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HEALTH INSTITUTION AS A CONSUMER PROTECTION FRAMEWORK IN MALAYSIA

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ABSTRACT: Consumer protection is becoming a world agenda in this era of globalisation and trade liberalisation. Globalisation and trade liberalisation promotes free trade activities in every part of the world. Consumer as a party to the trading activity contributes significantly to this activity and becomes a major contributor to the economy through this activity. However, consumer needs to be protected so that trading activities will benefit both the consumer and the economy. Health is becoming one of the major issues faced by the consumer in Malaysia. Globalisation and trade liberalisation resulted in free entry of pharmaceutical products from abroad without restriction. This phenomenon will bring a negative effect on consumer in Malaysia if the products are counterfeit. Thus, consumer needs to be protected in facing globalisation and trade liberalisation. Based on doctrinal research and by applying content analysis method, this paper will review the protection conferred by the Health Institution in protecting the consumer in Malaysia. The Malaysian Ministry of Health will be reviewed to examine their role in upholding consumer protection with regards to pharmaceutical counterfeit in Malaysia.

KEYWORDS: Consumer Protection, Health Institution, Ministry Of Health, Pharmaceutical Counterfeit

INTRODUCTION

Globalisation and trade liberalisation introduced a new concept of trade which is trading without borders. The consumers are well aware that world is no longer borders and market is no longer confined. This is a complex international free trade era and it is a confusing environment for the Malaysian consumers (Mahathir Mohamed, 2002). In this era, consumers can easily purchase goods and services needed but sometimes they are being misled by the traders and ended up purchasing goods and services that are not needed. This is one of the drawbacks of globalisation and trade liberalisation. Another problem is the availability of low quality of goods on the market. Since traders need to compete in order to survive, they tend to produce low quality of goods so that they will be able to sell them with cheaper price. Uninformed consumers will go for price rather than quality. As a result, they become victims of greedy traders. One of the issues that needs attention is regarding pharmaceutical products. It has becoming an acute problem to the consumers in Malaysia. The problem is expanding day by day due to the large amount of pharmaceutical products used by the consumers in Malaysia. Therefore, Malaysia should not receive trade liberalisation with open arms but to manage it wisely in the interest of consumers in Malaysia.

Consumer Protection in Malaysia

Consumer protection is important to create a good economic structure so as to contribute to a better society (Sakina Shaik Ahmad Yusoff, 2007). However, the existence of trade liberalisation resulted in failure of the market forces to protect the consumer since trade liberalisation leads to unfair bargaining power between consumers and traders (Ziegel, 1973). Technological advancement in this era resulted in the production of technically complex goods. These goods which are made available on the market will sometimes affect the uninformed consumers. The technically complex goods leads to uninformed consumers being unable to assess the quality of the goods while the traders on the other hand in a better position because they have access to the information regarding the goods produced. This is an example of market failure which according to Rachagan (1992), requires government intervention. He emphasised that government intervention is necessary in order to provide the best protection to the consumers.

Realising the importance of consumer protection, the Malaysia government enacted the Consumer Protection Act 1999, which makes the interest of consumers as its primary focus. This is an example of legal framework initiated by the Malaysian government in order to provide for consumer protection in Malaysia. Legal framework requires enforcement of the law to control or regulate the community (Summers, 1971). Apart from legal framework, institutional framework is also important. The institutional framework is dedicated to provide protection to consumers with the aid of the government.

Government Institution and Consumer Protection in Malaysia

The institutional framework is one of the components of consumer protection in Malaysia. Realising the importance of institutional framework as a means of consumer protection, the Government has established the Ministry of Domestic Trade and Consumer Affairs in 1990 which is later known as Ministry of Domestic Trade, Cooperatives and Consumerism in 2009. The Ministry is determined to address the problem of consumers who are victims of greedy traders. In order to achieve this objective, the ministry has drafted the Consumer Protection Act 1999, an Act with consumer protection orientation. Apart from this, the ministry also involved in drafting the National Consumer Policy (NDP), which was launched in 2002. Code of Ethics & Business Practices and Rukuniaga Malaysia was also introduced to provide for consumer protection in Malaysia.

The importance of consumer protection has been recognised by the Malaysian government by establishing eight Ministries with consumer orientation. These government institutions have been entrusted to provide protection to consumer in Malaysia. They are been identified in Table 1. The government has enacted a few consumer protection laws under these Ministries and they are to enforce the laws accordingly.

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Table 1.

| | Enforcement Agency | Laws |
|---|--|---|
| 1 | Ministry of Domestic Trade, Cooperatives and | Price Control Act 1946 |
| - | Consumerism | Control of Supplies Act 1961 |
| | | Trade Descriptions Act 1972 |
| | | (Amendment 1980) |
| | | Hire Purchase Act 1967 (Revised |
| | | 1978) |
| | | Direct Sales Act 1993 |
| | | Weights and Measures Act 1972 |
| | | Consumer Protection Act 1999 |
| | | Competition Act 2010 |
| 2 | Ministry of Agriculture and Agro-Based | Control of Padi and Rice Act 1994 |
| | | Pesticides Act 1974 |
| | | Animal Ordinance 1953 |
| | | Fisheries Development Authority of |
| | | Malaysia Act 1971 |
| 3 | Ministry of Housing and Local Government | Rent Control Act, 1966 |
| C | | Pawnbrokers Act 1972 |
| | | Housing Development (Control and |
| | | Licensing) Act 1966 |
| 4 | Ministry of Transportation | Road Transport Act 1987 |
| 5 | Ministry of Science, Technology and | Standards of Malaysia Act 1996 |
| | Environment | Environmental Quality Act 1994 |
| 6 | Ministry of Health | Food Act 1983 |
| | | Disease Prevention and Control Act |
| | | 1988 |
| | | The Medicines (Advertisement and |
| | | Sale) Act 1956 (Revised 1983) |
| | | Sale of Drugs Act 1952 |
| | | Poisons Act 1952 (Revised 1989) |
| | | Pharmacists Registration Act 1951 |
| 7 | Ministry of Human Resources | Occupational Health and Safety Act |
| | | 1994 Easteries and Machinery Act 1067 |
| 8 | Ministry of Finance, the Insurance Act 1966 | Factories and Machinery Act 1967The Banking and Financial |
| 0 | winnsu'y of Finance, the insurance Act 1900 | Institutions Act 1989 (BAFIA 1989) |
| | | Islamic Banking Act 1983 |
| | | Takaful Act 1984 |
| L | | |

Enforcement agency and consumer protection laws in Malaysia

Ministry of Health

Ministry of Health (MoH) is one of the Ministries which are faced with consumer issues. Ministry of Health plays an important role in curbing health issues in Malaysia. MoH aims to assist individuals in achieving and sustaining as well as maintaining a certain level of health status to further facilitate them in leading a productivity lifestyle economically and socially. In order to do so, MoH needs to provide a promotional and preventive approaches and

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efficient treatment and rehabilitation services by focusing on the less fortunate groups. Its vision is to work together for a better health. One of its missions is to ensure a high quality professionalism, respect for human dignity and communication participation.

Counterfeit Products

The major issue faced by the consumers in Malaysia in relation to health is counterfeit medicines and cosmetics which are easily available to the consumers on the market. (Eisha A. Rahman, 2012). This problem is also known as pharmaceutical counterfeit. There is no specific definition for pharmaceutical counterfeit under Malaysian law. However, under The Sale of Drug Act 1952, there are specific provision under regulation 7(1)(a) and 7(1A) (a-g) of Control of Drugs and Cosmetics Regulation which requires all products to be registered with National Pharmaceutical Control Bureau (NPCB) before entering the market. Hence, by the application of the provision, products which fail to comply with the requirement may be considered as unregistered drug in which counterfeit products could be among them (Mazlan Ismail, 2013). Pharmaceutical counterfeit is a threat to worldwide public health. It generates profits to the criminals and at the same time it threatens the pharmaceutical industries as it lead to huge financial loses to the industries. (Asiah Bidin, 2009). In 2011, MoH has issued 204 warning letters and 42 cases were referred for investigation. A total of 41 cases has been brought to the court with the sum of fine is RM 56 800. In 2012, 197 warning letters were issued and a total of 74 cases were referred for investigation and legal actions to be taken. A total of 24 cases has been brought to the court with the sum of fine is RM 24 500 (Hasan Abdul Rahman, 2012).

Institution under Ministry of Health

The MoH is well aware of this problem and has taken various steps to overcome the problem. For this purpose, MoH has established special divisions for the handling of pharmaceutical products and services. The divisons are:

- 1. Pharmacy Enforcement Division;
- 2. Pharmacy Practice and Developement Division; and
- 3. National Pharmaceutical Control Bureau.

Pharmacy Enforcement Division

Pharmacy Enforcement Division plays an important role to ensure that pharmaceuticals, traditional and cosmetics that are available in the market are genuine in terms of registration and notification. The division ensure that the supply and marketing; advertisement; and usage of the products comply with the existing legislation. The objective of Pharmacy Enforcement Division is to ensure all pharmaceutical and health products in the market are of quality and safe. Its function includes ensuring pharmaceuticals and health products, medicinal products and medical services advertisements comply with the rules and legislations. Pharmacy Enforcement Division is given the authority to seize counterfeit products on the market. Items seized by the Division include unregistered and adulterated products. Number of seizure done by the Pharmacy Enforcement Division is shown in Table 2.

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| Tal | ole | 2 |
|-----|-----|---|
| 1 | | _ |

| Year | No. of Product Seized | No. of Counterfeit | Percentage of |
|------|-----------------------|--------------------|---------------------|
| | | Product Seized | Counterfeit Product |
| | | | Seized |
| 2009 | 10 478 | 234 | 2.23% |
| 2010 | 11 934 | 362 | 3.03% |
| 2011 | 17 768 | 344 | 1.94% |
| 2012 | 13 028 | 93 | 0.71% |

Seizure of products by Pharmacy Enforcement Division

Pharmacy Practice and Development Division

The Division is responsible to ensure that pharmacy service strategic plans and policies are implemented accordingly. It will ensure effective distribution of human resource, relevant and continuous training are carried out, the practice of quality system, and administrative and financial matters are carried out according to rules and guidelines.

National Pharmaceutical Control Bureau

National Pharmaceutical Control Bureau (NPCB) was established in order to implement quality control on pharmaceutical products. It was set up in October 1978. The Bureau plays an important role in combating pharmaceutical counterfeit in Malaysia. NPCB is equipped with the infrastructure and facilities which meets the requirement for testing and quality control activities.

One of the functions of NPCB is to ensure the quality, efficacy and safety of pharmaceutical products through the registration and licensing. This is one of the actions taken by NPCB to overcome the problem of pharmaceutical counterfeit. Registered product might increase confidence of consumer in making purchases. However, there are cases whereby registration number of products has been copied and used on the counterfeit products in order to legalised them. In order to overcome this problem, MOH has implemented hologram technology which is known as Meditag hologram to complement the registration number on the product. The Meditag hologram is affixed on to the products. Only licensed importers and manufacturer with Good Manufacturing Practice (GMP) licensed are allowed to purchase the security labels for the affixation on to their products. Authenticity of the product can be detected by using Meditag decorder. Meditag decorder is put on the hologram. By sliding the decorder, the authenticity of the product can be detected. The authentic pharmaceutical products will clearly reveals the word KKM (Ministry of Health) on the hologram. The implementation of hologram enables the MoH to detect counterfeit pharmaceuticals products on the market. At the same time, it increase in seizures of counterfeit products, assist in tracking of counterfeit and unregistered products and facilitate in tracing illegal manufacturers and importers. Apart from this, a system to monitor products in the market was also made available for the medical professional and consumers. Public will be able to check the registration of the pharmaceutical products by using the system which could be found on the NPCB website. As for manufacturers and importers, they need to register their products by using the system which is known as Quest 3 (Annual Report NPCB, 2012).

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Efforts done by NPCB are recognised by the Malaysian government as well as other ASEAN countries. As a result, NPCB was given the opportunity to provide courses and training to personnel from the ASEAN countries such as Sri Langka, Bangladesh, Myanmar, Mongolia and Vietnam. NPCB also has been recognised by the World Health Organization (WHO) for its contribution in the field of regulatory affairs and was honoured with the recognition of "WHO Collaborating Centre for Regulatory Control of Pharmaceuticals" (Mazlan Ismail, 2013).

CONCLUSION

In the era of globalization and trade liberalisation, trading activities become borderless. Consumers are able to enjoy goods and services from all over the world. Due to high demand, traders decided to involve in mass production of goods. Mass production of goods leads to production of low quality of goods which later might risk or injure the consumers. If this situation continues, it will jeopardize the national interest. One of the issues faced by the consumer is health issues. Consumers are served with variety of pharmaceutical products on the market. Some of them are counterfeit products. Thus it is inevitable for the government to come out with a measure to protect the consumers in Malaysia. Realising this matter, the Ministry of Health has taken an initiative to protect the consumers by establishing institutions which provide protection to consumers. Among the institutions are Pharmacy Enforcement Division; Pharmacy Practice and Development Division; and National Pharmaceutical Control Bureau. No doubt, these institutions have proven to be effective in providing protection to consumer but future issue might be different. It is submitted that strong institutional framework is needed to combat this issue and the institutions need to keep pace with the changing tactics use by the counterfeiters.

REFERENCES

Annual Report. (2012). National Pharmaceutical Control Bureau, Ministry of Health.

- Asiah Bidin. (2009). Counterfeit Medicine: A Threat to the Public Health and *Pharmaceutical Industry*, International Conference on Corporate Law 2009, Surabaya, Indonesia.
- Eisha A. Rahman. (2012). Fake Drugs Big Problem, Laporan Bahagian Perkhidmatan Farmasi, Kementerian Kesihatan Malaysia.
- Hasan Abdul Rahman. (2012). Beware of Illegal Advertisements, Press Release, Malaysia Ministry of Health,
- Jolowicz, J.A. (1969). *The protection of the consumer and purchaser of goods under English Law.* Modern Law Review, 32(1), 2.
- Kennedy, J.F. (1962). Special message to the us congress on protection of consumer interest. US Congress 1962.
- Mahathir Mohamed. (2002). Globalisation and the new realities. Pelanduk Publication, Selangor.
- Mazlan Ismail, (2013). Counterfeit Medicinal Products: The Challenges and Nowadays Towards NCD. The Malaysian Experience. Ministry of Health. http://jknkelantan.moh.gov.my/khc2013/uploads/pdfs/ple01.pdf
- Mohd Hamdan Adnan. (2005). Perjuangan Perundangan Pengguna. IBS Buku Sdn. Bhd, Selangor.

Published by European Centre for Research Training and Development UK (www.eajournals.org)

- Rachagan, S. S. (1992). Consumer law reform A report. Universiti Malaya Press, Kuala Lumpur.
- Sakina Shaik Ahmad Yusoff. (2007). Undang-undang komersial dan pengguna. Dewan Bahasa & Pustaka, Kuala Lumpur.
- Summers, R.S (1971). The technique element in law. California Law Review, 59,733
- Ziegel, J.S. (1973). The future of Canadian consumerism. Canada Law Review, 52 (191), 193.

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