LEGAL UPDATE

# HEALTHCARE SECTOR UPDATE

**11 November 2014**

# NEW GUIDELINES AND PROPOSED REGULATIONS FOR THE HEALTHCARE SECTOR

## BACKGROUND

This article provides an update on a number of healthcare and life sciences related developments in recent months, namely:

(a) the Human Biomedical Research Bill;

(b) the two proposed regulations for "therapeutic products" under the Health Products Act (Cap. 122D) ("**HPA**");

(c) the new Personal Data Protection Commission ("**PDPC**") Advisory Guidelines for the Healthcare Sector; and

(d) the draft home care guidelines ("**Home Care Guidelines**") and centre-based care guidelines ("**Centre-Based Care Guidelines**") issued by the Ministry of Health ("**MOH**").

On 6 November 2014, MOH issued a public consultation on the draft Human Biomedical Research Bill. The Human Biomedical Research Bill will regulate the conduct of human biomedical research and issues relating to human tissues and tissue banks. It is noted that the intention is for clinical trials to continue to be regulated under the existing clinical trial regulations. MOH's public consultation will close on 18 December 2014.

In October 2014, the Health Sciences Authority ("**HSA**") launched a public consultation on two sets of proposed subsidiary legislation for the transfer of controls of certain pharmaceutical products which are currently regulated under various legislation such as the Medicines Act (Cap. 176) and the Poisons Act (Cap. 234) ("**Therapeutic Products**") to the HPA. The public consultation on these proposed regulations will close on 23 November 2014.

Another aspect which has come under the spotlight in recent years is in relation to the collection, use and disclosure of personal data within the healthcare sector. Traditionally, organisations in the healthcare sector collect a large amount of personal data, much of which are of a highly sensitive nature. While the Personal Data Protection Act 2012 ("**PDPA**") came into force earlier this year, the personal data protection requirements under the PDPA only operate as a baseline standard and do not override any existing or sector-specific requirements which healthcare organisations need to comply with. To this end, the PDPC, in consultation with MOH, has developed a set of guidelines specific to the healthcare sector, to address some of the unique circumstances faced by the healthcare sector in complying with the PDPA requirements. The new PDPC Advisory Guidelines for the Healthcare Sector was issued on 11 September 2014.

Further, with the number of elderly citizens in Singapore set to triple to 900,000 by 2030,[1] healthcare establishments and providers in Singapore are likely to see an increased demand for intermediate and long term care ("**ILTC**") services. Currently, ILTC services are generally provided through community hospitals, chronic sick facilities, nursing homes, hospices, eldercare centres or home care service providers. As part of MOH's ongoing efforts to enhance the quality of care in the ILTC sector, MOH launched a public consultation on two sets of draft guidelines, namely, the Home Care Guidelines and ("**Draft MOH ILTC Guidelines**"), one for home care ("**Home Care Guidelines**") and the other for centre-based care. The public consultation closed on 2 October 2014.

[1] Source: http://population.sg/key-challenges/

## PART I: PROPOSED HUMAN BIOMEDICAL RESEARCH BILL

On 6 November 2014, MOH issued a public consultation on the proposed Human Biomedical Research Bill.

The Human Biomedical Research Bill will regulate the conduct of human biomedical research and issues relating to human tissues and tissue banks.

### Regulation of human biomedical research

Under the Human Biomedical Research Bill, all human biomedical research will need to be conducted under the supervision and control of a research institution.

"Human biomedical research" is proposed to be defined as:

(a) any research that is intended to study:

(i) the prevention, prognostication, diagnosis or alleviation of any disease, disorder or injury affecting the human body;

(ii) the restoration, maintenance or promotion of the aesthetic appearance of human individuals through clinical procedures or techniques; or

(iii) the performance or endurance of human individuals,

where the research involves:

(1) subjecting an individual to any intervention (including any wilful act or omission) that has a physical, mental or physiological effect (whether temporary or permanent) on the body of the individual;

(2) the use of any individually-identifiable human biological material; or

(3) the use of any individually-identifiable health information; and

(b) any research that involves:

(i) human embryos or human gametes;

(ii) human-animal combination embryos created by the incorporation of human genetic material or human cells; or

(iii) the introduction of human genetic materials or human cells into animals, including prenatal animals.

In relation to the conduct of human biomedical research, the Human Biomedical Research Bill details various obligations on the research institution, the individual researchers and institutional review boards, including requirements in relation to:

(a) how consent is to be obtained from research subjects (whether they are adults or minors), including the types of mandatory information that must be provided to a research subject prior to taking their consent;

(b) the duty on every person who has obtained any individually-identifiable information or human biological material that is obtained for the purposes of human biomedical research to take all reasonable steps and safeguards as may be necessary to protect such information or material against accidental or unlawful loss, modification or destruction, or unauthorised access, disclosure, copying, use or modification;

(c) the appointment of one or more institutional review boards by a research institution for the purposes of reviewing human biomedical research conducted under the control or supervision of that research institution; and

(d) the submission of a declaration of compliance by a research institution in

respect of any proposed human biomedical research to be conducted by such research institution.

## Prohibited human biomedical research

It should be noted, however, that the following types of human biomedical research are prohibited under the Human Biomedical Research Bill:

(a) human biomedical research involving the development of human-animal combination embryos beyond 14 days or the appearance of the primitive streak, whichever is the earlier; and

(b) human biomedical research involving the insertion of brain-specific human cells or human stem cells into the brains of great apes.

## Regulation of human tissues and tissue banks

The Human Biomedical Research Bill also sets out regulations in relation to the collection and use of human tissue and the operation of tissue banks, including:

(a) the prohibition of commercial sale or supply of human tissues;

(b) the requirement to notify MOH's Director of Medical Services of any tissue bank which a research institution is directly or indirectly operating, or a tissue bank which is part of the research institution;

(c) the submission of a declaration of compliance by a research institution for all tissue banking activities conducted under the supervision or control of the tissue bank; and

(d) the requirements (*eg* consent) that must be satisfied before any human tissue can be removed from a donor for a therapeutic or diagnostic purpose, or for any other purposes.

It is pertinent to note that the Human Biomedical Research Bill also deals with "legacy human biological material" which includes any human biological material which has been removed from a human body at any time before the date on which the provisions in the Human Biomedical Research Bill come into legal effect.

## Feedback sought by MOH

MOH is currently seeking public feedback on the proposed regulatory frameworks for human biomedical research and human tissue use in research, including how these frameworks can be improved to:

(a) safeguard the safety and welfare of human research subjects;

(b) better protect the safety and welfare of tissue donors;

(c) prohibit commercial trading of human tissue effectively; and

(d) ensure human tissues used in biomedical research are obtained only through altruistic donations.

MOH's public consultation on the draft Human Biomedical Research Bill will close on 18 December 2014. MOH has also indicated that the Human Biomedical Research Bill may be enacted in 2015.

# PART II: PROPOSED NEW REGULATIONS FOR THERAPEUTIC PRODUCTS UNDER THE HEALTH PRODUCTS ACT

## Background

In 2012, HSA announced that there were plans to import the regulatory control of Western medicines (or medicinal products) under the HPA by way of a new category of regulatory products known as "Therapeutic Products" with the intent that the HPA will serve as the consolidated legislation regulating such medicines. At that time, HSA had conducted the proposed definition for the category of products termed Therapeutic Products.[2]

[2] Details on this public consultation may be accessed on HSA's website at: http://www.hsa.gov.sg/content/hsa/en/News_Events/Public_Consultation1/Proposed_Health_Products_Act_Amendment_Of_First_Schedule_Order.html

As part of this transfer of the regulatory controls for Therapeutic Products, HSA has indicated[3] that it will be releasing four sets of subsidiary legislation under the HPA. These will cover all aspects of Therapeutic Product regulation, including clinical trials, manufacture, registration, import, supply, presentation, advertisement, adverse event reporting and enforcement.

## Proposed Regulations

On 27 October 2014, HSA launched a public consultation on the first two sets of proposed subsidiary legislation pertaining to the transfer of controls of Therapeutic Products to the HPA.

The two sets of proposed subsidiary legislation relate to:

(a) advertisements for Therapeutic Products; and

(b) the licensing of retail pharmacies which supply, amongst others, Therapeutic Products

(hereinafter referred to as the "**Proposed Regulations**").

While HSA is proposing to retain the fundamental controls for Therapeutic Products and transfer these to the HPA, HSA has proposed several changes to the existing system of regulatory controls for this category of products in light of industry and market developments.

The key proposed changes include:

(a) removal of the existing permit system for advertisements of Therapeutic Products. Instead, the HSA is proposing for advertisers to self-regulate based on broad principles and requirements prescribed in the Proposed Regulations, while at the same time strengthening its post-market controls;[4]

(b) all direct-to-consumer advertisements of Pharmacy-Only Medicines will need to carry advisories and/or warnings as may be required by HSA; and

(c) new provisions on the provision of telepharmacy services (*ie* any retail pharmacy services by a registered pharmacist at a retail pharmacy through a computer, or video or audio link, to a person other than a registered pharmacist at another retail pharmacy) by licensed retail pharmacies.

HSA's public consultation on the Proposed Regulations will close on 23 November 2014.

## PART III: NEW ADVISORY GUIDELINES ON PERSONAL DATA PROTECTION IN THE HEALTHCARE SECTOR

The PDPC's Advisory Guidelines for the Healthcare Sector ("**PDPC Healthcare Guidelines**") provide some illustrative guidance as to the obligations under the PDPA relating to consent, purpose limitation, notification, access and correction, protection, accuracy, retention limitation, transfer limitation and openness. Guidance is also provided in relation to the Do-Not-Call provisions ("**DNC Provisions**") under the PDPA.

It should be noted that the PDPC Healthcare Guidelines do not have legally binding effect, and the intent is that the guidelines would provide only general guidance on the manner in which the PDPC will interpret provisions of the PDPA. Organisations in the healthcare sector will remain responsible for assessing what appropriate action or decision is to be taken or made in their particular circumstances, for purposes of complying with the PDPA.

For more details on some of the illustrations provided in the PDPC Healthcare Guidelines in relation to the data protection provisions and the

[3] See HSA's press release at: http://www.hsa.gov.sg/content/hsa/en/News_Events/Press_Releases/2014/hsa-seeksviewsproposedadvert-pharmacylicensing.html

[4] It may also be noted that the fines that may be imposed under the HPA for illegal advertisements (up to S$20,000, or up to S$40,000 for corporate offenders) are higher than those under the Medicines Act (which currently provides that fines up to S$5,000 may be imposed on a person).

DNC Provisions, please refer to our earlier legal update **here**.

## PART IV: THE DRAFT MOH ILTC GUIDELINES

The Draft MOH ILTC Guidelines are intended to set out the standard of care that all centre-based care and home care providers should aspire to achieve, in terms of delivering holistic and safe care, the dignity afforded to seniors and the organisational systems and management processes of these providers. The guidelines were developed by two committees comprising service providers, healthcare professionals and policy experts, based on existing good practices in the respective sectors.

In its press release on the Draft MOH ILTC Guidelines, MOH explained that the Agency for Integrated Care ("**AIC**") will be developing an interpretation guidebook to explain the intent of the guidelines and provide sample tools and checklists. Training roadmaps and curricula will also be developed by AIC to help service providers build up their capabilities in the areas articulated in the Draft MOH ILTC Guidelines.

MOH has indicated that it is targeting to finalise these guidelines by end of 2014.

### Draft Home Care Guidelines

Home-based services are provided within the homes of frail and home-bound elderly persons, and the services provided typically include home medical care, home nursing care, palliative home care, meals-on-wheels, escort and transport services and ensuite services (*eg* care services to assist an elderly person with personal hygiene, housekeeping, medication reminder service, mind-stimulating activities and other personal care tasks).

The draft Home Care Guidelines relate to four domains of care provision, namely:

(a) holistic home care;

(b) quality of care;

(c) informed and enabling care; and

(d) sustainable care.

To achieve the outcome of providing holistic home care, the draft Home Care Guidelines set out a detailed set of guidelines as to the role of providers in providing specific types of home care services (such as home medical and nursing services, home social care, home rehabilitation services, home palliative care, and psychological and dementia support), as well as the expected outcomes that care providers are to achieve. For instance, one of the expected outcomes is care coordination. In this regard, the draft Home Care Guidelines provide that it is the responsibility of care providers to deliver holistic, multi-disciplinary home care services by coordinating with its network of health and social care partners.

In relation to the quality of care to be offered by home care providers, the draft Home Care Guidelines also offers comprehensive guidance on several critical areas of care identified by MOH. These identified areas are continence and bowel care, pain management, dealing with pressure ulcers, handling and administration of medication, infection control and fall prevention. Home care providers are also required to ensure that the care provided is documented in a timely and accurate manner, and further that adequate, suitably-trained staff are available for the safe delivery of care and services.

Under the draft Home Care Guidelines, home care providers are also expected to work towards providing informed and enabling care. This means treating seniors with dignity and respect, and to promote seniors' independence by giving them adequate information as well as involving them and their caregivers in decisions about their own care, goal-setting and care plans. There is also an emphasis on the protection of seniors' privacy, and confidentiality of their information. Home care providers should also respect and manage all feedback and complaints from seniors and their caregivers fairly, promptly and without prejudice, in addition to implementing prompt and effective incident management and reporting systems.

MOH also emphasises the role of robust organisational systems and management processes in ensuring that quality of service provided by home care providers remains sustainable. To this end, effective corporate governance processes as well as financial

management and reporting processes should be implemented. Home care providers should also actively identify potential risks, and address them to ensure the safety of seniors, their caregivers and the care providers themselves.

## Draft Centre-Based Care Guidelines

Centre-based healthcare services cater to older persons who require care services during the day (*eg* community rehabilitation services, dementia day care services and social day care services). These services are mostly provided by day care centres located within the community, enabling those in need to receive services in a familiar environment close to their homes.

Similar to the draft Home Care Guidelines, the draft Centre-Based Care Guidelines cover the following four areas:

(a) provision of care services;

(b) safety;

(c) dignity of care; and

(d) orgnanisational excellence.

On the topic of provision of care services, the draft Centre-Based Care Guidelines provide that centre-based care providers are to facilitate seniors' access to services (*eg* in terms of transport to the centre), develop individualised care plans for seniors and adopt a multi-disciplinary, holistic approach in delivering care services. Care coordination with other centres and caregivers (*eg* to ensure proper handover and continuity of care) is also identified as one of the important service aspects for centre-based care providers. The draft guidelines also sets out the aims and the typical scope of services that should be provided where sessional rehabilitation services, social day care services, dementia care services or centre-based nursing services are offered.

In terms of safety, centre-based care providers should ensure that, first and foremost, they comply with the relevant statutory requirements, such as those concerning infection control. The draft Centre-Based Care Guidelines also provide guidance on hygiene, handling of medication, fire safety, restraints, equipment, food safety and fall prevention. In particular, the guidelines elaborate on the need to create a safe and conducive environment that considers the needs of seniors generally, as well as those with dementia and physical impairment.

An important aspect of centre-based care delivery is the dignity and autonomy of seniors who receive care from these centres. In this regard, the draft Centre-Based Care Guidelines encourages care providers to facilitate and empower seniors to make informed decisions about their own care and to be independent both within and outside the centre. Within the organisation, there should also be policies and procedures in place to protect elders from abuse (which includes physical or psychological ill-treatment, careless or reckless acts or neglect), as well as to regularly assess and address possible abuses within and outside the centre.

The draft Centre-Based Care Guidelines also elaborate on the organisational framework that centres should put in place to ensure effective and sustainable delivery of care services by their staff. For instance, there should be documented corporate governance policies that facilitate proper accountability, written policies on fees and charges, as well as documented internal controls on the handling of cash and deposits as well as spending approvals. Centres should also strive to improve their practices and quality of care on a continuing basis, as well as engage in regular risk assessment to ensure the safety of seniors and their caregivers.

## A step towards promoting greater transparency in the ILTC sector

Given the spate of reported cases over the last few years involving the abuse of elderly persons by caregivers and at eldercare centres, the proposed introduction of the draft Home Care Guidelines and the draft Centre-Based Care Guidelines appears timely. To date, there is no uniform set of requirements which have been made publicly available regarding the management and operations of care providers in the ILTC sector, or the standard of care that such providers are to maintain.

The issuance of the Draft MOH ILTC Guidelines will assist to shed more transparency on the standards of service provided by home and centre-based care providers. As indicated by MOH, the

Draft MOH ILTC Guidelines will serve as a basis for training and capability enhancement programmes for providers of home and community care. Further, the Draft MOH ILTC Guidelines are likely to promote greater transparency in the ILTC sector, in particular, in providing a useful reference as to the standards of care that the public can expect when they engage the services of centre-based and home care providers.

## REFERENCES

Please click on the following links to access the documents.

1. **Draft Human Biomedical Research Bill**
2. **Explanatory Notes on Draft Human Biomedical Research Bill**
3. **Draft Health Products Act (Amendment Of First Schedule) Order 2011**
4. **Draft Health Products Advertisement Regulations**
5. **Explanatory Guidance for Health Products Advertisement Regulations**
6. **Summary of Proposed Changes on Advertisements of Health Products**
7. **Draft Health Products Pharmacy Licensing Regulations**
8. **Summary of Proposed Changes for Pharmacy Licensing**
9. **PDPC Advisory Guidelines for the Healthcare Sector**

---

If you have any questions or comments on this article, please contact:

**Tony Yeo**
Director, Healthcare & Life Sciences
(Disputes & Intellectual Property)
T: +65 6531 2512
E: tony.yeo@drewnapier.com

**Benjamin Gaw**
Director, Healthcare & Life Sciences
(Corporate & Regulatory)
T: +65 6531 2393
E: benjamin.gaw@drewnapier.com

Drew & Napier LLC
10 Collyer Quay
#10-01 Ocean Financial Centre
Singapore 049315

**www.drewnapier.com**

T : +65 6535 0733
T : +65 9726 0573 (After Hours)
F : +65 6535 4906

LEGAL UPDATE