ANNEX 1

GUIDANCE FOR PHMCA / HCSA LICENSEES AND TELEMEDICINE SERVICE PROVIDERS ON ADVERTISEMENT CONTROLS OF HEALTH PRODUCTS AND PROVISION OF NON-PROMOTIONAL INFORMATION TO THE PUBLIC
<Version 01; Published 01 12 2022>

1 INTRODUCTION

1.1 This Guidance aims to clarify the principles on:

a) advertisement of health products as prescribed under the Health Products Act (HPA) and its subsidiary legislation, and
b) the provision of non-promotional information on health products to the public

by healthcare service providers.

1.2 The scope of advertisement is broad and encompasses the dissemination or conveyance of any information that directly or indirectly promotes the sale of a health product. Advertisements of health products published locally are required to comply with the advertising requirements as prescribed in the legislation. These legislative controls ensure that the information of health products conveyed through advertisements is accurate, truthful and does not mislead or create unrealistic expectations.

1.3 The legislative controls also specify the restrictions for advertising to prevent inappropriate or undiscerning use of health products, potentially leading to harm to the consumer. For example, health products that can only be prescribed by a medical doctor or dentist (i.e., prescription-only medicines, professional-use only medical devices and cell, tissue or gene therapy products) are not allowed to be advertised to consumers. The decision for use of such products is dependent on the clinical assessment and judgement of the medical professionals and requires informed discussion with their patients.

1.4 Healthcare service providers are reminded to ensure that advertisements of health products that are allowed to be advertised to public [i.e., Pharmacy-only medicines and general sales list medicines which are not restricted to supply by prescription, and non-Professional Use Only medical devices (non-PUO MDs)] comply with all prescribed requirements. Failure to do so may constitute an offence under the relevant legislation. Materials intended for educating or informing consumers on diseases or medical conditions should also not contain information that may lead to the promotion of any specific health product. Such materials fall within the definition of an advertisement and may therefore be considered contraventions to the Regulations if they do not comply with the prescribed requirements and restrictions.

1.5 MOH and HSA would like to remind all PHMCA / HCSA licensees and TM service providers to comply with the requirements under the relevant regulations, such as HPA and PHMCA.

2 DEFINITIONS

2.1 **"Healthcare service providers"** in this Guidance refers to:

a) Healthcare institutions licensed under the Private Hospitals and Medical Clinics Act,
b) Licensees under the Healthcare Services Act, and
c) Telemedicine service providers (both direct and indirect[1]).

2.2 **"Publish"** in relation to an advertisement, includes to distribute, show, display, exhibit, issue, disseminate or broadcast by any form of communication or in any manner.

3 ADVERTISEMENT CONTROLS OF HEALTH PRODUCTS

3.1 Advertisements of health products are regulated by the Health Sciences Authority (HSA) under the Health Products Act (HPA) and its subsidiary legislation:

- Health Products Act
- Health Products (Advertisements of Specified Health Products) Regulations
- Health Products (Medical Devices) Regulations

3.2 An 'advertisement' is defined as the publication of any information that promotes, **whether directly or indirectly**, the sale or use of a health product. As such, information on health products published by service providers, that is **assessed to promote the use or sale of these products** would fall within the definition of an advertisement. This includes information on health products published on any media including but not limited to:

a) Printed materials such as brochures, pamphlets and mailers;
b) Websites such as corporate or healthcare institutions' websites;
c) Social media platforms such as blogs, Facebook and Instagram;
d) Mobile applications such as telemedicine platforms; and
e) Electronic Direct Mailers (EDMs).

3.3 It is important to note that the reference to or feature of any health products, named or otherwise such as, feature of image, descriptions to imply a specific health product, may also constitute an advertisement subject to the prevailing requirements.

3.4 In general, the intention and context of the information published on a health product will be considered in totality to determine if it falls within the ambit of the advertising laws administered by HSA and whether there are any contraventions to the laws. For example, if there are accompanying messages, visuals, captions, hashtags of product names, copywriting that include mention of symptoms/conditions being treated, etc that directly or indirectly promote the use or sale of a specific health product.

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[1] Direct providers refer to independent doctors/dentists offering teleconsultations themselves, OR organisations which have set up clinical and operational governance for their doctors and/or dentists to provide teleconsultations. Indirect providers refer to those who do not provide direct medical care, and only offer the technology support for telemedicine (e.g. platforms offering software-as-a-service for teleconsultation, directory listings, payment solutions).

4 PROHIBITIONS/RESTRICTIONS AND REQUIREMENTS ON ADVERTISEMENTS OF HEALTH PRODUCTS

4.1 Health products refer to:

a) Therapeutic products (TPs), commonly known as western pharmaceutical drugs and vaccines, are products intended for use in humans for a therapeutic, preventive, palliative, or diagnostic purpose, and they typically contain chemical or biologic substances as active ingredients. They are classified into Prescription-only medicines (POM), Pharmacy-only medicines (P) or General Sales List (GSL) depending on its restrictions in supply[2].

b) Medical devices (MDs) are products such as instruments, machines, implants intended for use in humans for health-related purposes such as diagnosing, preventing or alleviating diseases as well as the modification or support of the anatomy. Certain MDs are classified as professional-use only MDs (PUO MDs)[3] where their use should be by or under the supervision of doctors or dentists.

c) Cell, tissue or gene therapy products (CTGTPs) are health products that contains human cells or tissues, viable animal cells or tissues or recombinant nucleic acids, that are intended for use in humans for a therapeutic, preventive, palliative or diagnostic purpose. Their use should be by or under the supervision of doctors or dentists.

Advertising Restrictions/Prohibitions

4.2 TPs that are Prescription Only Medicines (POMs), Professional Use Only MDs (PUO MDs), and CTGTPs are not allowed to be advertised to the public as the decision for use of such products is dependent on the clinical judgement of the medical doctors or dentists and requires informed discussion with their patients. Hence, healthcare service providers should not advertise or promote the sale or use of these products to members of the public. This also applies to unregistered TPs that are imported and supplied via the Special Access Routes (SAR)[4] as well as unregistered TPs compounded and supplied for patients' use. Information that promotes the sale or use of specific POMs, unregistered TPs, PUO MDs or CTGTPs, whether directly or indirectly, including any offer for sale, shall be construed as an "advertisement" under the HPA accordingly, and hence subject to the prohibition.

4.2 Advertisements of TP that are POMs, PUO MDs and CTGTPs by companies that are directed to healthcare professionals should also not be made freely accessible to the general public (e.g., published on publicly accessible websites or displayed in publicly accessible areas) to prevent undue patient influence on the preferred use of certain POMs, PUO MDs and CTGTPs.

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[2] Refer to Appendix A for classification of therapeutic products and medical devices.

[3] Refer to Appendix A for classification of therapeutic products and medical devices.

[4] Under HSA's Special Access Routes (SAR), approval from HSA is required for the import and supply of unregistered TP for patient's use.

Advertisement requirements

4.3 TPs that are Pharmacy-only medicines and general sales list medicines and non-PUO MDs may be advertised to the general public. However, healthcare service providers have to ensure that the advertisements comply with the principles and requirements as stated in the HPA and the respective Regulations. Prior approval by HSA for these advertisements is not required.

4.4 Healthcare service providers are advised to take note of the following points in the advertisement of these products to public:

a) Advertisements of registered TPs and MDs must be aligned with the intended uses (indications) as per registered with HSA. Advertisement of unapproved uses is not allowed.

b) For Class A MDs exempted from product registration, the presentation and advertisements for the intended use of the MD must not deviate from the Product Owner's specifications.

c) Advertisements directed to the public are not allowed to promote any health product for the prevention, alleviation, or cure of a specified list of diseases and conditions (refer to Appendix B). This includes diseases and conditions such as diabetes, cancer, hypertension, sexual function and contraception.

d) Information conveyed in the advertisements must be accurate, truthful and advertising activities should not mislead consumers or induce inappropriate or excessive use. The offer of TPs without charge or with any other medicinal / health product e.g., bundled offer consisting of different products, is not allowed under the Regulations.

e) Recommendation and endorsements by healthcare professionals or celebrities encouraging the use of TPs are prohibited under the Regulations.

f) Claims indicating or suggesting that the use of the health product is promoted, supported, or endorsed by the Government or any public authority are not allowed.

4.5 Further details can be found in the following guidance documents:

- Advertisements and promotions of therapeutic products
- Advertisements and promotions of cell, tissue or gene therapy products
- Advertisements and promotions of medical devices

5 PROVIDING NON-PROMOTIONAL INFORMATION ON HEALTH PRODUCTS TO PUBLIC

5.1 Publication of factual and educational information intended to provide information on diseases and range of treatment options is allowed. Service providers are to ensure that information published are factual, substantiated and aligned with any prevailing requirements or guidelines such as practice guidelines.

5.2 Materials intended for educating or informing consumers on diseases or medical conditions should be well-balanced. Information relating to health products should be presented in the context of a balanced overview of all treatment options and relevant disease information. The materials should **not** lead to the promotion of **any specific health product** where an individual would be encouraged to select or approach a qualified practitioner for the specific product.

5.3 Such materials should not contain promotional elements including, but not limited to the following:

a) Reference to health product by brands, implied or otherwise such as through visuals, descriptions alluding to a particular product;
b) Indications and benefits associated with specific products; and
c) Content or terms that induces consumer demand for specific product(s) such as the usage of promotional or laudatory terms e.g., 'get it now', 'at a discounted rate', 'fastest', 'best', 'safest'.

5.4 Materials containing promotional elements relating to health product (named or otherwise) or assessed to promote the sale or use of health product (named or otherwise) shall be construed as an "advertisement" subject to advertisement controls and requirements prescribed under the relevant legislation. For avoidance of doubt, these controls would also apply to materials jointly produced by healthcare service providers and the industry. Both the healthcare service providers and the companies are responsible in ensuring that these materials published comply with the prescribed requirements.

6 CONCLUSION

6.1 Healthcare service providers are encouraged to review this set of Guidelines in conjunction with the relevant legislation as highlighted in the sections above to ensure that information published on health products do not contravene stipulated regulations.

6.2 For general enquiries relating to the prescribed requirements, please contact:
Medical Advertisements and Compliance Monitoring Unit
Vigilance and Compliance Branch
Email: HSA_MA@hsa.gov.sg

6.3 Please note that HSA does not vet or edit specific advertising materials. You are advised to review our Guidelines and legislation and seek advice from your own legal department or other relevant consultants, where appropriate.

ANNEX 1

Appendix A

Classification for Supply of Therapeutic Products and Medical Devices

Therapeutic Products (TPs)

Therapeutic products, commonly known as western pharmaceuticals and vaccines, are products intended for use in humans for a therapeutic, preventive, palliative, or diagnostic purpose. Therapeutic products typically contain chemical or biologic substances as active ingredients.

TPs are classified into either of the following categories depending on its restrictions in supply:

(a) **Prescription-only medicines (POM)**: potent medicines that can only be obtained from a doctor or a dentist, or from a pharmacist with a prescription from a doctor or a dentist. The condition to be treated needs to be diagnosed and treated by a doctor. It can also have serious side effects which require a doctor's monitoring or follow up. Examples of TPs that are classified as POM include medicines for chronic diseases (e.g. amlodipine, atorvastatin), cancer drugs (e.g. trastuzumab, bevacizumab), sexual dysfunction drugs (e.g. tadalafil, dapoxetine), and aesthetic medicines (e.g. botulinum toxin, deoxycholic acid).

(b) **Pharmacy-only medicines (P)**: medicines used for minor ailments that are to be prescribed by registered doctors/dentists or purchased from registered pharmacists at a retail pharmacy. The condition to be treated is self-limiting and can be assessed and treated by pharmacists.

(c) **General Sales List (GSL)**: where sales are not restricted and can be freely obtained from any retailer. It can be used safely by the public without medical supervision and intended for short term self-treatment only.

Medical Devices

Medical devices are products such as instruments, machines, implants intended for use in humans for health-related purposes such as diagnosing, preventing or alleviating diseases as well as the modification or support of the anatomy.

Certain medical devices are classified as professional-use only medical devices (PUO MD) which should only be used on an individual solely by, or under the supervision of, a qualified practitioner i.e. registered doctors or dentists. Examples of PUO MDs include hyaluronic acid dermal fillers, proton therapy systems.

ANNEX 1

Appendix B

List of serious diseases and conditions under the Health Products (Advertisement of Specified Health Products) Regulations, Health Products (Medical Devices) Regulations and Medicines Act for which advertisements to the public on its prevention, alleviation or cure is prohibited:

1) Blindness
2) Cancer
3) Cataract
4) Diabetes
5) Drug addiction
6) Deafness
7) Epilepsy or fits
8) Hypertension
9) Insanity
10) Kidney diseases
11) Leprosy
12) Menstrual disorders
13) Paralysis
14) Tuberculosis
15) Sexual function
16) Infertility
17) Impotency
18) Frigidity
19) Conception and pregnancy