

Newsletter

December 2017

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Healthcare Newsletter

Introduction

This circulation is aimed at providing you recent updates in the healthcare industry in Malaysia.

In this edition, we provide a summary of key industry happenings, covering the proposed Pharmacy Bill, the Food (Amendment) (No.4) Regulations 2017, the Private Aged Healthcare Facilities and Services Bill, as well as new regulations concerning non-corrective contact lens under the Medical Device Act 2012.

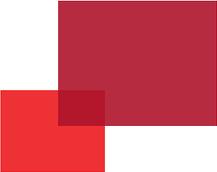
In these articles, you may click to read a more detailed summary with links to source materials.

1. Updates on the Pharmacy Bill

The Government has indicated that it expects to table a new Pharmacy Bill in the Malaysian Parliament in late October 2017. However, as of this date, the Bill has not been tabled.

The proposed Pharmacy Bill aims to consolidate and harmonise existing pharmaceutical related legislation, namely the Registration of Pharmacists Act 1951, the Poisons Act 1952, the Sale of Drugs Act 1952 and the Medicines (Advertisement and Sale) Act 1956. The Health Ministry hopes that the Pharmacy Bill will address gaps in the existing legislation and better safeguard public health and safety. Although the draft of the Bill is not publicly available yet, key changes are predicted to include:

- Increased penalties against counterfeit medicinal products, psychotropic distribution and the diversion of precursor chemicals;
- The current system under the Poisons Act 1952 categorises poisons into Groups A, B and C. To make it more reader friendly, the proposed Bill will re-categorise poisons into three categories – prescription only medicines, pharmacy medicines and general sales list medicines.
- Legitimate mechanisms will be implemented to regulate pricing of medicines to curb unregulated medicine pricing in private sector; and
- The guidelines on advertisements of medicines will become legally binding to encourage self-regulation, rather than relying on the Medicine Advertisements Board to screen through the advertisements prior to publication.



It is worth highlighting that after much debate and lobbying, the Health Ministry has decided against separating the roles of dispensing and prescribing medicines, which is the system practised in most developed nations. Malaysian doctors may continue to both prescribe and dispense medicines to their patients under the new Pharmacy Bill. While this does save patients a trip to the pharmacy, some are in doubt that there are sufficient checks on the safety and appropriateness of the prescription, without having pharmacists to review the same.

2. Changes to Malaysian Food Laws

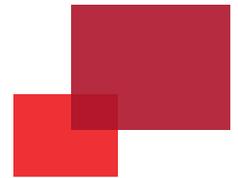
Coming into force on 1 December 2017, the Food (Amendment) (No. 4) Regulations 2017 amends the Food Regulations 1985 to allow for more efficient investigations and greater powers of enforcement as follows:

- An authorised officer will have the additional option of delivering samples to an analyst for microbiological, physical or chemical analysis through registered mail or by courier services, provided that the officer obtains an acknowledgement of receipt ("A.R.") for the delivery. Under the previous provisions, an officer must deliver samples to an analyst for physical and chemical analysis, personally by hand; and
- The penalty for contravening the Regulations will be increased by one fold from RM 5,000 (approx.. USD 1,194) to RM, 10,000 (approx. USD 2,388).

In addition, the Ministry of Health has exercised its powers conferred by the Food Act 1983 to issue regulations on compounding offences. Briefly, the rules are as follows:

- Schedule 1 of the Regulations sets out the compoundable offences.
- A compoundable offence can only be compounded if the Public Prosecutor gives his or her written consent in a prescribed form.
- The authorised officer must issue a written offer to compound the offence and the person committing the offence must accept the offer, in prescribed forms.
- If one accepts the offer to compound his or her offence, he or she may make the payment of the compound to the Deputy Director General of the Ministry of Health or an authorised officer in cash, by money order, postal order or banker's draft.

The Food (Amendment) (No. 4) Regulations 2017 and Food (Compounding of Offences) Regulations 2017 may be found [here](#) and [here](#).



3. Better Care For The Elderly Anticipated In Malaysia

With the objective of ensuring high standards in the aged care industry, the Ministry of Health ("MOH") Malaysia has tabled the Private Aged Healthcare Facilities and Services ("PAHFAS") Bill. The Bill reached the stage of second and third reading on 24 October 2017.

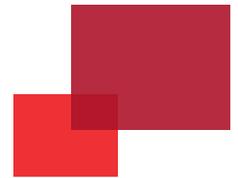
The Bill imposes key rules as follows:

- all individuals providing healthcare facilities and services to more than 3 aged persons (i.e. those within the age of 60 and above) are required to obtain (a) a prior approval and (b) an operating licence, from the Director General of Health ("DG");
- the premises of a licensed PAHFAS must either be a residential facility, a day care facility, any premises as the Minister may prescribe or any premises that incorporate specifications of any two or more of the foregoing premises;
- a licensee must arrange for a qualified healthcare professional to be available at the premises of the PAHFAS;
- a licensee must train its caregivers and ensure that they are competent;
- the person in charge of the PAHFAS must be trained, qualified and experienced, meeting the standard to be determined by the DG;
- a licensee may not use the PAHFAS for any other purpose than that licensed by the DG, save for incidental purposes;
- a licensee may admit persons below the age of 60, if the admittance is in accordance with the Care Centres Act 1993 ("CCA");

Individuals providing healthcare for their aged relatives and private healthcare facilities and services that have obtained licence under the Private Healthcare Facilities and Services Act 1998 are exempted from the scope of the Bill.

To complement the above changes, the Care Centres (Amendment) Bill 2017 was tabled to prevent overlap between the CCA and the PAHFAS Bill. With the amendments, only care centres providing care to those below 60 are covered by the CCA. Once the PAHFAS Bill comes into effect, registered care centres under the CCA which are providing care to more than 3 aged persons will have 5 years to apply for an approval and licence from the DG. Anyone who fails to obtain the required approval and/or licence may be liable to a fine of up to RM 30,000 (approx. USD 7,207) for an individual or a fine of up to RM 100,000 (approx. USD 24,024) for body corporate, partnership or society.

More information on the PAHFAS Bill and the Care Centres Act could be found [here](#) and [here](#) respectively.



4. Non-Corrective Contact Lens Declared A Medical Device

Effective from 1 January 2018, contact lens which are not used to correct, remedy or relieve any refractive abnormalities or optical defects of sight, will be deemed as medical devices, falling within the scope of the Medical Device Act 2012.

All establishments importing, exporting or placing in the Malaysian market non-corrective contact lens must apply for (a) registration of the non-corrective contact lens as medical devices; and (b) an establishment licence, from the Medical Device Authority ("**MDA**") within 6 months, by 1 July 2018. While awaiting determination of the application submitted to the MDA, the establishments may continue to import, export, sell or supply the non-corrective contact lens.

Please see [here](#) for more details.

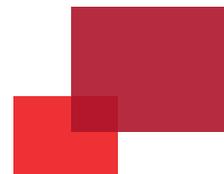
5. Gozout Banned Due To Non-Registration

On 28 November 2017, the Malaysian Ministry of Health banned the 'health product' Gozout due to failure to register with the National Pharmaceutical Regulatory Agency ("**NPRA**"), despite containing 100% active ingredients and being advertised as a cure for gout, hypertension and diabetes. The Ministry has conducted raids and seized RM 2.3 million worth of products.

The failure to register a drug product with the NPRA is a breach of Regulation 7(1)(a) and Regulation 30(1) of the Control of Drugs and Cosmetics Regulations 1984. Under Section 12 of the Sale of Drugs Act 1952, a person acting in breach of the regulations may be found liable to a fine of up to RM 25,000 (approximately USD 6,148), and/or imprisonment of up to three years; whereas a body corporate who is not in compliance with the regulations may be found liable to a fine of up to RM 50,000 (approx. USD 12,298). If the relevant person or company is found to be committing a second or subsequent offence, more serious penalties may be imposed.

6. Finalised Report On The Market Review Of The Pharmaceutical Sector In Malaysia To Be Issued

The Malaysian Competition Commission ("**MyCC**") has commissioned Third World Network ("**TWN**"), an independent non-profit international research and advocacy organisation, to conduct a market review on the pharmaceutical sector in Malaysia (the "**Review**"). The MyCC is conducting the market review pursuant to powers under Chapter 3 of the Competition Act 2010 ("**MCA**"), with a view to determine the pharmaceutical sector's market profile.



As part of the Review, TWN has prepared a draft final report on the outcome of the Review and made it available on MyCC's website for pharmaceutical companies and other relevant stakeholders to provide feedback by 9am on 7 December 2017.

The draft report has identified certain potential anti-competitive conduct including:

- the use of patent strategies and product life-cycle management measures to maintain dominance and delay the entry of generic medicines;
- intervention before regulators which determine marketing authorization;
- pricing and reimbursement of generic products and price discrimination.

TWN has recommended that the Malaysian government take action to revise existing regulations and policies which it believes facilitates anti-competitive conduct. Among other measures, TWN has suggested the regulation of mark-ups in the distribution chain and the introduction of rules to ensure increased transparency in pricing policies of industry players.

As the public consultation period has passed, we expect the finalized report to be issued shortly and be used by the MyCC as the basis for its analysis and findings of anti-competitive practices by pharmaceutical companies in Malaysia.

Please see [here](#) for the draft final report on the outcome of the review.