HSA's efforts in accelerating development and access to essential COVID-19 therapeutics and medical devices

SUPPORTING PRODUCT INNOVATION

125

Consultations conducted to provide early scientific and regulatory advice for COVID-19 therapeutics and medical devices

17

Expedited approvals for clinical trials on COVID-19 therapeutics

ENHANCING CLARITY OF REGULATORY REQUIREMENTS

14

Guidances published on health products used in the diagnosis, management and treatment of COVID-19

EXPEDITING MARKET ACCESS

172

Expedited approvals for therapeutics and medical devices to meet the essential needs for COVID-19

Approvals include

- **163** COVID-19 diagnostic tests
- **5** Ventilators
- **3** Decontamination devices
- **1** Therapeutic used in treatment of COVID-19 infection

1 COVID-19 vaccine authorised under the **Pandemic Special Access Route (PSAR)**

FACILITATING MANUFACTURE AND DISTRIBUTION

20

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

92

Consultations & applications completed to support manufacturing and distribution of novel therapeutics and vaccines

PARTNERSHIPS AND ENGAGEMENTS

Contributing our regulatory and scientific expertise in

18

local & international working groups and workshops on COVID-19

>7,900

Emails sent to stakeholders on COVID-19 updates

For more information, please visit: **https://www.hsa.gov.sg/covid-19-information-and-advisories**

REGULATORY UPDATES AND PROCESS ENHANCEMENTS

Public consultation on the proposed regulation for Cell, Tissue and Gene Therapy Products (CTGTP)

Nov 2020

HSA is introducing CTGTP as a new category of health products to be regulated under the Health Products Act. This fit-for-purpose regulatory framework will facilitate patients' access to medically important therapies that meet appropriate standards of safety, efficacy and quality, and supports product development and commercialisation.

In addition to conducting several focus group discussions over the past few years, HSA also held a public consultation which concluded in Nov 2020. Most of the feedback received involved operational and technical enquiries or clarifications which are addressed in the Summary of Responses published on HSA's website. There are no major shifts in our proposed draft regulations.

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New online form to facilitate reporting of medical devices adverse events by healthcare professionals

Nov 2020

HSA launched this user-friendly and mobile compatible form to simplify the reporting process. Healthcare professionals no longer have to submit the reporting forms through emails.

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Enhanced Complementary Health Products (CHP) Classification Tool

Sep 2020

The CHP Classification tool has been launched since Dec 2018 to guide dealers to determine the classification of typical CHP. It reduces the time and effort for companies to obtain classification advice.

HSA has recently enhanced the tool to improve the user experience. New features include a more user-friendly search function for the ingredients and intended uses, provision of ingredient-specific advice (e.g. maximum allowable quantity and required cautionary statement) and guidance for compliance with current regulations. The usage rate has increased by nearly 33% since the release of the enhanced tool.

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New web portal for healthcare professionals to access HSA-approved educational materials for therapeutic products

Apr 2020

Digital copies of the Physician Educational Materials, Patient Medication Guides and Patient Alert Cards can be conveniently accessed from HSA's new web portal. This enhances accessibility to the educational materials with essential information on significant safety concerns associated with specific therapeutic products, along with advice on the mitigation measures to take.

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New Digital Health webpage

Dec 2020

HSA launched this webpage as a one-stop portal to encourage innovation in the area of digital health by providing greater clarity on the regulatory controls and guidelines on the digital health products that are regulated as medical devices.

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Enhancing transparency and streamlining submissions for therapeutic products registration

May – Dec 2020

(i) Publication of HSA's summary reports of benefit-risk assessments for approved new chemical and biological entities enhances regulatory transparency through open communication with stakeholders and the public. The reports contain a summary of the quality, efficacy and safety data contributing to the benefit-risk assessment, as well as HSA's conclusion on the benefit-risk balance of the approved indication. This could also facilitate companies' filing in jurisdictions that offer reliance pathways, where these regulatory agencies could leverage HSA's assessments in their review.

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(ii) Launch of online form to streamline the submission of post-approval data and documents to fulfil therapeutic product registration conditions enables registrants to include multiple products sharing the same registration condition and supporting documents in a single submission. This reduces the need for duplicated submissions for a more efficient process.

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(iii) Streamlined approach for stability data requirements replaces the requirement for site-specific data of each manufacturing site sought in the registration and variation applications. Site-specific data is no longer required if the specified technical criteria are met to scientifically justify the extrapolation of stability study results from one manufacturing site to another.

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Updates on the e-labelling initiative for therapeutic products

Aug 2019 – Present

Starting with prescription-only medicines, this initiative was introduced to facilitate the efficient and timely dissemination of the latest approved package inserts and patient information leaflets in an eco-friendly manner. Instead of relying on hardcopies, companies may insert machine-readable codes or URLs on the product cartons that link to the digital product information located on secure online systems.

To date, e-labelling has been implemented for about 220 products. HSA is collaborating with the industry and healthcare professionals to refine the approach and targets to publish our final guidance in early 2021.

International Medical Device Regulators Forum (IMDRF)

HSA assumed the chairmanship for IMDRF in 2020 to drive strategic directions for medical device regulatory harmonisation. One of the key outcomes was the **endorsement of HSA as a member of the National Competent Authority Report (NCAR) Exchange Program**. Leveraging this program enables HSA to further strengthen our post-market surveillance system by contributing and gaining timely access to global updates on medical device adverse events.

Highlights of IMDRF activities

IMDRF STAKEHOLDERS FORUM
23 SEP 2020

27 Speakers

841 Registered participants

Interactive Q&A session on the latest regulatory updates for medical devices, IMDRF harmonisation activities and sharing of perspectives by our stakeholders

IMDRF-DITTA* JOINT WORKSHOP ON CYBERSECURITY
21 SEP 2020

17 Speakers

500 Registered participants

Gained insights on the collaborative efforts in strengthening medical device cybersecurity by the regulatory agencies, industry, healthcare institutions and standards organisations

**DITTA stands for the GlobalDiagnostic Imaging, Healthcare IT, and Radiation Therapy Trade Association*

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International Coalition of Medicines Regulatory Authorities (ICMRA)

HSA continues to actively support the strategic coordination and cooperation among global medicine regulatory authorities through ICMRA. During the COVID-19 pandemic, regulators discussed key regulatory developments and policies, as well as pragmatic approaches to enable regulatory agility for the development and approval of COVID-19 therapeutics and vaccines.

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Project Orbis

The U.S. Food and Drug Administration (FDA) Oncology Center of Excellence developed Project Orbis to provide a framework for concurrent submission and review of oncology products among international regulatory health authorities. HSA participates in this collaborative review project alongside international jurisdictions, including Australia, Brazil, Canada and Switzerland to facilitate early patient access to critical life-saving medicines for cancer. HSA has issued regulatory approvals for 5 applications through this collaboration.

Access Consortium, previously known as the ACSS Consortium

The Consortium was renamed from the previous Australia-Canada-Singapore-Switzerland Consortium (ACSS) in Oct 2020, due to the inclusion of the United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA) as a new member. The new name, "Access", reflects the group's key aim of providing patients with timely access to high-quality, safe and effective therapeutic products in the member countries through work-sharing initiatives.

Access' New Active Substance Working Group (NASWG) and Generic Medicines Working Group (GMWG)

HSA has completed 4 therapeutic products applications through the work sharing collaborations under the NASWG and GMWG. There are ongoing therapeutic product applications under review and HSA continues to receive expressions of interest from companies intending to benefit from simultaneous filling in Singapore and partner agencies through this collaboration pathway.

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Access' Complementary Health Products Working Group (CHPWG)

The CHPWG has made good progress in the convergence of the following technical guidelines and requirements amongst the member authorities:

(i) Completed the guidance on the minimum data requirements for the safety assessment of CHP ingredients to facilitate joint safety assessments between the WG members; and

(ii) Completed the Efficacy Evaluation Report template and guidance to enhance consistency in the approach to evaluate claims and efficacy of indications which require scientific evidence and/or traditional evidence to substantiate the intended uses of the products.

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ASEAN Traditional Medicines and Health Supplements Product Working Group (TMHSPWG)

Under HSA's chairmanship, the TMHSPWG has finalised the ASEAN Agreements on Traditional Medicines (TM) and Health Supplements (HS) in preparation for signing by the ASEAN Economic Ministers targeted in Q4 2021. These agreements will facilitate trade in safe and good quality TMHS products between Singapore and other ASEAN member states through the adoption of harmonised technical requirements and guidelines.

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Virtual workshop series on Complementary Health Products (CHP)

Nov 2020

HSA conducted a series of 5 virtual workshops which were attended by over 300 attendees from 250 companies. The topics covered included:

- **Knowing your CHP and its Regulations** - provided an overview of the regulatory requirements of CHP, updates on using the improved CHP classification tool as well as the sharing of practices to promote pricing transparency by our invited speaker from the Competition and Consumer Commission of Singapore;
- **Chinese proprietary medicines submission guidance** – conducted 2 sessions to facilitate stakeholders in making more robust applications by providing recommendations to avoid deficiencies in submissions;
- **Supporting your CHP with science** – provided guidance on the scientific principles to support product claims and facilitated better understanding of the references for herbal products; and
- **Protecting your consumer, towards a safer CHP** - focused on key areas that contribute to consumer safety, including the labelling requirements and use of cautionary statements, limits for vitamins and minerals, identification of high-risk CHP and introduction to herb-drug interactions.

We received positive feedback that the workshops provided useful information, which enriched participants' understanding of the approaches to market better quality and safer CHP.

Webinar: Medical Device Unique Device Identification (UDI) system

Oct 2020

Attended by over 500 participants, this webinar forms part of HSA's early engagements with stakeholders to share plans on the implementation of the UDI system in Singapore.

The UDI System provides a globally harmonized system to facilitate unambiguous identification of medical devices through distribution and use. When fully implemented, medical device manufacturers, distributors and healthcare providers can leverage the system to enhance patient health and safety through the improved identification and traceability of medical devices (e.g. during post market actions, recording of medical device use in patients).

READ MORE

Virtual workshop: Risk assessment of nitrosamine contamination in therapeutic products

Apr 2020

HSA hosted this workshop to share recommendations on the steps that industry stakeholders should take to detect and prevent nitrosamines contamination in therapeutic products. Attendees gained insights on HSA's regulatory approach as well as the risk assessment and mitigation strategies to address this issue.

Over 200 industry stakeholders attended this workshop. Most of the survey respondents (90%) found the workshop helpful in enhancing their understanding of the requirements.