HSA
Health Sciences Authority

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CONNECTING WITH OUR PARTNERS

APRIL 2024

INTERNATIONAL RECOGNITION

HSA Singapore Designated as WHO-Listed Authority for its Medicines Regulatory System

The Health Sciences Authority (HSA) has been designated by the World Health Organization (WHO) as a WHO-Listed Authority (WLA) on 26 October 2023 for its medicines regulatory system. This means that HSA is now recognised globally as operating at an advanced level of regulatory performance, ensuring that medicines in Singapore meet high safety, efficacy and quality standards. This could encourage more pharmaceutical companies to choose Singapore as one of the first few markets to register their novel and innovative medicines, which would enable patients in Singapore to gain earlier access to novel lifesaving medicines and treatments.

Read more

HSA's Stringent Regulatory Authority (SRA) Status for In Vitro Diagnostic Medical Devices (IVD)

HSA is now recognised as a WHO SRA for IVD. This would be beneficial to relevant medical device companies, as major international purchasers, e.g. the United Nations agencies, rely on the listing by the WHO Prequalification Programme. Hence, IVD manufacturers that register their IVDs with HSA would be able to use HSA's SRA status to gain expedited listing under the WHO prequalification programme, and as a springboard for faster access to various markets beyond Singapore.

Read more

REGULATORY UPDATES AND PROCESS ENHANCEMENTS

THERAPEUTIC PRODUCTS (TP)

HSA and Ministry of Food and Drug Safety (MFDS), Republic of Korea (ROK), Signed Mutual Recognition Agreement (MRA) on Good Manufacturing Practice for Medicinal Products

HSA and MFDS signed an MRA on the establishment of requirements for Good Manufacturing Practice (GMP) for Medicinal Products on 26 February 2024. The MRA will come into force on 1 May 2024. This MRA will reduce regulatory burden on the pharmaceutical and biologics manufacturers in Singapore and the ROK through reducing duplicative onsite GMP inspections by both regulatory agencies. By improving the efficient use of resources needed to assess manufacturing sites, trade and patients' access to medicinal products are facilitated in both countries.

Read more

Implementation of GMP Evidence for Drug Substance Manufacturers

Evidence of GMP compliance will be extended to chemical Drug Substance manufacturers to better assure the quality of therapeutic products supplied for use in our patients. This aligns Singapore's requirements with international standards. A 1-year transition period was initiated since 1 October 2023, with full implementation effective 1 October 2024.

Read more

Update Of Guidance Documents for Therapeutic Product Registration and PRISM Application Form

HSA has updated the Guidance on Therapeutic Product Registration in Singapore and Import and Supply of Registered Therapeutic Product on Consignment Basis. The PRISM application form was also revised. These updates are to improve regulatory efficiency and enhance clarity of our regulatory requirements and processes.

Read more

Implementation of Electronic Common Technical Document (eCTD) in Singapore

HSA will be introducing eCTD submission to allow better product life cycle management and minimise the need for submitting documents using storage media such as CD/DVD ROMs. An industry consultation was held from 2 May to 12 June 2023 to allow industry to provide feedback on the draft eCTD package version 0.9 for Singapore. We have also published an interim update on the key changes that will be incorporated in the updated eCTD package version 1.0, targeted to be published by Q2 2024.

Read more

CELL, TISSUE AND GENE THERAPY PRODUCTS (CTGTP)

Introducing "SHARE" - Your digital portal for CTGTP Dealer's Notice and Product Notification

HSA has launched the Singapore Health Product Access and Regulatory E-System (SHARE), a new customer-centric one-stop digital portal for CTGTP Dealer's Notice and Class 1 CTGTP Notification. This is part of our ongoing efforts to streamline the regulatory processes and to facilitate businesses to comply with HSA's regulations.

Read more

Cell, Tissue and Gene Therapy Product (CTGTP) Classification Tool

HSA has developed a new Cell, Tissue and Gene Therapy Product (CTGTP) Classification Tool to assist stakeholders in determining if their product is a CTGTP. This self-help tool was launched on 18 March 2024, and it features a guided questionnaire to aid stakeholders in categorising their products as a Class 1 or 2 CTGTP or a non-CTGTP. Relevant information on the regulatory requirements and linkages to guidance documents are also provided depending on the outcome of the classification.

Read more

New Webpage on Duties and Obligations of CTGTP Registrants, Manufacturers, Importers and Suppliers

HSA has developed a new webpage outlining the duties and obligations of registrants, manufacturers, importers, and suppliers (including wholesalers) of all CTGTPs to facilitate stakeholders dealing with CTGTPs. The webpage also provides clear details on record-keeping and traceability maintenance, product defect and serious adverse reactions reporting, and product recall notification to HSA.

Read more

MEDICAL DEVICES

Advancing Guidance on Clinical Evaluation: Real-World Evidence and Software Medical Device Evaluation

HSA conducted stakeholders' consultation on draft GN-20 Guidance on Clinical Evaluation between 27 October 2023 and 30 November 2023. The updates outline HSA's position on the use of real-world data to support medical device clinical evidence, along with specific clarifications regarding clinical evaluation for software medical devices. Where relevant, the contents have been aligned with the International Medical Device Regulators Forum (IMDRF) guidance on clinical evaluation.

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. Commencing from 1 November 2024, Phase 2 will be rolled out, which mandates the labelling of all Class D Medical Devices (general medical devices and in vitro diagnostic (IVD) medical devices) with UDI before import and distribution in Singapore. Registrants are required to update the necessary UDI information with HSA via MEDICS. Phase 1, which commenced on 1 November 2022, was successfully completed. Under Phase 1, coronary stents, orthopaedic joint replacement implants, and intraocular lenses were required to be labelled with UDI before import and distribution in Singapore. For additional details, please refer to GN-36: Guidance on Medical Device Unique Device Identification (UDI) System on the HSA website.

Read more

Accreditation of ISO13485 Certification - Requirements for Medical Device Dealers

Starting from 1 January 2025, medical device (MD) dealers who rely on ISO 13485 certification as a prerequisite for obtaining their HSA's MD dealer licence must ensure that the Certification Body issuing the ISO 13485 certification is accredited by the Singapore Accreditation Council. Accreditation ensures that the certification system is robust and aligns with the regulatory body's requirements. Dealers relying on Medical Device Single Audit Program certificates will not be affected. A webinar was held previously in March 2021 for stakeholders.

Read more

Enhancements in Risk Classification for In Vitro Diagnostic Medical Devices and Updated Tools

Following stakeholder consultation from 3 May 2023 to 30 May 2023 regarding proposed changes to the Guidance on the Risk Classification of In Vitro Diagnostic Medical Devices, the document was revised to integrate accepted suggestions. This resulted in expanded and clarified rules, including the classification of control materials and software. Additionally, the risk classification tool has been updated accordingly and is available for access here.

Read more

Revised Qualification Criteria for Immediate and Expedited Evaluation Routes for Medical Device Product Registration

The qualification criteria for the immediate (IBR condition 1) and expedited (ECR-1) evaluation routes are now updated to reflect the revised criteria of requiring ed as a marketing history of the device(s) of at least 3 years in the jurisdiction of the independent reference regulatory agency approval. This revision aims to provide greater clarity on the available routes and criteria for stakeholders.

Read more

Advancing Standards - HSA's Incorporation of IMDRF Recommendations for Software in Submission

HSA has revised the submission guidance and guideline documents to integrate International Medical Device Regulators Forum (IMDRF) recommendations concerning software/programmed or programmable medical devices. These updates are available in the following documents: Guidance on Medical Device Product Registration, Guidelines for Software Medical Devices - A Life Cycle Approach, Preparation of a Product Registration Submission for General Medical Device and In Vitro Diagnostic Medical Devices using the ASEAN CSDT and related technical references and e-submission guides. HSA is a member of the management committee of the IMDRF.

Read more

Complementary Health Products

Phase 2 of Voluntary Notification of Health Supplements and Traditional Medicines

HSA launched Phase 2 voluntary notification in August 2023 following the positive participation in Phase 1 implementation which covered 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. Under Phase 2, the voluntary notification included the rest of the remaining Health Supplements and Traditional Medicines, medicated oils and balms (MOB) and medicated plasters. The Voluntary Notification System aims to establish a local database of reliable, good quality and safe products that consumers can refer to when they are making their purchases.

Read more

Cosmetic Products

New Guidance for Reporting of Adverse Effects, Products Defects and Product Recalls for Cosmetic Products

A new guidance on "Procedures for Reporting of Adverse Effects, Product Defects and Product Recalls for Cosmetic Products" has been published on HSA's website. The guidance provides information to the cosmetics industry on the reporting of adverse effects, product defects and product recalls of cosmetic products to HSA required under the Health Products Act 2007 and the Health Products (Cosmetic Products–ASEAN Cosmetic Directive) Regulations 2007.

Read more

Active Pharmaceutical Ingredients

Implementation of Active Ingredients Regulations

Effective from 18 December 2023, active ingredients are regulated under the Health Products Act and its regulations, including the Health Products Act (Active Ingredients) Regulations 2023. This follows a public consultation that took place between July 2023 to August 2023 on the Proposed Regulation for Active Ingredients under the Health Products Act.

Read more

INTERNATIONAL & BILATERAL COLLABORATIONS

ACCESS CONSORTIUM

Access Consortium offers pipeline meetings to pharmaceutical and biotechnology companies

The Access Consortium is offering joint pipeline meetings to pharmaceutical and biotechnology companies, which are an opportunity exchange information on new developments and collaborate on new possibilities. Information discussed in these meetings will remain confidential and helps in planning for future applications.

Read more

Access Consortium Promise Pilot Pathway

The Access Consortium Promise Pilot Pathway has established an aligned process for priority review of new active substances which diagnose, treat or prevent a condition that is serious, life-threatening or severely debilitating; and for which no other treatment is currently registered and marketed for the proposed indication.

Read more

Advanced Therapy Medicinal Products Working Group (ATMP WG)

The Access Consortium has established a new working group for advanced therapy medicinal products (ATMPs) in November 2023. The main goals of this working group include fostering interdisciplinary (quality, non-clinical, clinical) scientific discussions on emerging innovative therapeutic concepts and technologies, and exploring potential synergies and opportunities for work-sharing, reliance and providing joint scientific advice. The work group is in its early stages of establishing the framework on the scope of collaborations and industry will be updated on its development subsequently.

Read more

Expression of Interest for Access work sharing initiatives for New Active Substances, Generics and Biosimilars

The Access Consortium has innovative work sharing initiatives for the coordinated assessment of an application that has been filed with multiple consortium agencies.

The New Active Substance Work Sharing Initiative (NASWSI), Generic Medicines Work Sharing Initiative (GMWSI) and Biosimilars Work Sharing Initiative (BSWSI) are currently actively seeking applications for these initiatives, which covers new chemical or biological entity, generic and biosimilar applications, that are submitted to at least two consortium agencies.

Companies can utilise these initiatives, which allows for simultaneous coordinated review via work sharing among Access agencies, consolidated Q&As from all regulators to which joint submission is made, shorter review timelines, with potential access to a combined market size of ~150 million and near simultaneous approvals in multiple markets.

Read more (NAS) Read more (Generics) Read more (Biosimilars)

ASEAN

The Thirty-Eighth Meeting of the ASEAN Cosmetic Committee and its Related Meetings

HSA hosted this event between 20 – 23 November 2023, which was the first in person meeting post pandemic. There were 159 registered participants from HSA, overseas regulatory agencies and national laboratories as well as local and overseas cosmetics industry. The meeting was successful in sharing the progress of the implementation of the ASEAN Cosmetic Directive and harmonising the technical requirements and testing methods on cosmetic products.

INTERNATIONAL

Permanent Forum on International Pharmaceutical Crime (PFIPC) International Laboratory Forum on Counterfeit Medicines (ILFCM)

HSA successfully hosted the PFIPC and ILFCM in Singapore from 25 to 29 September 2023. This event marked the 25th anniversary of the PFIPC and ILFCM's inception, and the continued commitment to protect global public health.

30 participants representing the regulatory law enforcement agencies and laboratories from 18 countries in Europe, North America, Asia, and Australia attended the event. With the increasing complexities in pharmaceutical crimes, the forums were critical in forging collaboration among its members, and allow the sharing of strategies, experience, and technical know-how in combating pharmaceutical crimes and safeguarding global public health.

HSA approvals recognised by MHRA's new International Recognition Procedure for medicines

United Kingdom's (UK) Medicines & Healthcare products Regulatory Agency (MHRA) has created a new international recognition route for medicines utilising pre-existing approvals from various countries, including Singapore's HSA, effective from 1 January 2024.

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

Read more

HSA's medical device marketing approval accepted for support of compliance by Hong Kong

Starting from 2 April 2024, the Hong Kong's Department of Health Medical Device Division will recognise marketing approvals granted by HSA for medical devices for listing with them. This applies to application for the listing of Class II/III/IV General Medical Devices and In Vitro Diagnostic Medical Devices.

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

Read more

ENGAGEMENTS

Public Consultation on the Proposed Amendments to the Health Products (Therapeutic Products) Regulations

29 February 2024

HSA invited public feedback on proposed amendments to Regulation 23 of the Health Products (Therapeutic Products) Regulations on patent declaration. The public consultation took place from from 1 March 2024 to 12 April 2024. The proposed amendments aim to provide clarity to industry stakeholders on the types of patents that must be considered when making a registration application for a therapeutic product, and for which the provisions under regulation 23 apply, and ensure a system that facilitates all industry stakeholders in making registration applications and minimise any potential indiscriminate use of the mechanism under regulation 23.

Read more

Complementary Health Products (CHP) Industry Training Workshop

31 October 2023

HSA hosted an industry training working with the aim to provide CHP dealers with insights on the expected safety, quality and labelling standards for health supplements, traditional medicines, medicated oils, balms and medicated plasters; and the VNS submission process. It was conducted in a hybrid manner on-site and online via Zoom. About 400 participants attended the session.

Public Webinar on draft E6(R3) Good Clinical Practice guideline

1 August 2023

HSA hosted a public webinar on the draft International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) E6 (R3) Good Clinical Practice guideline, which was available for public consultation. The webinar aimed to update stakeholders on the upcoming changes in the revised guideline. Stakeholders could then be better informed and submit their feedback, if any, as part of the public consultation. About 490 participants attended the two-hour session.

Read more

Industry briefing session on implementation of eCTD in Singapore

9 May 2023

HSA held an industry briefing session on 9 May 2023 on the implementation of eCTD in Singapore, as part of the industry consultation held from 2 May to 12 June 2023. About 400 participants attended the online briefing. The session provided a walkthrough of the draft eCTD specification as well as the eCTD submission procedure in Singapore. Stakeholders could then have a better understanding of the published draft documents and the opportunity to provide their feedback.

Read more