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Medical Product Liability in Malaysia: The Need of Legislative Intervention

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Abstract: A defective medical product directly affects patient in which they are unable to evaluate and make decision as a smart consumer, especially when faced with the use of cutting-edge, complex and sophisticated medical products. Patients who wishes to claim under Consumer Protection Act 1999, encounters many hurdles to satisfy the elements under Part X of the Consumer Protection Act 1999, particularly proving the defect itself and most demanding is proving causal relationship. Hence, the main focus of this article is to examine the challenges encountered by patients in seeking compensation for injury or death due to defective medical products in Malaysia. The objective of the article is to analyze the law of product liability, under the Malaysian Consumer Protection Act 1999, Thailand's Medical Device Act, BE 2551 and also Germany's Pharmaceutical Product Act 1976 aiming at improving the patient's mechanism of compensation. The finding of this article is that, the requirement of proof under Malaysia Consumer Protection Act 1999 for defective medical products is almost impossible to fulfill. Based on the law of Thailand and Germany the analysis highlights that a legislative intervention in the form of adding a particular section in the legislation should be implemented. Thus few improvements are suggested including the amendment to the provisions contained in the Malaysian Consumer Protection Act 1999 as well as including provision of civil liability in the Malaysian Medical Device Act 2012 and Poison Act 1952 to better assists patients in claiming compensation.

Key words: Product liability, medical device, consumer protection, consumer law, Malaysia

INTRODUCTION

Amin (2007) points out that Part X Consumer Protection Act 1999 serves as a redress for consumers due to defective products. This bit of enactment was intended to address the unevenness amongst consumers and producers. Consumer, particularly patients are inept to fathom the complexity nature of medical devices compared to the maker of it. Albeit Part X CPA 1999 objectives is to assist consumers in obtaining compensation, the provision requires several burdensome elements to be fulfilled, thus, it is more than a hindrance than a help in order for the manufacturer to borne the financial burden suffered by them.

Till date there are currently no decided cases in Malaysia challenging this piece of legislation. However, since CPA 1999 adopts the Product Liability Directive 1985 known as European Directive 85/374/EEC which have been implemented by European Union countries including United Kingdom's Consumer Protection Act 1987 and followed by other Commonwealth countries, decided cases in these countries are referred by the authors to analyze and study the disadvantages of this particular provision.

Previous studies by Mokhtar and Ismail (2013) draws our attention that CPA 1999 fails to respond the need of patients in obtaining compensation against the manufacturer of defective medical devices. She found that 'personal injury or wrongful death lawsuit arise from the use of defective medical devices, it inevitably presents complex, legal and technological issues that need to be dealt with before the court of law'.

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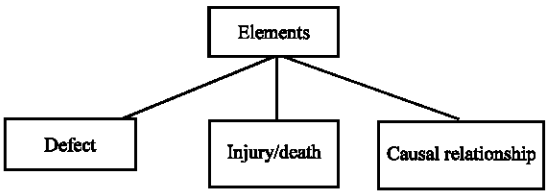

Fig. 1: Consumer protection Act 1999

Fahirah Syaliza also highlights that the repercussion of this is disastrous as the patients would have to borne heavy financial burden which the law fails to assist. Therefore, it is the aim of this article to look into other countries that have different approaches in addressing the matter after explaining in brief the hurdles patients have to go through under the strict liability regime of Part X CPA 1999. This article will look into Thailand's Medical Device Act, BE 2551 and Germany's Pharmaceutical Product Act 1976. These countries highlights a legislative intervention in the form of enacting specific legislature for defective medical products which will ultimately benefit patients (Fig. 1).

Malaysia's part x: consumer protection act 1999: The issue whether medical devices are 'products' under the ambit of Section 66 (Amin, 2007) CPA 1999 are well settled as it is used for personal consumption as per Section 3 CPA 1999. Section 3 (Amin, 2007) defines 'goods' which are primarily purchased, used or consumed for personal, domestic or household purposes. An example can be seen in the case of DJO Canada Inc. v. Schroeder in which the court held that pain pumps are 'goods' used for personal purposes within the meaning under Canada's Consumer Protection Act.

Article 4 of the European Directive 85/374/EEC states that 'the injured person shall be required to prove the damage, the defect and the causal relationship between the defect and damage.' Section 68 CPA 1999 adopts the same. In his studies, Fairgrieve and Howells (2007) stresses that 'defect is at the core of the strict liability regime under the Directive.' Therefore, it is pertinent for the patient to prove that the medical product is first and foremost defective. Cases such as Foster v. Biosil (breast implant); Richardson v. LRC Products Ltd. (condoms); Australia Carel-Hazell v. Getz Bros and Co. (Aust) Pty Ltd. (heartvalve); XYZ and Ors v. Schering healthcare Ltd. and Ors (oral contraceptive); Multiple Claimants v. Sanifo- Synthelabo Ltd and Anor0(epileptic medicine); Peterson v. Merck Sharpe and Dohme; Morris v. Alcon Laboratories (Australia) Pty Ltd. (contact lense implant); Bright v. Femcare Ltd. (Filshie Clips contraceptive) where the courts have mutually held that proving defect for medical products is the necessary precondition of liability. The courts in these cases have all rejected claimants claim for compensation as it was paramount that the claimant's prove not only that the medical product failed to function as intended but also how it became defective.

In order to prove defectiveness of a medical product, Section 67 CPA 1999 states that a 'product is defect if the safety of the product is not such as a person is generally entitled to expect taking account all relevant circumstances'. Fairgrieve and Howells (2007) claims that what consumer are entitled to expect is the safety level of external and internal features of the medical devices. It has been held in A.v. National Blood Authority that the term 'expectation' mentioned in this provision 'is not referred as the expectation of an individual but the expectation of the public at large'. This means that the defectiveness of a medical product is taken from the viewpoint of society (Grubbs, 2007). This clearly poses a huge problem for patients as when they purchase medical products as it is expected that manufacturers have abide all safety regulations, mandatory clinical trials and various tests. Furthermore if the expectation is from the standpoint of an ordinary consumer, it is not making assessment on the basis of his individual knowledge but on the basis of what the community mutually knows about the product. Mokhtar and Ismail (2013) maintains that the usage of medical devices is limited to a group of people using those particular medical devices such as pacemaker, implants or artificial hips. She stresses that it is difficult to evaluate their testimony as different patients reacts differently to these medical devices.

The second important element under Section 68 CPA 1999 that needs to be satisfied by the patient is causation or causal relationship between the injury and the defective medical product. This provision in also embedded in Article 4 Directive which is also pari materia with Section 2(1) CPA 1987 UK. In the case of Piper v. JRI (Manufacturing) Ltd. the patient claimed that the prosthetic hip implant was defective under Section 2 CPA 1987 UK and therefore the manufacturer was strictly liable. The court held that it is fundamental for the patient to prove that the prosthetic hips implant had in fact caused his injury.

Till date, after nearly 40 years, the requirement to prove causation still poses as a great hurdle for patients. The challenge is greater as medical devices have now become more sophisticated and high in technology. The question is how can a patient prove that the defective medical products caused the injury they suffered? It a is challenge to determine the sole cause of injury by the patients. Injuries sustained may be due to other factors such as using other medical products at the same time or

the patient suffers from primary or secondary illness which is difficult for the patient to determine which medical product is defective and caused the injury or whether the product is not defective but actually consequences of combining several medication at one time.

According to research by European Commission Green Paper of Liability for Defective Products (Miller, 2004) the element of causal relationship between an injury and defective product puts a heavy toll upon the plaintiff especially when such proof turns out to be technically complicated. For instance, in the case of Multiple Claimants v. Sanifo- Synthelabo Ltd. and Anor the plaintiff claimed that they were born with deformities due to medicine consumed by their mothers. The court denied their claims and held that the litigation was too complex and posed legal and scientific issues that were too technical. In the case of XYZ and Ors v. Schering Health Care Limited and Ors in which 10 epidemiologist testified in court for three months regarding the defective contraceptive pill. The court had difficulty in deciding the issue of causation as piles of documents were trawled back and forth from one expert witness to another which created more confusions and difficult to decide.

Hence, based on cases decided above, it is evident that proving defect of medical product and causal relationship between injuries sustained and defective product is almost impossible to succeed. It goes to show that the compensatory scheme under this legislature is only cosmetic in nature and the consequences are detrimental to patient as they would be left uncompensated for the wrongdoing of the manufacturer. Therefore it is best to look into the approaches of other countries such as Thailand and Germany that have enacted specific legislature for medical products to assist patients in claiming compensation.

THAILAND'S MEDICAL DEVICE ACT, BE 2551 (2008) AND GERMANY'S PHARMACEUTIAL PRODUCT ACT 1976

Thailand's Ministry of Health had taken initiative to enact Medical Device Act BE 2551 (2008) replacing Medical Device Act BE 2531 (1988). This new piece of legislation provides better and stringent regulation on medical products including provisions pertaining advertisement and registration of medical devices. Generally, the Thailand's MDA 2008 is identical to Malaysia's Medical Device Act 2012, except that under Thailand's MDA 2008 there is a provision of civil liability for manufacturer of medical products. Thailand's MDA 2008 provides protection for patients who are injured due to defective medical products by manufacturer, importer, distributer and also retailer. Chapter 11 Section 77 titled Civil Liability states as follows:

Section 77:

> The producer, importer or distributor of medical device shall be liable for the damage incurred in use of medical device, except it can be proved that such damage is from force majeure or it does not come from any defect in medical device or from the mistake of the injured person

Section 78:

> Any person uses or implements using of medical device to other person causing damage to life, body or hygiene, must be responsible for damage to such person from the medical device, except it can be proved that he/she has performed under the carefulness according to academic standard or such damage is in force majeure or from the injured person's own mistake

Based on the above Section 77, if patient suffers injury due to the usage of defective medical device, Thailand's MDA 2008 will hold the manufacture liable except if it can be proven that the injury was not due to manufacturer's medical device or the device was not defective. This means that the burden of proof is not upon the patient to prove that the medical device is defective but upon the manufacturer to prove otherwise. This is further supported by Section 78 which provides that the liability is not only borne by manufacturer but also anyone who was involved in dealing with the medical devices. Therefore, Section 77 and 78 Thailand's MDA 2008 directly removes the requirement of causation in medical product liability claims and this uplifts the burden upon patients to prove defectiveness of a medical product.

Germany on the other hand enacted Pharmaceutical Products Act 1976 (Arzeimittelgesetz). Reports from The Pharmaceutical Industry in Germany states that German is the third largest pharmaceutical producer in the world. Pharmaceutical companies in Germany produce medicine with the market value of EUR 27.1 billion in the year 2008 and invested another EUR 5 billion in research and development. Bayer Healthcare is one of German's pharmaceutical company that produce aspirin. Thalidomide tragedy in the 1960's was one of the important events in Germany. The children in the Thalidomide tragedy suffered deformities due to medicine consumed by their mothers that was produced by a German pharmaceutical company. German's newspaper

reported 161 children was affected and thousands more worldwide. This event has caused the German to revise their laws particularly Pharmaceutical Products Act 1961. This piece of legislation was amended and now known as Pharmaceutical Products Act 1976 (Arzeimittelgesetz). The PPA 1976 consists of 18 Chapters and 146 Sections in which under Chapter 16 provides absolute liability towards manufacturer of medical products titled Liability for Damages Caused by Medicinal Products. Section 84 states that if patients consumes medicine suffers injury, death or affects the wellbeing of a patient, manufacture or the person placing medicinal products on the market under his or her name shall be liable. The court shall determine absolute liability based on the composition of the medicine, recommended dosage, method of intake, symptoms, duration between intakes and other factors that may have caused injury and death. The approach taken by the court in evaluating a claim is by way of presumption or inferences based on the chemical reports and if the reports indicate that injury or death is caused by consumption of that particular medicine, absolute liability will be imposed. However, the court will decline claims made by patient if it could be proven that other factors may have caused the injury.

Legislative intervention: It is apparent from the study above that the approach of Thailand and Germany in dealing with medical product liability may be adopted in Malaysia. Analysis upon both countries clearly indicates that legislative intervention is highly recommended for better consumer protection and to uphold patients' right for redress for the injury sustained.

Few improvements can be made such as amending Part X Consumer Protection Act 1999. Studies have proven that the requirements are demanding and difficult for patients to fulfill in order to succeed (Goldberg, 2013). Based from the findings above, shifting the burden of proof onto the manufacturer is the best solution to overcome the issue of defectiveness and causation as practiced by Thailand's MDA 2008. It will tremendously assist patients in claiming for compensation as the burden is shifted to manufacturer who is in the best position to explain its product and prove it is not defective. Manufacturers are better equipped with experts, data and information regarding its product. With this amendment it gives justice to patients as it eliminates the requirement of causation.

Alternatively, besides amending Part X Consumer Protection Act, improvement can be made by amending the existing medical product legislation in Malaysia such as Poison Act 1952 and Medical Device Act 2012 which only provides criminal liability. There are no civil liability provision that provides compensatory regime for patients. It is strongly recommended that these respective legislations should insert provisions of civil liability and that the burden of proof is upon the manufacturer to prove that its medical products are not defective. This will uplift the hardship that has been placed upon the patient and increase the chance of succeeding in their claims such has been done by Thailand. However, should Malaysia follow the footsteps of Germany in adopting absolute liability towards manufacturers of defective medical products? It is the authors' opinion that, although, it will hugely assists patients in claiming compensation, justice also must be served to manufacturers.

CONCLUSION

This study was set out to determine the challenges encountered by patients in seeking compensation due to defective medical devices. This study has given account of and the reasons for the need of legislative intervention in the form of adding provisions of civil liability in Malaysia's Medical Device Act 2012 or Poisons Act 1952 and also amending Part X CPA 1999 as it is well established that claim of compensation is very challenging for the patients. It is feared that if no action is taken to overcome this matter, patients will be have to bare the financial burden at the expense of the fault of the manufacturer and this is clearly an injustice that deserves special attention by the legislature.

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