Newsletter

July 2016

In This Issue:

Drug Regulation Streamlined Under Health Products Act With Effect From 1 November 2016

More Than 25,000 Units of Illegal Health Products Seized by HSA as Part of Operation Pangea

Human Biomedical Research Act Partially In Force From 1 July 2016

MOH Suspends 2 Dental Clinics from CHAS

Public Consultation on Third Party Funding in Civil Litigation Ends 29 July 2016

For further information please contact

Andy Leck
+65 6434 2525
andy.leck@bakermckenzie.com

Lim Ren Jun
+65 6434 2721
ren.jun.lim@bakermckenzie.com

Baker & McKenzie.Wong & Leow
8 Marina Boulevard
#05-01 Marina Bay
Financial Centre Tower 1
Singapore 018981

www.bakermckenzie.com

Drug Regulation Streamlined Under Health Products Act With Effect From 1 November 2016

On 15 July 2016, new legislation was gazetted to streamline regulatory controls for pharmaceutical products under the Health Products Act ("**HPA**"), as a new category of health products under the HPA, known as "therapeutic products" ("**TP**"). The new legislation will come into force on 1 November 2016.

As explained in last December's edition of our Healthcare newsletter (here), these controls have been migrated from the Medicines Act and the Poisons Act.

Key changes include:

- Product licences under the Medicines Act will be converted to product registrations; the Certificate of Registration of a Pharmacy will be renamed to "Pharmacy Licence".
- Existing product licence holders will have to apply for an Importer's Licence ("**IL**") and/or Wholesalers' Licence ("**WL**") if they intend to import and/or wholesale their own registered TP.
- IL and WL holders will be required to name at least one Responsible Person ("**RP**") in their respective IL and WL. The RP is a person / registered pharmacist (if the company deals in medicines), who is employed and appointed by the licensee to implement and maintain an effective quality system that meets Good Distribution Practice (GDP) standard.
- Form A Poisons Licence will not be required for dealings in TP. However, the Poisons Act will still apply to Active Pharmaceutical Ingredients, laboratory reagents and veterinary products.
- Poisons Licence for companies dealing in TP only will be automatically deactivated, unless the HSA is informed otherwise by the company before 1 November 2016.

Applications for IL and WL may be done online from **1 August 2016**.

More information on the new regulations can be found on HSA's website here.

More Than 25,000 Units of Illegal Health Products Seized by HSA as Part of Operation Pangea

The Singapore Health Sciences Authority ("**HSA**") recently seized more than 25,000 units of illegal health products valued at about S$21,000 as part of Operation Pangea, an annual week-long, Internet-based enforcement action coordinated by INTERPOL.

Anabolic steroids, sleeping pills, pregnancy test kits, and medicinal drugs for infertility and weight loss were among the health products seized. The anabolic steroids, which had an estimated street value of S$13,000, were sold on various e-commerce platforms and at local gyms.

The HSA has also been collaborating with major local e-commerce websites and local online forums to detect and remove posts that sell illegal health products. These websites also provide advisories to inform users on what health products cannot be sold online.

Any sale in contravention of the law may result in prosecution under the Health Products Act, Poisons Act and/or Medicines Act. Offenders will face a fine of up to S$100,000 and/or imprisonment for up to three years under the Health Products Act; a fine of up to S$10,000 and/or imprisonment for up to two years under the Poisons Act, and a fine of up to S$5,000 and/or imprisonment for up to two years under the Medicines Act.

Human Biomedical Research Act Partially In Force From 1 July 2016

The Singapore Human Biomedical Research Act ("**HBRA**") was enacted in August 2015 and parts of it have come into force on 1 July 2016.

Essentially, the sections in force will establish the administrative body and advisory committees under the HBRA. These bodies will collectively promulgate codes of practice and codes of ethics to give guidance to the industry on the application of the HBRA.

The other provisions concerning the regulation of human tissue activities and biomedical research have yet to come into effect. In the meantime, companies may wish to review existing procedures for prophylactic compliance with the HBRA.

MOH Suspends 2 Dental Clinics from CHAS

The Singapore Ministry of Health ("**MOH**") has, for the first time, suspended 2 dental clinics which made fraudulent claims for dental treatments, from the Community Health Assist Scheme ("**CHAS**"). It was reported that several other clinics are also under investigation for making errant claims.

Some of the inappropriate claims include claims for procedures that were not carried out, or claims for ineligible treatments.

The matter has been referred to the police for further investigations. Any professional misconduct would be dealt with by the relevant disciplinary committee for the profession - in this case, the Singapore Dental Council.

Public Consultation on Third Party Funding in Civil Litigation Ends 29 July 2016

Third party funding of litigation has traditionally been frowned upon for public policy reasons, but this is set to change with the Singapore Ministry of Law's review of the Civil Law Act to allow third party funding for certain types of proceedings:

(i) international arbitration proceedings;
(ii) court / mediation proceedings arising out of international arbitration proceedings;
(iii) application for stay of proceedings pending arbitration; and
(iv) enforcement of arbitral awards.

The proposed legislative amendments to the Civil Law Act, and associated amendments to the Legal Profession (Professional Conduct) Rules 2015 will collectively:

(a) prescribe certain categories of dispute resolution proceedings which allow third party funding contracts;
(b) prescribe criteria for a third party funder to fulfil before it may enforce its rights under the third party funding contract; and
(c) lawyers will be under a duty to disclose the existence of a third party funding contract and identity of the third party funder to the Court / tribunal and to every other party to the proceedings.

The consultation is open for comments until 29 July 2016. Interested parties may obtain more information from the Ministry of Law's website here.