# 01 HEALTH PRODUCTS REGULATION GROUP

We are committed to maintaining the standards of health products in Singapore, while at the same time ensuring that access to essential health products is as quick and seamless as possible.

# REGULATORY DEVELOPMENTS AND REVIEWS

**We conduct regular reviews of our regulatory processes to facilitate the latest developments in health products.**

## OUR TIMELY RESPONSE TO THE PANDEMIC

### Facilitation of access to medical devices for COVID-19

In light of the demand for medical devices such as medical masks, COVID-19 diagnostic test kits, respirators and ventilators brought on by the pandemic, we exercised regulatory agility to ensure timely access to these critical medical devices while not compromising on their safety and effectiveness. This included establishment of the provisional authorisation route and providing relevant regulatory guidance such as guidance on the development of 3D printed medical devices.

As part of our regulatory efforts, we also published a guidance document on our website in June 2020 that covered the key regulatory requirements for decontamination devices and good practices for healthcare institutions and other user facilities.

**As of 31 March 2021, these devices were granted authorisation under the provisional authorisation route:**

**180** **COVID-19 diagnostic test kits**

**5** **Ventilators**

**3** **Decontamination devices**

### Ensuring safety standards of medical masks

Due to the surge in demand for medical masks in Singapore, many local companies (including those from non-medical related industries) responded by applying to set up mask manufacturing facilities. To ensure the quality and performance of locally manufactured masks, HSA set up a virtual inspection and desktop review process to ensure compliance with international standards.

### Conditional authorisation of Veklury (remdesivir)

In response to the urgent public health demands for remdesivir during the COVID-19 pandemic, HSA facilitated early access to the medicine through a conditional approval route in June 2020. This was subject to submission of data from ongoing clinical studies and manufacturing testing to ensure the continued safety and efficacy of the product.

### Pandemic Special Access Route (PSAR)

We introduced PSAR in December 2020 to facilitate early access to critical novel vaccines, medicines and medical devices required during pandemic situations.

PSAR enables HSA to prioritise the review of critical COVID-19 vaccines and treatments through a rolling submission process, where companies can submit real-time data as and when they are available from ongoing studies. This allows HSA to start the evaluation early while the clinical and quality studies are concurrently underway, instead of having to wait for the full dataset to be submitted before evaluation can commence under the usual regulatory process. HSA has expedited the access to two COVID-19 vaccines through PSAR interim authorisation, while ensuring scientific rigour in the assessment of quality, safety and efficacy.

**Singapore was the 1ST Asian country to approve the Pfizer-BioNTech COVID-19 vaccine and Moderna COVID-19 vaccine, on 14 December 2020 and 3 February 2021, respectively**

**17** **COVID-19 clinical trials, investigating novel antiviral agents, monoclonal antibody treatments, cell therapy and vaccines have been approved since the start of the pandemic**

### Remote inspections during COVID-19 circuit breaker and phased transition periods

With inspections being affected by COVID-19 safety measures, we turned to the use of secure technology platforms that allowed visual and audio communications to perform virtual inspections of the premises of licensed manufacturers and dealers, as well as retail pharmacies and clinical trials.

This approach enabled us to ensure that these companies complied with regulatory requirements, including Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) standards to ensure the continued supply of safe and good quality medicines.

It also allowed us to continue our Good Clinical Practice (GCP) inspection of clinical trials, including the electronic trial master files and electronic data capture systems used in the clinical trials, and to interact with sponsor representatives from different time zones.

### Building our capability in ultra-low temperature (ULT) cold chain vaccines handling

To ensure that we were able to handle ULT vaccines in our national vaccination programme, we have:

- Provided guidance and advice to distributors on ULT cold chain requirements (-70 degrees Celsius), as well as the storage and transport systems required
- Supported applications for Good Distribution Practice (GDP) Certifications and conducted audits to assess that companies' quality management systems complied with GDP requirements
- Reviewed temperature charts from temperature loggers accompanying vaccine shipments during transportation to ensure that transportation conditions were in order before the COVID-19 vaccines were released for use

**As of March 2021, HSA has received and approved**

**4** **GDP Certifications**

**2** **amendment applications for adding cold chain storage capabilities to dealers' licences**


*Photo credit: Marken Time Critical Express Limited (Singapore Branch)*

### Inspection of a COVID-19 vaccine manufacturer in China

In December 2020, we successfully conducted a GMP inspection of a COVID-19 vaccine manufacturing facility in China.

In order to meet the tight and rigorous travel requirements, we had to start our travel nearly three weeks before the actual inspection date. During the process, we also received cross-agency support from Singapore's Economic Development Board and Ministry of Foreign Affairs, which assisted with expeditious travel approvals, special clearances and logistic arrangements.

HSA's role in ensuring that overseas manufacturing facilities supplying COVID-19 vaccines to Singapore comply with international quality standards, and the importance of close inter-governmental agency support were amply demonstrated in this mission.



## NEW REGULATIONS FOR CELL, TISSUE AND GENE THERAPY PRODUCTS (CTGTP)

CTGTP are a novel and innovative class of health products. In February 2021, we gazetted 11 pieces of subsidiary legislation for CTGTP. The CTGTP regulations were implemented under the Health Products Act on 1 March 2021.

Prior to this, HSA had conducted extensive focus group discussions and public consultations with a diverse group of stakeholders. The collaborative efforts, valuable feedback and contributions of our stakeholders enabled the implementation of fit-for-purpose, risk-based regulations that support product development and commercialisation of these medically important therapies. The regulations also facilitate patients' access to novel products that meet the appropriate standards of safety, efficacy and quality.

## MANAGEMENT OF NITROSAMINE CONTAMINATION IN MEDICINES

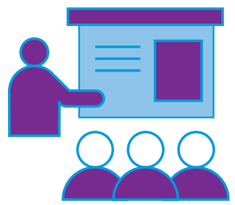
HSA continues to adopt a system-wide coordinated approach to manage the issue of nitrosamine contamination in medicines. Our efforts include:

- Collaborating closely with international regulators to discuss and formulate appropriate measures to address this issue to safeguard public health
- Engaging industry stakeholders to review the risk of nitrosamine contamination in their products and to mitigate any identified risk

In April 2020, we organised a virtual stakeholder briefing to clarify HSA's regulatory approach in managing this issue of nitrosamine contamination, to communicate the actions required by stakeholders and to address their concerns.

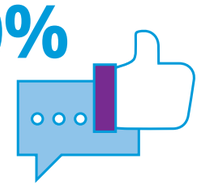
**Over**

**200** **industry stakeholders attended the briefing**

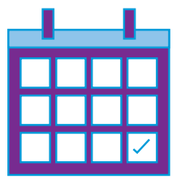


**Around**

**90%**



**of the feedback received rated the briefing as useful in enhancing the understanding of HSA's requirements**



**As of March 2021, more than** **85%** **of locally registered products were on track to meet the December 2021 deadline**

We have also been working with companies dealing with angiotensin receptor blockers (such as losartan and valsartan), which belong to a group of high blood pressure medicines, to review their manufacturing processes and implement changes to mitigate the risk of nitrosamine formation by December 2021.

## NEW REGULATIONS AND GUIDELINES

To ensure our stakeholders fully understand the impact of new regulations, we came up with several guidelines over the year-in-review.

| Guideline | Details |
|---|---|
| Collaboration with the Ministry of Health (MOH) for the MOH-AI Guideline for Safe Development and Implementation of Artificial Intelligence (AI) in Healthcare | • HSA addressed the risks present in the development and implementation of AI medical devices (AIMDs) in healthcare settings<br>• The purpose of the guideline is to encourage partnership between developers and implementers to ensure patient safety<br>• The guideline is targeted to be launched in the second half of 2021 |
| Guideline on changes relating to the new regulatory frameworks for Medical Devices Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR) | • The European Union (EU) introduced two new regulations — MDR and IVDR, in place of the current Medical Devices Directive (MDD)<br>• As a result of this change, revisions to device labelling and instructions for use on a significant number of medical devices are expected as many devices in Singapore share common labelling with those supplied in EU<br>• This new guideline serves to provide clarity on the changes which would require submissions to HSA<br>• The proposed guideline went through a focus group session in July 2020 and was finalised in October 2020 |
| New regulatory guideline for 3D Printed Medical Devices (3DP MDs) | • 3D printing allows for the production of medical devices matched to an individual's specific anatomy<br>• This new guideline for 3DP MDs serves to differentiate mass-produced from custom-made 3DP MDs and explain the regulatory controls involved<br>• The guideline was published in January 2021 for consultation and is expected to be finalised in Q3 2021 |

## PUBLISHING OF BENEFIT-RISK ASSESSMENT SUMMARY REPORTS

In June 2020, we began publishing summary reports of benefit-risk assessments for approved new chemical and biologic entities on our website. Through this initiative, we aim to enhance regulatory transparency through open communication with stakeholders and the public.

This is in line with current international best practices among global regulatory agencies and is beneficial for companies that may wish to leverage HSA's assessments as part of their filing strategy to jurisdictions that offer reliance pathways, as they can now freely access HSA's assessments and use the reports to support their regulatory filings in those countries.



## IMPLEMENTATION OF REVISED HEAVY METAL LIMITS FOR COMPLEMENTARY HEALTH PRODUCTS (CHP)

From September 2020, it has become mandatory for all CHP in the local market to comply with the revised limits of heavy metals. These limits have been revised to enhance consumer safety and align with international standards such as those set by the World Health Organization and ASEAN. Additionally, it will also help facilitate entry into other markets for companies dealing with such products.

To support these new limits, HSA has provided guidance to the industry on ways to minimise heavy metal contamination in CHP.

## STREAMLINED REQUIREMENTS FOR STABILITY DATA

HSA has introduced a streamlined approach for stability testing of multiple manufacturing sites for the same therapeutic product. This new approach allows the utilisation of stability data generated by one manufacturing site to support the shelf-life of the same product manufactured at another site when scientifically justified, thereby minimising the need for each manufacturing site to generate its own set of data.

## ROLLING OUT OF NEW E-PHARMACY FRAMEWORK

In light of the increasing prevalence of telemedicine, HSA rolled out a new e-pharmacy framework for the dispensing of medicines in May 2020.

This new framework covers the following safeguards to ensure patient safety:

- Closed loop system for the transmission of e-prescriptions to prevent prescriptions from being changed or reused by the patients, enable traceability to the prescribing doctor, and guard against cybersecurity threats
- Clear procedures and practices for the storage, packing, labelling, and secure delivery of medicines to the intended patients in accordance with the e-prescriptions received, and with the appropriate professional supervision by a qualified pharmacist
- A strict policy to prevent dispensing of medicines containing controlled substances

# STREAMLINING AND ENHANCING OUR PROCESSES

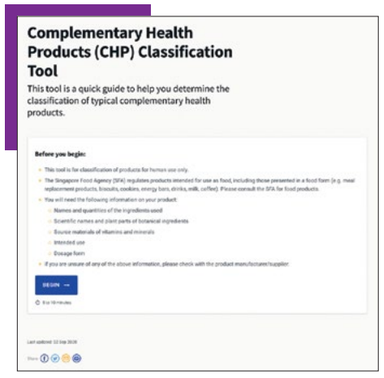
**We continually streamline and enhance our processes to deliver the greatest value to all our stakeholders.**

## NEW STREAMLINED DOCUMENT SUBMISSION PROCESS

A new FormSG form has been introduced to streamline the submission of post-approval data and documents to fulfil therapeutic products registration conditions.

Highlights of this new form include:

- Ability to include multiple products sharing the same registration condition in one single submission
- Access to control via Corppass for added data security
- Elimination of multiple submissions for greater process efficiency

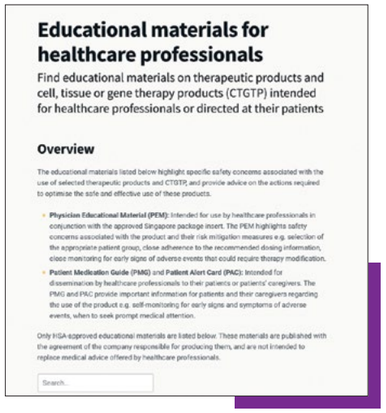



## ENHANCED CHP CLASSIFICATION TOOL

In September 2020, we launched an enhanced CHP classification tool. This new tool features a more user-friendly search function, ingredient-specific advice and guidance for compliance with current controls.

We have received positive feedback that the new tool is more efficient and informative.

**Since the release of our enhanced CHP tool, usage rate has increased by nearly 33%**




## ENHANCED ACCESS TO SAFETY INFORMATION

In line with HSA's ongoing digital transformation efforts, we have launched two new safety initiatives.

The first seeks to ensure that healthcare professionals have easy and on-demand access to trusted safety information on therapeutic products, and cell, tissue or gene therapy products either through our website or email. Healthcare professionals can access educational materials for their patients or themselves through a dedicated webpage, or subscribe to email updates regarding new postings on the HSA website.

The second is an online survey which was conducted to better understand how healthcare professionals currently obtain safety information on therapeutic products from HSA, and the barriers faced in accessing our communication channels. Data obtained from this survey will help us identify potential areas for improvement.

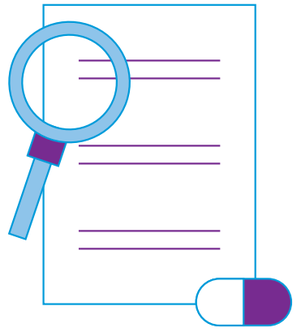


# STAYING VIGILANT

**Ensuring the safety and quality of health products rank amongst our top priorities.**

## SURVEILLANCE OF LOCAL PRODUCT DEFECTS

Over the year-in-review, more than 180 cases of product defects relating to locally registered therapeutic products were reported. The top three issues were related to:



**Manufacturing defects: 63 cases**

**Product packaging defects: 47 cases**

**Product contamination: 22 cases**

In response, HSA worked with companies to ensure that the appropriate corrective and preventive actions were taken to mitigate the impact on the safety and quality of the defective therapeutic products and their future batches. Such actions included:

**18 amendments to product registration**

**Issued 12 communications**
(e.g. Dear Healthcare Professional, Dear Purchaser Letters and press releases)

**Recalled 8 products from the market**

## MANAGING PRODUCT RISK

### Singapore-specific Risk Management Plans (RMP)

**39** **RMPs were reviewed** prior to therapeutic product registration

**6** **new RMPs were implemented**
(including provision of educational materials to healthcare professionals and patients, and submission of periodic benefit-risk evaluation reports)

### Safety signals

**147** **safety signals were assessed as part of post-market pharmacovigilance activities, resulting in:**

- Voluntary withdrawal of Esmya (ulipristal acetate 5mg) in October 2020 due to the risk of serious liver injuries identified from overseas reports
- Restrictions on the use of products containing montelukast due to the known but rare risk of neuropsychiatric events
- Amendment of local package inserts to address newly emerging safety concerns
- Provision of product safety information directed at healthcare professionals

### Risk assessments on adulterated health products

**19** **risk assessments on adulterated products were conducted as part of post-market surveillance, resulting in the issuance of press releases to warn the public about these products**

## COMMUNICATING THE IMPORTANCE OF SAFETY

**In FY20/21:**

**12** **press releases** containing advisories on **24** **products** were issued

**56** **company Dear Healthcare Professional Letters** (DHCPLs) were reviewed; and

**5** **DHCPLs** were written and issued by HSA

**3** **Adverse Drug Reaction News Bulletins** were published and sent to registered healthcare professionals

**2** **safety updates** were published on our website



# SHARING OUR KNOWLEDGE

**As the authority on health products regulation, we are always ready to share our expertise and knowledge with our stakeholders and partners.**

## REGULATION OF IN VITRO DIAGNOSTIC DEVICES (IVDD) WORKSHOP

In September 2020, speakers from HSA were invited to speak at a "Regulation of IVDD" workshop, which was organised by Duke-NUS CoRE.

The objective of the workshop was to bring about a fundamental understanding of the principles behind effective regulation of IVDD and equip participants to make an informed decision when planning for the development, market entry and management of such devices.

Our speakers covered the following topics:

- Regulatory requirements of IVDD throughout the product life cycle
- Roles of standards and guidelines
- Post-market surveillance

## REGULATION OF SOFTWARE AS A MEDICAL DEVICE (SAMD) WORKSHOP

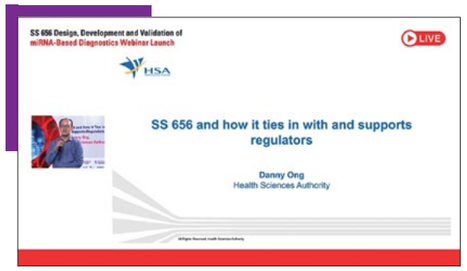
In December 2020, Duke-NUS CoRE organised a two-day workshop on the regulation of SaMD, and its related standards and guidelines.

The workshop which was targeted at industry professionals and academia, discussed the increasingly important role of software in medical devices that deliver critical healthcare services, as well as the importance of regulating them.

HSA was invited to share our approach in regulating SaMD through the software life cycle, including pre-market, post-market and change management controls. We also shared case studies to illustrate the importance of proactive monitoring in ensuring the safe and effective use of devices.

Additionally, we took the opportunity to share our regulatory approaches for AI during the workshop as we noted the increased use of AI in healthcare settings.


## SINGAPORE STANDARD 656 WEBINAR LAUNCH




Over the past year, HSA has been involved in the development of Singapore Standard 656 : 2020 (SS 656), which covers the design, development and validation of microRNAs (miRNAs) based diagnostics. miRNAs are particularly significant for their potential in disease screening, diagnosis, monitoring of disease progression or recurrence, and for predicting response to therapy.

At the official launch of SS 656 in September 2020, HSA was invited to speak at the webinar alongside other prominent speakers from around the world, covering topics such as how the standard can be applied in R&D, commercialisation of in vitro diagnostic products, clinical diagnostics and medical device regulation.

## IMPLEMENTATION OF MEDICAL DEVICE UNIQUE DEVICE IDENTIFICATION (UDI) SYSTEM IN SINGAPORE

In October 2020, HSA hosted a webinar to engage stakeholders, as well as gather feedback on the plans for the phased implementation of the UDI System in Singapore.

The UDI System is a globally harmonised system that facilitates unambiguous identification of medical devices through their distribution and use. It offers medical device manufacturers, distributors and healthcare providers a way to enhance traceability and identification of medical devices (e.g. during post-market actions, or recording of medical device use in patients).

Implementation of UDI in Singapore is expected to take place in phases from 2022, starting with high-risk implantable medical devices, followed by other Class D, C and B devices.



# BOLSTERING OUR INTERNATIONAL LINKS

**To maintain our world-class standing, we continued to foster strong ties with overseas partners.**

## INTERNATIONAL MEDICAL DEVICE REGULATORS FORUM (IMDRF)

Despite being the Chair of IMDRF in a year (2020) that was overshadowed by the COVID-19 pandemic, we managed to successfully organise the following events:

- First-ever virtual IMDRF Management Committee meeting
- Stakeholders' forum
- Joint cybersecurity workshop with the Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Association (DITTA)

We were also formally endorsed as a member of the IMDRF National Competent Authority Report exchange programme, which seeks to facilitate the exchange of post-market safety information on medical devices amongst global regulatory authorities, and trigger the rapid adoption of field safety corrective actions to better safeguard patients' health and safety.

**During our 2020 IMDRF chairmanship, we:**

**Finalised**
**10** **procedural and technical guidance documents**

**Approved**
**3** **new work item extensions on medical device adverse events terminologies, cybersecurity and personalised medical devices**

**Established** **1** **new working group on artificial intelligence medical devices**

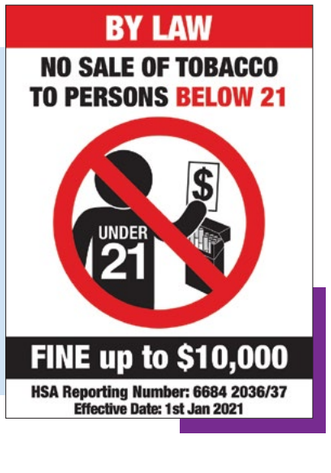
# LOCAL OUTREACH PROGRAMMES

**We are committed to serving our local stakeholders through various outreach programmes.**

## INCREASE IN THE MINIMUM LEGAL AGE (MLA) FOR TOBACCO

As part of Singapore's ongoing efforts to reduce smoking prevalence, the MLA for the purchase, use, possession, sale and supply of tobacco products was raised from 20 to 21 years old on 1 January 2021.

We sent notifications and new signage stickers to all tobacco retailers to help them prepare for the revised age restriction. Our officers also engaged with tobacco retailers to remind them about the new law during routine inspections.




## STANDARDISED PACKAGING (SP) FOR TOBACCO PRODUCTS

As of 1 July 2020, all tobacco products sold in Singapore come in standardised packaging with enlarged graphic health warnings ("the SP Measure"). The SP Measure applies to all tobacco products, including cigarettes, cigarillos, cigars, beedis, *ang hoon* and other roll-your-own tobacco products.

To help tobacco manufacturers, importers, wholesalers and retailers prepare and adjust, they were given a notice period of 12 months starting from 1 July 2019. During this period, we regularly sent our officers, as well as letters and circulars, to remind tobacco licensees of this new measure.

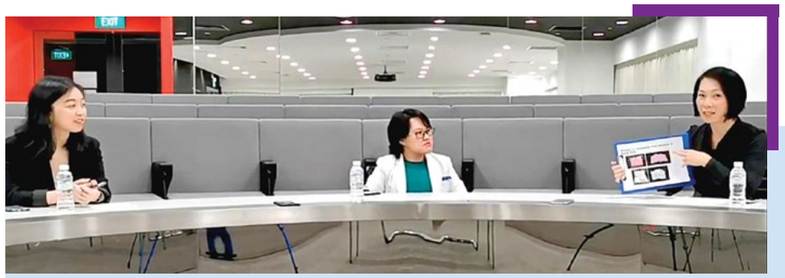

## INAUGURAL VIRTUAL ROADSHOW ON ADVERSE EVENT (AE) REPORTING

In September 2020, we held our inaugural virtual roadshow on the importance of pharmacovigilance and AE reporting for healthcare professionals in Sengkang General Hospital.

The session was met with encouraging feedback from participants and demonstrated HSA's agility in adapting to new situations brought on by the COVID-19 pandemic.

**1ST roadshow conducted at Sengkang General Hospital**

**Over 100 participants comprising doctors and pharmacists attended**



## PARTICIPATION IN PHARMACEUTICAL SOCIETY OF SINGAPORE PHARMACY WEEK 2020

In October 2020, we participated in Pharmacy Week's virtual carnival organised by the Pharmaceutical Society of Singapore (PSS). Pharmacy Week is a public event organised annually by PSS to educate the public on the safe and effective use of medicines.

As part of our ongoing public education initiative to raise awareness on the side effects of health products and medicines, HSA participated in a panel discussion. We also delivered a talk about the dangers of purchasing health products from dubious sources online and advised the public to consult healthcare professionals when in doubt. The video recording of the talk was posted on the PSS website together with HSA's video about the dangers of purchasing health products from dubious sources online.

# NEW LOCAL PARTNERSHIPS

**We collaborate and partner with local organisations to further our work in health products regulation.**

## UPDATE ON PUBLIC HEALTH RESEARCH IN PHARMACOGENETICS

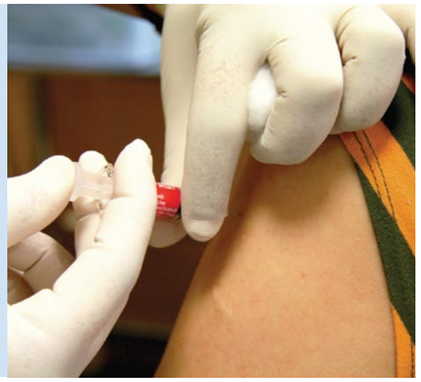
In August 2020, Sengkang General Hospital entered into a research collaboration agreement with HSA, joining four other public healthcare institutions (National University Hospital, Singapore General Hospital, Changi General Hospital and National Skin Centre) in the ongoing "Pharmacogenetics of Adverse Drug Reactions — Serious Skin Rash" study.

The findings of this study will allow HSA to evaluate the pharmacogenetics associations of serious skin reactions in the local population, and to formulate genotyping recommendations at a national level.

## PROJECT AGREEMENT WITH A*STAR TO DEVELOP TESTING CAPACITY FOR COVID-19 VACCINES

In September 2020, HSA signed a project agreement with the Agency for Science, Technology and Research (A*STAR) Bioprocessing Technology Institute to develop new in-house capabilities for the testing of locally manufactured or imported COVID-19 vaccines.

Areas of collaboration include setting up and validating test methods for independent analytical testing of COVID-19 vaccines, as well as training new HSA officers to perform lot release testing functions.





# KNOWLEDGE EXCHANGE

**Over the year-in-review, we collaborated with international partners to share and build up our knowledge and expertise.**

## THAILAND'S FOOD AND DRUG ADMINISTRATION (FDA) RELIANCE-BASED PROGRAMME

In September 2020, Thailand's FDA started their reliance-based programme, which allows them to leverage HSA's evaluation reports of Singapore-registered medical devices*.

The initial pilot programme has successfully concluded with 12 reports shared, and will now become a mainstay programme between the two regulators. The next phase of the programme will additionally include capacity building sessions through virtual platforms.

*With due consent from local registrant companies

## PROJECT ORBIS

Project Orbis is an ongoing collaboration with the US Food and Drug Administration (FDA) Oncology Centre of Excellence to provide a framework for concurrent submission and review of oncology products among international regulatory health authorities.

**Through this collaboration, HSA issued regulatory approvals for**

**5 applications**

## ACCESS CONSORTIUM

Previously known as ACSS Consortium, it was renamed in October 2020 to Access Consortium. With this new name comes the inclusion of the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) as a new member.

**Evaluation of**

**4 therapeutic products applications have been completed by HSA through this work-sharing collaboration**

## HSA-NATIONAL PHARMACEUTICAL REGULATORY AGENCY (NPRA) COLLABORATION

As part of our ongoing collaboration with Malaysia to evaluate generic medicines, we kicked off our first work-sharing project in April 2020. Our progress from parallel review to work-sharing is a significant step towards achieving regulatory efficiency.

## PARTICIPATION IN WORLD HEALTH ORGANIZATION (WHO) UPPSALA MONITORING CENTRE (UMC)'S MEDSAFETYWEEK 2020


In November 2020, HSA participated in WHO UMC's 5th MedSafetyWeek, a global social media campaign which carried the theme of "Every Report Counts" and garnered participation from 76 countries. HSA was part of the six-member organising committee and contributed to the development of three short animated videos that were aimed at encouraging the public and healthcare professionals to report AE.

Other highlights included:

- Collaborating with the Pharmaceutical Society of Singapore and Health Promotion Board to post video animations on their social media platforms
- Being featured in the October 2020 Uppsala Report (an e-publication by WHO-UMC)

## PILOT PROJECT ON PHARMACEUTICAL GMP INSPECTION BETWEEN KOREA AND SINGAPORE

In August 2020, we embarked on a one-year pilot project with Korea's Ministry of Food and Drug Safety (MFDS) to mutually recognise GMP inspections of pharmaceutical products conducted by both authorities.

The scope of this project applies to all pharmaceutical products for human use, including investigational medicinal products, drug substances, biopharmaceuticals and herbal medicinal products.

The eventual aim is for both authorities to sign a Mutual Recognition Agreement on GMP inspection of pharmaceutical products under the framework of the Korea-Singapore Free Trade Agreement.

**As of March 2021, both authorities have exchanged 7 GMP inspection reports each**



## INVOLVEMENT IN PIC/S ACTIVITIES

In December 2020, we participated in the 2020 Pharmaceutical Inspection Co-operation Scheme (PIC/S) Seminar on "Distant Assessment of GMP Compliance", which was hosted online by the Finnish Medicines Agency (FIMEA). The event saw regulators from different jurisdictions sharing their experience on "the conduct of distant GMP assessment" and "the security of information technology and communication tools".

HSA also participated as a member of the PIC/S Working Group on Revision of Annex 2 (Manufacture of biological medicinal substances and products for human use), which has been completed and effective since 1 May 2021.

## INVOLVEMENT IN INTERNATIONAL CONFERENCES

We were invited to share about the topics of "Remote Inspections within HSA and ASEAN", as well as "the Pharmaceutical Inspection Co-operation Scheme (PIC/S) and International Reliance Programmes" at several local and international events.

This included an invitation by Korea's Ministry of Food and Drug Safety (MFDS) to speak at the 2020 Korea-ASEAN Pharmaceuticals Inspectors Training and 2020 Korea-ASEAN GMP Conference in November 2020, and another by the ISPE Singapore Affiliate for the 2020 ISPE Singapore Virtual Conference in December 2020.


## INVOLVEMENT IN WHO WORKING GROUP

From October to December 2020, HSA participated as a member of the WHO Listed Authority (WLA) Working Group for Regulatory Inspections and Establishment.

The objective of this working group was to add a performance evaluation framework to the existing WHO Global Benchmarking Tool (GBT), to enable better assessment of national regulatory authorities that were applying for WLA status.

Our participation in this working group validated our experience and expertise in the area, and demonstrated our strong support to the WLA initiative.

# CLAMPING DOWN ON ILLEGAL ACTIVITIES

**We stayed vigilant in our efforts to disrupt illegal activities involving health and tobacco products.**

## TARGETED RAIDS

Over the year-in-review, we collaborated with law enforcement agencies to disrupt the illegal supply of sexual enhancement medicines, cough syrups and pills through targeted raids in areas such as Geylang.

**120** joint operations conducted

Illegal health products seized amounted to a street value of more than **$335,000**

**34** suspects investigated

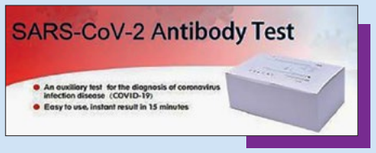
## SMUGGLING THROUGH OVERSEAS PARCELS

Together with the Singapore Police Force (SPF), we discovered six overseas parcels containing illegal sexual enhancement medicines (SEMs) in a Sims Drive residential unit.

**62,000** units of SEMs worth over **$90,000** seized

## HEALTH PRODUCTS SOLD ONLINE WITH FRAUDULENT AND MISLEADING COVID-19 CLAIMS

At the start of the COVID-19 pandemic in Singapore, there was an increase in the online sale of health products with fradulent and misleading claims such as being able to prevent, treat or diagnose COVID-19. Such products included home-based test kits, health supplements, herbs, traditional medicines and hand sanitisers.




**652** listings removed from local e-commerce platforms including Carousell, Lazada, Shopee, eBay and Facebook

Over **451** warning letters issued to the sellers

## REVOCATION AND SUSPENSION OF TOBACCO RETAIL LICENCES

In our fight against the illegal sale of tobacco products to persons below the Minimum Legal Age (MLA), we revoked

**3** tobacco retail licences and suspended a further **8** licences (for a period of 6 months)

*Photo credit: ICA*

## SMUGGLING CHEWING TOBACCO

In September 2020, Immigration & Checkpoints Authority officers at Tuas Checkpoint detected sachets of chewing tobacco in the engine compartments and drivers' cabin bed bunks of five Malaysia-registered bowser lorries.

The case was referred to HSA and our investigations revealed that the smugglers used a similar mode of operation in all their smuggling activities — by delivering illegal chewing tobacco to designated contact persons at carparks in Singapore.

**53,249** sachets of chewing tobacco worth around **$213,000** in street value seized

**5** smugglers aged between **37** and **51**, were convicted in court and sentenced to imprisonment terms ranging from **5** to **16** weeks

## SALE OF ILLEGAL ELECTRONIC VAPORISERS (E-VAPORISERS)

Between April 2020 and March 2021, we successfully cracked down on the illegal sale of e-vaporisers through cyber-surveillance and enforcement activities. These peddlers had purchased e-vaporisers and related components from overseas suppliers and sold them illegally on various local social media and e-commerce platforms.

**26** peddlers were prosecuted for selling e-vaporisers and related components, and fined between **$5,000** and **$47,500**

In total, fines of more than **$484,500** were meted out to convicted persons

A 33-year-old repeat offender was sentenced to **1** week's imprisonment and fined **$61,000**

The youngest offender, aged 20, was sentenced to **15** months supervised probation



# NEW AWARD

**We achieved the following award in recognition of our efforts to keep our community smoke-free.**

## WHO "WORLD NO TOBACCO DAY AWARD"

2020's theme for World No Tobacco Day was "Protecting youth from industry manipulation and preventing them from tobacco and nicotine use".

For our work in providing analytical and advisory services as well as enforcement support on tobacco products, we were jointly awarded, together with the Ministry of Health and Health Promotion Board, WHO's "World No Tobacco Day Award" on 31 May 2020.