HSA Health Sciences Authority

NEX2US
CONNECTING WITH OUR PARTNERS

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REGULATORY UPDATES & PROCESS ENHANCEMENTS

Therapeutic Products (TP)

New Online Tools Launched: Application Timeline Calculator and Cloud-based Platform for dossier submission

The Health Sciences Authority (HSA) has introduced two new online tools to enhance regulatory predictability and efficiency: (i) a web-based Application Timeline Calculator enabling industry stakeholders to estimate key milestone timelines for NDA, GDA, and MAV-1 applications, and (ii) "EasiShare", a cloud-based file exchange platform for application dossier submissions. These tools offer user-friendly solutions for companies to plan their regulatory submissions and simplify the transmission of application dossier from companies to HSA.

Read more

Release of SG-HSA specification package (v1.0) for eCTD Implementation in Singapore

HSA has released the Electronic Common Technical Document (eCTD) specification package version 1.0 for industry stakeholders to prepare for test and actual eCTD submission. This is an updated version of the previously published version 0.9 incorporating changes based on the feedback received during the industry consultation exercise held in May-June 2023.

Read more

Pilot Programme Launched to Extend e-labelling to Pharmacy only (P) and General Sale List (GSL) therapeutic products (TP)

HSA has rolled out a pilot exercise to assess the feasibility of extending electronic labelling (e-labelling) to non-prescription TPs (P or GSL). It aims to enhance accessibility to up-to-date information for patients and promote environmental sustainability. Companies are encouraged to participate in this pilot programme.

Read more

Update of Guidance on Therapeutic Product Registration

HSA has updated the Guidance on Therapeutic Product Registration in Singapore to enhance clarity of our regulatory requirements, including guidance for industry on the list of post-approval changes that can be implemented without notifying HSA. The Risk Management Plan (RMP) requirements for biosimilar applications have also been streamlined and the Singapore-Specific Annex (SSA) is no longer required.

Read more (28 March 2024)
Read more (1 August 2024)

Clarification on Criteria for Expediated Review of Pending MIV Applications

HSA has introduced an online request form to guide applicants on the eligibility criteria for expedited review of MIV applications. Companies are strongly encouraged to plan their filing accordingly to minimise supply disruptions of therapeutic products in Singapore.

Read more

Implemented GMP requirements for chemical DS manufacturers

HSA has fully implemented the requirement for Evidence of Good Manufacturing Practice (GMP) Compliance for manufacturers of chemical drug substance (DS) on 1 October 2024. This follows a one-year transition period which commenced in September 2023 to enable companies to better assure the quality of therapeutic products supplied in Singapore.

Read more

Medical Devices

Change Management Program (CMP) for Software as Medical Device (SaMD)

HSA had rolled out CMP for SaMD, including Machine learning-enabled SaMD, as part of our ongoing initiative to improve regulatory efficiency, following a public consultation held from August to October 2024.

CMP is a new optional regulatory pathway specifically for SaMD that is incorporated into HSA's Premarket Product Registration and Change Notification (CN) processes, which also introduces the concept of pre-specified changes. The objective is to facilitate timely implementation of software changes for SaMD.

Read more

Milestone in Patient Safety: Phase 2 of Implementation of Unique Device Identifier (UDI) system in Singapore

To enhance patient safety through improved medical device tracking and identification, HSA initiated the implementation of the Medical Device UDI System framework. Phase 2 has been rolled out from 1 November 2024, which mandates the labelling of all Class D Medical Devices (general medical devices and in vitro diagnostic (IVD) medical devices) with UDI before supply in Singapore. Thus far, all the Class D registrations have submitted UDI information on SMDR, and UDI will progressively expand to include Class C and B devices. For additional details, please refer to GN-36: Guidance on Medical Device Unique Device Identification (UDI) System on the HSA website.

Read more

Supporting Digital Health Product Innovation

HSA and the Ministry of Food and Drug Safety (MFDS) Korea have collaboratively released guiding principles for conducting clinical trial for machine learning-enabled medical device (MLMD). The purpose of these guiding principles is to address the unique challenges posed by MLMD in clinical studies. HSA and MFDS aim to facilitate the development and assessment of MLMD, ensuring that they meet rigorous standards for safety and effectiveness.

Read more

Cell, Tissue and Gene Therapy Products (CTGTP)

"SHARE": One-Stop Digital Portal for CTGTP Dealer's Notice, Class 1 CTGTP Notification and Class 2 CTGTP Registration

HSA has updated SHARE (Singapore Health Product Access and Regulatory E-System), a one-stop digital portal for handling of CTGTP applications. SHARE was initially launched in January 2024 for CTGTP Dealer's Notice and Class 1 CTGTP notification, and the system has been expanded to include Class 2 CTGTP registration in October 2024.

Read more

Streamlining Access to CTGTP Information

To further facilitate businesses, HSA has also streamlined our web content and regulatory guidance documents for CTGTP. This will provide greater transparency and clarity on CTGTP registration related matters.

Read More

Clinical Trials and Innovation Office

Formalisation of the Innovation Office

HSA's Innovation Office provides scientific and regulatory advice on novel investigational products that are either Therapeutic Products (TPs) or Class 2 Cell, Tissue and Gene Therapy Products (CTGTPs), at any stage of development. Interested parties may seek advice on one or more of the following – non-clinical studies required to support clinical development, clinical trial design and clinical development plans, Chemistry, manufacturing and controls (CMC) and manufacturing requirements.

Read more

Upcoming Implementation of the Principles and Annex 1 of the revised ICH E6 (R3) Guideline on Good Clinical Practice (GCP)

The ICH E6 (R3) Guideline for GCP is intended to address increasingly diverse trials and facilitate technological innovations in the conduct of clinical trials. The revised guideline will be implemented in Singapore on 1 January 2026. A HSA-SCRI Public Webinar was held on 28 February 2025 to familiarise stakeholders with the upcoming changes.

Read more

Therapeutic Products and Cell, Tissue and Gene Therapy Products

Launch of new Risk Management Plan webpage (1 April 2024) – with implementation of new online form for safety notifications and revised interactive Singapore-Specific Annex (SSA)

HSA launched a new Risk Management Plan (RMP) webpage that serves as a one-stop portal to facilitate industry stakeholder's access to important information on local RMP requirements. Together with the new RMP webpage, a new online form for the submission of safety notifications to HSA, as well as a revised Singapore-Specific Annex (SSA) in PDF format have also been implemented to provide clearer guidance to industry stakeholders on HSA's requirements regarding the information required in these submissions.

Read more

International and Bilateral Collaborations

Access Consortium

The Access Consortium has launched the renewed strategic plan for 2025 – 2028, and this plan will guide Access toward enhanced efficiency of our national regulatory systems, while optimising synergies and alignment between regulatory authorities and reducing duplication for industry. More information can be found at Access's new landing page.

Read more

Project Orbis

HSA is one of the international regulatory partners that participates in Project Orbis, an initiative and coordinated by the US Food and Drug Administration (FDA) Oncology Centre of Excellence. Project Orbis provides a framework for the collaborative review of oncology products among international regulatory partners.

Read more

HSA Signs Memorandum of Understanding with the Ministry of Health, Malaysia

HSA and the Ministry of Health, Malaysia signed a Memorandum of Understanding (MOU) for continued cooperation in matters pertaining to pharmaceutical products and cosmetics including post-market vigilance, enforcement and Good Clinical Practice for clinical trials on 6 May 2024. This MOU is a renewal of the MOU signed in 2012 and marks an important milestone in solidifying ties between the two regulatory authorities.

Read more

Introduction of Swissmedic as HSA's reference agency

HSA has added Swissmedic as one of our reference agencies, alongside EMA, FDA, Health Canada, MHRA and TGA.

Read more

Regulatory Leverage

Facilitating product approvals to other markets and positioning Singapore favourably as a biomedical hub, through the following:

- **Reliance and Recognition Arrangement in GMP Inspections for Good Manufacturing Practices (GMP) Inspections for Medicines:**
  - Mutual Recognition Agreement (MRA) Partners: Australia, New Zealand, South Korea
  - ASEAN Mutual Recognition Arrangement on GMP Inspection of Manufacturers for Medicinal Products
  - Access Consortium Statement on GMP Inspections Reliance and Recognition
- **Recognition as a comparable regulator in other jurisdictions:**
  - Australia for prescription medicines and medical devices (MDs)
  - ACCESS Consortium (Australia, Canada, Singapore, Switzerland and United Kingdom)
  - Hong Kong and Philippines for MDs and medicines
  - Brunei and Egypt for medicines
  - Thailand for MDs

News and Engagements

Next Generation Medical Devices (NextGen MD) Initiative Webinar

13 June 2024

HSA conducted a virtual seminar on the NextGen MD initiative, aimed at streamlining the registration process for next generation medical devices. The programme enables applicants to leverage existing data from registered devices, thereby facilitating a more efficient pathway for bringing next-generation medical technologies to market. The webinar was attended by about 370 industry representatives.

Read more

More than 40 under probe after multi-agency raid in Geylang on illegal and vice activities

26 – 29 August 2024

HSA took part in a multi-agency enforcement operation conducted in Geylang from 26-29 August, as part of a larger operation that ran from 23 August to 1 September. During HSA's involvement, unregistered health products, including cough syrup, with an estimated street value of $9,100, were seized. Three men, aged between 23 and 33, are under investigation. If they are found guilty of importing, manufacturing and/or supplying unregistered health products, they can be jailed for up to two years and fined up to $50,000.

Read more

Good Submission Practice Workshop

28 August 2024

HSA conducted a Good Submission Practice Workshop with about 500 industry representatives attending. The primary objective of the workshop was to emphasise on the critical documentary requirements that are often overlooked during Medical Devices submissions. The workshop aimed to empower stakeholders to furnish good submission documents, thereby ensuring expedited processing or resolution of their applications.

Read more

Industry Training Workshop on (i) Product Defect Reporting and Recall Procedures, and (ii) Management of Nitrosamine Impurities in Therapeutic Products

29 & 30 October 2024

HSA conducted an online industry training workshop on 29 and 30 October 2024 attended by 589 participants. The workshop provided a comprehensive overview of the procedures and requirements of product defect reporting and recall for therapeutic products and cells, tissue and gene therapy products. It clarified HSA's current approach, recommendations, and regulatory requirements for managing nitrosamine impurities in therapeutic products.

Read more

Complementary Health Products Training Workshop

18 November 2024

HSA hosted an industry training workshop on 18 November 2024. The workshop adopted an efficient two-phase approach, participants first viewed four pre-workshop videos on HSA's YouTube channel. This preparation then enabled the live session to focus on interactive quizzes, targeted recaps, and addressing specific industry queries, maximising the learning experience for all attendees. The workshop provided insights into common submission errors for Chinese Proprietary Medicines, the Voluntary Notification System for health supplements and traditional medicines, substantiation of ingredient safety and health claims, and testing requirements for health supplements and traditional medicines. More than 250 industry representatives joined in the virtual session.

Read more

HSA Removes Over 3,000 Online Listings of Illegal Health Products in First Joint Operation with Online Platforms

23 September – 23 October 2024

HSA removed 3,336 illegal health product listings and issued 1,471 warnings to sellers on local e-commerce and social media platforms from 23 September to 23 October 2024, in a first-of-its-kind large-scale collaboration with online platform administrators. The eight platforms that participated in the operation are Amazon Singapore, Carousell, Ebay Singapore, Facebook, Lazada, Qoo10, Shopee and Tiktok.

Read more

Engaging clinical trial stakeholders on ICH E6 (R3) Good Clinical Practice (GCP) Guidelines

28 February 2025

HSA and Singapore Clinical Research Institute (SCRI) co-hosted a public webinar on the on the final version of the Principles and Annex 1 document of the ICH E6 (R3) Good Clinical Practice (GCP) guideline, which provided clinical trial stakeholders with an overview of the major changes and the implementation timeline for Singapore. More than 1500 participants from 28 countries attended the four-hour session. The ICH E6(R3) GCP guideline will be implemented in Singapore from 1 January 2026.

Read more