

Direct advertising of schedule 4 medicines to consumers



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Should Schedule 4 medicines be directly advertised to consumers?

This essay will examine a number of arguments for and against direct advertising of Schedule 4 medicines to consumers, but it will argue that schedule 4 medicines should not be advertised directly to consumers. In the last decades advertising has grown and pharmaceutical companies are advertising directly to consumers. These days, consumers are facing the most advance and domesticated advertised about medicine. The research suggests that direct advertising to consumers is both beneficial and disadvantageous to public health in general. The TGA is the only authority that regulates direct advertising to consumers, advertisements for all therapeutic goods must comply with therapeutic good regulation act 1989. There are limits on direct advertisement product containing schedule 3, 4 and 8 to be advertised to consumers in Australia. Some groups of people argue the rules are too relaxed and are inadequate to enforce the Law that protects consumers , others supporting direct advertise to consumers (Mangin 2006), this number is evenly distributed and balanced , both side have been supporting their arguments with evidence. Currently there are a number of methods of advertising medicines to consumers. First type provides information to the consumers to seek treatment from their doctor about a particular problem without naming the drug. The second method is those which advertise their medicine directly to consumers by naming the drug, what it's used for, how it used, how many tablets you take per days and the price of the drug. The last one is the common type of advertising,

product claims such as efficacy, safety and quality of the drug. The entire drugs are subject to different TGA regulatory restriction.(Shaw March 2008)

The Therapeutic Goods Administration (TGA) is the branch of the Australian Department of Health and Aging, responsible for regulating therapeutic goods, prescription medicines, medical devices and non-prescription medicines including over the counter medicines in order to protect public health and safety. The TGA put in place the systems of national scheduling or classifying medicines to control medicines and chemicals that pose risks to consumers. Medicine is classified according to the level of risk. The TGA classified medicines and poisons into schedule from 1-9." Schedule 4 (prescription only) medicines and Schedule 8 (drugs of addiction) is regulated by the Poisons Act 1964 and the Poisons Regulations 1965 State legislation). Schedule 4 medicines are Prescription only Medicine are defined by the poison act as this medicines are needed to be evaluated for safety and efficacy and for safe and appropriate use due to the complex nature of the medicine potential toxicity, compared with relatively safe over counter drug which do not require a prescription.(Health 2008) Under section 23(2) (e) together with substance or preparations intended for therapeutic use. The safety, quality and efficacy require further evaluation; the prescribing of certain S4 medicines is restricted to medical specialists in some cases Prescription of certain medicines to patients, who are suffering from chronic disease like skin disease and cancer. There are some drugs prescribe by dermatologist, gynaecologist that are restricted to medical practitioners.(C. Lee Ventola 2011)

New Zealand and the United States of America are the only countries allowed direct advertising Schedule 4 medicines. This is not allowed by law in the most countries around the world including Australia. Direct advertisements to consumers failed to provide necessary information about the drug, instead they appeal and tend to sell and promote their products. It also contains misleading, inaccurate information.(Barbara Mintzes 2006)

Today medicines are available in markets in two main forms in Australia, those required prescriptions from general practitioners and those you can buy directly without prescription(over the counter drug). Pharmaceutical companies can directly advertise to health professionals but not to the general public at all, this will affects the relationship that existed between patient and general practitioner. The health practitioners have good relation with their patients; they have also a legal responsibility in both prescribing the medicine and also informing the potential risk. In 21st the century people attitude is changing the use of health services by accessing many range of information's from the media. Restricting direct advertises schedule 4 medicines to consumers are justified due to safety concern. (Mangin 2006)

For instance, the most recent evidences direct advertising can cause harm risk to consumer come from Vioxx. There was no enough evidence to suggest that Vioxx is more effective to treat arthritis pain and inflammation it has only benefited reduced risk of gastrointestinal effect. However the trail shows disadvantage outweighs the benefit which increases in heart attack and stroke. Many discussions have raised about the safety effects of direct advertising schedule 4 medicine to the consumer. The US cardiologist argued that the FDA has failed to stop direct advertising; Vioxx to US public, they

failed to protect the public health and safety while cardiac risk grew. During those periods Merck has spent more than 500million for direct advertising their wonder drug to the world in its five years in the market. Vioxx case was one of the examples about the effects of direct advertising prescription medicine to the public and its potential impacts on individual patients and public health at large, based on the available evidence. Advertising schedule 4 medicine should be banned; it may expose people with serious medical problems. (Barbara Mintzes 2006)It is possible to change the law to safeguard the public from direct advertisement prescriptions medicine. The changes in policy about direct advertise prescription medicine to consumers can assist the connection between public advertising and public health.

The people who are supporting direct advertising schedule 4 medicines to consumer argue that freedom of speech, commercial freedom, the right to get important information to consumers, In order to enable them to make a decision. They think direct advertising prescription medicine is very important human right, to know more information about a potential treatment for the disease they suffered from. They believe also access to their health information can be available to them with the availability of the drug, and (Assistant Professor The impact of advertising prescription medicines directly to consumers in New Zealand: lessons for Australia)information what is best for them. Defenders of direct advertise prescription medicine to consumers focused their campaign on the particular class of medicines that treat illness that symptom are already known to consumers. The defendant argues allowing direct advertise to consumers enablement and autonomy. The argument highlights the types patient who

will benefit from direct advertise including the following, people those are poor who are an ability to have access health information, those who have temporary conditions, would prefer direct access information and those who have experience managing chronic pain and recurring long term conditions. In general, consumers who are adult they have capacity, entitled and right to make a decision about the products and good and services. The pharmaceutical company believes direct advertising to consumer has played important role in informing and educating the consumer about the condition that are treated by brand name drugs.

Advertising schedule 4 medicines to consumers is undesirable because direct advertising does not provide necessary information about adverse effects, alternative treatments and the cost of drugs. According ED Mierzwinski, consumer program director for U. S PIRG. Direct advertising causes “ over prescription of drug for condition people weren’t aware of it, has resulted in massive profit for the industry by preying on vulnerable consumers” in addition, to discouragement doctor and patient relationship. This advertisement can give misleading information about the brand drug, exaggerate the benefits and under reporting the side effect or risk. The consumers that are exposed to direct advertising constantly think drug is the only solution to a health problem, instead of taking up healthy living, good diet and exercise. The result clearly shows, advertising new drug before fully known serious adverse effects, and current post market surveillance sometimes fails to identify adverse events that of a particular drug, which is heavily endorsed early in the process of production, which can present public health. Vioxx was such drug that mostly advertised in the U. S from 1999-

2004. ⁴ On September 30, 2004, Merck voluntarily withdrew Vioxx from the market. Before it withdrew patients requesting for Vioxx by asking the drug relying on the company advertisement they believe the Vioxx is better than other drugs treat the same conditions, not knowing that this drug can cause stroke or other heart problems. benoxaprofen (Oraflex, Eli Lilly) for arthritis, troglitazone (Rezulin, Parke-Davis) for diabetes, cisapride (Propulsid, Janssen) for gastric reflux, ceriva statin (Baycol, Bayer) for high cholesterol, and tegaserod (Zelnorm, Novartis) are other drugs that were heavily advertised to consumers, which have linked to safety risk. (C. Lee Ventola 2011)

Advertising has been the major tools of marketing to consumers for pharmaceutical companies. The profit generated by increasing spending on direct advertisement to consumer by pharmaceutical companies is the main driver of increasing prescription drug and raised the consumer expectation of drug treatment that influence both patients and doctors. The claim direct advertising can provide necessary information that could help the patients about the drug. It has been a point of discussion among patients, pharmaceutical companies and medical professionals in relation to direct advertisement to consumer. one group argues the knowledge from advertising may assist the patients in making decisions with their doctors to have a choice of treatment they need. Others argue advertising new drug to the consumer led to aggressive marketing of Vioxx the drug, which has been found unsafe and risk to consumers, such a case has put big pressure on FDA not to speed up the release of a new drug without proper clinical trials. In recent times, more people have been calling for cessation of direct

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advertisement to safeguard consumers from unnecessary effects of direct advertisement and to put limits into misleading and false information. To improve access option for drug treatment, we need comprehensive, unbiased and accurate information.

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