sales and distribution processes

i) Ability to integrate and handle adverse events

2. Standard and automated; this is one of the key components of a complaint management system. It should be in such a way that the problem reaches the regulatory authorities in time (15-30 days). The cost of the system should be minimum such that most of the processes are automated and not manual.
3. Safety and security; since the system interfaces with many departments in the drug production, it should be such a way that the security of the data is not compromised. This is because huge chucks of information that is very essential flow through the system. The design of the system should be such a way that it protect and ensures the security of the information in it.
4. Performance; the solution to an effective complaint management system should have a high performance with multiple interfaces for workflows and data elements. Simplicity of the system with clear rules and design is also key to an effective solution. The notification system should be effective and easy with a highly performing reporting system.

2.2.2 Further Exploration Of The System

The complaint management system should some functions used in some stages of the process. Some of these functionalities are as below:

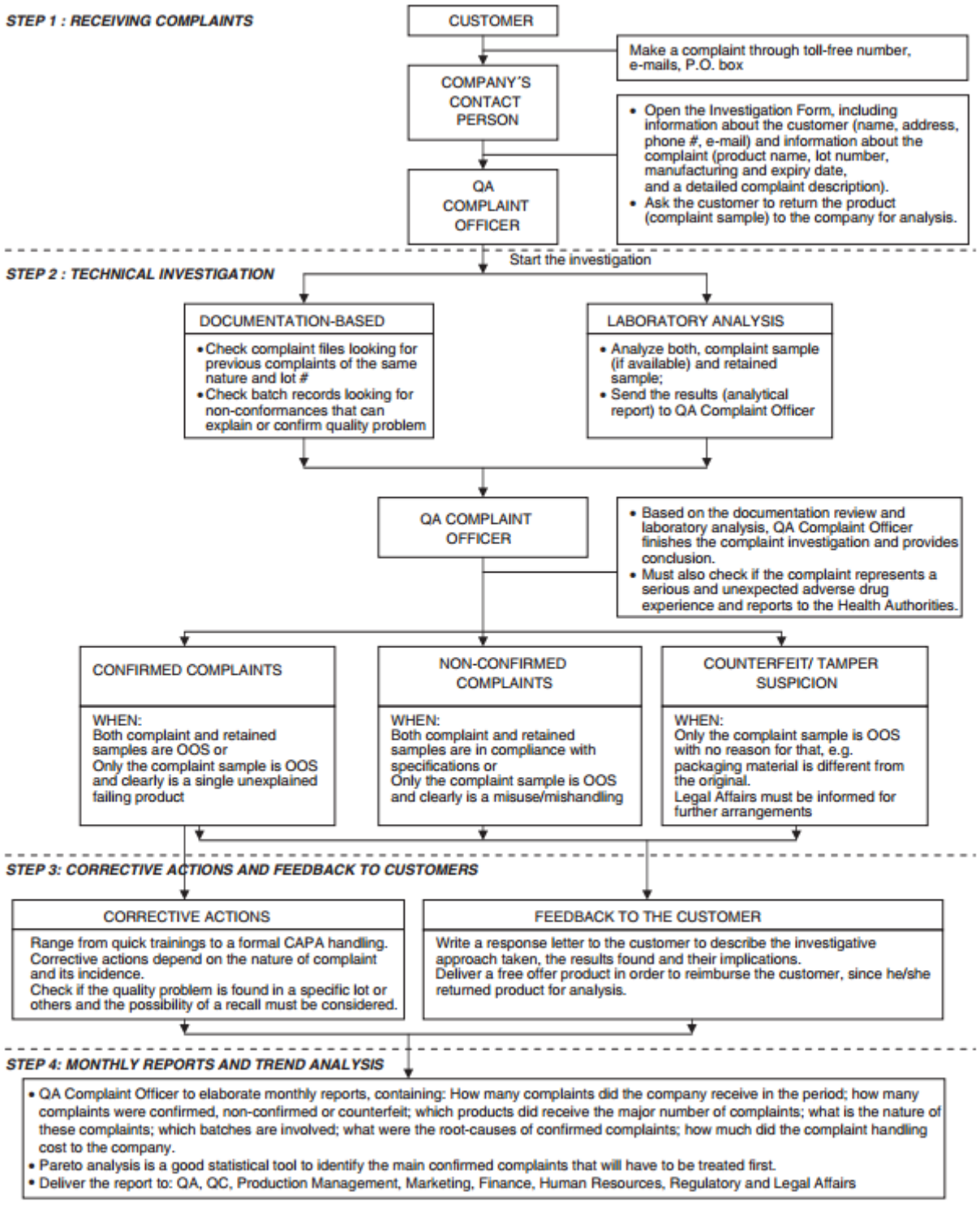
- Receipt; this helps the system to capture the complaints from different medium or ways of delivery. The channels to deliver complaints are such as the internet, calls, emails, and many others. These channels should get into a uniform platform. There should be chat and review portals for customers to submit their complaints and ask questions. The system could also have toll free number for customers' complaints.
- Management of Data and complaints; an effective and efficient solution should have the capacity to capture and filter critical complaints for a product. It should also have an internet-based system that follows a complaint until a credible solution or feedback is given to the client. The system should store, archive, and retrieves documents that comply with the product. It is important to upload the data when bringing up the complaint, this helps during the investigation of the complaint. During investigation the investigation progress data can be uploaded for the complainant to see.
- The complaints should be automatically directed and rated according to the level of severity and type. Examples are complaints to do with quality should be directed to quality control while those of packaging to sales team. This ensures that alarms on non-completed jobs and actions are raised to ensure that there is workflow. It also gives an organization an opportunity to correct their internal errors and improve on quality.
- The tasks are managed automatically as complaints are processed.
- The system processing and reporting should ensure that similar reports could be processed and reported together. Departments such as production and quality control complaints reports should be in the same form. In addition, the solution should be able to filter reports and complaints according to type, product, and

department. This helps the company to know recurring complaints and departments that require monitoring for quality purposes.

- The system should provide a way that helps to track the users to offer efficient follow-up. This helps to retain the customers and improve company's reputation.

Some of the stakeholders of a pharmaceutical complaint system are the doctors, the pharmaceutical companies, patients, among others. The system should provide an interactive interface with all the stakeholders for effective monitoring of complaints and feedbacks. The system main functions should integrate with the product life cycle, customer complaints, and other applications used by the solution (Ombudsman, 2008). The diagram below shows a typical complaint management solution.

Figure 2.4: An effective solution for complaint management system



Flow chart 1. The four steps of a complaint handling system.

2.2.3 How The Solution Works

The system provides the process and technology to gather, classify, and preserve all information relating to a product. This ensures that issues and complaints relating to that product are resolved and little or no reoccurrence of the same complaint. The solution offers access to information of a product allowing quick solving of a problem and monitoring of services to customers. It alerts the management of frequent customer complaints and of defective products so that they can control the defects on the products before the problems gets out of control.

The solution follows business principles that enables the company to reduce cost involved with warrants. It also tackles fines from regulatory bodies because of the reduction in error associated with the accurate information the solution offers. The compliance cost is also reduced because processing time of complaints is significantly reduced. The products are of high quality satisfying customers across the board (Biwas & Chougule, 2009).

Some of the benefits of this solution to companies are:

- A standard global system to receive and process complaints
- Increases the consistency of data and enhances reporting of data
- More sales and higher market share because of enhanced customer loyalty
- High level of compliance with regulatory bodies
- Central data location for all products
- Increased consistency of data since complaints forms are uniform
- Ability to apply the same system globally to all braches within a short period

2.3 BENEFITS OF COMPLAINT MANAGEMENT

- It enables the company to comply with regulatory authorities and the industry standards.
- Helps to reduce the cost and cycle time by increasing efficiency and quality
- Helps to maintain the reputation of the company and the safeguards the brand

- Complaint management reduces the number of repeated complaints because of the follow-up actions by the system.
- It uses closed-loop processes thus has little chances of having data that is not complete
- It provides a system that is flexible but controlled with process workflows
- It enhances the operations of the company through alerts, dashboard, and excellent reporting ability.
- It provides the company with improved accountability enabling inter-relationship of every step and process in the company.

Exhibit 2 shows a diagram of a typical diagram of the complete complaint management system as described above.

2.4 PHARMACOVIGILANCE

In the Pharmaceutical Sector Complaint Management is known as Pharmacovigilance.

2.4.1 Defination Of Pharmacovigilance

This is also the drug safety; it is a pharmacology science that helps to collect, detect, monitor, and prevent extreme effect of pharmaceutical product. The name Pharmacovigilance is made of two root words. The words are *pharmakon*is a Greek word for drug and *vigilare*a Latin word for keeping watch. Pharmacovigilance has placed a high emphasis on the adverse drug reactions (ADR). These are any responses that arise from use of drugs that are unattended such as lack of efficacy occurring during doses used for prophylaxis, diagnosis of disease, or those used to modify physiological function. Other areas of interest in Pharmacovigilance are errors in medication like overdose, and others like abusing and misusing drugs. The ultimate goal of Pharmacovigilance is to identify hazards in pharmaceutical products and reducing chances of harm to patients.

2.4.2 Terms Used In Pharmacovigilance

a)Adverse drug reaction (ADR) – this is a side effect that occurs from a drug that the cause is proven or known to exist.

b)Adverse event (AE) – This is a drug side effect where the cause of the AE by the drug is not known.

c)Benefits –This is the proven therapeutic good of a product but patient's subjected assessment effects should be included.

d)Clinical Trial – This is the program organized to study the efficacy of a drug to patients. It has several designs depending on the drug and the phase in the development. During this process, the drug is tested using control groups. The drug during the trials may face dechallenge or rechallenge whereby the trials are stopped or restarted in a patient.

e)Effectiveness – This is the ability of a drug to treat a real disease in a real case scenario

f)Efficacy – Is the extent or the ability of a drug to work in ideal situations example is during the clinical trials.

g)Harm – Refers to the state and extent of damage caused.

ı)Implied causality – This refers to a situation where the causality is presumed positive in spontaneously reported adverse reaction cases.

i)Life threatening – This is an event that places the patients in an immediate risk of death

j)Phase – In this scenario, these are the four phases of drug development. The first phase is the safety trials done during early stages of drug development. The second phase safety and efficacy trials, while the third phase is the key trials, and the final phase is the post-marketing trials. These phase are accompanied by intermediate phases labeled a, b, c example is phase 2b.

k)Risk – This is the probability of harm expressed as a percentage of the total treated population.

l)Risk factor – Is a characteristic of patient that may increase the risk of developing an adverse event that is or not related to the drug. Example is obesity, which potentially increases ADRs

m)Signal – This is a reported safety measure for a drug that needs further investigation. The three signal types are confirmed signals, refuted signals, and unconfirmed signals.

n)Temporal relationship – Exist when an adverse event occurs when a patient is taking the drugs. It helps develop the relationship between the adverse event and the drug though one cannot fully conclude that the adverse event occurred because of the drug.

o)Triage – This refers to the placement of an event report in a category like non-serious, serious, or no case.

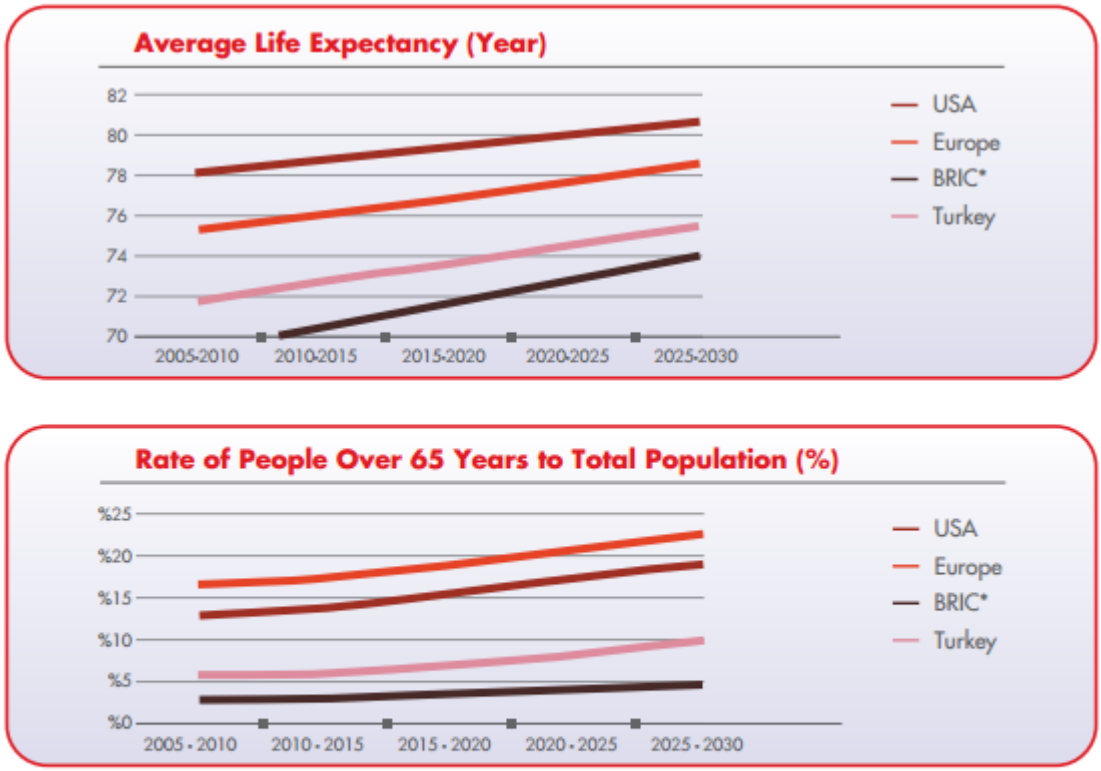
3. AN ANALYSIS OF THE SECTOR

The republic of Turkey pharmaceutical sector has strong factors that facilitate an efficient system. Some of these factors are:

- Successful healthcare reform- this is due to increase in the scope social security services.
- A steady macroeconomic structure and rapid growth rates
- Modern law system supported by economic and political stability
- Turkish pharmaceutical industry ranks 7^{th} in Europe, 16^{th} in the world
- Strong production facility infrastructure; 76 percent of drugs consumed in Turkey on a box basis and 49 percent on a value basis are locally produced
- Has a high industrial employment of about 25000.
- The industry sponsored more than 300 clinical trials in 2011
- Increase capacity in learning centers for fundamental sciences, medicine, and pharmaceutical departments
- Increase in the number of specialist physicians from 18000 in 2002 to 31000
- High competency in diagnosis and treatment, and strong development of healthcare tourism
- The country is strategically located thus is a regional center and thus has a high possibility and advantage of exports to markets(Ilac gibi geleck, 2012). The markets centers are Middle East and Eastern Europe.

The Life expectancy in Turkey is approximately 73 years below that of USA and Europe. Turkey also has a population of about 10 percent of the population above 65 years of age. Turkey is above BRIC (Brazil, Russia, India, and China) in life expectancy and in population above 65 years of age.

Figure 3.1: Turkey's life expectancy



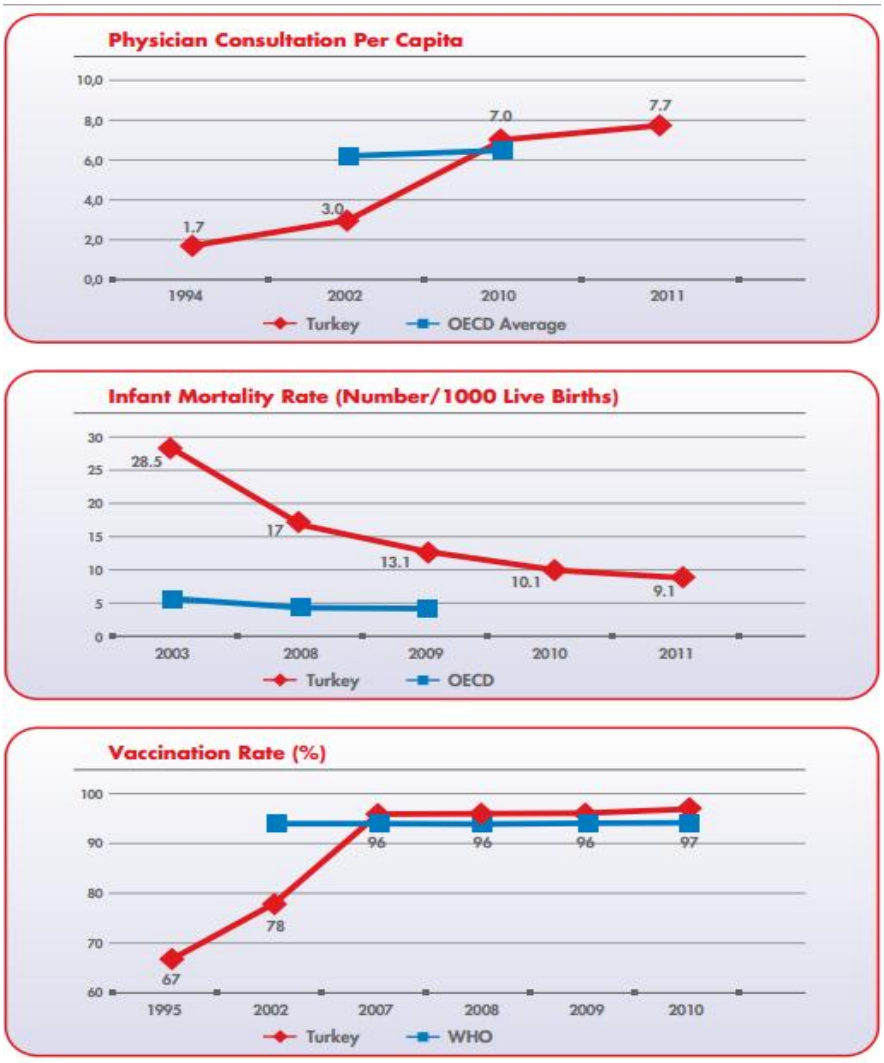
* BRIC: Brazil, Russia, India and China
Source: PwC Analysis, PhRMA, OECD, Earthtrends, WHO, International Diabetes Federation

With health transformation program, Turkey achieved progress in 8 years that the OECD accomplished in 30 years.

The physician consultation per capita has grown from 3.0 in 2002 to 7.7 in 2011. The infant mortality rate that is number per 1000 live births reduced from 28.5 in 2003 to 9.1in 2011. The percentage vaccination rate from 78 percent in 2002 to 97 in 2010. According to the statistical reports in exhibit three, on section three, life expectancy at birth has increased over the years from 72.5 years in 2004 to 74.3 in 74.3 in 2011. The

life expectancy in men is lower than that of women according to the statistical data in the exhibit. The infant mortality rate has lowered from 20.5 in 2004 to 10.1 in 2011. This shows a pharmaceutical sector that is improving and developing over the years.

Figure 3.2: Turkey's health data



Source: Ministry of Health Yearbook 2011 and 2012 Budget Presentation, WHO, OECD

3.1 THE PHARMACEUTICAL SECTOR IN TURKEY

Turkey's pharmaceutical sector is ranks 16th in market value, and 36th in clinical research especially in pharmaceutical export. This poses a risk of lagging behind the competition to attractinvestment in the pharmaceutical investment for Turkey. The

graph below shows the pharma market size in 2011 and clinical trials sponsored by the industry in 2011.

Table3.1: Turkey's world rankings in pharma industry market's size

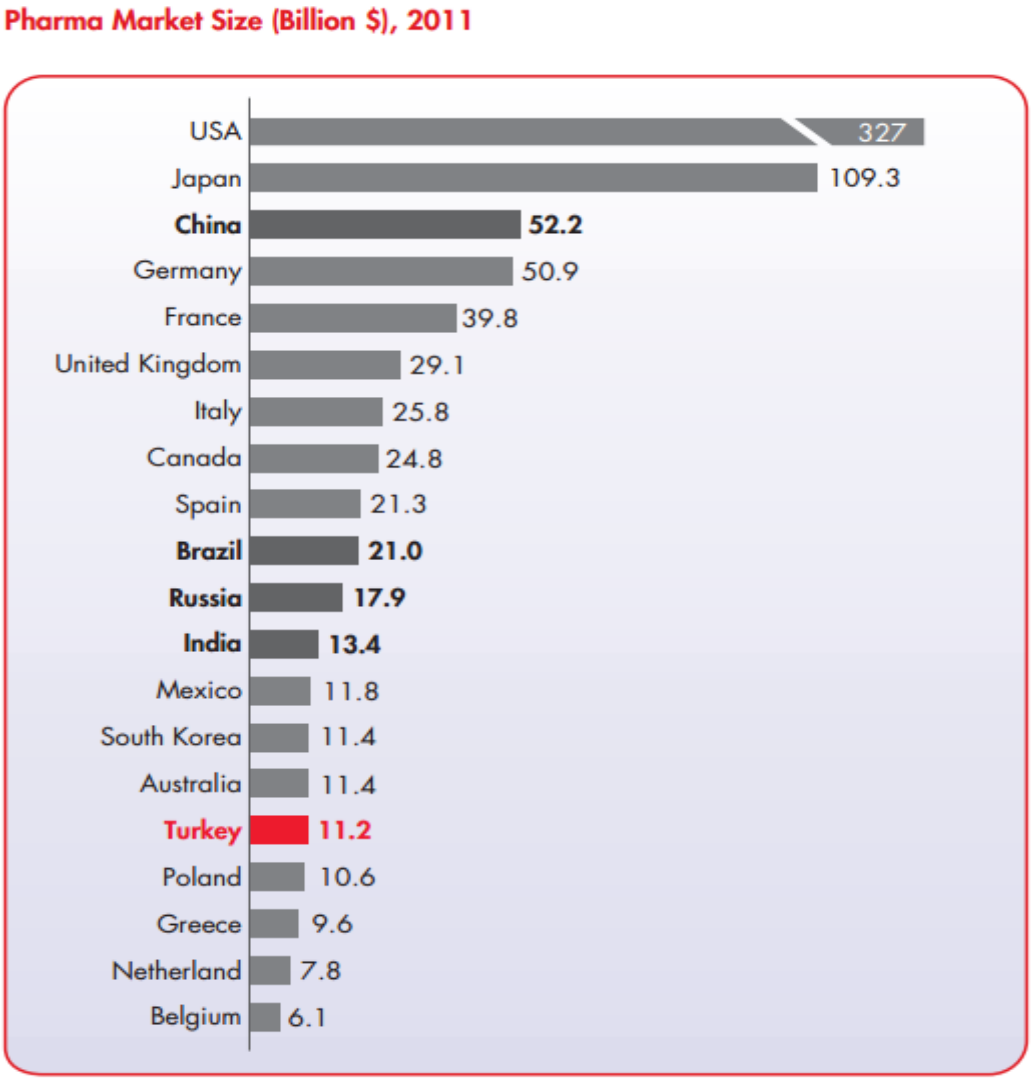
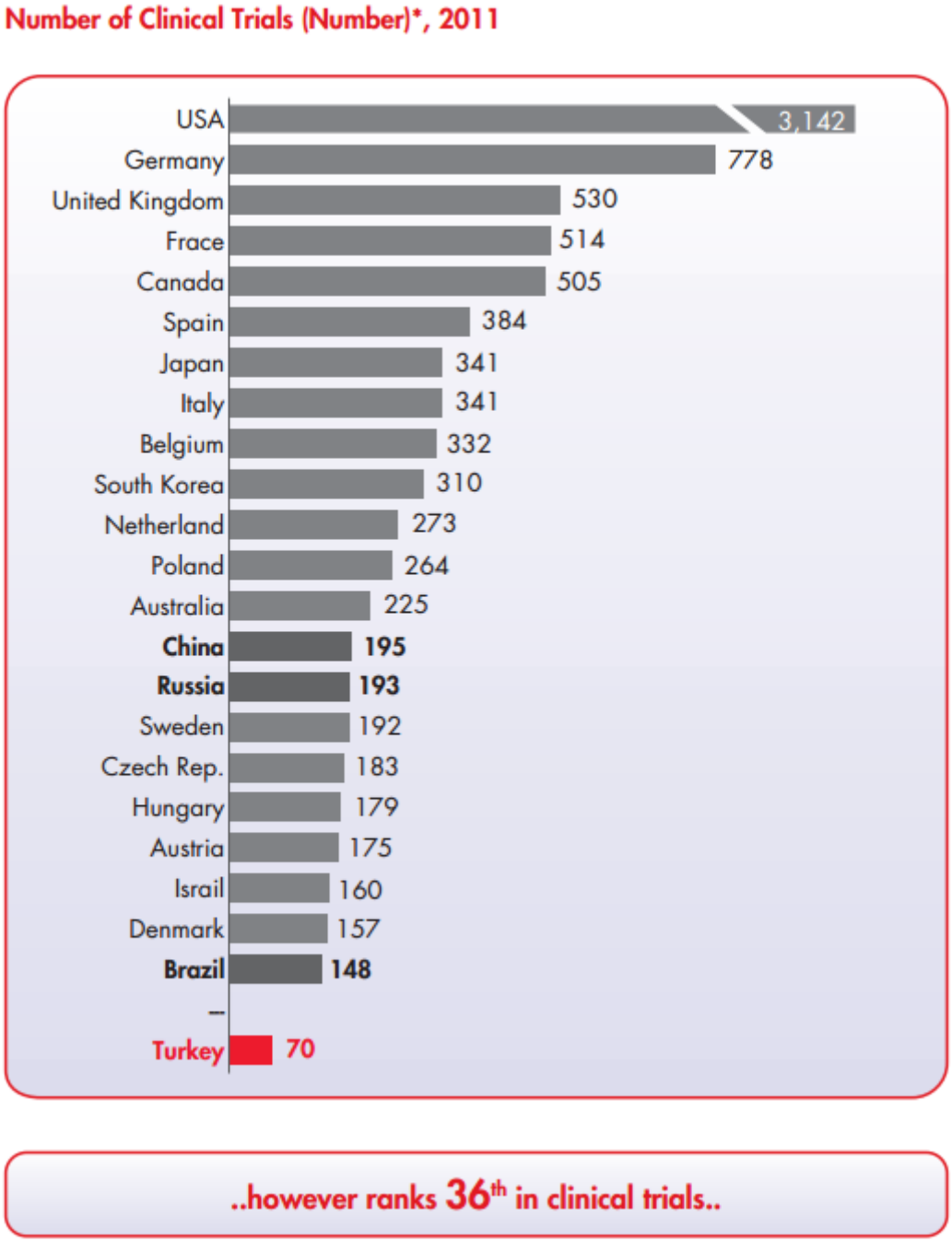
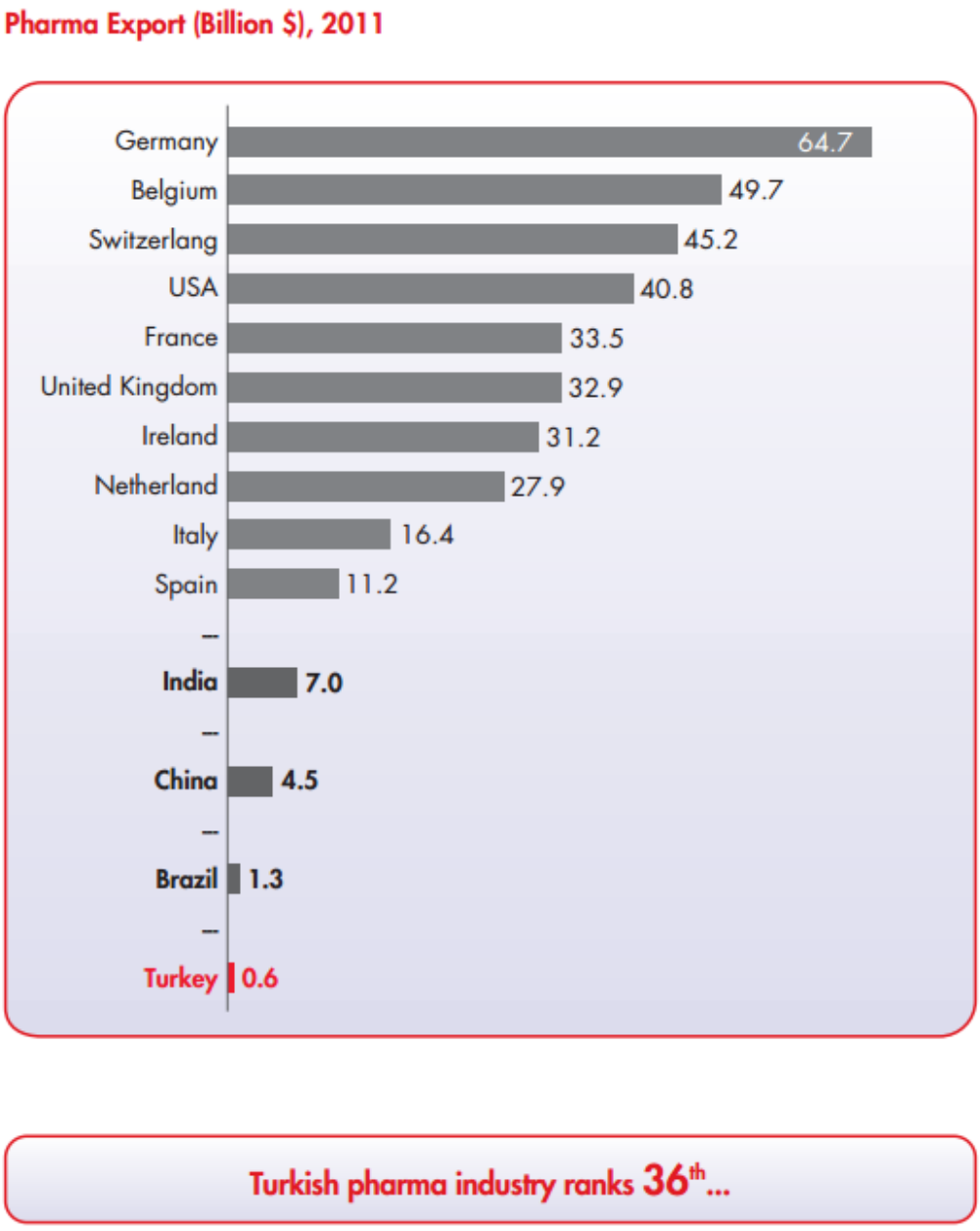


Figure 3.3: Turkey's world rankings in clinical trials



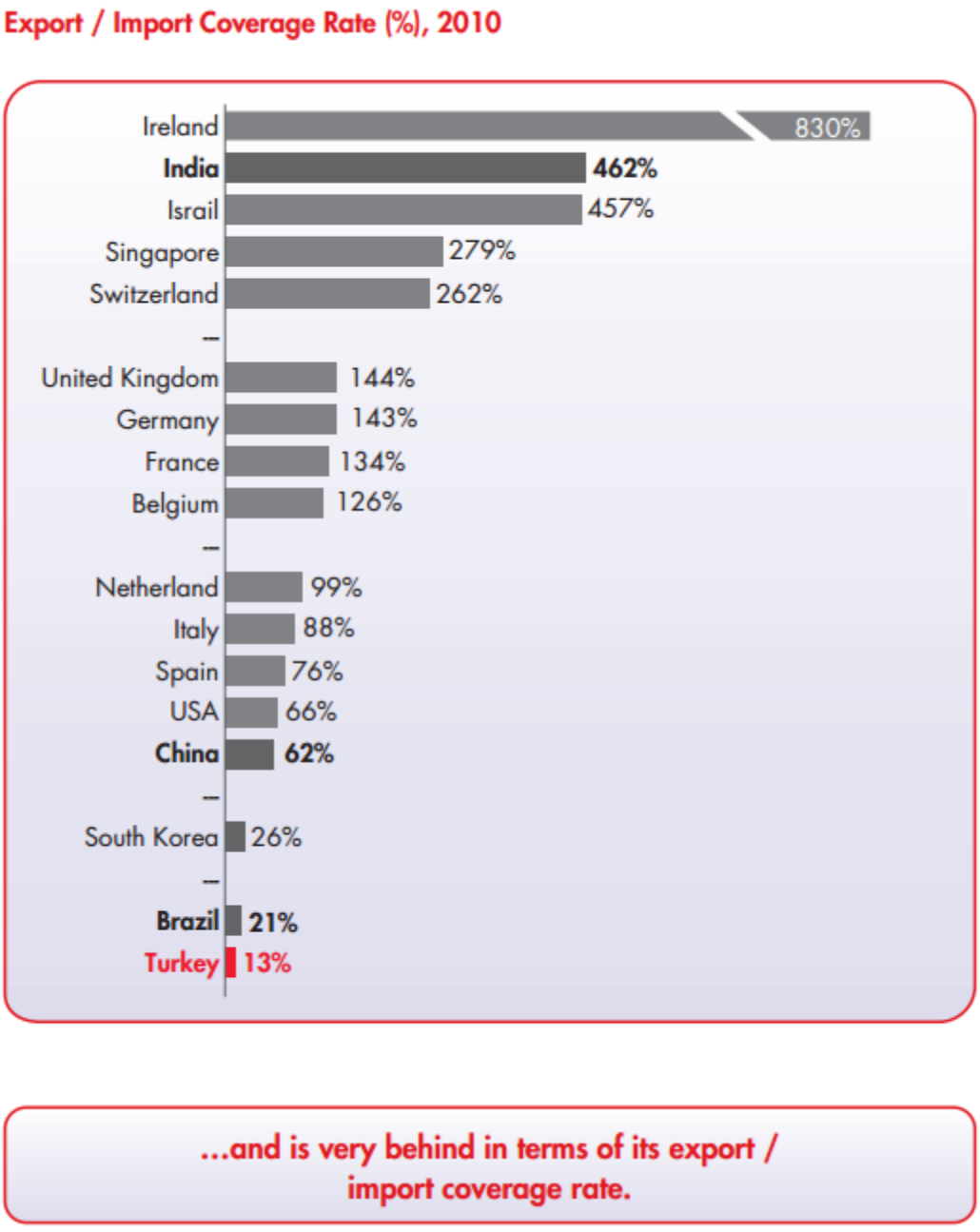
In terms of export volume, Turkey pharmaceutical industry ranks 36th and in the rate of export/import coverage, Turkey is very behind.

Figure 3.4: Turkish pharma industry world ranking



36th in pharma industry

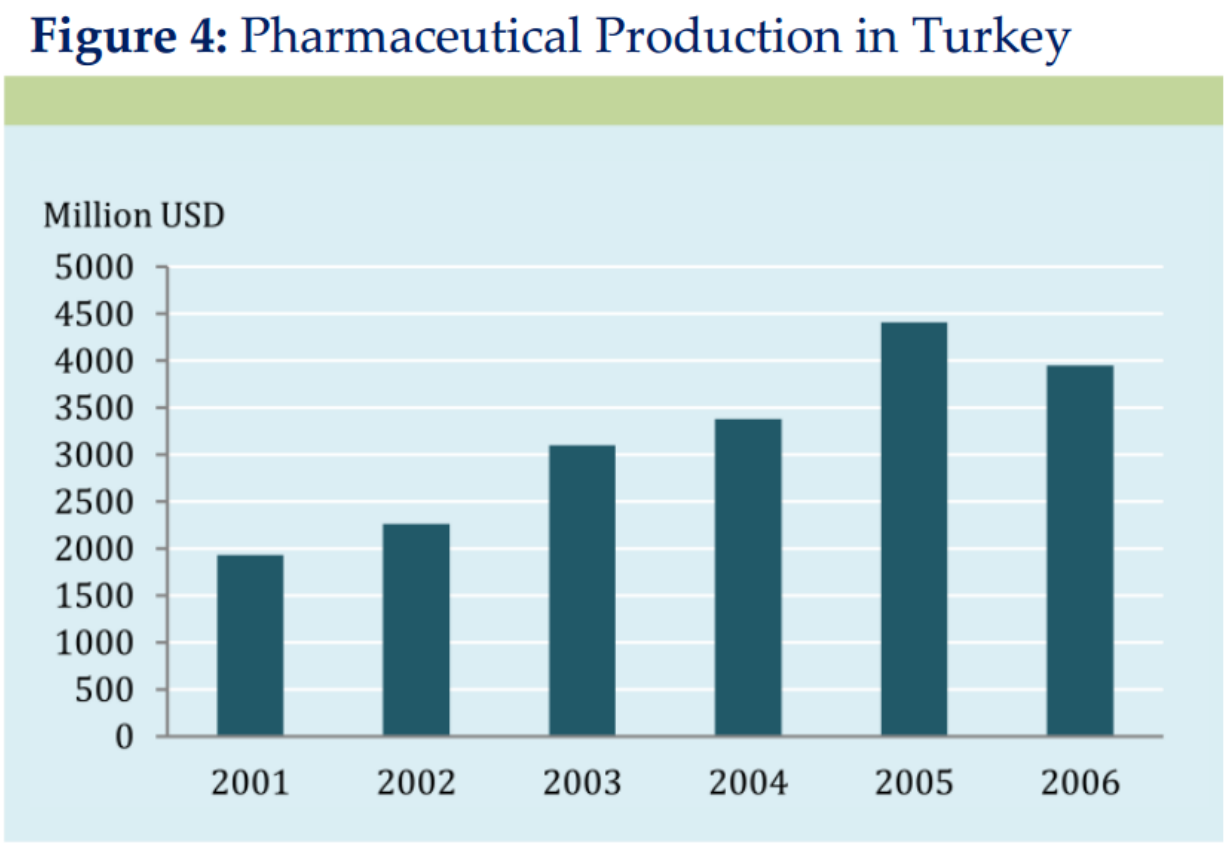
Figure 3.5: Turkey's world ranking in import and export



Turkey emerges as one of the leading pharmaceutical producers in Central Asian Region. It has 134 pharmaceutical companies meeting over 90 percent of its demand.

The market has grown immensely leaving Turkey in position 16 among the 35 countries that lead in pharmaceutical production. Turkey is now in a group of market called "Pharmerging markets" (Caddesi, 2011) because it is among the fastest growing pharmaceutical markets.

Figure 3.6: Turkey's pharmaceutical production



Source: Export Promotion Centre of Turkey.

Turkey is a member of Organization of Islamic Cooperation (OIC) and is the top producer in pharmaceutical products. The table below shows how the members operate in the region in exports and imports. Turkey has 30 percent of the market share on imports and 23 percent of the exports in pharmaceutical products.

Table 3.2: Turkey's ranking in exports and imports of pharmaceutical products

Table 1: OIC Top-10 Pharmaceutical Exporters and Importers, 2010

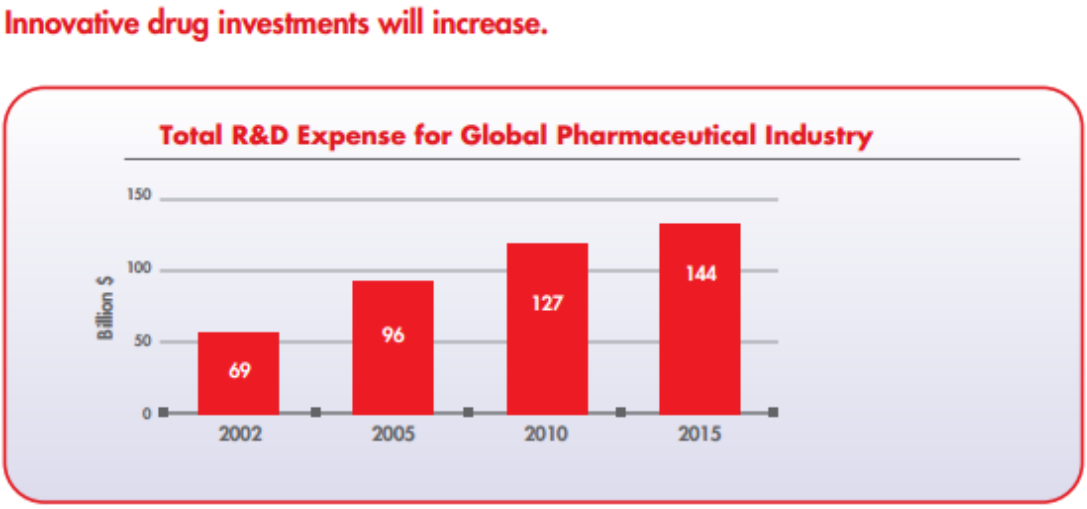
Rank	Country	Exports (mln.US$)	Share in OIC Total	Rank	Country	Imports (mln.US$)	Share in OIC Total
1	Jordan	688	26%	1	Turkey	4778	30%
2	Turkey	611	23%	2	Algeria	1719	11%
3	Indonesia	333	13%	3	UAE	1259	8%
4	Malaysia	308	12%	4	Egypt	1246	8%
5	Egypt	250	9%	5	Malaysia	1133	7%
6	UAE	162	6%	6	Kazakhstan	940	6%
7	Pakistan	136	5%	7	Indonesia	736	5%
8	Morocco	82	3%	8	Pakistan	650	4%
9	Oman	24	1%	9	Morocco	548	3%
10	Kazakhstan	17	1%	10	Jordan	483	3%

Source: UN Comtrade online database.

3.2 THE ADVANCEMENTS IN THE SECTOR

Use of Technology in medicine in the areas of computer-aided of drug, customization of drugs, among others(BMI, 2012). Collaborations with colleges and research institutions to enhance research and development. The graph below shows the total investments in research and development in the world. Turkey has highly investment in research and development and keeps investing to remain competitive in the industry.

Figure 3.7: Showing the total research and development expense for global pharmaindustry



Another area of advancement is management of adverse event reporting forms, these forms are highly advanced and detailed to ensure that they comply with the regulations form authorities and maintenance of international standards.

3.3 THE DOWNFALLS IN THE SECTOR

Lack of adequate skilled labor to be used in production and development of the sector. This is because the sector requires highly trained human skills like those of scientists, biologists, pharmacists among others. This requires Turkey to enhance the academic sector to focus on sciences, which helps to impart mind and develop better skills in natural sciences. Turkey is tackling this in vision 2023, which aims to make Turkey a leading pharmaceutical producer in the world (Caddesi, 2011).

The department of research and development requires improvement of its facilities and equipment. This will help develop the pharmaceutical industry and reduce defective products. This in turn will raise the standards in the industry.

Collaboration with other countries in the region is low; Turkey should send students and educate students from other so that they can develop the sector and make it more competitive in the industry.

Improper management of complaints, this calls for pharmaceutical companies to adopt international standards for their products to remain competitive in the world. This will call for the country to cooperate with international organization like WHO to maintain the standard and to open up their market to the world (BMI, 2012).

3.4 PHARMACOVIGILANCE IN TURKEY

The pharmaceutical sector in Turkey has developed a Pharmacovigilance guideline for registration of all medical products manufacturers (TUFAM, 2005). It contains the following:

i-)The objectives, scope, and legal basis of the document

ii-)Responsibilities of the pharmaceutical companies, the roles and responsibilities of the company and the pharmacovigilant unit are clear in the document.

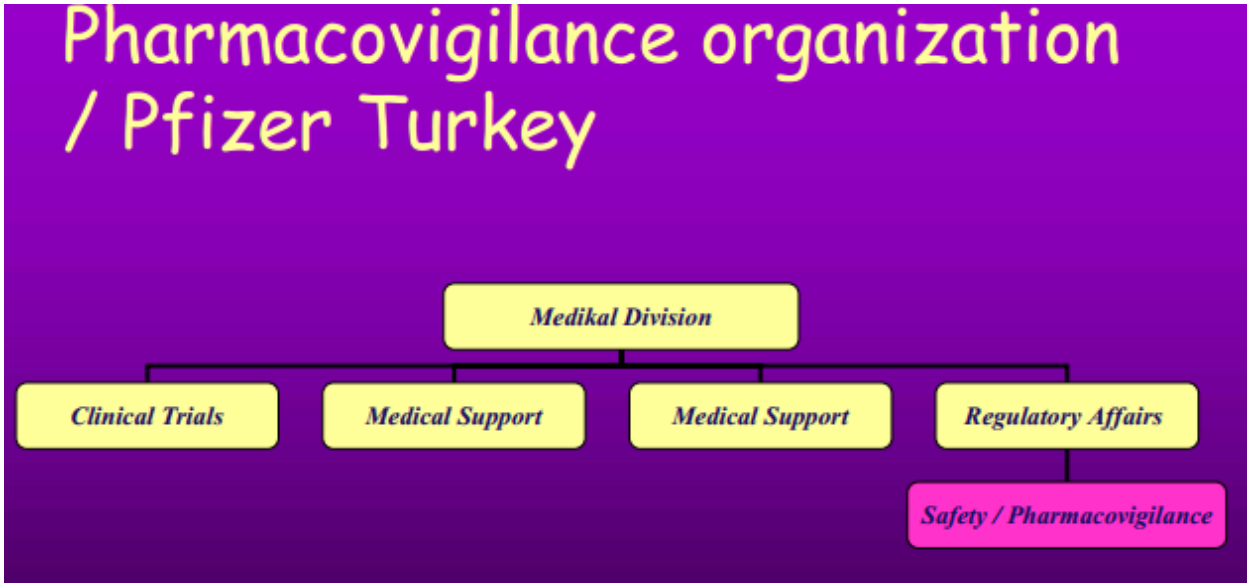
iii-)Section III contains the reporting procedures and what is required in every unit, this includes reporting of adverse events, the scope, and the other types of reporting and how they affect the drug profile once they have been reported. It also contains details of the reporting for form. This section also contains how reporting should be done in special circumstances. It contains reporting procedures between registration application and when the issuance is issued. Procedures in dealing with parameters causing modifications in risk/benefit information. Also reporting for cases when products are used during pregnancy. It also contains data collection methods such as surveys and patients systems. Others in this category of special circumstances are ineffectiveness, overdose, drug abuse, and misuse of drug.

iv-)Section IV contains the periodic safety update reports. This section of the guidelines contains presentation periods, principles, periodic safety update report sample, and content of PSUR bridge summary report.

v-)Section V contains the post-licensing including the company-sponsored post-licensing safety studies. In this, we have the scope, objectives, study types, drugs promotion, physician participation, and other ethical matters.

vı-)Section VI deals with evaluation pursued especially in the post-registration period. This deals with communication, recalling a product , developing the benefit/risk ratio, and principles of benefit/risk evaluation.

Figure 3.8: Pharmacovigilance organization



In Turkey, the sources of adverse events in clinical trials are spontaneous reports, publications, and regulatory authorities.

The appendix contains the annexes contained in the guidelines.

3.5 ALTERNATIVES IN THE INDUSTRY

The various alternatives the pharmaceutical sector in Turkey should employ to have efficient complaint management (pharmacovigilance). Some of the alternatives are:

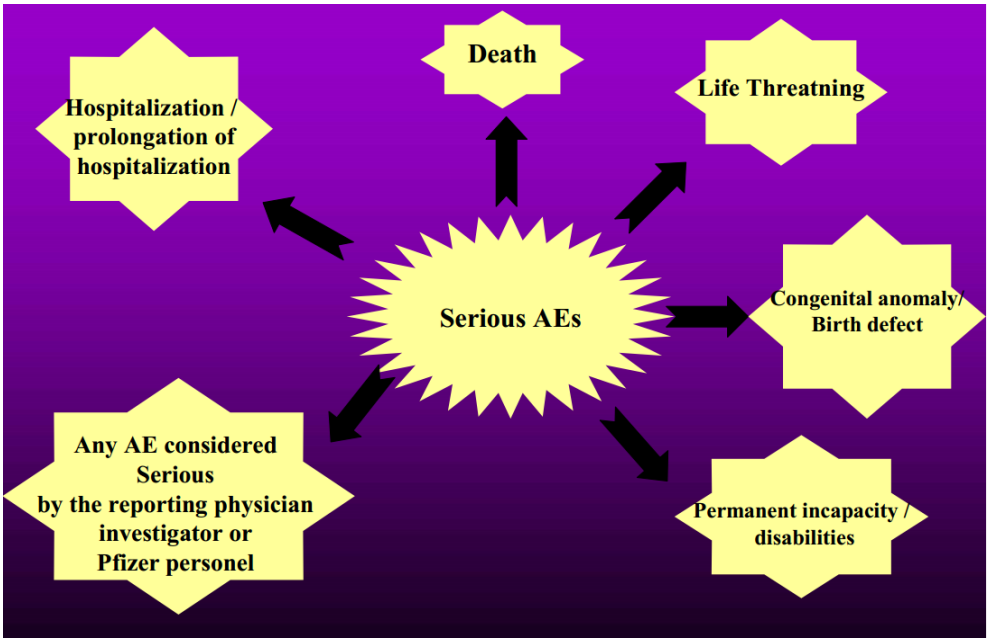
Use of a standard adverse Event report form. This form should be used in all pharmaceutical companies in Turkey.

Mandatory training of all medical personnel within a given time-period such as 30 days of employment on adverse event reporting responsibilities and procedures. Professional medical personnel should train also all relevant medical &marketing employees on spontaneous on spontaneous reporting responsibilities. The training materials and sources should be availed so that all the pharmaceutical's new employees can be given to study and availed for older employees to remind themselves (Caddesi, 2011). The diagram below in figure various serious adverse events that require to be reported by all medical and healthcare professionals in Turkey. This is vital so that the medical products can attain the correct profile.

Another alternative for pharmacovigilance in Turkey is to have fixed timelines for reporting of cases to regulatory bodies and the company's pharmacovigilance unit within 2 business days for serious adverse event and 10 days for non-serious events.

Audits or performance reports should for the pharmaceutical companies should be conducted in the pharmacovigilance units to check if the companies conduct training and reporting of adverse events according to the effective standards from regulatory bodies. These are local reviews to be conducted by local quality assurance officer and periodic audits from Pfizer, a Turkey corporate pharmaceutical regulatory group. This will help to maintain the standards of the industry.

Figure 3.9: Various serious adverse events



3.6 PROBLEMS FACING THE SECTOR

Some of the problems facing the pharmaceutical sector are the inability to access EU countries. This is because of the perception as a burden or unwanted activities. The other is lack of It support, when this will increase in its integration, management of pharmacovigilance will be much easier just the normal management of complaints where information will be more easily managed in the country. The drug profile will be enhanced and reduced cases similar serious adverse events (BMI, 2012).

3.7 DEVELOPMENTS IN THE SECTOR

Efforts have been raised for harmonizing Turkish pharmaceutical regulations with those of the European Union. Those of pharmacovigilance are on the way. There is also importance of close follow up of recent European Union developments on pharmacovigilance regulations. This will help in improving the sector and making it more competitive and a main source of revenue for the country.

4. THE SECOND AND THIRD DEPARTMENT CONSOLIDATION

Complaint management is essential for any company that requires handling and retaining its customers. In pharmaceutical industry, complaints management is not a wish of the company but a requirement by law. Complaint management is what so far we have seen is called pharmacovigilance by the pharmaceutical industry. This is more about management of medicinal products because they are used by people and may lead to death of several people if they are not properly managed. Use of drugs requires careful vigil that is why government and regulatory bodies across the world have regulations to manage these products. Pharmaceutical companies do not struggle to keep customer loyalty, but they struggle to manage consumers. There are many regulations by the government on release and clinical testing of the medical products. Any serious or non-serious event must be reported and labeled in the profile of the product. The process of pharmacovigilance is an international process and has various bodies giving the standards to be followed.

4.1 INTERNATIONAL COLLABORATION IN PHARMACOVIGILANCE

Pharmacovigilance is essential in all countries worldwide and organizations have collaborated with other institutions to ensure a proper oversight is provided for the pharmaceutical industry.

4.1.1 CIOMS

This refers to the Council for International organization of Medical sciences. A think tank offers guidance to drug safety. It is a part of WHO and its reports are usable for designing new drug regulations; the WHO has used many of its proposed policies after adoption. Some of the reports are current challenges in Pharmacovigilance, Management and safety of clinical trials among others.

4.1.2 ICH

The main purpose of this organization is to recommend global standards for the pharmaceutical companies and regulatory bodies worldwide. The abbreviations stand for International conference on harmonization (ICH). It has members for the European

Union, Japan, and United States. The steering committee, the governing body, oversees the progress of harmonization. It was established in 1990 and has members form its founders. Other members are the observers in the steering committee such as the World Health Organization (WHO), Health Canada, and the European Free Trade Association. The other non-voting member of the Steering committee is the International Federation of pharmaceutical manufacturers association (ICH, Organisation of ICH, 2013). The structure of the ICH is as shown below:

Figure 4.1: Showing the organizational structure of ICH

4.1.3 Who

Is an abbreviation for World Health Organization (WHO). The WHO International drug-monitoring program provides the principle basis for worldwide collaboration. Using this they help the member countries to urge their healthcare professionals to record adverse drug reaction in the patients. The reports are assessed locally and dealt with within the country. The reports are further posted to a local database where they are archived in a database. Countries can view reports of adverse events recorded in other countries. When a drug has several reports, a signal may be detected from them. Once a signal has been conclusively assessed, the data is then recorded and member countries are alerted.

4.2 NATIONAL AND REGIONAL DRUG REGULATORY AUTHORITIES

These bodies play a key role in national oversight of Pharmacovigilance. The drug regulating body in Canada is marketed Health Products Directorate. It has two branches the health products and food products. Pharmacovigilance in Egypt is under the ministry of Health with the Egyptian Pharmacovigilance center as the regulatory body.European Medicine Agency governs the drug regulations in the European Union. It helps in maintenance and development of Pharmacovigilance database for all reported adverse reaction cases in the European community. In India, The regulatory bodies are the national Pharmacovigilance protocol, ministry of health and Family welfare, and the government of India. Some countries have online reporting like Kenya with the regulatory body being Pharmacy and Poisons Board. In Latin America, the standards have been kept high so that they are in line with the international standards. U.S contains the largest drug regulatory body in the world, which is the FDA. It enforces code of federal regulations to ensure that all regulations are followed. All drug manufacturers andNGOs play a key role in Pharmacovigilance.

5. RESEARCH

5.1 COMPLAINT MANAGEMENT AND REPORTING IN THE PHARMACEUTICAL INDUSTRY

5.1.1 Adverse Event Reporting

Pharmacovigilance most essential activity is adverse event reporting. It is consumes most of the resources of drug regulatory authorities and drug safety departments in pharmaceutical companies. It involves receipt, triage, data entry, assessing, distributing, reporting, archiving the adverse event data, and documenting it (ORACLE DATA SHEET, 2009). The sources of AE reports are healthcare professionals, patients; patients support programs, post-marketing studies, literature sources, media, and drug regulatory. It is compulsory in most countries for pharmaceutical companies to carry out adverse event reporting(U.S. Department of Health and Human Services, 2009).

5.1.2 The Four Elements Of An Adverse Event Case

The determination of the constituents of what constitute adverse drug reporting is a key principle in adverse event reporting. A triager has to determine if the four elements of an adverse event case are present, in the triage phase of a potential AE report. The four elements are:

1. A patient _ must be identifiable
2. The reporter_ must be qualified and identifiable
3. The suspected drug
4. A reportable adverse event

The four elements must be present for an adverse event report to be valid, although there are some cases where a physician reports the name of the patients as X; such cases are taken to be valid because the reporter had first-hand information about the patient and identifiable. The ability to identify is essential to avoid duplication of cases permitting follow-up to gather additional information. The other three factors also must adhere to the concept of identifiability to prevent cases of fiction and lies where competing

company or an individual tries to defame the company or its products (TUFAM, 2005). The reporter must thus remember the drug they were taking, be identifiable, and remember the symptoms they experience to make the report viable. Reports without real drug name and exact symptoms have no importance to the Pharmacovigilance department or the regulatory authorities.

5.1.3 Adverse Events Coding

Adverse events reports are written using the standard medical terms from the medical coding terms dictionary. This converts the reported information into identifiable and analyzable terminologies. Example of a common medical dictionary is the MedDRA that uses preferred terms (PT).

5.1.4 Seriousness Determination

Pharmacovigilance uses intuitive criteria to determine the seriousness of an adverse event. To be considered serious the adverse event must meet one or more of the criteria below.

i. Resulting in death
ii. Threatens life
iii. Leads to prolongation of an hospitalized patient
iv. Causes persistent or significant incapacitation or disability
v. Causes birth defect
vi. It may also be considered serious if its application leads to prevention of any of the above. It is thus considered as medically significant.

Definition of life threatening is something that may cause immediate death risk like cardiac or respiratory arrest. Hospitalization prolongation means that the patients' treatment caused them to stay in hospital longer than usual because of the medication or drugs taken. Other criteria like incapacitation and disability are subject to if they occurred before or after drug application.

5.1.5 Expedited Reporting

This refers to an individual case study report that has a serious event that is no labelled but considered to be because of using the drug. Most countries require that an expedited case be reported within 15 days of notification. In clinical trials the cases serious cases are given seven days. Non-serious cases are reported periodically.

5.1.6 Clinical Trial Reporting

These are serious adverse event reported during clinical trials. Clinical trials provide safety information that the drug is proper for human use. This information provided by clinical trial is essential for the drug regulatory authorities to decide if the drug can be granted market authorization. Serious Adverse event is captured from study patients who experience adverse event during clinical trials. Non-serious adverse events are given a separate record. The information captured by the serious adverse event includes the medical background of the patient and forwarded by the investigator for assessment and reviewing. The information is further given to the entity responsible for reporting the information, such as the pharmaceutical company.

5.1.7 Spontaneous Reporting

This refers to the core data-generating system that relies on health professionals for the world Pharmacovigilance. In some countries, the consumers are allowed to report too. The information reported is any adverse events to the drug authorities or the drug manufacturer themselves (ICH, ICSR Public Consultation page, 2011). These reports are submitted voluntarily but may sometimes be encouraged by the media reports, medical articles, or lawsuits. Many parts in the world today use electronic transmission using a standardized defined message (Vigibase, 2008). The significant weakness of this kind of reporting is that it has underreporting, less than 100 percent of the occurring cases are reported. Studies also indicate that adverse event reporting varies from country

to country thus complicates the assessment of the reports, this variation is less than 10%. Less serious conditions are not reported while only serious life-threatening conditions are reported. This indicates that physicians and other medical personnel will give priority to only serious adverse events and ignore no serious events. Sometimes if the cases are serious, symptoms it may not be clear that the drug caused them. The medical personnel are not compelled to report some case, thus reports from patients become of value and even of significant value if confirmed by a qualified medical professional. These reports are key elements of world-wide Pharmacovigilance forming the core database of World Health Organization, these reports were about 4.6 million (January 2009) and increase by a quarter a million annually (Mann & Andrews, 2002).

5.1.8 Aggregate Reporting

It is the compilation of drug safety information for a long period in contrast with single or individual reporting of adverse events. Aggregate reporting is essential to assess the safety of drugs. Its main advantage is provision of a broader view of a drug safety profile. For world-widePharmacovigilance Periodic Safety Update Report (PSUR) is the significant aggregate report. This report got an update in 2012 to Periodic Benefit Risk Evaluation Report (PBRER). This report provide the drug's benefit-risk profile, this include all relevant data of the drug since its development.

5.1.9 Other Reporting Methods

In some countries, doctors and physicians are obliged by law to carry out spontaneous reporting. Most countries require pharmaceutical companies to submit all their drug reports received via their Qualified Person for Pharmacovigilance (QPPV) to the national regulatory authority. Other countries have intensive focus on new product, or controversial products, or on how doctors prescribe, or reports from pharmacists. All these ways and methods provide useful information.

5.2 RISK MANAGEMENT

This Pharmacovigilance discipline deals with signal detection and drug's risk-benefit profiles. It also deals with compilation of Risk management plans and aggregate reports such as DUSR, PBRER, and PSUR.

5.2.1 Causality Assessment

This refers to determination of causality, but it is one of the most vital, yet a challenging problem in Pharmacovigilance. The relationship between a given drug and the adverse event is what is referred to as causality. Lack of credible data is what determination of causality a difficult problem. The difficulty in assessment of causality is the existence of temporal positive AE, the complex human physiology, and the disease. To establish a causality between AE and a drug, it is important to exclude the possibility of other possible causes and factors. In determining causality of an adverse event of a certain drug, one requires to establish if the event occurred with the drug or if it was because of using the drug. This happens because a patient on a drug can develop a condition that is not associated with the drug. This is true for diseases like cancer, which develop over a long period. Some adverse reactions like thrombosis occur within a short duration after exposure. In order to rule out or confirm a causal relationship it is essential to determine the risk factors.

The most effective way of confirming a causal relationship is to use a control group to study the cases where the incidence occurs. This determines if the background of the adverse event is lesser than that of the group taking the drug. If the incidence is the higher in the placebo group than in the control group then the causal relationship is likely to exist to the drug assessed, unless there are other factors existing that have not been considered.

5.2.2 Signal Detection

These are a range of techniques found in CIOMS VIII. The World Health Organizations defines safety signal as reported information on the causal relationship that was previously unknown. More than one report is required to come up with a signal. This depends on the event and the data available(Gavali, Kulkarni, Kumar, & Chakraborty, 2009). Data mining of databases of Pharmacovigilance helps in the signal declaration. This can be calculated using mathematical signals using information contained in individual case study reports. A signal is declaration happens when the calculated results crosses a particular threshold. Signals that need analysis are investigated using all the available data so that they can be confirmed or refuted. Inconclusive analysis of a signal requires additional data such as one collected through post-marketing. Signal detection is key to Pharmacovigilance because it helps discover the adverse reaction the drug description considered unexpected so that a product can be labeled to minimize the risk in the patient population(Singhal & Chakraborty, 2012).

5.2.3 Risk Management Plans

This document contains the description of all risks associated with a drug. The document assures positive risk-benefit profile once the drug is in the market. Risk management Plan contains the identified, potential, and unknown risks. It also contains the steps that the pharmaceutical company will undertake to reduce the risks that accompany use of the drug. The steps focus on labeling of the product and the health professionals. This document also contains the risks involved in using the drug off the label.

5.2.4 Risk/Benefit Profile Of Drugs

Pharmaceutical companies are required to test all the new drugs on people before releasing them to the market, in the clinical trials. This occurs after the drug has been tested, using animals, for toxicity. The clinical trials use a placebo and a control group to test the new drug. Clinical trials determine if the drugs work and how well it works. It also determines how harmful the drug is. Another purpose of the clinical trial is

determine if the condition is improved and how much drug should be taken. It also determines the potential harm of the drug and the seriousness of the harm.

The clinical trials provide reliable information for large population that may have the same characteristics as the trial group such as ethnic region, gender, age, state of health among others. Because of the control nature of the clinical trials, they can never tell the effect of the drug in all situations. Clinical trials just tell enough information required by the legislation and other benefits and risk judgment, but once in the market any patient population even those with characteristics not studied can take the drug. Different set of warning and precautions should be included in the drug labeling to maintain a positive risk/benefit profile in all possible areas where the drug may be used.

Pharmacovigilance gives rise to other branches of ensuring safety of drugs such as pharmacoepidemiology, which provides data and information on the adverse reactions of drugs to patients by use of drug agents. Others are pharmacogenetics and pharmacogenomics, pharmacogenitics is the study of how genes affect a person's response to drugs. Pharmacogenomics helps to discover new drugs and provide characteristics of older drugs.

5.3 PHARMACOENVIRONMENTOLOGY

The monitoring of drugs and its effects on the environment lacks proper procedures despite the efforts to place attention and regulations by agencies and regulatory bodies(Ruhoy & Daughton, 2008). Pharmacoenvironmentology is a concept of Pharmacovigilance suggested by Rahman Syed in 2006(Rahman & Khan, Environmental pharmacology: A new discipline , Dec 2006). It deals with the impact of a drug to the environment and the living organism(Rahman, Khan, Gupta, & Uddin, July 2007).

5.4 PHARMACOVIGILANCE OF MEDICAL DEVICES

A medical device is anything that is used in treatment of a disease without any chemical action in the body; it includes instruments, apparatus, and implants among others. The action by drug products is physiological processes, but medical devices use mechanical

or thermal means. These devices vary in application and size; examples include thermometers, medical robots, neuroprosthetics among others.

Pharmacovigilance of medicinal products and medical devices is quite different because of the differences in them. These devices are classified according to the level of the risk of failure in the scale of 1-3, those rated as 1 have the least risk, and those rated 3 have the highest risk. This rating is on how the device is likely to cause harm if it fails an example of a high-risk device is the cardiac pacemakers. Medical device reporting (MDR) contains reports for adverse events for the medical devices. This is similar to reporting in drugs but has some differences, for example in U. S. the healthcare professionals are required to by law to report any death and known serious injuries they suspect has been caused by the medical device to the manufacturer and the FDA(FDA, 2013). This contrast the reporting of adverse events of drugs because it is voluntary.

5.5 PHARMACOVIGILANCE OF HERBAL MEDICINES

Health regulatory bodies and the public have had concerns about the safety of the herbal medicines(WHO Guidelines, 2004). The use of these drugs has grown extensively across the globe. Increasing number of people is using the traditional option instead of the pharmaceutical products. The reporting of the adverse events by the media is not adequate and conclusive thus misleads the public. The difficulty is the difficulty in identifying the causes of adverse events because of lack of data and few regulations on reporting and use of the drugs (Rahman & Singhal, 2002).

6. CONCLUSIONS AND RECOMMENDATIONS

6.1 RECOMMENDATIONS

Pharmacovigilance is important for the growth of the pharmaceutical industry.Some of the recommendations for management of complaints in this industry are:

Integration of the complaint management system with the technology. This will involve reporting, processing, feedback, and follow-up through a computer system. This system can be web-based where complaints are directed to the quality assurance and production department. This web-based system should be comprehensive enough to handle all report types and categorize them appropriately. The level of integration should be high such that the technology system records and keeps data in terms of product type and product profile. The system should also offer a database system to store all the data. The technology employed to should have the capability to give any report requested by the personnel.

Increase in the number of skilled labor or human labor. This will ensure that complaints are managed effectively and timely in accordance to the regulations from regulatory authorities. This is possible through encouraging the education system to concentrate in chemistry and biology and other natural sciences. This will enhance and improve management of complaints in the future. Currently, there is need to teach and train the sales staff and new employees on how to manage complaints in the sector.

Cooperation with international pharmaceutical organization so that they can remain relevant and more tuned to the system. This will ensure that the sector has employed the international standards, which emphasizes on timely reporting of adverse events and other reporting. Pharmacovigilance is not only a requirement of local regulatory authorities but also the international authorities.

The pharmaceutical companies should ensure that they have qualified pharmacovigilant personnel. The personnel should ensure that there is efficient and proper reporting of all adverse events in time. The reporting forms should also be similar and uniform to ensure consistency in reporting of all cases.

6.2 CONCLUSIONS

Complaint management system is a requirement by any company that produces goods or services. This is essential not only for the growth of the company but also the sector as well. Pharmacovigilance is a method of managing complaints in the pharmaceutical industry. Since the complaints in the industry are sometimes fatal, there are severe guidelines for any company to form and run a pharmaceutical industry.

Pharmaceutical industry in Turkey is growing rapidly making the sector a key in the growth of the economy. Efficient management of complaints is key in development of the sector. It requires integrating with technology and increasing the size of skilled labor to succeed in developing the sector to have excellent standards.

Across the world, regulatory bodies in different regions manage pharmacovigilance. These bodies provide the standards for every company to follow. These include the standard reporting forms for adverse events, the time required to report a matter, among others.

In conclusion, a successful pharmacovigilance system is one that can use technology to ease reporting of events, one that employs a large team of skilled labor, and one that employs international standards to run the complaint management system.

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APPENDICES

Exhibit 1: Adverse reaction report form

ADVERSE REACTION REPORT FORM
Turkish Pharmacovigilance Center

1. Patient Initials	2. Age	2a. Date of Birth	3. Sex	4. Height cm.	5. Weight: __kg.	2. Severity Criteria
		Day/Month/Year	Female Male			Check the suitable box Death Day/Month/Year

B. ADVERSE REACTION(S)			
1. Describe the Adverse reaction	Reaction Onset (Day/Month/Year	Ending Date	Result	
			Recovered/Healed Recovering/Healing	Life Threatening Caused Hospitalization and/Or Prolonged Hospitalization Period (..days)
			Recovered/Healed with Sequeal Continues Terminated with death	Caused Permanent or Significant Disability or Incapacity Congenital Anomaly and/or Birth Defect Other
			Unknown Other	Reason for death if the patient has died
				Has autopsy been conducted? Yes No (If yes, attach the relevant document)

3. Laboratory Findings (With dates – Day/Month/Year)

4. Relevant Medical Story/Concomitant diseases: (For instance: Allergy, pregnancy, consumption of cigarettes and alcohol, hepatic/renal impairment, diabetes, hypertension, etc.) With regard to congenital anomalies, please indicate all drugs taken by the mother at pregnancy, exposed diseases and last month of period. (Day/Month/Year).

1. Name of suspected drug	2. Route of Administration	3. Daily Dosage	4. Date for starting medication (day/month/year)	5.Date of quitting the Drug (day/month/year)	6. Indication	7. Has the drug been quitted?	8. Have adverse reactions decreased when quitting the drug or lowering the dosage?	9. Has the drug been re-administered?	10. Have the adverse reactions re-occurred when re-administering the drug?
						Yes No Unknown	Yes No Unknown	Yes No Unknown	Yes No Unknown
						Yes No Unknown	Yes No Unknown	Yes No Unknown	Yes No Unknown
						Yes No Unknown	Yes No Unknown	Yes No Unknown	Yes No Unknown

11. Concomitant Drug(s): (Except for Those Used in the Treatment of the Adverse reaction)

						12.Other Observations and Comments: (In case of a Problem related with the quality of the Medicinal Product for Human Use, Please indicate the Batch Number of the Suspected Product, its Expiration Date and the Relevant Problem).

13. Adverse reaction: (Together with the drugs used for treatment and the date of usage (day/month/year))

D. INFORMATION PERTAINING TO REPORTING PERSONS	E. INFORMATION PERTAINING TO REGISTRATION/PERMIT HOLDER (To be filled only in case of reports submitted by the registration/permit holder: Name, surname and contact information of Drug Safety Officer

1. Name, Surname:	2. Profession:	1. Name of Registration/Permit Holder:	
4. Address	3. Tel No:		
4. Address:	5. Fax:	2. Tel. No:	3. Fax:
4.	6. E-mail:	4. Address of Registration/Permit Holder:	5. Type of Report:
7. Signature:	8. Has the report also been notified to the company? Yes No		Initial Follow-Up
9. Date of Report:	10. Type of Report: First Follow-Up	6. Report Number of Registration/Permit Holder:	7. Source of Report: Foreign Consumer Observational Study Literature
	11. Medical Record No:	8. Date of First Notification of the Registration/Permit Holder	Healthcare professional a) Physician b) Pharmacist c) Dentist D) Nurse
		9. Date of this Report:	Institute Other than the Institute Registration holder Others

e-mail: TUEAM@saglik.gov.tr fax: 0312 309 71 18 tel: 0312 309 53 97 Please complete the form as accurately as possible. You may attach a page to the form.
Annex 2: CIOMS Form

SUSPECT ADVERSE REACTION REPORT	

I. REACTION INFORMATION

1. PATIENT INITIALS 2. (first, last)	1a. COUNTRY	2. DATE OF BIRTH	2a. AGE	3. SEX	4-6. REACTION ONSET	8-12. CHECK ALL APPROPRIATE TO ADVERSE REACTION
7-13. DESCRIBE REACTION(S) including relevant tests/lab data)						PATIENT DIED INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION INVOLVED PERSISTENCE OR SGNIFICANT DISABILITY OR INCAPACITY LIFE THREATENING

CV Etc. Etc. Sub-total			
Etc.			
TOTAL			

The number of patients-cases represented with the tabulated terms should be indicated as a footnote(or elsewhere). (e.g.: x-spontaneous/administrative, y-clinical research, z-literature cases)
** This table is only an example for various possible data presentations held by the right holding registration owner (e.g.: severe and non-severe reactions may be indicated in the same or different tables, etc.)

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) include generic name)		20. DID REACTION ABATE AFTER STOPPING DRUG? YES NO NA
15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION	21. DID REACTION REAPPEAR AFTER REINTRODUCTION? YES NO NA
17. INDICATION(S) FOR USE		
18. THERAPY DATES (from/to)	19. THERAPY DURATION	

III. CONCOMITANT DRUGS AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

24a. NAME AND ADDRESS OF MANUFACTURER		
	24b. MFR CONTROL NO.	
24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT SOURCE STUDY LITERATURE HEALTH PROFESSIONAL	
DATE OF THIS REPORT	25a. REPORT TYPE INITIAL FOLLOW-UP	

Annex 3 Periodic Safety Update Reports Tables 3.1-3.3.

Table 3.1:
Individual Presentation of Individual Case Stories
(See Subsection 1.4.3.6 for Detailed explanation)

Source	Type of Case	Only Summary Chart	Ranking List and Summary Chart
1. Reports Submitted Directly to the registration holders - Spontaneous adverse reaction reports* - Studies and early drug access programs	S NS UL NS L** S R	- - + -	+ + - +
2. Literature	S NS UL	- -	+ +
3. Other Sources - Administrative authorities - Contracted partners - Register records	S S S	- + +	+ - -

* Medically non-confirmed reports must be attached to the PSUR as a ranking list and/or special chart.
** The ranking list should be attached to the PSUR only in case of demand from the Pharmaceutical General Directorate
S=Severe
L=Listed
R=Regarded to be related with the Researcher of the sponsor
NS=Non-severe (Not Severe)
UL=Unlisted

Table 3.2:

Sample Special Chart**
Number of Reports Obtained from Spontaneous (Medically Confirmed), Clinical Research and Literature Cases on a Term Basis (Findings, Symptoms and Diagnosis): All Severe Adverse Reactions

***means unlisted adverse reactions.**

Body system/adverse reaction term	Spontaneous/Administrative authorities	Clinical Researches	Literature
CNS Hallucinations* etc. etc. Sub-total	2	0	0

Table 3.3:

Sample Ranking List

REGISTRATION HOLDER NO.	COUNTRY	SOURCE	AGE/GENDER	DAILY DOSAGE Mg/day	DATE OF COMMENCEMENT OF REACTION Or the period before the commencement of the reaction	TREATMENT DATES Or treatment period	DEFINITION OF THE REACTION	RESULT	COMMENT ON THE RESULT

Annex 4
PSUR presentation template

<Batch no. > PERIODIC SAFETY UPDATE REPORT
relevant

ACTIVE SUBSTANCE(S): <Name(s) >
ATC CODE(S): <Code(s) >

MEDICINAK PRODUCTS COVERED:

Name of medicinal Product	Registration Number	Registration Date Indicate Date of Birty**	Registration Holder
<>	<>	<>	<>

WORLD REGISTRATION DATE: <Date>
PERIOD COVERING THE REPORT:
From-to (Data lock point)

DATE OF THIS REPORT:
Date

VOLUME: Number / Total number of volumes

OTHER INFORMATION:
<Other distinguishing or explanatory information, upon the of the registration holder>

DATA LOCK POINT OF THE NEXT REPORT:
<Date>
NAME AND ADDRESS OF REGISTRATION HOLDER:
<Name>
<Address>

NAME AND CONTACT INFORMATION OF THE OFFICER RESPONSIBLE FOR THE SAFETY OF THE MEDICINAL PRODUCT FOR HUMAN USE:
<Name>
<Address>
<Telephone number>
<Fax number>
<e-mail address>

SIGNATURE: <Signature>

LIST OF BATCH NUMBERS

<Batch numbers>	<period of coverage>

DISTRIBUTION LIST

<Competent authority>	<Number of copies>

Exhibit 2: A typical complaint management system

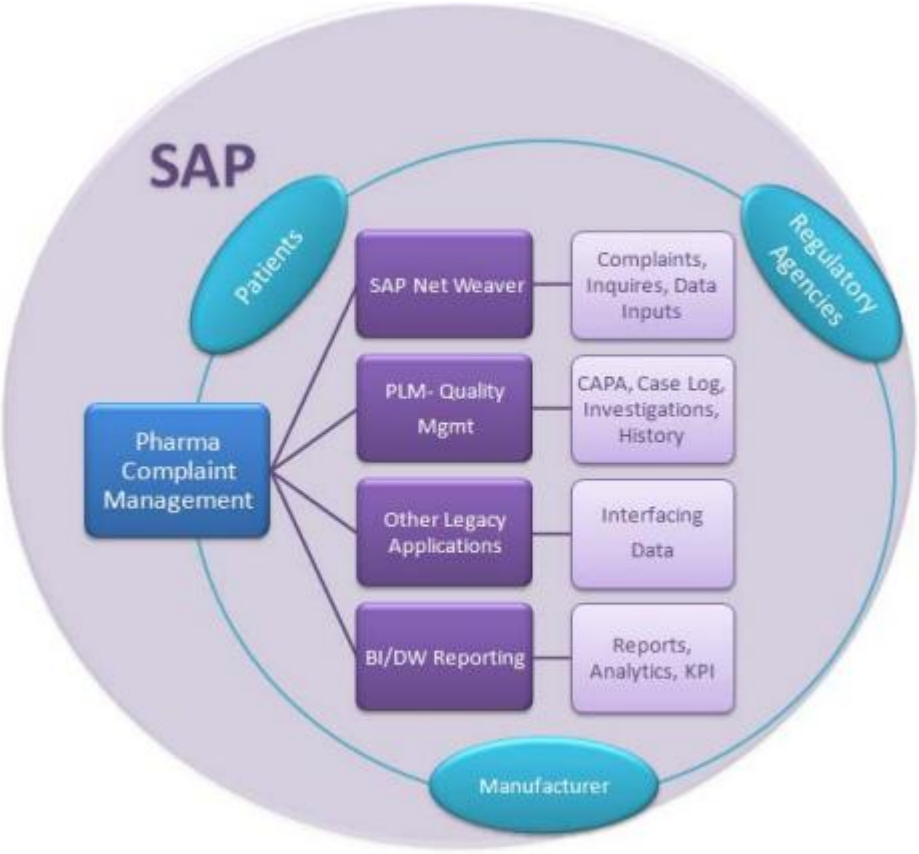

Exhibit 3: Turkey's statistics

Country statistical profile: Turkey 2013

	Unit	2004	2005	2006	2007	2008	2009	2010	2011
Production and income									
GDP per capita	USD current PPPs	10 162	11 391	12 895	13 894	15 025	14 443	15 604	..
Gross national income (GNI) per capita	USD current PPPs	..	..	..	..	..	..	..	..
Household disposable income	Annual growth %	..	..	..	..	..	..	..	..
Economic growth									
Real GDP growth	Annual growth %	9.4	8.4	6.9	4.7	0.7	-4.8	9.2	8.5
Net saving rate in household disposable income	%	..	..	..	..	..	..	..	..
Gross fixed capital formation	% of GDP	28.4	17.4	13.3	3.1	-6.2	-19.0	30.5	18.3
Economic structure									
Real value added: agriculture, forestry, fishing	Annual growth %	2.8	7.2	1.4	-6.7	4.3	3.6	2.4	5.3
Real value added: industry	Annual growth %	11.3	8.6	8.3	5.8	0.3	-6.9	12.8	9.2
Real value added: services	Annual growth %	10.4	9.8	10.3	8.3	6.8	6.3	5.7	7.7
Government deficits and debt									
Government deficit	% of GDP	..	..	0.8	-1.5	-2.8	-7.0	-2.6	..
General government debt	% of GDP	..	..	..	..	..	..	..	..
General government revenues	% of GDP	..	..	33.7	33.0	32.0	33.5	36.4	..
General government expenditures	% of GDP	..	..	33.0	34.5	34.8	40.5	39.0	..
Expenditure									
Public expenditure on health	% of GDP	3.8	3.7	4.0	4.1	4.4	..	..	..
Private expenditure on health	% of GDP	1.5	1.8	1.8	1.9	1.6	..	..	..
Public social expenditure	% of GDP	9.9	9.9	10.0	10.5	10.7	12.8	..	..
Private social expenditure	% of GDP	..	..	..	..	..	..	..	..
Public pension expenditure	% of GDP	..	5.9	5.8	6.1	5.5	6.8	..	..
Private pension expenditure	% of GDP	..	0.0	0.0	0.0	0.1	0.1	0.1	..
Net official development assistance (Aid)	% of GNI	..	..	..	..	..	..	..	..
Taxes									
Total tax revenue	% of GDP	24.1	24.3	24.5	24.1	24.2	24.6	26.0	..
Taxes on income and profits	% of GDP	5.3	5.3	5.3	5.7	5.8	5.9	5.6	..
Taxes on goods and services	% of GDP	11.5	12.0	11.9	11.5	11.0	11.2	12.4	..
Taxes on the average worker	% of labour cost	42.8	42.8	42.7	42.7	39.9	37.4	37.9	37.7
Trade									
Imports of goods and services	% of GDP	26.2	25.4	27.6	27.5	28.3	24.4	26.8	32.7
Exports of goods and services	% of GDP	23.6	21.9	22.7	22.3	23.9	23.3	21.2	23.8
Goods trade balance: exports minus imports of goods	Bln USD	-34.4	-43.3	-54.0	-62.8	-70.0	-38.8	-71.6	-105.9
Imports of goods	Bln USD	97.5	116.8	139.6	170.1	202.0	140.9	185.5	240.8
Exports of goods	Bln USD	63.1	73.5	85.5	107.3	132.0	102.1	114.0	134.9
Service trade balance: exports minus imports of services	Bln USD	12.8	15.2	13.6	13.3	17.7	17.3	15.5	18.3
Imports of services	Bln USD	10.1	11.7	12.0	15.6	17.8	16.6	19.3	20.7
Exports of services	Bln USD	22.9	26.9	25.5	28.9	33.1	33.9	34.7	39.0
Current account balance of payments	% of GDP	-3.7	-4.6	-6.1	-5.9	-5.5	-2.1	-6.3	-9.8
Foreign direct investment (FDI)									
Outward FDI stocks	Mln USD	..	..	..	..	..	22 250	22 509	26 398
Inward FDI stocks	Mln USD	..	..	..	..	..	143 724	185 806	138 752
Inflows of foreign direct investment	Mln USD	..	..	924	2 106	2 549	1 554	1 464	2 464
Outflows of foreign direct investment	Mln USD	..	..	20 185	22 047	19 504	8 409	9 038	15 878
Prices and interest rates									
Inflation rate: all items	Annual growth %	8.6	8.2	9.6	8.8	10.4	6.3	8.6	6.5
Inflation rate: all items non food non energy	Annual growth %	10.3	8.5	9.2	7.5	7.1	5.7	7.2	5.9
Inflation rate: food	Annual growth %	6.8	4.9	9.7	12.4	12.8	8.0	10.6	6.2
Inflation rate: energy	Annual growth %	4.7	14.7	11.3	6.3	22.4	5.1	10.5	9.9
Producer Price Indices (PPI): manufacturing	Annual growth %	11.0	9.6	9.3	5.6	11.8	-0.6	6.0	13.3
Long-term interest rates	%	..	..	..	..	..	..	..	..
Purchasing power and exchange rates									
Purchasing power parities	TRY per USD	0.81	0.83	0.85	0.86	0.89	0.92	0.97	1.00
Exchange rates	TRY per USD	1.43	1.34	1.43	1.30	1.30	1.55	1.50	1.67
Indices of price levels	OECD = 100	56	61	59	64	64	58	63	57
Energy supply and prices									
Total primary energy supply (TPES)	Mtoe	80.9	84.4	93.0	100.0	98.5	97.7	105.1	114.2
TPES per unit of GDP at 2000 prices and PPPs	Toe per '000 USD	0.11	0.11	0.11	0.11	0.11	0.12	0.12	0.12
Renewables' contribution to total primary energy supply	%	13.3	12.0	11.1	9.6	9.5	10.2	11.1	10.2
Crude oil import prices	USD per barrel	34.90	50.65	61.48	68.59	98.07	61.27	78.26	109.81
Information and Communications Technology (ICT)									
ICT investment in non-residential fixed capital formation	%	..	..	..	..	..	..	..	..
ICT related occupations: business sector employment	%	..	..	..	..	..	..	..	..
Households with access to the Internet	%	..	7.7	..	..	..	..	41.6	..

Country statistical profile: Turkey 2013

	Unit	2004	2005	2006	2007	2008	2009	2010	2011
Environment									
Water abstractions	Mln m^3	..	44 320	..	..	..	..	40 560	..
Fish landings in domestic and foreign ports	'000 tonnes	484	523	489	589	443	..	..	..
Aquaculture	'000 tonnes	94	118	129	140	152	..	..	..
Municipal waste total	'000 tonnes	..	31 350	..	..	..	..	28 210	28 210
Municipal waste per capita	Kg	..	460	..	..	..	..	390	..
CO_2 emissions from fuel combustion	Mln tonnes	207	216	240	265	264	256	266	..
Education									
Tertiary attainment in population aged 25-64	%	..	10.2	..	..	..	..	13.1	..
Expenditure per student: non-tertiary, 2009 prices	USD constant PPPs	..	..	..	..	..	..	..	..
Expenditure per student: tertiary, 2009 prices	USD constant PPPs	..	..	..	..	..	..	..	..
Youths 15-19 not in education nor employment	%	..	..	35.0	34.5	37.1	28.7	25.6	..
Youths 20-24 not in education nor employment	%	..	..	48.8	46.3	46.1	46.1	43.7	..
Employment									
Employment rate in population aged 15-24	%	30.0	30.2	30.3	30.2	30.3	28.9	30.0	32.1
Employment rate in population aged 25-54	%	52.6	53.0	53.2	53.2	53.5	52.9	55.4	57.5
Employment rate in population aged 55-64	%	29.5	28.0	27.6	27.1	27.4	28.2	29.6	31.4
Incidence of part-time employment	%	6.1	5.6	7.6	8.1	8.5	11.1	11.5	11.7
Self-employment rate: total employment	%	45.5	43.0	41.1	39.6	39.0	40.0	39.1	38.3
Self-employment rate, men: male employment	%	42.2	40.0	38.3	36.8	36.1	36.6	35.1	34.2
Self-employment rate, women: female employment	%	55.1	51.7	49.2	47.6	46.8	48.9	49.3	48.4
Unemployment									
Unemployment rate: total labour force	%	..	9.2	8.8	8.8	9.7	12.6	10.7	8.8
Unemployment rate, men: male labour force	%	..	9.2	8.6	8.7	9.6	12.5	10.4	8.3
Unemployment rate, women: female labour force	%	..	9.4	9.1	9.1	10.0	12.6	11.4	10.1
Long-term unemployment: total unemployed	%	39.2	39.4	35.7	30.3	26.9	25.3	28.6	26.5
Labour compensation and hours worked									
Labour compensation per unit labour input, total economy	Annual growth %	20.7	7.1	10.8	..	..	..	..	..
Average time worked per person in employment	Hours per year	1 918	1 936	1 944	1 911	1 900	1 881	1 877	1 877
Research and Development (R&D)									
Gross domestic expenditure on R&D	Mln USD	3 735	4 617	4 845	6 314	6 380	7 110	7 664	..
Researchers: full-time equivalent	Per '000 employed	1.7	2.0	2.1	2.4	2.5	2.7	2.9	..
Population									
Total population	'000 persons	67 723	68 566	69 395	70 215	71 079	71 897	72 698	..
Population growth rates	%	1.3	1.2	1.2	1.2	1.2	1.2	1.1	..
Total fertility rates	Children	2.1	2.1	2.1	2.2	2.2	2.1	2.0	..
Youth population aged less than 15	% of population	28.0	27.7	27.4	27.0	26.5	26.1	25.8	25.4
Elderly population aged 65 and over	% of population	6.6	6.6	6.6	6.7	7.5	7.6	7.7	7.8
International migration									
Foreign-born population	% of population	..	..	..	..	..	..	3.8	..
Foreign population	% of population	..	..	..	..	..	..	..	..
Unemployment rate of native-born men	% of labour force	..	..	..	..	..	..	..	8.6
Unemployment rate of foreign-born men	% of labour force	..	..	..	..	..	..	..	10.3
Unemployment rate of native-born women	% of labour force	..	..	..	..	..	..	..	10.5
Unemployment rate of foreign-born women	% of labour force	..	..	..	..	..	..	..	13.6
Health									
Life expectancy at birth	Years	72.5	73.0	73.2	73.3	73.6	73.8	74.3	..
Life expectancy at birth: men	Years	70.5	70.9	71.1	71.1	71.4	71.5	71.8	..
Life expectancy at birth: women	Years	74.6	75.0	75.3	75.6	75.8	76.1	76.8	..
Infant mortality	Per '000	20.5	18.4	16.9	15.9	14.9	13.1	10.1	..
Overweight and obese aged 15 and over	% of population	..	..	..	..	..	..	49.9	..
Suicide rates	Per 100 000 persons	..	..	..	..	..	..	..	..
Transport									
Goods transport	Mln tonne-km	178 197	181 719	192 916	204 145	229 076	231 892	241 463	..
Passenger transport	Mln passenger-km	179 475	187 188	192 870	214 668	211 195	217 838	232 404	..
Road fatalities	Per mln inhabitants	62	62	62	68	57	58	56	..

Last updated: 28 February 2013; *disclaimer:* http://oe.cd/disclaimer

.. Not available

Source: OECD Factbook statistics. For explanatory notes, see OECD Factbook 2013 (DOI: 10.1787/factbook-2013-en)

http://dx.doi.org/10.1787/csp-tur-table-2013-1-en