

# Research paper on therapeutic goods administration

[Business](#), [Management](#)



Discuss the roles of the Therapeutic Goods Administration (TGA) and the Pharmaceutical Benefits Scheme (PBS) in the provision of drugs.

Therapeutic Goods Administration is one of the major Australian Government Department of Health and Ageing branches and it focus mainly on helping the government to regulate various forms of therapeutic goods such as the medicines, medical equipments, implants, vaccines and haematological products. The importance of their role to the community is that those goods are something that people use every day. The goods are used in the management of different major medical conditions (Australian Government, 2011).

The regulatory body is formed also to oversee produced for therapeutic claims so to ensure that those goods are listed, registered before supply to consumers in Australia. The body also evaluates that the produced or imported therapeutic goods before being supplied to the market and ensures that those goods are monitored once they are in the market to ensure their standards do not diminish (Australian Government, 2011).

TGA provides regulatory rules to the manufacturers of such goods to ensure that their activities are regulated and their products are up to standard for the country. The regulatory body tend to work more with the consumers of such products, the health care providers/professionals, the manufacturers and some other international counterparts within the market in order to ensure that the outcome of their activities or produced goods are up to standard (Australian Government, 2011).

In view of the goals why the TGA was established, their roles in regulating the produced medication and health related products to consumers, it can be concluded that such goal is related to risk management. That approach will help certified the produced drugs and health related products are up to standard without causing any health problems when consumed by the public. The regulatory body achieved this with their policy, which also focus on the pharmaceutical companies and the suppliers (Australian Government, 2011).

The Australian Pharmaceutical Benefit Scheme, which is known as the PBS, is a scheme established by the Australian government to improve on the country's health care sector. The aim of establishing the scheme is to enhance the public access to affordable medications. Modalities in which such goal of "improved access to cheaper drugs" to the public is to focus on ensuring that factors that could hinder access are controlled and department of health and ageing in the country are facilitated to achieve their establishment goals. Another important role of the scheme is to control the importation or production of substandard drugs that have been found to have issues with safety. The body also create ways in which the drugs could be made available to the public and those modalities are the; authority required listing, restricted listing and general listing. The three measures or modalities are used to manage those drugs with the aim of achieving aims of the scheme.

It is another approach at improving on the state of the health care system, which focuses majorly on provision of medicines to the people at

Government-subsidised rates. The scheme by the Australian department of health and ageing provide wider benefits to the consumers because of the level of rise in the price of medications globally. The scheme is made to have certain medications listed among those that would be subsidized. Provide some important information regarding the requirement for prescription of PBS medications. It also helps provide information regarding the scheme to the prescribers such as the doctors and dentists. The price a patient or consumer is required to pay under the scheme is also provided and all the stated modalities are frequently updated to ensure they are up to the primary aim of creating the scheme.

Discuss three issues that are currently impacting on the continued viability of the Pharmaceutical Benefits Scheme.

Several main issues usually affect the viability of the PBS in Australia. One of those main issues is the one found to be associated with the cost of treatment. This issue is related to the approval for an authority listing for high cost treatments. It has also been found that this approval is something that has become somewhat stringent over the years. Compliance by prescribing physicians could also be a major impacting issues regarding the viability of the PBS because of the task behind all necessary documentation before the medication can then be approve or when there is need for the prescribed medication to be change to other ones by the physician (Medicine Australia Inc, 2005).

The second considered issue regarding viability of PBS is that of the restriction towards the number and types of medications needed to be listed and this tend to affect the consumer's access to the necessary drugs. Certain drugs that are needed for successful management of some major cases might also be restricted and this leads to impaired accessibility to those medications. Government in its aim of managing financial costs of the scheme, cause another forms of limitation in achieving the primary goal of PBS. The resultant effect of this cutting expenditure is the unwanted restriction to some of the major drugs that essential. The overall effects of that the consumers are no more buying at a subsidized rate but at the regular price that are not usually affordable (Medicine Australia Inc, 2005).

The third of the considered issues is that which relates to the increasing burden of evidence. That clinical evidence will help prove the standard nature of the medication according to the global standards and safety. This is just to show with evidence by clinical researches and documentation. The result of that approach is that some of the newer medicine will be restricted from the consumer access (Medicine Australia Inc, 2005).

Discuss the key components of a national drug policy.

The national drug policy outlined by the World Health Organization has certain major key components that help in achieving the goals of the national drug policy. Such key components will be discussed below.

## **Affordability**

Affordability is a major key component, which affects all major segments of the health department because of the health goals. Problems with old drugs such as the resistance and development of new microorganism strains or development of newer diseases leads to an urgent need to more newer and effect medicines to counter those newly developed problems. The role of the affordability aspect of the national key policy is to form policies that will allow the people to be able to afford those new drugs. A major strategy in this case is to formulate a policy that would allow tax cut for industries in that field (WHO, 2003) with the aims of influencing the price determination by those companies to favour the public.

## **Selection of essential medicines**

Another important key component with goals of achieving great access to quality health care, standard and rational drug's use in the focus country. The regulatory body set priorities for the key players in the industry to achieve drug selection. The industry and morbidity influence the selection of a drug into the list of essential medicines (WHO, 2003).

## **Financing options**

This is the third component of the national drug policy. It has issues which relates to the financing some aspect of the essential goals. The limitation with the option is that it is not applicable to most nations because of different economic states and other factors affecting the development of the country. Country's policy regarding the finance of major health policies will help in achieving the key goals of the policy (WHO, 2003).

## **Supply System**

This policy influences the drug supply to the populace to improve their health quality. If this system is achieved effectively without issues, it can help to mainly achieve the major goals of improve access to standard and essential drugs. In most cases, this aspect is not always easy to achieve but the government of those supporting nations should strive to achieve it (who, 2003).

## **Regulation and quality assurance**

This focuses on quality assurance without compromising the health for all goals. Strategies to achieve it focus on formation of rules, which helps in inspection of production modalities and management of the produced drugs. The resultant effects of this are to produce high quality medications that reduce the risk of hazards or drug induced issues (WHO, 2003).

In view of this policy, each of those stakeholders should help to focus on achieving the government's dream to the entire community. This focuses on the goal of better health outcomes, which are consequences of improved access to good medications and health care. Quality health care as regards to the need of the people must be provided to achieve the golden goals of the policy (Australian Government, 2000).

The paramedics also have some roles to play in enforcing standard medications. This comes in terms of consideration towards the drug suppliers and how those medications are being supplied to those in need of it (Australian Government, 2000).

Quality use of medications under the national policy helps prevent unnecessarily prescription of drugs. Produced alternatives are much lesser in price compared to the older ones. Consideration towards collaborative efforts with participating partners in the field to achieve the stated goals in the health sector (Australian Government, 2000).

My experience being a paramedic has helped in several patients' management. Informed decision, which is part of the medical process in providing care for patient, must be achieved before any major procedure. As a paramedic, I do help my patient to achieve such kind of informed decision, which helps in their management. I also educate them regarding their use of various drugs and the precautions needed. Good quality of use of medications by various patients is also influenced by the roles of the paramedics, which help in assisting the patient's management. The continuous knowledge update regarding changes associated with the management of various forms of patient and the medication used for them is an added advantage for me regarding my role in high quality patient care. Although this role of ensuring quality use of drugs by paramedic is still not optimal, hence need to be improved upon.

Determine the MeSH term for your profile drug

Results: 2

A short-acting beta-2 adrenergic agonist that is primarily used as a bronchodilator agent to treat ASTHMA. Albuterol is prepared as a racemic



mixture of R(-) and S(+) stereoisomers. The stereospecific preparation of R(-) isomer of albuterol is referred to as levalbuterol.

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### **In your workbook:**

List the drug information resources that you have identified and consider appropriate (e. g. Therapeutic Guidelines).

Provide an explanation of the reasons for including each resource in your personal list.

Identify the possible limitations of each of these drug information resources.

Looking at the entire research process and the information gathered. I can conclude that journals and practice guidelines as drug information resources are appropriate and I tend to include both sources in my personal list.

Credibility regarding the provided information is somewhat questionable hence not fully reliable. Frequent knowledge updating is essential regarding the new areas and development. Achieving the knowledge update can be fully achieved from sources such as the international journal sites or published textbooks.

Over-the-counter drugs are drug that is available in a local pharmacy were they can be purchased by the consumers without a medical practitioner's prescription. An important type of such drugs is that which is known as the

Maximum strength melatonin and its melatonin content is 10mg per tablet and has 60 capsules with produce no 019491 (ProductReview. com, 2011). The major chemical name of the melatonin content is n-actyl-5-methoxy-tryptamine. This medication is design majorly for people with sleeping issues. It is an over-the-counter drug and manufactured by Nature's bounty (Nature's bounty, 2011). The published content include that the " alternative sleep aid for occasional sleeplessness, clinically studied ingredient nutritionally supports restful sleep" (Nature's bounty, 2011).

## **Circadin and Child Use**

How would you respond if an exhausted parent asked you whether it is okay to use Circadin for sleep disorder in a 6-month-old baby who is assessed as developmentally normal? Your answer should explain the basis for your decision.

This scenario reveals that the mother complains of the child not sleeping as expected. The child was also found to be normal regarding the developmental check done. The main precaution towards achieving a greater perspective and result is that all other causes of the problem with inability to sleeping should be considered before starting any form of major management. This drug in questions is not considered for children because of lack of sufficient data supporting the usage in this age group. The underlying cause of the child's problem must be considered and diagnosed before any form of management. (Net doctor, 2010).

## **The Herbal medications review**

Hawthorn leaf has a role in management of mild heart failure and that was stated as the main indication because it helps in the improvement of the performances of the cardiac musculature. The way the herbal medicine usually is to exert some positive inotropic action which contribute to the increase in the coronary blood flow. Other properties that contribute to the increase blood flow, which are the prolonged refractive period and vasodilatation effects of the components of the herbal drug (De Smet PA, 2002).

This herbal medicine has a role in the management of mild heart failure because of its contributory effect to increase cardiac flow. The major consideration towards prescribing this drug is to actually consider the side effects and then explain those effects to the patient before prescribing it to the patient. In explaining the use of the drug and prescribing, the patient's past medical history plays an important role in decision making towards making the prescription. The major identified side effects in such group of patients are the chest pain, circulatory issues, palpitations and some forms of gastrointestinal symptoms. (De Smet PA, 2002).

## **Karli's Scenario Question**

Karli is a 22-year-old asthmatic woman (using a preventive DPI and a reliever MDI) who has decided to use CardiprinR in an attempt to prevent travellers' DVT on an 18-hour plane trip. In your response you should identify all considerations about the potential risks and benefits of Karli's decision to use CardiprinR in this setting.

Karli's decision is not acceptable because of the associated effects of the drug she prescribed for herself. It's important to note that cardiprin which is a salicylate medicine exhibit same allergic reactions as other salicylate drugs. Its use with anticoagulant therapy is something that must be done with caution simply because of the interactions and effects that occur when used together (BMJ, 2004). Peptic ulcer condition and asthmatic events or attacks are also main side effects occurring with the use of cardiprin. These will then be exacerbated when the medication is being taken by Karli as in this case where she prescribed the drug for herself. She did not consider her use of the preventive DPI or the reliever MDI medications that she is using. This may be because of her knowledge of the interaction that may exist between those medications.

The major related change that is likely to occur is that the Cardiprin may actually not perform its role of reduction of exacerbation because of the interaction from other medicine she is using. This decision of Karli is a poor decision regarding the use of medication in the by individual with getting appropriate advice from the paramedics or the doctors. Her poor information regarding the risk associated with DVT is poor hence, her understanding of medication that might actually serve her purpose with less associated exacerbation of asthma are well available around. The use of flight stockings is an important measure regarding her long trip with aeroplane.

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