Wong & Partners.
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# Newsletter

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## Healthcare Newsletter

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

In this edition, we provide a spotlight summary of key industry happenings, covering the Dental Bill 2017, the Private Aged Healthcare Facilities and Services Act 2018 ("**PAHFAS**"), the Care Centres (Amendment) Act 2018 ("**CCA**"), the Malaysian government's decision to invoke compulsory licensing to allow Hepatitis C patients to gain access to affordable medicine, as well as key amendments in the revision of the Drug Registration Guidance Documents ("**DRGD**").

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

We hope that you find these updates useful. Please contact us if you have any queries or require any assistance.

## New Dental Bill to Give Teeth to the Dental Council and the Dental Therapist Board

In late 2017, the Dental Bill 2017 ("**Dental Bill**") was passed by the Malaysian parliament and is currently pending royal assent.

If it comes into force, the existing Dental Act 1971 ("**1971 Act**") will be repealed and the following key changes will be introduced:

- The Malaysian Dental Council ("**Council**") and the Malaysian Dental Therapist Board ("**Board**") will be established to enhance the regulatory framework for the practice of dentistry. Briefly, the Council will govern dental practitioners and specialists and be represented by accredited dental surgeons from both the public and private sector; whereas the Board will govern dental therapists and post-basic dental therapists. The existing dental council established under the 1971 Act will be dissolved.

- The existing Dental Register will also provide for the registration of specialists. Unless a dentist is registered as a specialist in that particular specialty, he/she is not allowed to represent himself/herself as a specialist or carry out dental procedures which are usually carried out by such specialists.

- Dental therapists, formerly known as school dental nurses who practise exclusively in the public sector to provide basic dental care to school children aged 12 years and below, will be able to practise in the private sector as well as the public sector.

- The provisions of the Bill will be administered by the Council and the Board. The Director General of Health is also empowered to exercise powers of enforcement through its public officers. This will substantially strengthen enforcement in the practice of dentistry, given that the existing 1971 Act does not provide for enforcement against illegal dentists or unregistered practitioners practising in registered premises.

The Dental Bill and the explanatory note of the same may be found here.

## Higher Standards in the Aged Care Industry Anticipated

On 28 March 2018, the Private Aged Healthcare Facilities and Services Act 2018 ("**PAHFAS**") and the Care Centres (Amendment) Act 2018 ("**CCA**") received royal assent and will come into force on a date to be appointed by the Minister of Health. As Malaysia has recently experienced a change of Government, it is uncertain when the Minister of Health will appoint this date.

The PAHFAS and the CCA aim to ensure that there is a clear line of demarcation between regulations which are applicable to centres which provide care to those below 60 and those which provide care to aged persons (i.e. persons who are 60 years old or above). More stringent requirements are imposed on the latter. Among others, operators of the centres which provide care to aged persons will have to obtain a pre-approval and an operating licence from the Director General of Health ("**DG**") and observe various obligations imposed upon them. These include, among others, ensuring that there is at least one qualified healthcare professional available at their premises, ensuring that the caregivers are trained and competent as well as ensuring that the managers in charge are trained, qualified and experienced, meeting the standard to be determined by the DG.

Our previous article on the changes which will be introduced by the PAHFAS and CCA is available here.

## Malaysia Invokes Compulsory Licensing of Hepatitis C Drug

In September 2017, the Malaysian Government announced that it had exercised its rights under the Rights of Government provision in the Patents Act to exploit the use of the Hepatitis C drug, "Sofosbuvir". The provision allows the government to exploit a patented invention without the agreement of the patent owner where, among others, it deems that there is a national emergency or where the public interest, such as nutrition or health.[1]

[1] https://kpkesihatan.com/2017/09/20/press-statement-minister-of-health-20th-september-2017-implementation-of-the-rights-of-government-for-sofosbuvir-tablet-to-increase-access-for-hepatitis-c-treatment-in-malaysia/

Malaysia is the first nation in the world to invoke compulsory licensing, which authorises a local import company to bring in the generic version of the Hepatitis C drug or to manufacture it itself by a local generic company.

The move, which allows Hepatitis C patients in Malaysia to gain access to affordable medicine, received international recognition in January 2018, when Malaysia was awarded the Leadership Award in Intellectual Property and Access to Medicines at the Global Summit of Intellectual Property and Access to Medicines. The summit was organised by the International Treatment Preparedness Coalition, which brings community representatives, governments, civil society, academics, experts and international agencies together to look at the impact of international trade rules on public health.

The Government's move highlights the plight of Malaysians who suffer from Hepatitis C and are unable to afford the medication which can cost up to RM 300,000 (approx. USD 74,055). As it is considered a middle income country, Malaysia does not receive special prices from pharmaceutical companies for newer drugs.[2]

The eventual result in the long-run will be that Sofosbuvir is available at an affordable price in public health facilities. In the short-run, it is estimated that 2,000 chronic Hepatitis C patients out of the 23,000 registered with the Ministry of Health will undergo the first phase of Sofosbuvir-based direct-acting antiviral (DAA) therapy across eighteen selected government hospitals for free within this year.[3]

## Spring-Cleaning the Drug Registration Guidance Document

The National Pharmaceutical Regulatory Agency ("**NPRA**") has made key amendments in the January 2018 revision of the Drug Registration Guidance Documents ("**DRGD**"). The key changes include changes on requirements for the registration of generic products, changes to the timeline for submitting additional documents or information, and additional requirements for the limit test for heavy metals.

**Registration of generic products.** It is now a requirement for product registration holders ("**PRH**") to provide patent declarations. These declarations are that all legal provisions in Malaysia will be complied with, that the government is not responsible for any committed offence and that the PRH will indemnify the government if a claim arises from the PRH's breach of law.

**Timeline.** The timeline for submitting any additional document or information has been standardised and streamlined. Such submissions should be made within 60 days from the date when appeal confirmation has been given. Not only is this a far shorter timeline, it is also applicable to all categories of products. Prior to this

[2] https://www.thestar.com.my/news/nation/2018/01/19/malaysia-awarded-for-gutsy-move-govt-invokes-compulsory-licensing-for-affordable-hepatitis-c-medicin/
[3] Bernama Plus (2018), '*18 Hospitals Offer Free DAA Therapy for Treatment of Hepatitis C*', [online]. Available at: http://plus.bernama.com/v1/news2.php?id=1445960

amendment, the timeline was 180 days for new drug products and biologics, and 90 days for all other products.

**Limit test for heavy metals.** There have also been changes to the requirements for when limit test for heavy metals should be conducted. The test must now be conducted specifically on the finished product of health supplements. Previously, the test may be done either on the raw materials or on the finished products.

It is clear that the NPRA has taken measures to improve the DRGD, thereby making the guidelines more straightforward and reducing confusion.

The latest version of the DRGD and the complete list of amendments made to the DRGD are available here and here.

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