Health Sciences Authority
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INFORMATION ON THE REGULATIONS OF THERAPEUTIC PRODUCTS UNDER THE HEALTH PRODUCTS ACT (FOR DOCTORS AND DENTISTS)

EXECUTIVE SUMMARY

1) From **1 November 2016**, pharmaceutical products will be regulated as "***Therapeutic Products***" (TP) under the Health Products Act (HPA), replacing existing controls under the Medicines Act (MA) and the Poisons Act (PA).

2) Compounding of TP include repacking or relabelling of the TP, e.g. transferring the TP from its original container supplied by its manufacturer into another container before dispensing. New labelling requirements will apply to these compounded TP, i.e. (i) Name of TP and quantity of active ingredients (e.g. XYZ Tablet 500 mg), (ii) expiry date and (iii) batch number.

3) Noting that time might be required to adjust clinic management systems to take in these new labelling requirements, HSA will allow a period of 6 months from 1 November 2016 to 30 April 2017 for practitioners to comply with the labelling requirements.

4) Labelling requirements for dispensing of TP remain the same. As a good practice, the expiry dates should be available on the dispensed TP for patients' information so that the TP is not used beyond this date.

5) To facilitate prompt access to therapies fulfilling an unmet medical need, the import and supply of unregistered TP, commonly referred to as the '*Named-patient exemption route*', will continue to be allowed. This special access route will be referred to as import and supply of TP '*for patients' use*' under the HPA.

6) Advertisement controls of TP remain the same. Direct to consumer advertisements on Prescription only medicines (POM) will not be allowed and such materials should not be made available in publicly accessible areas e.g. patients' waiting areas.

7) General Sale List medicines (GSL), which currently can be purchased off the shelves and are deemed to be sufficiently safe to be used by public, will be allowed to be sold via vending machines.

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BACKGROUND

The Health Products Act (HPA) was introduced in 2007 with the aim to consolidate and streamline all the regulatory controls of health products under one single Act. The consolidation is done in phases to cover a range of health products, beginning with the Medical Devices Regulations in 2007.

From **1 November 2016**, pharmaceutical products (e.g. Western medicines and vaccines) will be regulated as "***Therapeutic Products***" (TP) under the HPA, replacing the existing controls under the Medicines Act (MA) and the Poisons Act (PA). Nonetheless, the regulatory controls of TP under HPA are largely similar to those under MA and PA. The objectives remain to ensure that appropriate safeguards are in place to protect public health through assuring safety, quality and efficacy of the TP as well as ensuring proper integrity of supply chain and product traceability.

The following sections provide information on the regulatory controls on TP that would be most relevant to doctors and dentists ("practitioners"), namely in the (A) labelling requirements for TP, (B) import and supply of unregistered medicines via special access route, (C) advertisement controls of TP and (D) supply of general sales list medicines (GSL) via vending machines.

A. LABELLING REQUIREMENTS FOR THERAPEUTIC PRODUCTS (TP)

1) Compounded TP

Compounding of TP refers to the activity to formulate, mix, assemble, package or label the TP, with the intention of dispensing or administering the TP to a patient. This include repacking or relabelling of the TP, e.g. transferring the TP from its original container supplied by its manufacturer into another container before dispensing (e.g. for liquids or loose tablets/capsules).

Table 1 below lists the requirements for labelling of compounded TP. These requirements are set out to ensure that the identification, quality and traceability of the compounded TP are maintained throughout the supply chain up to the safe use by patients.

The practitioner has the flexibility to design and implement the appropriate processes to comply with these requirements in his/her clinical practice. These processes must be sufficiently robust to ensure that compounded TP can be identified and traceable (e.g. in product recall situations), as well as within its expiry dates to ensure that the TP is not used beyond this date.

Table 1: Labelling requirements for compounded TP

Information required	Purpose
1) Name of TP	For the identification of the TP e.g. XYZ Tablet 500 mg
2) Quantity of the active ingredient(s)	
3) Expiry date of the TP	To ensure that the TP is not used beyond this date
4) Control number (e.g. Serial/lot/batch number)	For traceability of the TP supplied should there be any recall or adverse events

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For illustration purposes, please see a sample label for repacked TP, XYZ Tablet 500 mg:

XYZ Tablet 500 mg Expiry date: DD MMM YYYY Batch No.: 1234

Expiry dates: The stability of the TP may have been altered (e.g. shortened) when it is removed from its original immediate packaging (primary packaging). Therefore, for compounded TP, an appropriate expiry date should be assigned either in accordance with the Pharmacopoeias* or supported by a stability study to ensure that those supplied remain of good quality for consumption.

*[*Note: Recognized Pharmacopoeias are the British Pharmacopoeia (B.P); the European Pharmacopoeia (Ph. Eur) and the United States Pharmacopoeia and the National Formulary (USP/NF)]*

For TP transferred from their original container into another container (e.g. for liquids or loose tablets/capsules), the expiry date of the repacked TP can generally be assigned as 1 year from the date of repacking or the manufacturer's expiry date, whichever is earlier. This is in line with the recommendations in the Pharmacopoeias* e.g. USP/NF.

Control number e.g. serial/lot/batch number must be available on the compounded TP to ensure traceability e.g.:

- *For TP transferred from their original container into another container (e.g. for liquids or loose tablets/capsules):* The control number of the repacked TP can be the same as that stated on the original packaging supplied by the manufacturer.

- *For TP packaged following mixing and/or reformulation:* Mixing and/or reformulation of multiple TP is a subject of professional discretion. The practitioner is responsible for quality, safety, efficacy and traceability of the final compounded TP. The practitioner must ensure that any control number assigned will allow the traceability and identification of the compounded TP.

For clarity, tablets/capsules in their original blister strips (primary packaging) repacked into zip-lock bags may already have the expiry dates and batch numbers indicated on their blister strips. Therefore, there is no need to reproduce these information on a separate label. If these are not present on the blister strips but present on the products' original outer carton labels, the information should be made available accordingly on the repacked TP prior to dispensing for patient's information.

Implementation of the labelling requirements for compounded TP:
Noting that time might be required to adjust clinic management systems to take in these new labelling requirements, HSA will allow a period of 6 months from 1 November 2016 to 30 April 2017 for the practitioners to comply with the new requirements.

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2) Dispensing of TP

Table 2 below lists the labelling requirements on a dispensing label of a TP. These requirements are similar to the current requirements under the Medicines Act.

Table 2: Labelling requirements during the dispensing of TP

Information required
1) Name of TP e.g. XYZ Tablet 500 mg 2) Name of patient 3) Directions of use of the TP 4) Date of dispensing of the TP 5) Name and address of the hospital or clinic which dispensed the TP As a good practice, the expiry dates should be available on the dispensed TP for patients' information so that the TP is not used beyond this date.

B. IMPORT AND SUPPLY OF UNREGISTERED TP VIA SPECIAL ACCESS ROUTE

This is commonly referred to as the '*Named-patient exemption route*' and will continue to be allowed to facilitate prompt access to therapies required to fulfil an unmet medical need. This special access route will be termed as the import and supply of TP '*for patients' use*' under the HPA.

Prior product evaluation is not conducted by HSA for unregistered TP. To ensure the integrity of the supply chains, companies dealing in such activities will be required to meet Good Distribution Practice (GDP) standards through the relevant Importer's Licence (IL) and Wholesaler's Licence (WL). Hospitals, medical clinics and retail pharmacies which are conducting their own import of unregistered TP for patients' use will not be required to hold the IL and WL.

Upon the request of the Medical and Dental Associations, Table 3 below lists the companies currently holding the valid IL and WL, and are dealing in the import and supply of unregistered TP for patients' use. Please note that this list is accurate as of 20 October 2016 and remain dynamic as the business models of companies dealing in TP may change over time.

Table 3: List of companies currently holding the valid IL and WL, and are dealing in the import and supply of unregistered TP for patients' use (as of 20 Oct 2016)

S/N	**Companies**
1	ABBVIE PTE LTD*
2	AI BIOMED (S) PTE LTD
3	APEX PHARMA MARKETING PTE LTD
4	BAYER (SOUTH EAST ASIA) PTE LTD*
5	DKSH SINGAPORE PTE LTD
6	LF ASIA DISTRIBUTIION
7	NOVARTIS (SINGAPORE) PTE LTD*
8	NOVEM HEALTHCARE PTE LTD

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9	PAN-MALAYAN PHARMACEUTICALS PTE LTD
10	PHARMAFORTE SINGAPORE PTE LTD
11	SANOFI-AVENTIS SINGAPORE PTE LTD*
12	STEWARD CROSS PTE LTD
13	TRANSMEDIC PTE LTD
14	UNITED ITALIAN TRADING CORPORATION (PRIVATE) LIMITED
15	ZUELLIG PHARMA PTE. LTD.

**Multinational companies (MNCs) which may likely deal in their own brand of products.*

C. ADVERTISEMENT CONTROLS OF TP

Advertisement controls of TP remain the same to ensure that accurate and truthful information is disseminated and that the advertisement and sales promotion activities do not mislead consumers or induce unnecessary consumption of the HP.

Direct to consumer advertisements on Prescription only medicines (POM) will not be allowed and such materials should not be made available in publicly accessible areas e.g. patients' waiting areas. Nonetheless, practitioners can continue to share information of POM with their patients during consultation if deemed required.

D. SUPPLY OF GENERAL SALE LIST MEDICINES (GSL) VIA VENDING MACHINES

The access controls of TP in Singapore are calibrated based on the inherent risk of the TP and are categorised as one of the following:

- ***Prescription-only medicines (POM)***: the supply can only be made by a practitioner or by a pharmacist according to a prescription by a practitioner.
- ***Pharmacy-only medicines (P medicines)***: the supply can be made by or under the supervision of a pharmacist without a practitioner's prescription.
- ***General Sale List medicines (GSL),*** which can be purchased off the shelves and are deemed to be sufficiently safe to be used by public.

The supply of GSL via vending machines will be allowed under the HPA as an alternative route to the retail supply via a shop front.

Nonetheless, certain conditions are to be fulfilled as safeguards to consumers' safety and traceability of the GSL supplied:

- The name and the contact information of the vending machine operator should be prominently displayed to allow easy contact on matters related to the vending machine (e.g. reports on faulty machines) and the traceability of the GSL supplied
- The vending machine must be equipped and secure (e.g. tamper proof), to ensure appropriate storage conditions are maintained to prevent degradation of the GSL stored
- The GSL supplied must be labelled, packaged and in the pack size approved by HSA
- To ensure appropriate control in the quantity of medicines sold, the total amount of the GSL in each package does not exceed a total dosage of 3 months per individual

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REFERENCE

The following new subsidiary legislation have been gazetted on 15 Jul 2016 and are available on the Attorney-General's Chambers (AGC) website:

- Health Products Act (Amendment of First Schedule) Order 2016
  - Definition of "therapeutic products"
- Health Products (Therapeutic Products) Regulations 2016
- Health Products (Clinical Trials) Regulations 2016
- Health Products (Therapeutic Products as Clinical Research Materials) Regulations 2016
- Health Products (Advertisement of Therapeutic Products) Regulations 2016
- Health Products (Licensing of Retail Pharmacies) Regulations 2016

These are also available under the '*Regulation of Therapeutic Products under the Health Products Act'*, on the HSA Website at the following address:

http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/therapeutic-productsportover.html

CONTACT US:

Should you have any enquiries on the Regulations of Therapeutic Products under the Health Products Act, please email us at HSA_TPPortOver@hsa.gov.sg