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HSA UPDATES

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INTERNATIONAL CONSORTIUM AIMS TO FACILITATE AVAILABILITY OF GENERIC DRUGS FOR PATIENTS THROUGH FOCUS ON GENERIC DRUG REVIEW COLLABORATION

The Heads of Agencies Consortium, comprising Singapore's Health Sciences Authority (HSA) and health regulatory agencies from Australia, Canada and Switzerland, has selected generic drug review as a priority area for collaboration. This initiative aims to facilitate greater availability of generic drugs for patients through the convergence of regulatory requirements and approaches, promoting more efficient use of available resources, reducing regulatory burden and duplication of effort, and improving application approval times.

2 The Consortium aims to enhance agencies' abilities to handle the ever increasing numbers of marketing applications of generic drugs and the complexity of products and challenges associated with globalisation. It has initiated a comprehensive and proactive plan of action that includes the sharing of reviews, staff exchanges and identifying opportunities for convergence. This is in alignment with arrangements in place under each agency's legislative framework for sharing information with other regulatory authorities.

3 It is expected that the work of the consortium will serve as a “proof of concept” for broader international initiatives underway in this area.

Background on Heads of Agencies Consortium

4 Globalisation of health products, including rapid emergence of new technologies, increased international flow of health products and limited resources, affects the capacity of a single regulatory agency to address health risks and promote timely access to safe therapeutic products. Recognising these challenges and the importance of international collaboration among like-minded health regulatory agencies, the Heads of Agencies Consortium was established in 2007 as a means to promote regulatory convergence and foster synergy to address scientific and regulatory issues.

5 The Consortium consists of health regulatory agencies from:

- the Therapeutic Goods Administration (TGA) of Australia;
- the Health Products and Food Branch (HPFB) of Health Canada, Canada;
- Swissmedic, Swiss Agency for Therapeutic Products, of Switzerland; and
- HSA of Singapore.

6 The Consortium meets on a regular basis to exchange information on issues and challenges. The collaboration aims to better align the regulatory systems and reduce unnecessary duplication and differences.

7 The Consortium’s work focuses on concrete regulatory work sharing initiatives including but not limited to:

- Good Manufacturing Practices (GMPs);
- Good Review Practices (GRPs);
- Post-market medicines safety and surveillance;
- Assessment reports for pharmaceuticals including generic drugs and new chemical entities; and

- Coordination of involvement of technical experts in the International Conference on Harmonisation (ICH) working groups, and the collaboration on the Information Technology (IT)-architecture.

8 Further information on the generic drug review collaboration will be available in the near future.

HEALTH SCIENCES AUTHORITY
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- **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, 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 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/.

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