HSA Health Sciences Authority

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CONNECTING WITH OUR PARTNERS

MARCH 2023

AWARDS & RECOGNITION

HSA won five Public Service Transformation (PST) Awards 2021/2022

The Public Sector Transformation Awards were presented by the Public Service Division which recognised public officers and agencies for service, innovation, and organisational excellence. Health Sciences Authority (HSA) received the following five awards:

1 Agility Award 2021 for Supporting SG's Fight Against COVID-19

This Award recognised HSA's agility and proactive regulatory facilitation, which was instrumental in securing the expeditious access to essential vaccines/medicines and medical devices for our population during the pandemic. The comprehensive suite of regulatory initiatives such as the PSAR and rolling submissions review of dossiers had ensured our population was one of the earliest in the world to have access to critical vaccines and therapies to manage the pandemic at the onset and enabled Singapore to swiftly roll out COVID-19 diagnostic testing.

2 One Public Service Award 2021 for COVID-19 PCR Testing Capacity Expansion

HSA was part of the multi-agency effort to expand Polymerase Chain Reaction (PCR) testing capability and capacity to meet the rapidly growing demand as COVID-19 infections spiked. Beyond COVID-19, this collaboration across the healthcare value chain had also helped create critical networks and public health response capabilities to enable more effective response to future pandemics and civil emergencies.

3 One Public Service Award 2021 for Securing Access to COVID-19 Vaccines

HSA was part of the multi-agency team formed to secure early access to vaccines, as a key measure to ensure the protection of Singapore's population and initiate the safe re-opening of our economy.

4 Dare to Do Award 2022 for ARISE (Activating Resource In aSsay of vaccinEs)

HSA and Agency for Science, Technology and Research (A*STAR) formed a team of domain experts to develop analytical assays and to build up the talent pool to perform validated analytical test methods for COVID-19 vaccines. The invaluable experience and new capabilities built expeditiously will ensure Singapore's resilience in our fight against COVID-19 and future disease Xs.

5 Exemplary Leader Award 2022 for A/Prof Chan Cheng Leng

A/Prof Chan, Group Director of the Health Products Regulation Group of HSA was recognised to be instrumental in driving excellence and innovation in regulatory science. Under her leadership, HSA became the first national agency in the world to be awarded the highest recognition for an advanced medicines regulatory system by the WHO.

At the onset of COVID-19 pandemic, she swiftly drove the implementation of risk-calibrated regulatory pathways coupled with "rolling submissions", cutting approval timelines by over 80% and accelerating access to critical health products such as vaccines and diagnostic tests. Numerous regulatory initiatives were recognised for their agility, facilitation, and pro-enterprise orientation, without compromising on safety.

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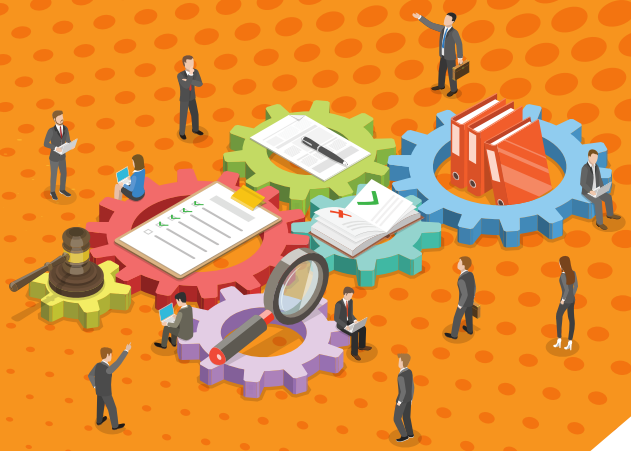
REGULATORY UPDATES AND PROCESS ENHANCEMENTS



THERAPEUTIC PRODUCTS (TP)

Enabling regulatory efficiency and industry self-help

In April 2022, the checklists for post-approval minor variations (MIV-1 and MIV-2) were revised to include the expansion of Do-And-Tell changes with the re-categorisation of a list of Chemistry, CMC variations from MIV-2 Notification to Do-And-Tell, and introduction of new Do-And-Tell checklists. The MIV-1 checklists also reflected the new changes, as well as clarify the eligible conditions and documentary requirements.

The expansion of the Do-And-Tell changes aims to reduce regulatory submission burden and enable timely implementation of administrative and minor Chemistry, Manufacturing and Control (CMC) changes that do not have any impact on the product's safety, efficacy, and quality.

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In April 2022, the type of products applicable for new drug application filing via the verification evaluation route was extended from chemical products to biological products, including biosimilar products, to enable greater leveraging of reference agencies' assessments and minimise duplication of effort.

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For generic drug applications, an online Questions and Answers relating to bioequivalence study requirements and Singapore Reference Product was published in May 2022. These are HSA's ongoing initiative to improve regulatory efficiency and enhance clarity in our regulatory requirements and processes for the industry.

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MEDICAL DEVICES (MD)

Publication of Regulatory Guidelines for Laboratory Developed Tests (LDTs)

Following a consultation with the stakeholders, HSA has published the regulatory guidelines for LDTs, which will come into effect from 1 March 2023. The document provides an overview of the scope of LDTs and the regulatory requirements applicable, which includes Product controls, Manufacturing Quality controls and Post-market controls. It will provide guidance and clarity in assisting clinical laboratories in understanding the applicable regulatory requirements.

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COMPLEMENTARY HEALTH PRODUCTS

Launch of Voluntary Notification System for Health Supplements and Traditional Medicines

HSA has launched the Voluntary Notification System for Health Supplements and Traditional Medicines on 1 Aug 2022, for dealers to voluntarily notify their products with HSA. Products that meet the required safety and quality standards, as well as labelling requirements are published on the HSA's website, providing consumers with a local database of safe and good quality complementary health products that they can refer to when making their purchases. It will also allow for better traceability and follow-up actions by HSA if there are any safety or quality issues.

The system has been implemented in phases from 1 August 2022, starting with commonly purchased products, such as vitamin and mineral supplements, and products at higher risk of adulteration, such as those for weight loss, pain relief and male vitality enhancement.

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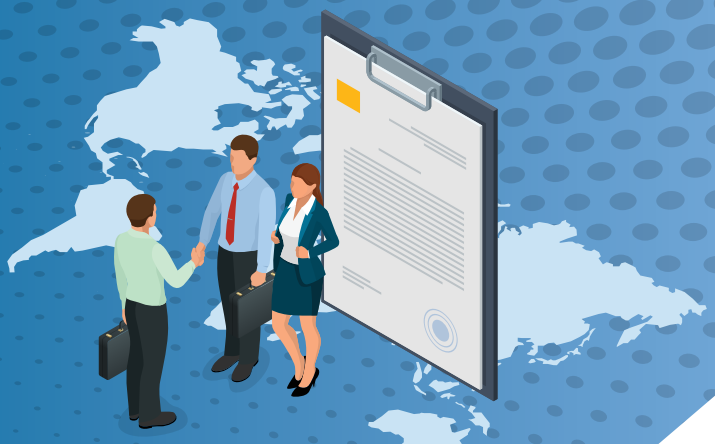
INTERNATIONAL & BILATERAL COLLABORATIONS



HSA Singapore the First National Regulatory Authority Awarded the Highest Recognition for an Advanced Medicines Regulatory System by the World Health Organization

The Health Sciences Authority (HSA) was recognised as the first National Regulatory Authority (NRA), and Singapore as the first World Health Organization (WHO) member state to achieve Maturity Level (ML) 4 for its advanced medicines regulatory system in Jan 2022.

This is an important milestone and validation of HSA as an NRA that operates at an advanced level of performance and continuous improvement. It affirms the high standards, quality and rigour of HSA's regulatory work in ensuring that medicines approved for use in Singapore are safe, of good quality and are effective for our population.

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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 Consortium and its working groups continue to make good progress in our collaborations. Key outcomes in 2022 included:

Publication of the Access Consortium Statement on GMP Inspections Reliance and Recognition

In alignment with the Access Consortium's strategic objective to expand and maximise collaboration throughout the product lifecycle, this collective statement issued by the Access Heads of Agencies serves to solidify the Consortium's commitment to demonstrate greater inspection reliance and accept GMP inspection outcomes. This reduces the regulatory burden on stakeholders and could facilitate our populations' timely access to high quality, safe and effective pharmaceutical products.

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Collaboration to enable faster access to treatment

HSA has collaborated with four other international regulatory agencies under the Access Consortium to enable faster access to two new therapeutic products under Access' New Active Substance Working Group (NASWG).

Read more (1)

Read more (2)

ASEAN Pharmaceutical Regulatory Policy and ASEAN Pharmaceutical Regulatory Framework

The development of a policy document on pharmaceutical regulation, i.e., the ASEAN Pharmaceutical Regulatory Policy (APRP) marks a new milestone in working towards the longer-term target to establish and adopt a common policy that provides a basis for structuring regulatory systems for pharmaceutical products across ASEAN.

The APRP has been adopted by the ASEAN Health Ministers and ASEAN Economic Ministers as of June 2022. Discussions are ongoing for the establishment the ASEAN Pharmaceutical Regulatory Framework (APRF), that will supplement the APRP by providing a common reference for implementation of its principles. The APRF aims to provide a structure to realise the integration of the pharmaceuticals market in the region.

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HSA recognised as a Comparable Overseas Regulator for medical devices

Australia's Therapeutic Goods Administration (TGA) recognised HSA as a Comparable Overseas Regulator (COR) with comparable system for the evaluation of medical devices from September 2022.

This makes us one of the five listed TGA CORs, as we now join the ranks of other established regulators in European Union, United States of America, Canada and Japan.

With this recognition, medical devices evaluated and approved by HSA are eligible for expedited registration pathways in Australia. Companies that are interested in gaining access to the Australian market can benefit from shorter processing timelines if their medical devices had obtained prior approval from HSA. This helps to provide faster access of safe and effective medical devices to healthcare institutions and patients.

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HSA included in Hong Kong's list of reference countries for registration of new chemical or biological entity

Hong Kong's Pharmacy and Poisons Board has included Singapore in their list of reference countries for registration of new chemical or biological entity (NCE) from November 2022.

With this inclusion, companies that are interested in gaining access to the Hong Kong market can now leverage their registration approval in Singapore.

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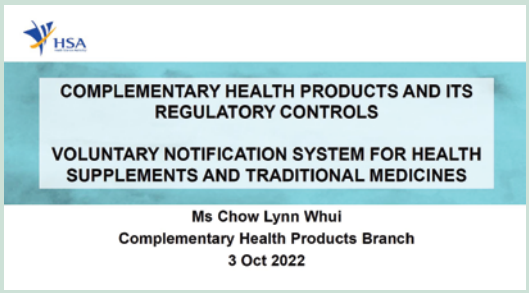
NEWS AND ENGAGEMENTS



Complementary Health Products (CHP) Industry Training Workshop

3 - 4 October 2022

More than 350 industry representatives joined in the virtual workshop. The workshop provided CHP dealers with insights on the expected safety, quality and labelling standards for health supplements and traditional medicines and the Voluntary Notification System submission process.

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Webinar on Dental Laboratory Regulatory Requirements in Singapore

10 May 2022

This webinar forms part of HSA's early engagement with stakeholders on the upcoming risk-calibrated requirements for local standalone dental laboratories.

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