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Drug approval process and safety recall procedures in therapeutic goods administration Australia

R.Suthakaran*, Raju Manda, DVRN Bikshapathi, M. Ramesh

[1,3,4]*Department of Pharmaceutical Chemistry and Regulatory Affairs, Vijaya College of Pharmacy, Munaganoor, Hyderabad ,Telangana, India.*

[2]*Department of Pharmaceutics and Drug Regulatory Affairs, Holy Mary Institute of Technology and Science (College of Pharmacy), Bogaram, Keesara, Ranga Reddy District, Hyderabad, Telangana 501301.*

***Corresponding Author: R.Suthakaran**

Email id: drsutha.2010@gmail.com

ABSTRACT

Demonstration of safety and efficacy of the drug product for use in humans is essential before the drug product can be approved for import or manufacturing of new drug by the applicant by Regulatory authority in any country. Once preclinical and clinical trial data have been collected, a New Drug Application must be submitted to the regulatory authority for approval. Although the requirements for this submission have similarities around the world, until now, the applications have been different. Substantial documentation and data are required in these types of submissions, resulting in large, complex applications. Till date, applicants have used many different approaches in organizing the information and the differences in organization of data in each application has made reviewing more difficult and can also lead to omission of critical data or analyses. Thus, a common format of submission will help in overcoming these hurdles. With the help of regulatory guidelines laid down by the respective countries Australia and New Zealand, the marketing of drugs are been done under proper guidelines. The implementation of safety recall methods have also proven helpful in retaining a drug or pharmaceutical from the current market and avoiding the sale of such adverse drug on the health care of common public.

The Amendments, guidelines, drug approval process and safety recall procedures play one the important role in the country's fate in pharmaceutical industry.

Keywords: TGA, Medsafe, Drug Approval Process, Safety Recall procedures

INTRODUCTION TO AUSTRALIAN REGULATORY BODIES

Country background-some basic facts [5, 6]

- As at 1999, Australia has a population of 19 million.5 The Gross Domestic Products (GDP) of Australia in 1998-1999 amounted to AUS$593 billion (or HK$ 2.7 trillion).
- As at 1999, there were 4 954 approved pharmacies7 in Australia, representing a pharmacy to population ratio of one pharmacy to about 3 800 people. There were

approximately 182.7 million prescriptions dispensed through pharmacies in 1997-1998.

- Between July 1998 and June 1999, Australian households spent an average of AUS$699 (or HK$3, 166.5) each week on goods and services. Of which, AUS$8 (or HK$36.2) were spent on medicines, pharmaceutical products and therapeutic appliances.
- According to a National Health Survey conducted by the Australian Bureau of Statistics in 1995, about 69% of the Australian population had used some form of medicines in any two weeks during 1995. The National Health Survey also found that 59% of the population had used prescription or non-prescription medicines, 26% used vitamins and minerals and 9% used herbal or natural preparations for health related purposes.
- Expenditure on medicines by both government and private sector represented 12% of the recurrent health expenditure in Australia in 1994-1995, reaching a total of AUS$4,200 million (or HK$19,026 million).10 Over half of this expenditure (51%) was incurred by the private sector and the remaining by the government, largely through the Pharmaceutical Benefits Scheme (to be detailed in paragraphs 17.3 - 17.4)
- In 1999-2000, the value of imports of human use pharmaceuticals was AUS$3.33 billion (or HK$15.1 billion) whereas the value of exports of human use pharmaceuticals was AUS$1.62 billion (or HK$7.3 billion).
- The pharmaceutical industry is the largest funder of medical research and the second most innovative manufacturing industry in Australia.12 It generally takes on average 15 years to research and develop a new medicine; and only three in 10 approved medicines may produce sales that match or exceed the average R&D (research and development) costs.

EGISLATIVE FRAMEWORK OF MEDICINES [5, 6]

Legislative Framework

- The main legislation governing medicines in Australia is the Therapeutic Goods Act 1989. The Therapeutic Goods Act is supported by the Therapeutic Goods Regulations, and various Orders and Determinations made pursuant to the Therapeutic Goods Act. Other Commonwealth, State and Territory legislation may also apply to certain medicines. The Therapeutic Goods Advertising Code and the Australian Code of Manufacturing Practice for Therapeutic Goods are the two main codes governing the advertising and manufacturing of medicines in Australia.
- The objective of the Therapeutic Goods Act is to provide for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods including medicines in Australia.
- The Therapeutic Goods Act sets out requirements for manufacturing, supplying, advertising and labelling medicines in Australia. It also details the requirements for listing or registering medicines in the Australian Register of Therapeutic Goods.
- The Therapeutic Goods Act applies to all parties who supply medicines or manufacture medicines for supply in Australia, and all parties who import or export medicines. Therapeutic Goods Regulations
- The objective of the Therapeutic Goods Regulations is to prescribe matters in respect of the manufacture, supply, advertising, registering or listing of medicines in Australia so as to make it necessary or convenient to carry out or give effect to the Therapeutic Goods Act. Therapeutic Goods Advertising Code
- The objective of the Therapeutic Goods Advertising Code is to ensure that the marketing and advertising of medicines to consumers is conducted in a manner that promotes the quality use of medicines, is socially responsible and does not mislead or deceive consumers. Legislative Council Secretariat Regulation of Medicines in Australia Research and Library Services Division page 10
- The Therapeutic Goods Regulations require that all advertising about therapeutic goods including medicines must comply with the Therapeutic Goods Advertising Code. Australian Code of Manufacturing Practice for Therapeutic Goods
- The Australian Code of Good Manufacturing Practice is a set of principles and procedures which are necessary to follow in order to

provide assurance that each medicine product is safe and of the required quality. It comprises requirements relating to premises, equipment, personnel, documentation and quality control. These requirements are enforced through systems of factory audits and mandatory licensing of factories which manufacture medicines.

- The Therapeutic Goods Act 1989 requires Australian manufacturers of medicines to hold a licence. Licence holders are required to comply with the Australian Code of Good Manufacturing Practice under the Therapeutic Goods Act 1989.
- Overseas manufacturers of medicines supplied to Australia must provide evidence that the goods are manufactured to a standard of Good Manufacturing Practice equivalent to that expected of Australian manufacturers of the same goods.

Authorities Involved in the Regulation of Medicines

- The Therapeutic Goods Administration is a division of the Commonwealth Department of Health and Aged Care and is responsible for administering the Therapeutic Goods Act.
- The Therapeutic Goods Administration's overall control of the supply of medicines in Australia is exercised through five main processes:

1. Pre-market evaluation and approval of medicines intended for supply in Australia;
2. Licensing of manufacturers in accordance with international standards under Good Manufacturing Practice;
3. Post-market monitoring, through sampling, adverse event reporting, surveillance activities, and response to public inquiries;
4. Development, maintenance and monitoring of the systems for registering and listing of medicines; and
5. The assessment of medicines for export.

REGULATION OF MEDICINES [5, 6]

Pre-Market Assessment

All medicines must be either listed or registered in the Australian Register of Therapeutic Goods before they can be supplied in Australia. They are also required to undergo an assessment before they can be listed or registered. The assessments of listed and registered medicines are different in terms of the complexity of the procedures undergone and the standard of requirements to be met.

Patent Medicines

Infringement of Regulations[5,6]

Regulation of Pharmacies [5, 6]

Pharmacies are subject to the control of state/territory legislation. Different states and territories may impose different controls on pharmacies.

Ownership of Pharmacies,

REGISTRATION OF PHARMACISTS

Fees and Charges [5, 6]

Annual Charge, Evaluation Fee, Licence Fee

Effectiveness of the Medicines Evaluation Process [5, 6]

ANALYSIS [7]

This research report describes the means through which the Australian government regulates medicines.

REGULATION OF MEDICINES

It may be fair to say that rigid control has been placed on the manufacturing, evaluation, labelling, import, and sale of medicines in Australia.

Mandatory Licensing of Manufacturers of Medicines

Mandatory Pre-Market Assessment and Regular, Responsive Post-Market Vigilance of Medicines

Timely Evaluation of Medicines

IMPORTS-Control of Imports[7]

Good Manufacturing Practice for Medicines Manufactured Overseas

Imported Medicines Manufactured Overseas

Table 5.1 Licenses/Permits required for importing medicines in Australia and Figure 5.1 with the imports history is shown below

Table 5.1 - Licences/Permits Required For Importing Medicines in Australia

Licence/Permit	Issuing Authority	Purpose
Both an import licence and an import permit	Therapeutic Goods Administration	To import medicines containing substances listed in Schedule 4 of the Customs (Prohibited Imports) Regulations. Examples are methadone, morphine, etc.
An import Permit	Therapeutic Goods Administration	To import medicines containing substances listed in Schedule 8 of the Customs (Prohibited Imports) Regulations. Examples are thalidomide, or preparations that purport to be aremedy for drunkenness alcoholic habit or drug habit..
A quarantine Permit	Australian Quarantine and Inspection Service	To import medicines containing biological ingredients.
An Australian CITES[1] permit	Department of Environment and Heritage	To import medicines containing ingredients which are subject to the treaties governing the trade in protected species of plants and animals.

EXPORTS

Latest figures from the Australian Bureau of Statistics show Australian pharmaceutical exports declined by 18 per cent to $2.9 billion in 2014, compared to $3.6 billion in the year before.

Since 2012, when they peaked at around $4.3 billion, Australian pharmaceutical exports have declined by more than 30 per cent.

Broadly, the proposal called on the Government to:

- Ensure a stable, predictable and efficient business operating environment,
- Strengthen Australia's intellectual property system,
- Enable growth in Australia's local biotechnology sector, and
- Enact globally competitive incentives such as tax breaks to encourage investment.

The Pharmaceutical exports of Therapeutic Goods Administration is shown in Figure 5.2

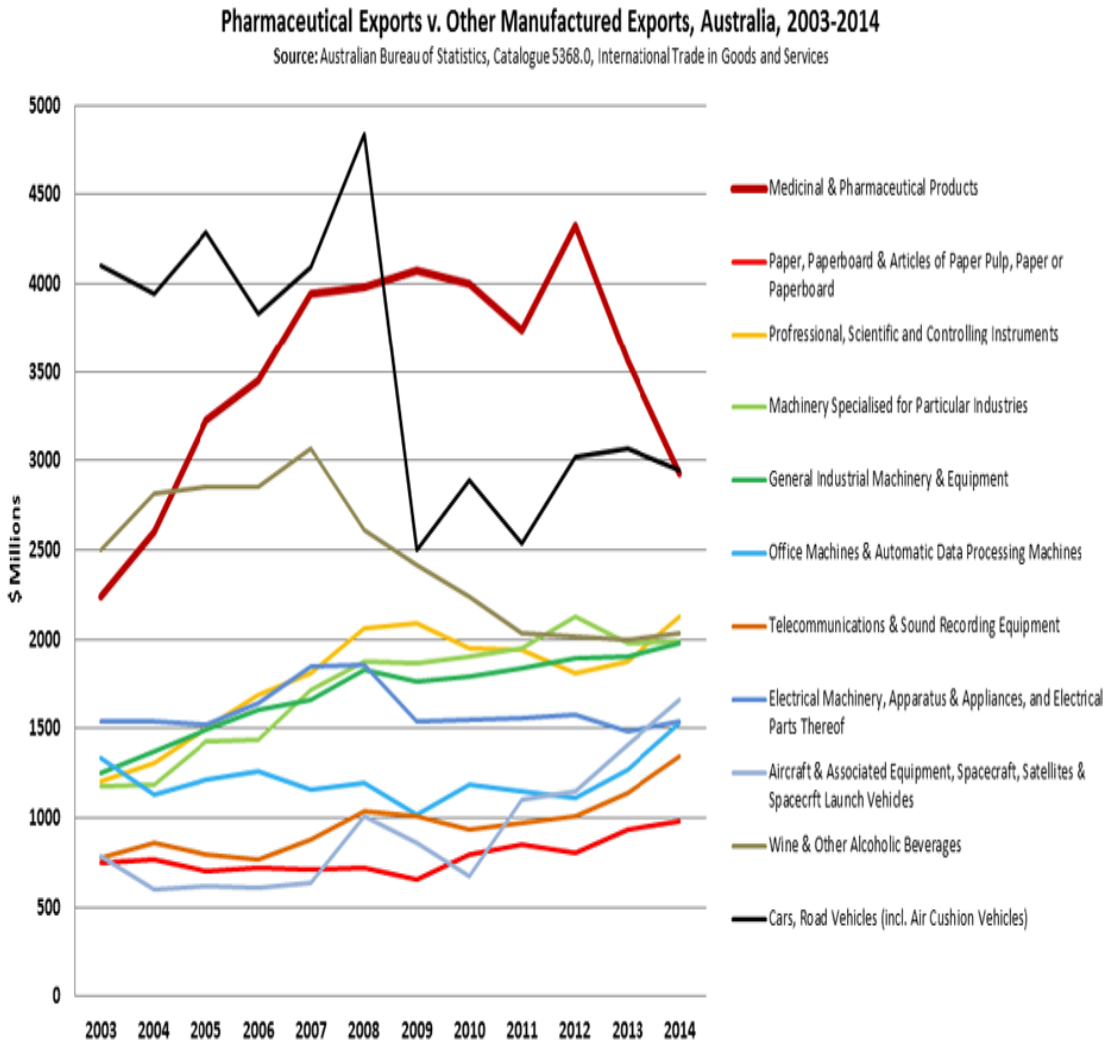

Figure 5.2- Pharmaceutical Exports v. other manufactured exports, Australia

THERAPEUTIC GOODS ADMINISTRATION [7]

Introduction

The Therapeutic Goods Administration (TGA) is the regulatory body for therapeutic goods (including medicines, medical devices, gene technology, and blood products) in Australia. It is a Division of the Australian Department of Health established under the Therapeutic Goods Act 1989 (Cth). The TGA is responsible for conducting assessment and monitoring activities to ensure that therapeutic goods available in Australia are of an acceptable standard and that access to therapeutic advances is in a timely manner. This came into effect on 15 February 1991. [1]

Structure

The Therapeutic Goods Administration is part of the Regulatory Services Group in the Australian Government Department of Health (link is external).

The Regulatory Services Group includes

- Therapeutic Goods Administration (TGA)
- Office of the Gene Technology Regulator (OGTR)
- Office of Chemical Safety (OCS)

Regulatory Services Group Executive

The RSG Executive is:

- Deputy Secretary, Adjunct Prof John Skerritt

- Principal Medical Adviser, Dr Tony Gill (acting)
- Principal Legal and Policy Adviser, Ms Philippa Horner PSM
- Office of Gene Technology Regulator, Dr Robyn Cleland (acting)
- Office of Chemical Safety, (incorporating NICNAS &AgVet Chemicals), Dr Brian Richards
- First Assistant Secretary, Regulatory Practice and Support Division, Mr Jaye Smith
- Therapeutic Goods Administration, Medicines Regulation Division, Ms Mary McDonald
- Therapeutic Goods Administration, Medical Devices and Product Quality Division, Dr Larry Kelly

REGULATORY DIVISIONS OF TGA [7]

The TGA has two regulatory divisions, the Medicines Regulation Division and the Medical Devices and Product Quality Division and a third support division, the Regulatory Practice and Support Division (RPSD). The RPSD provides regulatory support services that enable the Group to undertake its regulatory responsibilities.

Medicines Regulation Division
Medical Devices and Product Quality Division
Regulatory Practice and Support Division

Structural Groups of TGA [7]

The TGA's offices are grouped into three core groups - Market Authorisation Group, Monitoring and Compliance Group and Regulatory Support Group

CHART

1. TGA Executive,
2. Market Authorization Group (MAG)
3. Monitoring and Compliance Group (MCG)
4. Regulatory Support Group
5. Office of Regulatory Integrity(ORI)

TGA Executive

The TGA Executive has overall responsibility for the management of the TGA's regulatory functions and activities. The TGA Executive comprises:

TGA National Manager ,Principal Medical Adviser, Principal Legal Adviser, Chief Regulatory Officer, Chief Operating Officer

Market Authorization Group (MAG)
Monitoring and Compliance Group (MCG)
Regulatory Support Group
Office of Regulatory Integrity (ORI)

OVERVIEW [7]

The TGA regulates the supply of

Medicines prescribed by a doctor or dentist ,medicines available from behind the pharmacy counter ,medicines available in the general pharmacy ,medicines available from supermarkets ,complementary medicines, these include vitamins, herbal and traditional medicines ,medical devices, from simple devices like bandages to complex technologies like heart pacemakers ,products used to test for various diseases or conditions (in vitro diagnostic devices), such as blood tests; and vaccines, blood products, and other biologics and the manufacturing and advertising of these products.

Regulating medicines

The regulation of medicines includes the following features:

Classifying the medicine based on different levels of risk to the person taking them ,implementing appropriate regulatory controls for the manufacturing processes of medicines ,Medicines assessed as having a higher level of risk (prescription medicines, some non-prescription medicines) are evaluated for quality, safety and efficacy ,Ingredients in medicines with a lower risk (medicines purchased over the counter, such as complementary medicines) are assessed for quality and safety ,Medicines determined to be available for lawful supply by the Therapeutic Goods Administration can be identified by either an AUST R number or an AUST L number on the outer packaging. Please note, there are a small number of medicines that are exempt and do not require this information on the label ,Once available for supply, medicines are subject to monitoring by the TGA. This monitoring includes a comprehensive adverse event reporting programme.

Regulating medical devices

The regulation of medical devices includes:

Classifying the medical device based on different levels of risk to the user ,assessing compliance with a set of internationally agreed essential principles for their quality, safety and performance ,implementing appropriate regulatory controls for the manufacturing

processes of medical devices ,including the medical device in the Australian Register of Therapeutic Goods ,Once available for supply, medical devices are subject to monitoring by the TGA. This monitoring includes a comprehensive adverse event reporting programme.

Other therapeutic goods regulated by the TGA

The TGA also applies a risk management approach to the regulation of:

In vitro diagnostic medical devices (IVDs), blood ,blood components ,plasma derivatives ,tissue and cellular products ,tissue and cell based derivatives, sterilants and disinfectants

What the TGA doesn't do

The TGA does not regulate:

Veterinary medicines, food, health insurance, cosmetics, chemicals, Healthcare professionals.

How the TGA regulates

The Australian community expects therapeutic goods in the marketplace to be safe, of high quality and of a standard at least equal to that of comparable countries.

The TGA regulates therapeutic goods through:

Pre-market assessment; post-market monitoring and enforcement of standards; and Licensing of Australian manufacturers and verifying overseas manufacturers' compliance with the same standards as their Australian counterparts.

Therapeutic goods are divided broadly into two classes: medicines and medical devices. Medicines must be entered as either 'registered' or 'listed' medicines and medical devices must be 'included' on the Australian Register of Therapeutic Goods (ARTG) before they may be supplied in or exported from Australia, unless exempted.

If a problem is discovered with a medicine, device or manufacturer, the TGA is able to take action. Possible regulatory actions vary from continued monitoring to withdrawing the product from the market.

Risk management

The TGA approves and regulates products based on an assessment of risks against benefits.

The TGA's approach to risk management involves:

- identifying, assessing and evaluating the risks posed by therapeutic products
- applying any measures necessary for treating the risks posed; and
- Monitoring and reviewing risks over time.
- The risk-benefit approach assures consumers that the products they take are safe for their intended use, while still providing access to products that are essential to their health needs.

The risk-based approach to regulation

Two types of risk

The risks involved with therapeutic goods can be divided into two types:

Product risks

These risks are inherent to the product. They also include the risks involved in overdose (i.e. patient non-compliance).

Compliance risks

These risks are related to the risks involved if a manufacturer or sponsor fails to comply with legal requirements (either unintentionally or intentionally). The TGA actively regulates both product risks and compliance risks.

Product risk: pre-market activities

The TGA regulates therapeutic goods before the products reach the market (pre-market) and afterwards, when they are in general use (post-market).

At the pre-market stage the TGA acquires the information necessary for a decision about whether or not to register, list or include therapeutic goods on the Australian Register of Therapeutic Goods (ARTG). It can do this through accepting certification, actively evaluating information supplied by sponsors or manufacturers, or by direct inspection.

Product risk: post-market activities

Post-market activities relate to the monitoring of the continuing safety, quality and efficacy of listed, registered and included therapeutic goods once they are on the market.

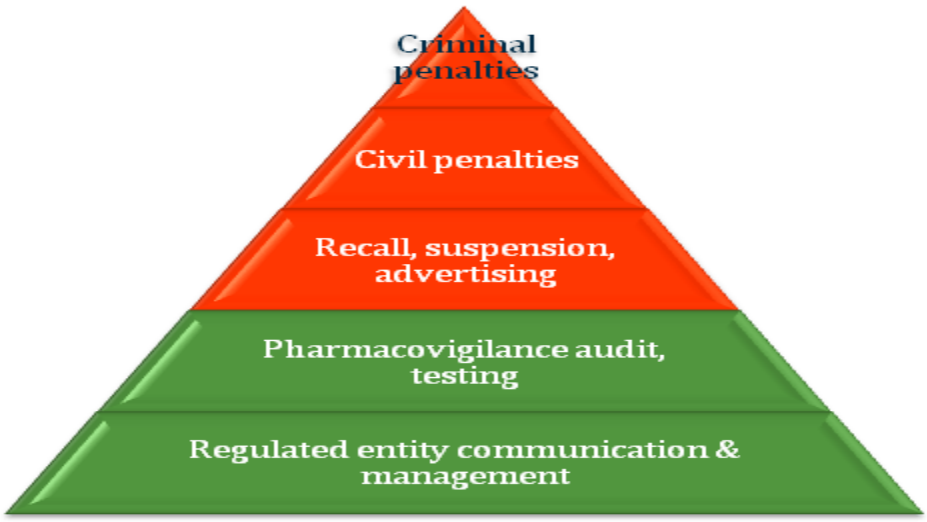

Figure 5.3 Compliance risk: achieving voluntary compliance

Managing compliance risks

Table No 5.3 - TGA compliance strategy

Help and support	Inform and advise	Correct behaviour	Enforcement action
Make ongoing compliance easy	Help to become and stay compliant	Deter by detection	
Regulated entity - attitude to compliance			
Voluntary compliance	Accidental non-compliance	Opportunistic non-compliance	Intentional non-compliance
• Effective compliance systems • Management is compliance oriented	• Ineffective and/or developing compliance systems • Management compliance oriented but lacks capability	• Resistance to compliance • Limited or poor compliance systems • Management not compliance oriented	• Deliberate non-compliance • No compliance systems • Criminal intent
"Committed to doing the right thing"	"Trying to do the right thing but don't always succeed"	"Don't want to comply but will if made to"	"Decision to not comply"
Low compliance risk		High compliance risk	

TGA as a world-class regulator

The TGA has invested significant effort into establishing itself as a leading regulator of therapeutic goods. This has involved:

- Attracting staff with the right balance of technical and regulatory skills ,supplementing this world-class expertise with external experts (TGA advisory committees) ,working closely with international regulators ,developing appropriate regulatory processes, developing timely and appropriate internal and external communication processes.

- The effective management of both product risks and compliance risks depends on the collection, collation and analysis of information from all regulatory areas of the TGA. Applying a collaborative, whole-of-regulatory-cycle view of therapeutic goods and regulated entities allows the TGA to tailor appropriate risk management strategies.
- Effective communication and collaboration between different parts of the TGA are facilitated by the following:
- the TGA being structured along functional responsibilities ,identification of the existing interdependencies between TGA regulatory areas in order to facilitate collaboration ,lines of communication and collaboration that maximise the ability to identify and manage product safety risks and regulated entity compliance risks ,the implementation of processes to improve how the TGA communicates and provides information to stakeholders.
- In conclusion, the key features of the TGA regulatory framework are:
- A risk-based approach is taken to regulation, with different levels of risks for different products. Regulation occurs both pre-market and post-market
- Both product risks and compliance risks are regulated. There is a focus on fostering voluntary compliance among the TGA regulated community. Continual improvement is achieved by ongoing review and changes to the regulatory structures and processes.

Therapeutic product vigilance [7]

TGA's approach to therapeutic product vigilance

The aim of therapeutic product vigilance is to continually monitor and evaluate the safety and efficacy (performance) profile of therapeutic products and to manage any risks associated with individual products.

The TGA's approach to therapeutic product vigilance is guided by the following principles:

1. Communication of safety information to the public Therapeutic product vigilance should provide a mechanism for involving consumers and health professionals in the provision and the appropriate use of safety information related to therapeutic products in Australia.
2. Uphold product efficacy and safety standards The requirement for specific vigilance activities will be for the purpose of protecting the health and safety of Australians and will in no way result in the reduction in a product's requisite efficacy and safety.
3. Adopt a product lifecycle approach It is well recognised that therapeutic product vigilance needs to occur throughout a product's lifecycle to take into account the entire body of evidence that accumulates throughout the lifecycle of the product.
4. Align with international best practices and standards The TGA has committed to aligning its regulatory approaches related to therapeutic product vigilance, wherever possible, with those of comparable international regulatory counterparts. This includes a commitment to the integration of internationally harmonised vigilance tools which provides the vehicle through which international work and information sharing can proceed.
5. Facilitate industry compliance with vigilance best practices, The TGA will provide regulated parties with guidelines to follow vigilance best practices.
6. Align with the TGA's decision-making framework Therapeutic product vigilance activities are guided by two key components these being transparency and timely decision-making, and meaningful public involvement.
7. Continuously improve therapeutic product vigilance The TGA recognises that therapeutic product vigilance activities may change over time as knowledge of a product evolves. A product's vigilance requirements should be subject to reconsideration over its lifecycle, on the basis of the evolution of knowledge, technology and society's expectations. Also, therapeutic product vigilance tools will be evaluated for effectiveness in carrying out their desired purposes.

TGA- FUNCTIONS

Health professionals, patients and consumers

Australia's therapeutic product vigilance system

Figure 5.4 depicts the product vigilance and benefit risk management cycle.

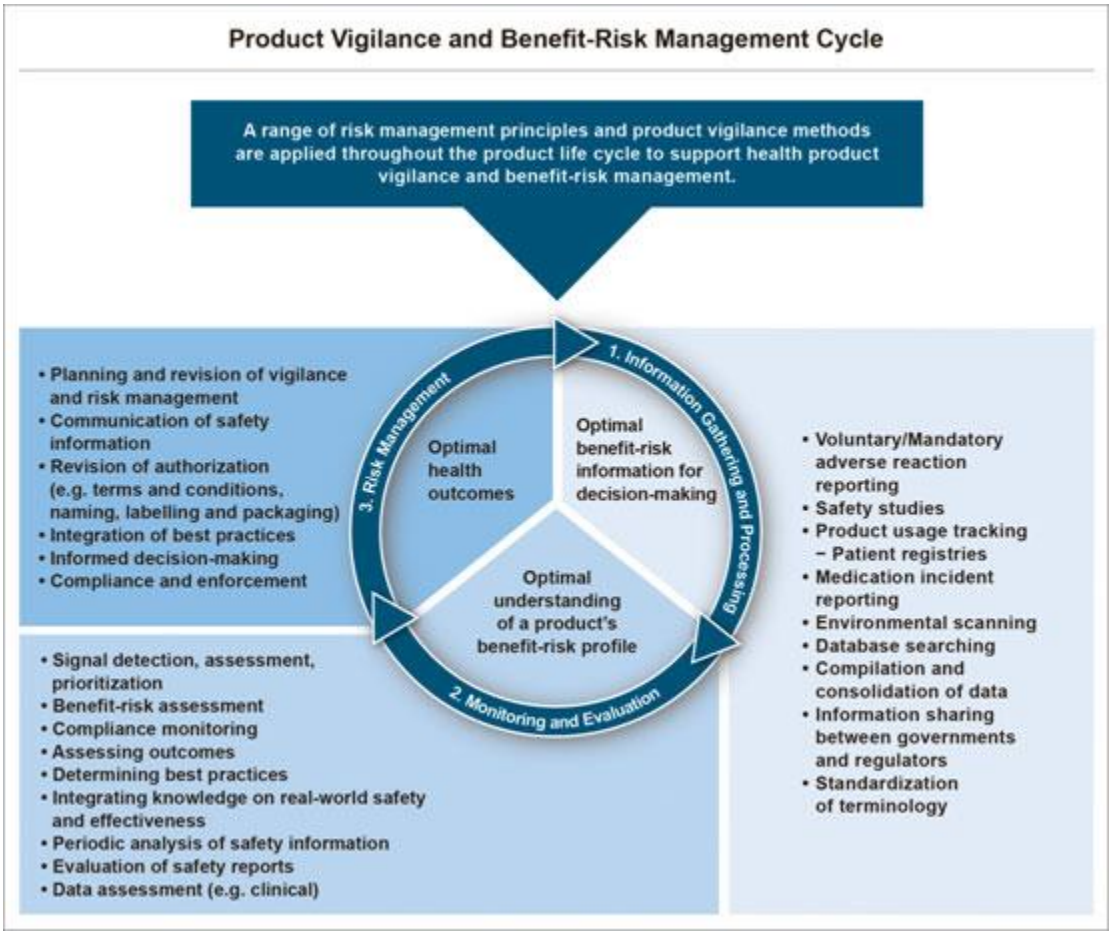

Figure No 5.4 Product Vigilance and Benefit Risk Management Cycle

Product vigilance tools

Product vigilance (PV) tools are defined by the World Health Organisation (WHO) (link is external) as tools used to detect, assess, understand or prevent adverse events or any other health product-related problems. For the purpose of the TGA, therapeutic product vigilance tools are defined as tools designed to facilitate the collection and evaluation of information pertaining to the benefits and risks associated with the use of therapeutic products. A description of the product vigilance tools in use or in development is found in table 5.4 below.

Prioritisation and benefit risk assessment
Communicating vigilance activities
Practical aspects of the product vigilance system [5, 6, 7]

Treatment of information provided to the TGA [5, 6, 7]
Authorised release of official information [5, 6, 7]
Circumstances where release of official information is permitted

The TGA, as part of the Department of Health, may release official information (including information provided by a third party) in certain circumstances.

These circumstances include the following:

- To the extent required by law or by a lawful requirement of any government or governmental body, authority or agency including any administrative or statutory review, audit or inquiry (whether within or external to the TGA)
- If required in connection with legal proceedings (such as a request for information in response to a subpoena)
- For purposes of public accountability, including disclosure on request to other Government

Agencies, and a request for information by parliament or a parliamentary committee or a Commonwealth Minister

- To allow the TGA to fulfil its statutory functions including as permitted under the provisions as set out in section 61 of the Therapeutic Goods Act 1989 (link is external) which includes release of information, release of which is necessary to ensure the safe use of particular therapeutic goods
- In response to the exercise of the authorised function, power, right or entitlement of the Auditor-General, the Ombudsman or the Privacy Commissioner.

Commercially confidential information

About the work of the TGA - a risk management approach

Whether applying a bandage, relieving a headache with items from the supermarket or undertaking a prescribed course of treatment to manage a serious illness, Australians can expect the medicines and medical devices they use to meet an acceptable level of safety and quality.

No therapeutic good is risk free. The work of the TGA is based on applying scientific and clinical expertise to decision making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines, medical devices and other therapeutic goods. For example, some blood pressure medications may include side effects, such as a tickle in the throat or persistent cough, but this risk is outweighed by the benefits of reducing the risk of a heart attack or stroke. The risk - benefit approach assures consumers that the products they take are safe for their intended use, while still providing access to products that are essential to health needs.

Risk information is used by the TGA when deciding whether to approve a medication for supply and the conditions that might be imposed on that approval. The level of TGA regulatory control increases with the level of risk the medicine or device can pose and determines how consumers can access these goods. For example a low-risk product may be safely sold through the supermarket, while higher-risk products may only be supplied with a prescription.

A product's 'risk' is determined by a number of factors, including whether:

- The product contains a substance scheduled in the Poisons Standard
- The product's use can result in significant adverse effects
- The product is used to treat life-threatening or very serious illnesses
- There may be any adverse effects from prolonged use or inappropriate self-medication

Risk is not an absolute concept. It is an assessment of the potential of a product to do harm to those it is intended to help, or to others (such as children) who may come in contact with it regardless of whether the harm results from following or disregarding the directions for use.

HISTORY OF THERAPEUTIC GOODS REGULATION IN AUSTRALIA [5, 6, 7]

Outline

The TGA today represents the product of a long history of evolution of therapeutic products regulation in Australia. This publication aims to capture this evolutionary process not only as an interesting example of the development and role of a regulator but also to understand the directions for the future.

What are 'therapeutic goods'?

Many of us use medicines or medical devices in our daily lives. When we:

- Apply a bandage, relieve a headache with items from the supermarket
- Take vitamin tablets, receive an injection, undertake a prescribed course of treatment to manage a serious illness.

Is it a therapeutic good or a cosmetic?

One of the main factors in determining whether a product is a cosmetic or a medicine (or a medical device) is the claims made about the product. For example, moisturisers that contain a sun screening agent as a secondary component and have a stated therapeutic purpose (e.g. 'helps protect skin from the damaging effects of UV radiation') are medicines.

Even if a product is intended for marketing as a cosmetic, it may be classified as a medicine. This depends on:

- Its ingredients
- The route of administration
- If therapeutic claims are made on its label, or in advertising.

Current Structure of TGA

The Therapeutic Goods Administration is part of the Regulatory Services Group in the Australian Government Department of Health (link is external). The Regulatory Services Group includes:

- Therapeutic Goods Administration (TGA)
- Office of the Gene Technology Regulator (OGTR) (link is external)
- Office of Chemical Safety (OCS) (link is external)

TGA plans & reports

- TGA business plan 2014-2015As part of the Department of Health the TGA safeguards and enhances the health of the Australian community through the effective and timely administration of the Therapeutic Goods Act 1989.
- TGA external communication and education framework Describes TGA's approach to providing better information to consumers, health professionals and the therapeutic goods industry
- Half-yearly performance reports Statistical reports on TGA's performance in pre- and post-market activities
- TGA key performance indicators and measures: Regulator Performance Framework The TGA developed its outputs and evidence against six key performance indicators (KPIs) outlined in the Regulator Performance Framework. The Framework was developed by the Australian Government to measure the performance of regulators and will apply from 1 July 2015
- TGA key performance indicators Eight KPIs have been endorsed by the Australian Therapeutic Goods Advisory Council following consultation with the TGA-Industry Consultative Committee
- Market research: Informing TGA education and communication activities In 2013, market research was conducted with consumers, health professionals and industry to inform the development of targeted and effective educational materials and improve our communication strategies and practices.
- TGA reforms: A blueprint for TGA's future: Progress reports Progress reports on reforms to the TGA relating to the 'blueprint for TGA's future'
- TGA records listings Indexed listings of the Therapeutic Goods Administration's files

TGA reforms

The TGA mandate is to regulate medicines, medical devices and biological products throughout their lifecycle. The TGA is focusing on implementing changes to ensure a greater emphasis on transparency of regulatory decision-making processes, a continuing focus on business process reform and a more strategic approach to the use of information technology to support regulatory operations.

Reforms underway as part of TGA Reforms: a blueprint for TGA's future include:

- Advertising of therapeutic goods
- Complementary medicines regulatory reforms
- Medical devices reforms
- Medicine labelling and packaging review
- Over-the-counter business process reforms
- Streamlined Submission Process project (prescription medicines)

CONCLUSION

- The study was undertaken with an aim to study the Drug approval process and Safety Recall procedures in Therapeutic goods administration, Australia To study the guidelines, safety recalls procedures.
- Constraining the rapid escalations of health care costs while extending health immune insurance coverage to all the primary objectives of the health care reform will require significant improvements in the performance of our system of health care. This performance imperative is especially important because of some factors behind rising health care expenditures, such as the aging of the population, are external to the health care system. In permeable to this report, we set forth the committee's review that the fundamental goals of reform are to maintain and improve health and wellbeing, to make basic health coverage universal, and to encourage the efficient use of limited resources.
- The preceding sections of this document have provided a broad framework for accessing whether and how different reform proposals would pursue these goals.
- The elements of that framework extending

access to health care, containing health care costs, assuring quality of care, financing reform, and improving the infrastructure for effective change—all need to be addressed if system performance is truly to be improved.

- At various periods, the idea of patent as an instrument of justice to the inventor has been advanced and rewarding inventive ingenuity seems to underlie the legal protection of patents. However, every inventor may not benefited, but the protection in the form of a monopoly over an invention enable the inventor to get the economic benefits. As against market monopoly, it has been argued that there are other methods of rewarding inventive ingenuity. At times, patents are justified on the ground that it acts as an information system whereby an invention can be used by the society for economic development as it encourages industrial growth in the economic system.
- The main objective of the proposal is to provide clarity and consistency in naming (as far as possible) to support the quality use of medicines. The proposal also aims to minimise administrative costs for industry, thereby supporting the commercial viability of supplying medicines to Australian consumers. This option would increase the alignment of Australian ingredient names with widely accepted international terminology by harmonising a large proportion of the identified inconsistencies. At the same time, harmonisation will not be imposed when the regulatory costs would potentially outweigh the benefits. The net regulatory cost of this Option will be offset by other gains, such reduced risk of incorrect use of medicines and clarity for patients and healthcare providers. This option will also result in a small reduction in barriers to trade for individual companies, however it is not expected to have a noticeable effect on the market overall.
- A four year transition period for these changes is proposed. This transition period would minimize most of the costs of the ingredient name changes as it fits well with business as usual label changes identified by industry during consultation.
- To mitigate the risks to consumers, medicines with ingredients identified as of 'high clinical significance' would be dual-labelled with both the old and new name for an additional three years. Following this period, sponsors could then start using the new ingredient name as the sole name.
- Due to the qualitative gains from harmonisation, this option is expected to result in an overall net benefit to consumers, healthcare professionals and industry once the name changes are embedded in Australian nomenclature.

REFERENCES

[1]. Sarah Schaffer –Reading Intellectual Property Rights- 2006.
[2]. Dr Henry Thomas, History of intellectual property rights- A pharmaceutical research journal: 2007, 39-43.
[3]. Kevin Wallace, Regulatory Affairs: Regulatory affairs play an important role in field of pharmaceutical industry: International Journal of PharmTech Research ISSN: 0974-4704,4(1), 2010, 652-689.
[4]. Lewis Hubert et al, Role of regulatory affairs in pharmaceutical industry, IJDDHR 1(1), 2011, 18-19.
[5]. Edward Wayne et al, Therapeutic Goods Administration: A New Approach: IJRAP 2(6), 2011, 1795-1797.
[6]. Internet: https://en.wikipedia.org/wiki/Therapeutic_Goods_Administration
[7]. Internet: http://en.wikipedia.org/wiki/Forms_Australian_TGA
[8]. Jessica George et al, A thesis on the role of drug approval with a new approach in the pharmaceutical industry: AsianJ. Med. Pharm.Res.2(3):58-60,2012.
[9]. Dr Vivian Rowland et al, Approved protocol for pharmaceutical products in Australia.ISSN-0975-1491 9(5), 2012.
[10]. Juliana Watson et.al, Product Safety Activities Recent trend of development of pharmaceutical recall process in TGA J., 20, 2002, 22-28.
[11]. Enosh Immanuel et al, Safety recall procedures- Recent ammendments and developments in Therapeutic Goods Administration, Australia, 4(3), 2013, 139-144.
[12]. Reuben Thomson, Development and approval of drugs to treat motor neurone disease (MND), 3(2), 2012, 46-52.