



MH 78:04/4-2\_V15 HSA 006:02/03 MOH Directive No. 02/2022

1 December 2022

All Private Hospitals and Medical Clinics Act (PHMCA) and Healthcare Services Act (HCSA) licensed Institutions
Telemedicine Service Providers

## PROVISION OF INFORMATION ON HEALTH PRODUCTS BY PHMCA / HCSA LICENSEES AND TELEMEDICINE SERVICE PROVIDERS AND ACTIONS TO BE TAKEN

The Ministry of Health (MOH) and the Health Sciences Authority (HSA) have received an increasing number of feedback on healthcare institutions (HCI) and telemedicine (TM) service providers publishing information on health products, which include therapeutic products and medical devices, on their websites and/or social media platforms. Some of the information is published in a manner considered as advertisements promoting the use of certain health products. Such advertisements and publications are not allowed as they contravene the advertisement regulations within the Health Products Act (HPA).

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

## **Advertisement Controls of Health Products**

3. Health product advertisements are regulated by HSA under the HPA and its subsidiary legislation, namely the Health Products (Advertisement of Specified Health Products) Regulations [for therapeutic products and cell, tissue or gene therapy products] and the Health Products (Medical Devices) Regulations [for medical devices]. Publication of any information that promotes the sale or use of a health product directly or indirectly is deemed as an advertisement under the HPA. This includes information published in any media including digital media (such as electronic direct mailers, corporate or healthcare institution's websites and social media platforms, including blogs, Facebook and Instagram).











- 4. Therapeutic products¹ that are Prescription Only Medicines, unregistered therapeutic products² as well as Professional Use Only medical devices³, and cell, tissue or gene therapy products⁴ are not allowed to be advertised to the public. The appropriate use of these products requires clinical assessment of the patient's medical condition, and informed discussion between healthcare professionals and their patients. Hence, PHMCA, HCSA licensees, and TM service providers should not advertise or promote the sale or use of these products directly to members of the public.
- 5. Notwithstanding the above, the legal framework is not intended to restrict factual or educational information that serves to inform consumers on diseases, medical conditions, and available treatments. Such information is allowed, provided they are not misleading, and do not create unjustified expectations of the treatments, results by, or promote the use of specific health products. On the other hand, information that focuses on or draws attention to a specific product may be considered as an advertisement of the product as it could encourage individuals to request for the specific product from their healthcare professionals. Such materials will be subject to the prescribed controls. For avoidance of doubt, these controls would also apply to materials featuring specific products jointly produced by PHMCA/HCSA licensed healthcare institutions and the industry. PHMCA/HCSA Licensees and TM service providers are therefore reminded that they and the companies are responsible in ensuring that these materials published comply with the prescribed requirements.
- 6. Please refer to Annex 1 for the Guidance for PHMCA/HCSA Licensees and Telemedicine Service Providers on Advertisement Controls of Health Products and Provision of Non-Promotional Information to the Public. The detailed requirements can be found in HSA's guidance documents available on the HSA website (www.hsa.gov.sg)<sup>5</sup>.

<sup>&</sup>lt;sup>5</sup>Advertisements and promotions of therapeutic products (<u>www.hsa.gov.sg/therapeutic-products/advertisements</u>), Advertisements and promotions of cell, tissue or gene therapy products (<u>www.hsa.gov.sg/ctgtp/advertisements</u>) and Advertisements and promotions of medical devices (<u>www.hsa.gov.sg/medical-devices/advertisements-promotions</u>).











<sup>&</sup>lt;sup>1</sup> 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. For further examples of therapeutic products, please refer to <u>Annex A</u> of the accompanying guidance – Guidance for PHMCA/HCSA Licensees and Telemedicine Service Providers on Advertisement of Health Products and Providing Non-Promotional Information on Health Products to Public.

<sup>&</sup>lt;sup>2</sup> This includes TPs that are not registered with HSA but are imported via the Special Access Routes (SAR) or compounded and supplied for patients' use.

<sup>&</sup>lt;sup>3</sup> 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. For further examples of medical devices, please refer to Annex A of the accompanying guidance – Guidance for PHMCA /HCSA Licensees and Telemedicine Service Providers on Advertisement of Health Products and Providing Non-Promotional Information on Health Products to Public.

<sup>&</sup>lt;sup>4</sup> Cell, tissue or gene therapy products 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.

## **Actions required**

- 7. PHMCA/HCSA Licensees and TM service providers are given a grace period of up to **31 March 2023** to review your current published materials regarding health products, including product features on your websites and other digital media pages to ensure compliance with the prescribed requirements. Following the grace period, enforcement action may be taken for non-compliances by licensees. For TM service providers that continue to contravene prevailing advertising requirements for health products, this may be taken into consideration during your application for a HCSA licence in mid 2023 and may also result in delisting from MOH's Voluntary Listing of Direct Telemedicine Service Providers<sup>6</sup>.
- 8. Under the HPA, anyone who contravenes the prescribed requirements may be subject to penalties on conviction, which include a fine not exceeding \$20,000 or to imprisonment for a term not exceeding 12 months or both. In addition, HSA may also direct the advertiser to take corrective measures such as issuance of a corrective advertisement.

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<sup>&</sup>lt;sup>6</sup> Listing of Direct Telemedicine Providers: Transition Approach Prior to Licensing Under the Healthcare Services Act (HCSA) (<a href="https://www.moh.gov.sg/licensing-and-regulation/telemedicine">https://www.moh.gov.sg/licensing-and-regulation/telemedicine</a>)











## **Annexes**

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









