

NEX²US

CONNECTING WITH OUR PARTNERS

JANUARY 2022



AWARDS & RECOGNITION

HSA won two awards at the Pro-Enterprise Panel - Singapore Business Federation (PEP-SBF) Awards 2021

The PEP-SBF Awards is an annual platform that celebrates the contributions of government agencies and businesses towards strengthening Singapore's pro-enterprise environment. At the awards ceremony held on 17 Nov 2021, HSA received two Pro-Enterprise Initiative Awards:



[GOLD Award] Regulatory agility – Supporting businesses and timely access to health products during the pandemic

Through proactive regulatory facilitation and agility, HSA swiftly implemented various initiatives to support and diversify our local businesses during the pandemic. These include interim authorisation pathways, consultations and virtual audits, which have enabled the swift roll-out of accurate COVID-19 tests and ensuring that our population is one of the earliest in the world to have access to critical vaccines, medicines and medical devices to combat COVID-19.



[BRONZE Award] Enhanced Complementary Health Products (CHP) Classification Tool

The [CHP Classification Tool](#) was developed for industry players to self-help in determining their product classification and facilitate faster market access, expansion and diversification. The time taken to obtain classification advice has been shortened from 1 to 2 weeks in the past, to just a few minutes with the tool. More than 500 companies have used the tool to classify over 750 products.

[Read more](#)



REGULATORY UPDATES AND PROCESS ENHANCEMENTS

THERAPEUTIC PRODUCTS (TP)

Facilitate TP registration and post approval variation

Jun – Sep 2021

TP post-approval Minor Variation (MIV) Tool

This tool enables applicants to quickly determine the correct application type, variation category and documentary requirements for their TP MIV applications with a few simple clicks.

Industry stakeholders could leverage this tool to gain better understanding of the regulatory information for good quality submissions, facilitating a more expedient application process. The number of MIV related enquiries received has decreased by 30% following the launch of this tool.

Streamlined the application screening process to improve efficiency by:

- Providing further guidance on the documentation deficiencies that lead to applications non-acceptance. This aids applicants in improving their submission quality.
- Enabling applicants to leverage HSA's acknowledgement email on the receipt of the Letter of Access from Drug Master File (DMF) holder as documentary proof that all required documents from the DMF holder have been submitted.

[Read more](#)

Extension of the Dossier Clarification Supplement to New Drug Applications (NDA) for biologics submitted via the abridged evaluation route. This facilitates companies in providing HSA with the confirmation that the CMC* aspects of a TP for which regulatory approval is sought, are the same as those approved by a reference agency.

*CMC: Chemistry, Manufacturing & Controls

[Read more](#)

Finalised guidance on e-labelling of TP

Apr 2021

Through positive feedback received from consultation with the industry and healthcare professionals, HSA has finalised the guidance to provide greater clarity on the requirements for e-labelling of the approved package inserts and patient information leaflets for TP.

To date, e-labelling has been implemented for over 350 prescription-only TP. HSA will continue to review the feasibility of extending e-labelling to non-prescription TP.

[Read more](#)

CELL, TISSUE AND GENE THERAPY PRODUCTS (CTGTP)

New Regulations for CTGTP

Mar 2021

The CTGTP regulations were implemented under the Health Products Act on 1 March 2021. The collaborative efforts and valuable contributions from our stakeholders enabled the implementation of fit-for-purpose, risk-based regulations that support product development and commercialisation of these medically important therapies. These regulations also facilitate patients' access to novel products that meet the appropriate standards of safety, efficacy and quality.

[Read more](#)

MEDICAL DEVICES (MD)

Refined MD Product Classification Guide

Nov 2021

HSA has refined the guide to provide greater clarity for stakeholders to determine whether their products are classified as MD. The list of commonly enquired products, along with their respective classifications, are presented in this clear and comprehensive guide.

[Read more](#)

Enhanced Medical Device Information and Communication System (MEDICS) to capture Unique Device Identification (UDI) data

Sep 2021

HSA has enhanced MEDICS to enable registrants' submission of essential UDI information. These information are now available via:

- Singapore Medical Device Register (SMDR) for class B or higher medical devices; and
- Class A MD database.

MD manufacturers, distributors and healthcare providers may leverage the UDI information for better identification and traceability of MD to further enhance patient safety (e.g. facilitate traceability for field safety corrective actions and timely identification of MD in medical events).

[Read more](#)

Finalised guidelines for 3D-Printed MD

Jul 2021

HSA has published the final guidelines and FAQs for 3D (three dimensional)-printed MD following our stakeholder's consultation last year. This guidance provides companies with greater clarity on HSA's regulatory perspectives and risk-based approach for the control of MD manufactured using 3D-printing technology.

[Read more](#)

MD Grouping Tool

Feb 2021

This interactive tool enables companies to determine if their MD are eligible for grouping and submission under a single registration application instead of separate applications. It also provides information on the applicable grouping categories, along with the application requirements and processes.

Leveraging this tool enables companies to further strategise and streamline their product registration submission plans. To date, the tool has assisted over 1,500 users.

[Read more](#)



INTERNATIONAL & BILATERAL COLLABORATIONS

Therapeutic Products

Access Consortium

HSA remains committed to strengthen collaboration with other Access members, so that our combined population of 150 million can continue to enjoy timely access to high-quality, safe and effective health products. Access and its working groups continue to make good progress in our collaborations. Key outcomes in 2021 include:

- **Developed the Strategic Plan for 2021-2024** to guide Access towards enhanced efficiency of our national regulatory systems, while optimising synergies and alignment between regulatory authorities and reducing duplication for industry.
- **Published 3 joint statements** to provide clarity on the Access' collective regulatory positions for COVID-19 vaccines and therapeutics.
- **HSA completed 7 therapeutic products applications through the work sharing collaborations** under Access' New Active Substance Working Group (NASWG) and Generic Medicines Working Group (GMWG).

[Read more](#)

Project Orbis

HSA continues to participate actively in this project led by the U.S. Food and Drug Administration (FDA), alongside other regulatory authorities to facilitate early patient access to critical life-saving medicines for cancer. In 2021, **HSA issued regulatory approvals for 5 applications** through this collaboration.

Singapore's HSA and Republic of Korea's (ROK) Ministry of Food and Drug Safety (MFDS) established mutual confidence in the Good Manufacturing Practice (GMP) Inspections of Pharmaceutical Products

HSA and MFDS had embarked on a pilot project to establish mutual confidence in each Party's GMP inspection regulatory framework and its implementation. The pilot concluded in Jul 2021 with a positive outcome. MFDS would rely on HSA's inspection outcomes based on GMP certificates issued by HSA, without the need to conduct additional inspections on our local manufacturers who are intending to market their products in the ROK and vice versa. This reduces the duplication of GMP inspections for our local manufacturers and enhances regulatory efficiency.

Moving forward, both agencies will explore an opportunity to formalise this arrangement through a Mutual Recognition Agreement (MRA) on GMP Inspection of pharmaceutical products.

Medical Devices

International Medical Device Regulators Forum (IMDRF) Medical Device Single Audit Programme (MDSAP)

HSA has been recognised as the **Affiliate Member of IMDRF MDSAP** since Apr 2021. [MDSAP](#) enables recognised Auditing Organisations (AO) to conduct a single regulatory audit of a medical device manufacturer which satisfies the relevant requirements of multiple member jurisdictions, thereby reducing the duplication of effort. Currently, the MDSAP members include Australia, Brazil, Canada, Japan and the United States.

The affiliate membership paves way for HSA's future recognition as a full member of MDSAP, which will translate into reduced regulatory burden for companies that are audited based on MDSAP requirements.

HSA registered medical devices are now eligible for expedited registration pathways in more ASEAN markets

Companies can leverage HSA's medical devices approvals for faster entry into the following ASEAN markets:

- **Thailand** – High-risk medical devices approved by HSA are eligible for expedited evaluation by the Thailand Food and Drug Administration.
- **Philippines** – Class B, C or D medical devices approved by HSA using the Common Submission Dossier Template (CSDT) are eligible for Philippines Food and Drug Administration's abridged registration process.



NEWS AND ENGAGEMENTS

News

Regulatory Fee Revision for Health Products

1 Jul 2022

As announced in Dec 2021, a fee revision averaging 3% with a minimum increase of \$1 and capped at \$200 per fee item will be implemented from 1 Jul 2022. This fee revision is necessary to recover part of the costs for the services rendered to businesses. We will continue to streamline our processes and deliver value to all our stakeholders.

[Read more](#)

Engagements



Complementary Health Products (CHP) Industry Training Workshop Series 2021

4-6 Oct 2021

The workshops aim to provide CHP dealers with insights and updates to Chinese Proprietary Medicines application and manufacturing, as well as guidelines on ensuring the safety and quality of traditional medicines and health supplements.



2021 WHO-UMC*-HSA Inter-Regional Pharmacovigilance Training Workshop: Enhancing Preparedness for Pharmacovigilance

20-22 Sep 2021

HSA organised the fifth biennial training workshop in collaboration with WHO, UMC and CoRE Duke-NUS. This virtual workshop served as a platform to enable in-depth discussions on topics including COVID-19 vaccines and digital innovations to further enhance pharmacovigilance.

**UMC stands for the Uppsala Monitoring Centre which is established as the World Health Organization (WHO) Collaborating Centre for International Drug Monitoring. UMC operates the technical and scientific aspects of WHO's worldwide pharmacovigilance network.*



Webinar: ISO13485 Certification for Medical Device (MD) Licensed Dealers

2 Mar 2021

This webinar forms part of HSA's early engagement with stakeholders on the plans to enhance the robustness of Singapore's ISO13485 certification for MD dealers

[Read more](#)

2021 Snapshot of HSA's regulatory facilitation and agility during the COVID-19 pandemic (Jan – Dec 2021)



SUPPORTING PRODUCT INNOVATION & FACILITATING SUBMISSIONS

More than

6 Expedited approvals for clinical trials on COVID-19 therapeutics and vaccines

40 Consultations conducted to provide scientific and regulatory advice for COVID-19 therapeutics, vaccines and medical devices



EXPEDITING MARKET ACCESS TO COVID-19 THERAPEUTICS, VACCINES & MEDICAL DEVICES

75 Interim authorisations*

15 Registrations

163 Approved amendments

Interim authorisations* and registrations by product categories include:



6 COVID-19 vaccines and therapeutics



13 COVID-19 self-test kits



71 COVID-19 diagnostic tests

*Via the Pandemic Special Access Route and Provisional Authorisation



FACILITATING MANUFACTURING & DISTRIBUTION

116 COVID-19 consultations, audits and applications to facilitate manufacturing and distribution of novel therapeutics and vaccines

14 New local manufacturers of medical masks licensed, boosting nationwide manufacturing capacity



ENHANCING SAFETY MONITORING & REGULATORY CLARITY

8 Reports published to provide timely updates on suspected adverse events following COVID-19 vaccination in Singapore, facilitating early detection of safety issues

8 Regulatory guidances and consumer advisories published on health products used in the diagnosis, management and treatment of COVID-19