A STUDY ON ADEQUACY OF MALAYSIAN LAW GOVERNING DRUG ADULTERATION : SILDENAFIL

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ABSTRACT

As the adulteration of poison in Malaysia is still rampant, it causes a big impact on the government, enforcement agencies and users. It is a library-based research, however, semi-structured interviews were also carried out which lead to a few findings of this study.The main Act that govern the manufacturing of poison is the Poisons Act 1952 (Act 366). Besides Act 366, the manufacturing of poison are also governed under the Sales of Drugs Act 1952 (Act 368) and the Control of Drugs and Cosmetics Regulation 1984. Subsequently, there is a role of the Good Manufacturing Practices that needs to be complied with. Apart from that, the regulatory being controlled by the Drug Control Authority, the Pharmacy Enforcement Division and the National Pharmaceutical Control Bureau including their roles in Pre and Post Marketing Surveillance, the use of Adulterated Database and also the new safety feature using distinct Hologram for registered products in Malaysia are clearly identified. Certain provisions in the Poison Act 1952, the Sales of Drugs Act 1952 and the Control of Drugs and Cosmetics Regulation 1984, need to be reviewed to accommodate with the current situation. The study examines and compares the existing laws in other country, namely the United State of America. It is recommended that stiffer penalty be imposed and to have a single specific Act that governs poison, for legal and administration improvement.

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CHAPTER ONE

THE STUDY

1.0 INTRODUCTION

1.0.1 What is sildenafil?

In Malaysia, sildenafil and its analogue (or its salt) are categorized as Group B poison in Part I Poisons List of First Schedule of Poisons Act 1952 (PA). This group of poison is further classified as vasodilators in the Appendix of Poisons List. Vasodilators are the agents that act as blood vessel dilators and open vessels by relaxing their muscular walls thus resulting in vasodilatation. [1] Vasodilatation refers to the widening of blood vessels resulting from relaxation of smooth muscle cells within the vessel walls, particularly in the large arteries, smaller arterioles and large veins.[2]

Sildenafil citrate is an active ingredient in *Viagra*, clinically it has been a major advancement in the treatment of male erectile dysfunction (impotence) and pulmonary arterial hypertension. The most frequent side effects of sildenafil are headache and facial flushing as the vasodilating action of sildenafil affects both the arteries and the veins. For that reason, patients prescribed with sildenafil must be closely monitored by physicians and could only be obtained at pharmacies with the prescription from doctors.

Since they are Group B Poison under PA, sildenafil and its analogue are controlled under several existing laws in Malaysia in the aspect of their importation, possession, manufacture, compounding, storage, transport, sale and use.[3] The governance of all poisons is by enforcing the PA. However when a poison is used as an ingredient of medicine, few other Acts and regulation also be applied to regulate it namely, the Sales of Drugs Act 1952, the Control of Drugs and Cosmetics Regulation 1984, the Medicines (Advertisement and Sale) Act 1956 and the Registration of Pharmacists Act 1951. They are many terms used to indicate medicine

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1 A.S Hornby, *Webster's New World™ Medical Dictionary* (Wiley Publishing, Inc 3rd edn 2008)
2 Ibid
3 Preamble of the Poisons Act 1952