



SINGAPORE, 20 JULY 2016

HSA UPDATES

“HSA UPDATES” addresses topics of current public interest, and is subject to change as more information becomes available.

HSA UPDATES NO 3/2016

HSA UPDATES ON THE TRANSFER OF CONTROLS OF PHARMACEUTICAL PRODUCTS TO HEALTH PRODUCTS ACT

With effect from 1 November 2016, the Health Sciences Authority (HSA) will be streamlining and transferring the existing regulatory controls for pharmaceutical products under the Medicines Act (MA) and Poisons Act into a single legislation, the Health Products Act (HPA).

2 Under the HPA, pharmaceutical products, or conventional chemical and biologic drugs, will be referred to as “therapeutic products” (TP), and regulatory controls will be stratified based on the risk profiles of the products. The new Regulations will cater to different operational and business models in the rapidly evolving pharmaceutical landscape, while remaining relevant and adequate to safeguard public health and facilitate timely access to TP.

3 A total of six pieces of subsidiary legislation for the controls of therapeutic products under the HPA were finalised and gazetted on 15 July 2016. HSA had considered responses from stakeholders through two public consultation exercises and several focus-group discussions held over the proposed regulatory controls of TP under the HPA. The six pieces of subsidiary legislation under the HPA are as follows:

- [Health Products Act \(Amendment of First Schedule\) Order 2016](#)
- [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](#)

Correspondingly, two pieces of subsidiary legislation for the controls of other medicinal products under MA and one piece of subsidiary legislation for the controls of medical devices under HPA used in clinical trials were updated and gazetted on 15 July 2016. This is to ensure that the controls are aligned with the controls for TP under the HPA. The three pieces of subsidiary legislation are as follows:

- [Medicines \(Clinical Trials\) Regulations 2016](#)

- [Medicines \(Medicinal Products as Clinical Research Materials\) Regulations 2016](#)
- [Health Products \(Medical Devices\) \(Amendment\) Regulations 2016](#)

4 For more details on the feedback gathered during the 2 public consultation exercises, please refer to the [Conclusion to the Public Consultation](#) report.

5 To facilitate the transition to the control of TP under the HPA on 1 November 2016, HSA will be organising workshops for the industry and affected stakeholders in the coming weeks. Interested parties may look out for the announcement of these workshops on the [HSA website](#) or register their email address with HSA to receive updates. They may also refer to this link for more information on the transfer of regulatory controls of TP to HPA and the related legislation.

**HEALTH SCIENCES AUTHORITY
SINGAPORE
20 JULY 2016**

▪ **About the Health Sciences Authority (HSA)**

The Health Sciences Authority (HSA) applies medical, pharmaceutical and scientific expertise through its three professional groups, Health Products Regulation, Blood Services and Applied Sciences, to protect and advance national health and safety. HSA is a multidisciplinary authority. It serves as the national regulator for health products, ensuring they are wisely regulated to meet standards of safety, quality and efficacy. As the national blood service, it is responsible for providing a safe and adequate blood supply. It also applies specialised scientific, forensic, investigative and analytical capabilities in serving the administration of justice. For more details, visit <http://www.hsa.gov.sg/>.

For more updates on public health and safety matters, follow us on Twitter at www.twitter.com/HSAsg.

▪ **About HSA Updates**

The “HSA Updates” seeks to provide current information, in a consistent and accurate manner, on topics of public interest. For all issues of HSA Updates, please visit www.hsa.gov.sg, click “News”, and select “HSA Updates”.

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