FAQS ON TRANSFER OF REGULATORY CONTROLS FOR PHARMACEUTICAL PRODUCTS TO THE HEALTH PRODUCTS ACT (HPA)

HEALTH PRODUCTS (ADVERTISEMENT OF THERAPEUTIC PRODUCTS) REGULATIONS 2016

1. Why is there a need to review the existing permit control regimes for advertisements of therapeutic products / western medicines?

The review of advertisement controls for therapeutic products ("TP") was part of the overall review to streamline the regulatory controls for TP to a more efficient framework.

Advertisement controls for health products is important to ensure that accurate and truthful information is being disseminated and health products advertised or promoted for sale do not adversely affect public health, mislead consumers or induce unnecessary consumption.

However, with information so readily available online, the Health Sciences Authority (HSA) recognises that imposing stringent controls via the existing permit control regimes for advertisement of TP is no longer an efficient and practical regulatory tool. Therefore, the shift from the controls via the current permit regime to prescribing controls to ensure compliance to the broad principles of advertisement of TP as described in the legislation was deemed to be a more efficient approach. This approach has taken into consideration that other controls are in place to ensure the quality, safety and efficacy of TP in Singapore. These controls include the robust assessments of the efficacy, safety and quality of the TP which are done prior to entry of TP into the market.

HSA would continue its post-market efforts to conduct surveillance and monitoring of advertisements as well as continue to follow up and assess any feedbacks or complaints received to ensure that the companies comply with the prescribed requirements / criteria.

For more information on the prescribed requirements, please refer to < Explanatory Guidance to the Health Products (Advertisement of Therapeutic Products) Regulations 2016>

2. How would this review affect the advertisement control for other product groups?

There will be no changes to the regulatory requirements of advertisement control for other product groups, which continue to remain under the Medicines Act, such as Complementary Health Products (CHPs) which include Chinese

Proprietary Medicines, Traditional Medicines, homeopathic medicines and Quasi Medicines (vitamin and mineral preparation, medicated plasters etc.).

There are also no changes to the regulatory requirements for advertisements of medical devices, which are stipulated under the Health Products Act and the Health Products (Medical Devices) Regulations

3. **Will the same review be performed for the advertisement controls of other product groups? For example: Complementary Health Products (CHPs) or Medicinal Products which are exempted from licensing?**

   Similar reviews for other groups will also be conducted in a phased approach in due course as HSA conducts the port over of regulatory controls of the remaining categories of health products to HPA. Industry will be engaged and provided sufficient notice when the regulatory reviews are made, similar to the exercise to port-over therapeutic products control to HPA.

<u>Prescribed requirements</u>

Corporate / retailer websites / press releases

4. **Corporate websites of TP registrants and licensees are allowed to feature information on their own products, such as information of Prescription Only Medicine (POM) and references to restricted diseases / conditions, as long as the information presented is factual and not false and misleading, and that no discussion board / forums relating to the product is held.**
   What about other internet platforms / sites used by the company? For example websites of parent companies which are not licensees / registrants of the TP, micro-sites and e-commerce websites. Can such platform carry information of POM / reference to restricted diseases / conditions like the local corporate websites?

   HSA is aware that other than corporate websites, there exist other online platforms that carry information on medicinal products. Examples of these online platforms include microsites and e-commerce sites e.g. retailer's website. When these websites feature TPs are directed at consumers, the product advertisements will be subjected to advertisement controls set out in the prescribed requirements including the prohibition of POM advertising and references to restricted diseases / conditions.

For more information on the prescribed requirements on 'Advertising on the Internet', please refer to <Explanatory Guidance to the Health Products (Advertisement of Therapeutic Products) Regulations 2016>

5. **What are the informational statements of a TP that can be featured on local corporate websites and press releases?**

   Informational statements are information that is intended to provide factual information about the TP.

   Such information includes:

   a) Registration status
   b) HSA approved package insert (PI) and/or patient information leaflet (PIL)
   c) Approved product intended uses or indications, mechanism of action, contraindications and warning etc.
   d) Scientific studies that provide further information / details about the TP e.g. benefit-risk profiles

   Informational statement should not contain promotional elements for the purpose of inducing sale and usage e.g. information on sales promotion activities, terms such as 'most popular product', "number one", "most recommended by Doctors" etc.

   For more information on the prescribed requirements, please refer to < Explanatory Guidance to the Health Products (Advertisement of Therapeutic Products) Regulations 2016>

6. **Can approved intended uses / claims of a TP be reflected on retailer's catalogues / websites?**

   HSA approved intended uses (indications) and claims can be featured on retailer's catalogues / websites. However, all requirements stipulated under the HPA and its Regulations, including the prohibition of POM advertising and references to restricted diseases / conditions apply.

   For more information on the prescribed requirements, please refer to < Explanatory Guidance to the Health Products (Advertisement of Therapeutic Products) Regulations 2016>

7. **How would HSA determine if the local registrant is responsible for the advertisements placed on the Internet, especially if the platform does not belong to the registrant?**

   While HSA conducts post-publish surveillance and follow-up on advertisements (including those featured on the Internet); HSA takes the following into consideration (non-exhaustive) when assessing for compliance with the requirements:

   a) The intention and targeted audience e.g. if it is promotional in nature, and if it is directed to the mass public
   b) The entity responsible for the platform or advertisement

8. **What if new data relating to the TP's safety, efficacy or quality becomes available after the TP has been registered? Can the new data be advertised?**

   In general, any representation relating to a TP's safety, efficacy and quality are to be furnished to and verified by the HSA upon application to register the TP.
   An advertisement cannot promote a TP beyond the approved therapeutic intended use (indication) / dosing regimen or patient population, in Singapore.
   In the event that there is new data relating to the safety, efficacy or quality of the TP, fulfilling the criteria for Minor / Major Variation amendments, such information must be submitted to HSA for approval prior to advertising. Please see Guidance on Therapeutic Products Registration for more information.

   For more information on the prescribed requirements, please refer to < Explanatory Guidance to the Health Products (Advertisement of Therapeutic Products) Regulations 2016>

9. **Why does HSA now disallow POM information and advertising in clinics, which is a common practice for a long time?**

   Direct to consumer advertisements of Prescription Only Medicines (POMs) have always been prohibited. POMs are potent medicines that are used for treatment of serious medical conditions and some are associated with significant side effects, and should only be used under the medical supervision of a doctor and/or pharmacist. Doctors and pharmacists should be the main 'gatekeeper' in advising patients on the appropriate POMs to treat their medical conditions and patients should not be influenced by information or advertisements that might be promoting a particular type of POM in clinics. This is to ensure appropriate and safe use of such medicines.

With the current review and the port-over of therapeutic products controls, we are reiterating the position and highlighting that any form of direct to consumer advertisements of POMs will be prohibited, including those displayed in publicly accessible areas of clinics and hospitals.

Sales Promotions

10. What is the maximum discount that can be applied for sale promotion activities?

There is no specification of the discount allowable for the sales promotion activities. The onus is on the company to ensure that the advertisements and sales promotion mechanics employed do not encourage inappropriate or excessive use or purchase of the TP according to the prescribed requirements in the Regulations. When planning promotional activities, advertisers are reminded to take into consideration the TP's intended purpose, appropriate duration for self-medication, the risk of accidental overdose etc., so as to balance between meeting customers' needs and the potential of excessive use or purchase of the TP.

For illustration, promotion targeted at the public for 100 tablets (10 x 10's tablets / box) of analgesic will not be appropriate as such mechanic may lead to excessive use of TPs, delay in seeking appropriate medical consultation or increasing the chances of an accidental / deliberate overdose.

For more information on the prescribed requirements, please refer to < Explanatory Guidance to the Health Products (Advertisement of Therapeutic Products) Regulations 2016>

Press releases

11. My company has just registered a new Prescription only medicine (POM) and we would like to issue a press release. What are the requirements?

Information in press releases should be factual, non-promotional, genuinely newsworthy and not be used as a mechanism to promote a TP.

Factual information about a TP e.g. mechanism of action, approved intended uses (indications), benefit-risk profile may be provided to the media community through press releases.

Information relating to the TP must be substantiated by objective evidence and aligned with the approved intended purposes. Prior approval by HSA is not required for press releases.

For more information on the prescribed requirements, please refer to < Explanatory Guidance to the Health Products (Advertisement of Therapeutic Products) Regulations 2016>

Operations

12. How would HSA ensure that the prescribed requirements / criteria are adhered to after the permit system for Therapeutic Products advertisements is removed?

To ensure that companies comply with the prescribed requirements and criteria, HSA will continue to conduct surveillance and monitoring of advertisements as well as continue to follow up and assess any feedbacks or complaints received.

13. What will happen to the existing permits?

The existing permits granted for TPs **only** will be invalid upon the port-over as they will no longer be applicable under the new HPA regime. Auto-renewals will be deactivated for such advertisement permits.

HSA will also stop accepting advertisement applications for TPs from 11 October 2016 (14 working days prior to the TP port over implementation date).

The existing permits granted involving other product groups that remain under the Medicines Act e.g. Chinese Proprietary Medicines, Traditional Medicines, Quasi medicines, medicated oil and balms etc. will remain valid for the advertisements of these products. Existing permit holders may wish to contact the Medical Advertisement Unit at HSA_MA@hsa.gov.sg for any clarifications regarding their existing permits.

Existing permits issued for:	**Status of permit upon port-over**
Western Pharmaceuticals (to be known as Therapeutic Products after the port-over)	Invalid
Other product groups that remain under the Medicines Act i.e. - CPM	No changes. Permits granted for this category of products remain valid

Existing permits issued for:	Status of permit upon port-over
- TM - QM - Medicinal products exempted from licensing requirements	
WP + Other product groups that remain under Medicines Act	No changes. Permit valid only for the other product groups that remain under Medicines Act

14. Will HSA continue to provide review service for TP advertisements?

HSA will not provide review or screening services for TP advertisements. Companies are encouraged to review their advertising material against the prescribed requirements for compliance and seek their own legal advice if required. For more information on the prescribed requirements, please refer to < Explanatory Guidance to the Health Products (Advertisement of Therapeutic Products) Regulations 2016>

15. How do I file a complaint / provide feedback on a published advertisement?

All complaints and feedback should be directed to the Medical Advertisement Unit at HSA_MA@hsa.gov.sg.

To facilitate reviews and follow-ups, all complaints / feedback should provide the following information:

a) Details of where and when the advertisement was published (a copy or image of the advertisement to be provided)
b) Details of the concerns identified with the advertisement. The identified non-compliance including the clause / provision / prescribed requirements referred to should be provided.