TRANSFORMING FOR TOMORROW

HEALTH SCIENCES AUTHORITY
ANNUAL REPORT 2023/2024

TRANSFORMING FOR TOMORROW

Over the past year, we have intensified our efforts to optimise and make the most of our finite time and resources. By streamlining our processes, reprioritising our work, and leveraging new technologies and digitalisation, we aim to become a more efficient and effective organisation that is better equipped to navigate future challenges. Our dedication to excellence in all that we do is underscored by our focus on delivering value to our stakeholders and fulfilling our mission and vision.

OUR VISION

To be the leading innovative authority protecting and advancing national health and safety

OUR MISSION

To wisely regulate health products
To serve the administration of justice
To secure the nation's blood supply
To safeguard public health

OUR CORE VALUES

SERVICE TO THE NATION

We are part of the Singapore Public Service, committed to integrity, excellence and efficiency.

PASSION FOR EXCELLENCE

We aim to be the best in all that we do.

DEVELOP OUR COMMUNITY

We value our people and build trusted teams.

INSPIRE TRUST

We act with credibility, professionalism and integrity, to instil public trust and confidence.

LIVE INNOVATION

We seek constantly to improve and transform.

CONTENT

CHAIRMAN'S MESSAGE

In our unwavering commitment to safeguarding public health and safety, the Health Sciences Authority continuously adapts to an ever-changing environment. We have embraced data-driven digital strategies to address current needs and anticipate and develop solutions for the future. Additionally, we collaborated with like-minded local and overseas partners to exchange expertise and resources, thereby expanding capabilities and optimising efficiency.

BUILDING DIGITAL AND DATA CAPABILITIES

We have embarked on initiatives to enhance digital capabilities within HSA and to empower our staff to become citizen developers with the knowledge to use digital tools to streamline their work processes and enhance efficiency. We have completed the Robotic Process Automation (RPA) Citizen Developer Workshop and established an RPA community on SG-Teams to foster cross-sharing and learning of RPA use cases. Additionally, many of our staff have benefited from the operationalisation of the data analytics platform, Tableau, to derive valuable insights and make data-based decisions.

We have also partnered GovTech to organise an internal Data Arcade Tournament and participated in a whole-of-government Data Arcade Tournament. The top three winning teams developed dashboards that highlighted significant crime statistics and drug abuse trend insights, and data on Severe Cutaneous Adverse Reactions. These activities deepened our staff's data analytics skills and also led to valuable insights and recognition, including GovTech's Platinum Tier Award for our active participation in the tournament.

IMPACTFUL LOCAL COLLABORATIONS

We harness the expertise of our local partners, leveraging collective knowledge to enhance our operational capabilities and further our goals in protecting and enhancing public health and safety. A good example is the collaborative development of the Vaping System for Enforcement & Registry (VaSER) with the Ministry of Health (MOH) and Open Government Products (OGP) team. The system enables the enforcement team to automate the issuance of notices for vaping-related offences and significantly expanded our case handling capacity.

Our collaboration with a multidisciplinary workgroup comprising specialists from various healthcare institutions has also led to the successful development of the National Guidelines on Clinical Transfusion. These guidelines standardise indications for blood transfusion in Singapore and promote effective and safe clinical transfusion practices, enhance patient safety, and optimise the utilisation of blood components among clinicians.

CULTIVATING SYNERGISTIC PARTNERSHIPS

Beyond our borders, we have cultivated strong partnerships with international counterparts to leverage diverse expertise, resources, and perspectives. Our recent Mutual Recognition Agreement (MRA) with the Republic of Korea's Ministry of Food and Drug Safety (MFDS) and the Memorandum of Understanding (MOU) with Poland's Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (URPL) are pivotal in promoting regulatory cooperation and enhancing health products accessibility. Additionally, our collaboration with the National Institute of Metrology China and our involvement in the Access Consortium are instrumental in advancing our scientific and technical capabilities and optimising synergies among regulatory authorities.

READY FOR THE FUTURE

With strengthened digital capabilities, thriving local collaborations, and increasing synergistic international partnerships, I am confident that we are better-equipped to navigate the evolving landscape and will continue to make an impact in the days ahead.

Professor BENJAMIN ONG
Chairman

CEO'S MESSAGE

Over the past year, HSA has intensified efforts to optimise and make the most of our finite time and resources. Through streamlining processes, reprioritising work, and leveraging new technologies and digitalisation, we are committed to transforming and becoming an even more efficient and effective organisation, better equipped to tackle future challenges.

Every single transformation effort contributes to better productivity, better service, or a more pleasant work experience. Transformation requires hard work, dedication, and a willingness to embrace change.

ADVANCING PUBLIC HEALTH AND SAFETY: IMPROVING STAKEHOLDER CONVENIENCE AND ENHANCING SURVEILLANCE

In January 2024, we introduced the Singapore Health Product Access and Regulatory E-System (SHARE), a one-stop portal for Cell, Tissue and Gene Therapy Products (CTGTP) Dealer's Notice and Class 1 CTGTP Notification. SHARE enables the seamless submission, checking, and updating of new dealer's notices and product notifications within a unified system. This new portal is part of our ongoing efforts to streamline regulatory processes and to achieve efficient transactions and enable closer collaboration between regulators, businesses, industry partners and the general public, facilitating access to safe health products in Singapore.

To enhance our surveillance of health products in Singapore, we used data analytics and artificial intelligence to improve and optimise the generation of adverse event statistics for trend analysis. We strengthened our analysis of electronic health records data by harnessing natural language processing models, large language models, and new algorithms to detect adverse drug reactions and facilitate safety signal evaluation. This enables us to take proactive and swift measures, to safeguard public health when required.

SECURING THE BLOOD SUPPLY: ENLARGING DONOR POOL AND ENHANCING ACCESSIBILITY

In our commitment to securing the blood supply, we have kept abreast of the latest scientific evidence. We reviewed and eased our restrictions on donors who have previously lived in the variant Creutzfeldt-Jakob Disease (vCJD)-risk areas of France, Ireland, and the United Kingdom from October 2023. This is in light of recent international data indicating minimal risk of vCJD transmission through leucodepleted blood products. This revision, which applies to apheresis donation, has expanded the pool of eligible donors.

To make blood donation more accessible, we opened our fifth Bloodbank, Bloodbank@One Punggol, in August 2023. Strategically located in the North-East region, Bloodbank@One Punggol is a convenient facility for our donors who are living, working, and studying in the area. It also features smart digital solutions, including self-help BMI machines, post-donation refreshment vending machines, and an enhanced queue management system.

Our commitment to patient-centric care led to the successful right-siting of pre-transfusion testing previously conducted by HSA's Crossmatch Laboratory for all private healthcare institutions. This enables private hospitals to undertake the testing in their own premises. Right-siting has enhanced patient safety by making compatible blood available within private hospitals. As a result, this initiative has led to expedited pre-transfusion testing, minimised risk of errors, and reduced waiting times for patients.

FURTHERING OUR SCIENTIFIC EXPERTISE: INNOVATIONS IN VACCINE, URINE, AND DISASTER VICTIM IDENTIFICATION ANALYSIS

We have developed a Lot Release App for locally manufactured vaccines. The digitalisation and automation of the lot release process has enabled us to streamline the workflow and improve efficiency, productivity, and data management. This has led to significant savings in man-hours. The new system also features real-time tracking of lot release status and an alert system that triggers different actions to ensure timely lot release.

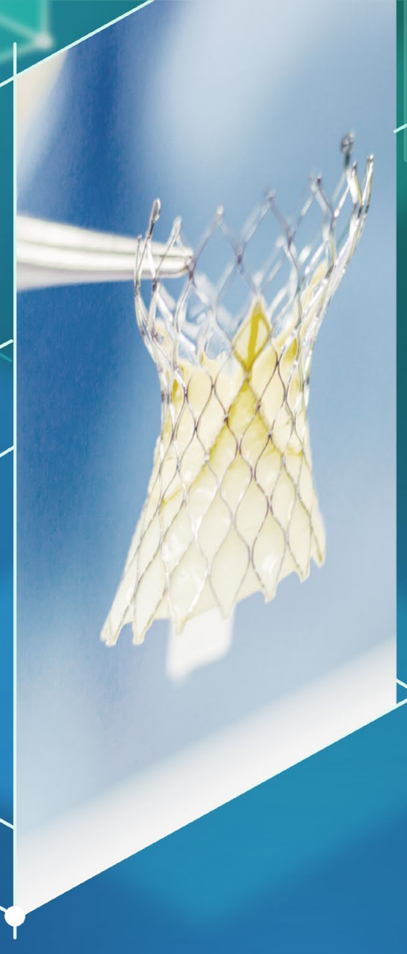
We have also introduced automation for drugs of abuse urine sample analysis, which has notably reduced cannabinoid analysis processing time from two working days to four hours, resulting in a saving of 350 man-hours annually. The urine testing service has also been expanded to cover emerging drugs and achieved enhanced sensitivity in our testing of controlled drugs in a wide range of edible products, including medications.

We are the first laboratory outside of the United States to implement CODIS 11 to enhance our Disaster Victim Identification (DVI) capabilities. This enables us to process DNA profiles and perform kinship reconciliation from DVI incidents in-house, strengthening our capabilities for DVI in mass fatality incidents.

LOOKING TOWARDS A BETTER FUTURE FOR ALL

By optimising resources, embracing new technologies, and streamlining processes, we are well-positioned to fulfil our mission and vision. Our focus on innovation and dedication to enhancing public health and safety, securing the blood supply, and advancing the administration of justice has enabled HSA to be well-prepared to fulfil our responsibilities and duties for a better future for all.

Dr CHOONG MAY LING, MIMI
Chief Executive Officer



HEALTH PRODUCTS REGULATION GROUP

ENHANCING REGULATORY AGILITY

We adopt a forward-looking mindset towards developing regulations, ensuring flexibility and adaptability to safeguard public health and safety.

COVID-19 RELATED WORK

We do our part to fight COVID-19 through regulatory vigilance.

CESSATION OF PANDEMIC SPECIAL ACCESS ROUTE (PSAR)

With the COVID-19 situation in Singapore having moved towards an endemic norm, HSA ceased receiving applications for interim authorisation of vaccines under PSAR in March 2023.

Accordingly, six PSAR interim authorisations for vaccines and therapeutics, including Comirnaty, Spikevax, Nuvaxovid and Paxlovid were transitioned to full registrations.

Additionally, in response to the continued evolution of COVID-19 and the emergence of new variants, HSA introduced a new minor variation (MIV) submission category. This category facilitates the updating of COVID-19 vaccines to target new virus strains. COVID-19 vaccines that fell under this category included the updated Comirnaty and Spikevax vaccines, each comprising a monovalent component that corresponds to the Omicron XBB.1.5 variant. These were authorised in September 2023 and October 2023 respectively.

ENHANCED SAFETY MONITORING OF COVID-19 VACCINES

Since the onset of the pandemic, we have enhanced our safety surveillance of COVID-19 vaccines, using real-world data to detect and validate potential safety signals.

These included analysing for the risk of myocarditis and pericarditis, as well as eight adverse events of special interest for potential safety signals. These were subsequently published in peer-reviewed scientific journals, such as Vaccine: X and Singapore Medical Journal, underscoring the recognition and credibility of our work within the scientific community.

We also shared our work at the following platforms:

September 2023
Singapore Pharmacy Congress, Singapore

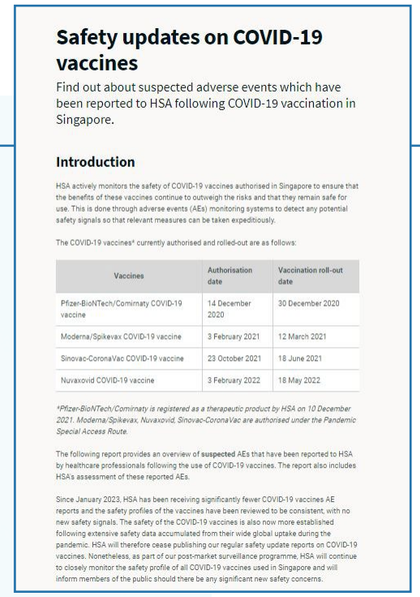
October 2023
15th Asian Conference on Pharmacoepidemiology, India

November 2023
International Society of Pharmacovigilance 22nd Annual Meeting, Bali, Indonesia

FINAL HSA COVID-19 VACCINE SAFETY UPDATE ISSUED

In July 2023, HSA issued its final regular public safety update relating to COVID-19 vaccines. HSA will continue to closely monitor the safety profiles of all COVID-19 vaccines used in Singapore and inform the public of any significant new safety concerns.

15 COVID-19 vaccine safety updates have been published since May 2021



Safety updates on COVID-19 vaccines

Find out about suspected adverse events which have been reported to HSA following COVID-19 vaccination in Singapore.

Introduction

HSA actively monitors the safety of COVID-19 vaccines authorised in Singapore to ensure that the benefits of these vaccines continue to outweigh the risks and that they remain safe for use. This is done through adverse events (AEs) monitoring systems to detect any potential safety signals so that relevant measures can be taken expeditiously.

The COVID-19 vaccines* currently authorised and rolled-out are as follows:

Vaccines	Authorisation date	Vaccination roll-out date
Pfizer-BioNTech/Comirnaty COVID-19 vaccine	14 December 2020	30 December 2020
Moderna/Spikevax COVID-19 vaccine	3 February 2021	12 March 2021
Sinovac-CoronaVac COVID-19 vaccine	29 October 2021	18 June 2021
Nuvaxovid COVID-19 vaccine	3 February 2022	18 May 2022

*Pfizer-BioNTech/Comirnaty is registered as a therapeutic product by HSA on 10 December 2021. Moderna/Spikevax, Nuvaxovid, Sinovac-CoronaVac are authorised under the Pandemic Special Access Route.

The following report provides an overview of **suspected** AEs that have been reported to HSA by healthcare professionals following the use of COVID-19 vaccines. The report also includes HSA's assessment of these reported AEs.

Since January 2023, HSA has been receiving significantly fewer COVID-19 vaccines AE reports and the safety profiles of the vaccines have been reviewed to be consistent, with no new safety signals. The safety of the COVID-19 vaccines is also now more established following extensive safety data accumulated from their wide global uptake during the pandemic. HSA will therefore cease publishing our regular safety update reports on COVID-19 vaccines. Nonetheless, as part of our post-market surveillance programme, HSA will continue to closely monitor the safety profile of all COVID-19 vaccines used in Singapore and will inform members of the public should there be any significant new safety concerns.

FACILITATION OF ACCESS FOR COVID-19 MEDICAL DEVICES

341 COVID-19 diagnostic tests have been granted marketing authorisation

PARTICIPATION IN COVID-19 VACCINES & THERAPEUTICS WORKING GROUP

As part of our efforts to monitor and assess new safety issues associated with COVID-19 vaccines and therapeutics, HSA has been actively involved in Access Consortium's Pharmacovigilance Subgroup Meetings.

REGULATORY UPDATES AND REVIEWS

We enhance our governance and compliance frameworks to ensure the safety of products throughout their lifecycle while streamlining regulatory obligations for the industry.

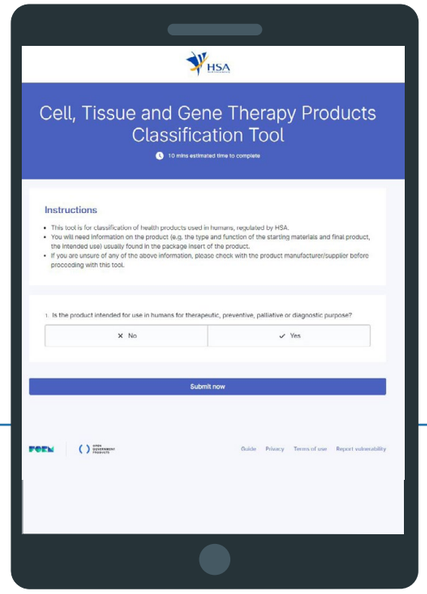
SUCCESSFUL IMPLEMENTATION OF HEALTH PRODUCTS (ACTIVE INGREDIENTS) REGULATIONS

In December 2023, we streamlined the regulation of active pharmaceutical ingredients into a single piece of subsidiary legislation to provide greater clarity on the legal requirements and regulatory controls for all active pharmaceutical ingredient manufacturers, importers and wholesalers.

This new fit-for-purpose, risk- and activity-based regulatory framework aligns with international standards and enhances mutual confidence among HSA and our overseas counterparts. This will pave the path for Singapore to be recognised as an EU equivalent Third Country with regulatory regime and Good Manufacturing Practices (GMP) standard for active pharmaceutical ingredients.

ONLINE SELF-HELP CELL, TISSUE AND GENE THERAPY PRODUCT (CTGTP) CLASSIFICATION TOOL

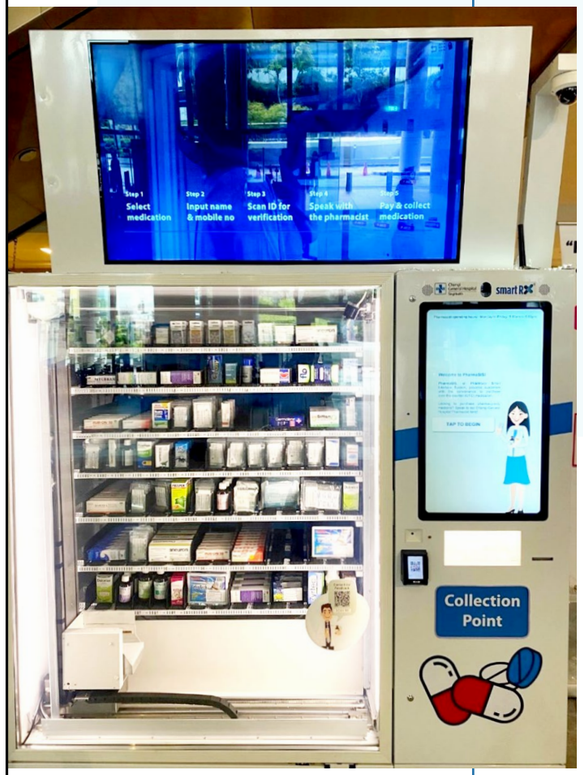
As part of our pro-enterprise initiative, we launched a new CTGTP Classification Tool on the HSA website in March 2024. This self-help tool assists stakeholders in determining if their product is a Class 1 or 2 CTGTP or a non-CTGTP.



PHASE 2 VOLUNTARY NOTIFICATION SYSTEM (VNS) INITIATIVE FOR COMPLEMENTARY HEALTH PRODUCTS (CHPs)

In August 2023, HSA launched Phase 2 of its VNS for CHPs to include products such as probiotics, medicated oils and balms, and medicated plasters. This follows Phase 1 which was launched in August 2022 for commonly purchased products (e.g. vitamin and mineral supplements) and products at higher risk of adulteration (e.g. products intended for weight loss, pain relief and male vitality).

This initiative aims to establish a reliable CHP database for consumers to refer to when making their purchases, and facilitates traceability and regulatory actions by HSA if there are safety or quality issues.



SUPPORTING PHARMACIES AND HOME DELIVERY SERVICES

This past year, HSA worked closely with Synapxe and Ministry of Health's (MOH) Chief Pharmacist's Office on the National Central Fill Pharmacy initiative, which seeks to ensure that pharmacies have in place robust processes for safeguarding the safety and quality of medicines being delivered to patients.

We also approved several innovative healthcare delivery services for retail pharmacies, including e-pharmacy, vending machines for Pharmacy Only Medicines (P), and medication delivery services to enhance patients' accessibility to medicines.

GUIDANCE NOTE PUBLISHED FOR MEDICINES VENDING MACHINES

In April 2023, HSA published a new guidance note on "Retail Supply of Registered Therapeutic Products – Pharmacy Only Medicines (P) and Prescription only Medicines (POM) via Vending Machines". This note guides retail pharmacies on the regulatory requirements and expectations for operating such vending machines in Singapore.

LAUNCH OF SINGAPORE HEALTH PRODUCT ACCESS AND REGULATORY E-SYSTEM (SHARE)

In January 2024, we launched the Singapore Health Product Access and Regulatory E-System (SHARE), a one-stop digital portal for Cell, Tissue and Gene Therapy Products (CTGTP) Dealer's Notice and Class 1 CTGTP Notification. This new portal is part of our ongoing efforts to streamline regulatory processes to achieve efficient transactions and enable closer collaboration among regulators, businesses, industry partners and the public, facilitating access to safe health products in Singapore. With the introduction of SHARE, applicants can now submit, check and update new dealer's notices and product notifications all in one system, resulting in enhanced process efficiency, regulation and compliance. SHARE will be progressively rolled out to other product types and eventually replace the Pharmaceutical Regulatory Information System (PRISM).

REGULATORY ENHANCEMENTS FOR MEDICAL DEVICES

We made the following updates to enhance regulatory processes and ensure alignment with global standards:

JANUARY 2023

Clarified the qualification criteria for immediate and expedited evaluation routes (IBR and ECR-1) to specify that devices must have a marketing history of at least three years in the jurisdiction of the approving regulatory agency

JULY 2023

Improved the risk classification for in vitro diagnostic medical devices and self-help tools through the expansion and clarification of specific risk class rules

SEPTEMBER 2023

Updated the "Medical Device Adverse Event Reporting for Medical Device Dealers" form to include unique device identifiers (UDI) and International Medical Device Regulators Forum (IMDRF) Adverse Event Reporting Terms and Codes

MARCH 2024

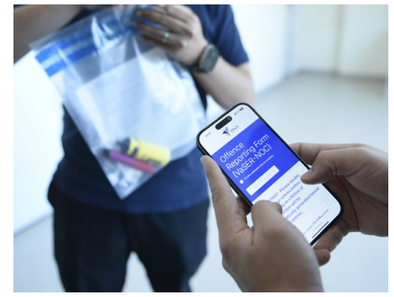
Highlighted the need to provide essential information such as the software development life cycle summary, software requirement specification (SRS) and traceability analysis during regulatory submission for software or programmable medical devices

TECHNOLOGY AND INFRASTRUCTURE

We leverage new technologies and build upon our existing infrastructure to raise productivity levels.

STREAMLINING THE ISSUANCE OF NOTICES OF COMPOSITION USING VaSER

In December 2023, we collaborated with the Ministry of Health (MOH) and Open Government Products (OGP) team to develop the Vaping System for Enforcement & Registry (VaSER). Leveraging open government products (FormSG, PaySG and Plumber), the system radically streamlines the process of issuing notices of composition, as well as provides a convenient payment platform for fines. It resulted in significant resource savings and expanded our Tobacco Regulation Branch's case handling capacity by 4.5 times.



ENHANCED SURVEILLANCE OF SAFETY SIGNALS

To enhance our surveillance of health products in Singapore, we used data preparation and visualisation software to improve our data preparation processes and increase the efficiency of generating adverse event statistics for trend analysis.

We also enhanced the way we analysed our electronic health records data by using natural language processing models and large language models, as well as new algorithms to identify and detect adverse drug reactions and facilitate safety signal evaluation.

THE POWER OF GOING DIGITAL – HSA ADVERSE DRUG REACTION (ADR) NEWS BULLETIN

The HSA ADR News Bulletin serves to communicate product safety information to healthcare professionals. Over the years, several key enhancements have been made:

- Redesigned bulletin format to facilitate easier picking up of safety information
- Introduction of digital copies to reduce printing and be more environmentally-friendly

Higher cost savings | **Wider reach** | **Increased readership**

STAYING VIGILANT

To ensure public health and safety, we endeavour to remain alert at all times.

SINGAPORE-SPECIFIC RISK MANAGEMENT PLANS (RMP) AND SAFETY SIGNALS

To ensure the safety of consumers in Singapore, we conduct regular surveillance activities on therapeutic products and cell, tissue and gene therapy products in the market.

144 *Safety signals assessed*

41 *Singapore-specific RMPs evaluated*

11 *New RMPs implemented*

This resulted in several notable regulatory actions being taken, including:

- Withdrawal of pholcodine-containing medicines due to the risk of perioperative anaphylaxis with use of neuromuscular blocking agents
- Reminder to healthcare professionals on the risk of psychiatric disorders and sexual dysfunction associated with isotretinoin

The following advisories were issued:

7 *Dear Healthcare Professional Letters (DHCPLs) issued by companies and HSA*

3 *Adverse Drug Reaction (ADR) news bulletins*

1 *Safety update*

ADULTERATED HEALTH PRODUCTS

Our post-marketing surveillance activities have enabled us to detect the presence of adulterated health products in Singapore. Advisories were issued to warn the public about such products.

9 press releases
issued including safety advisories on
22 products

DEFECTIVE LOCALLY REGISTERED THERAPEUTIC PRODUCTS

HSA received a total of **236 product defect cases** over this past year. HSA worked closely with the associated companies to ensure appropriate corrective actions were taken. These included:

29 *Communications issuances (e.g. DHCPLs, Dear Purchaser Letter, press release)*

25 *Amendments to product registration (e.g. variation submission)*

14 *Product recalls*

MEDICAL DEVICE POST-MARKET SURVEILLANCE AND VIGILANCE SYSTEM

Safety signals and risk management actions

3,952 *Safety signals assessed*

13 *Follow-up assessments conducted on device safety issues*

7 *Local product defect complaints investigated*

Device issues

Of the medical device defects reported, the top 5 problems were related to:

82 *Material integrity*

62 *Output*

55 *Electrical/electronic property*

48 *Infusion or flow*

43 *Patient device interaction*

Adverse events reported

We received a total of 763 reports of adverse events related to medical devices. The top 3 medical specialty areas from which the reports were received included:

311 **Cardiovascular** *(involving devices such as pacemakers, implantable heart valves and cardiovascular stents)*

164 **General hospital** *(involving devices such as infusion pumps, patient monitors and ventilators)*

87 **Ophthalmology** *(involving devices such as intraocular lens, contact lens and ophthalmic surgical systems)*

Field safety corrective actions and advisories

We undertook a total of 668 field safety corrective actions (FSCA) related to locally supplied devices. Top 2 categories of FSCA issues reported:

135 *Device operation*

70 *Physical property specifications issue*

HSA worked with companies to ensure that appropriate corrective and preventive actions (CAPA) were taken to mitigate the impact on the safety and quality of the defective medical devices as well as their future batches. The actions included:

437 *Communications pieces published on website*

350 *Issuances of additional safety information*

246 *Safety corrective actions*

89 *Change review submissions for implementing CAPA and mitigating risk*

72 *Product recalls*

Two noteworthy cases included ophthalmic products impacted by foreign particulate contamination, and defective medical devices illegally sold through overseas online platforms.

We also issued and reviewed the following advisories:

23 *DHCPLs issued by companies and HSA*

2 *Medical device safety updates*

2 *Medical device safety alerts*

2 *Consumer safety articles*

ENFORCEMENT

We continue to crack down on the sale of illegal health products and prohibited tobacco products.

ILLEGAL SALE OF HEALTH PRODUCTS

159 *Operations conducted*

43 *Suspects investigated*

23 *Prosecutions*

11,516 *Illegal product listings removed*

2,780 *Warnings issued*

Estimated value of seized items:

>1.4 million units
worth over $1 million

OPERATION PANGEA

Operation Pangea is an initiative by INTERPOL to target the online sale of illegal health products. Over the past year:

2 *Operations involving **89 countries** were conducted*

360 *Parcels were investigated, more than **7,000 illegal product listings removed** and **1,886 warnings issued***

PROHIBITED TOBACCO PRODUCTS

Together with our partner agencies, we continued to closely monitor the sale of illegal tobacco products in Singapore. A total of 22 raids were conducted, resulting in:

Total seizure value of smokeless tobacco and e-vaporisers:
>$7.3 million

Number of peddlers prosecuted:
53

Total number of notices of composition issued:
>9,000

Number of illegal tobacco product listings removed:
>6,000

NEW LOCAL PARTNERSHIPS

Our strong network of local partners enables us to bolster our efforts and advance our objectives.

STRENGTHENING ENGAGEMENT WITH OUR PUBLIC HEALTH INSTITUTIONS

We conducted meetings with partner hospitals and institutions such as National Cancer Centre, Changi General Hospital, Khoo Teck Puat Hospital and SingHealth to gather feedback on current clinical practices, systems and operational issues related to Adverse Event (AE) reporting.

This was followed up with educational engagement activities, where we shared clinical case studies which enhanced understanding of the value of AE reporting.

Through these exercises, we were able to reach out to healthcare professionals more effectively to improve AE reporting, and at the same time foster a more holistic approach for signal identification and safety assessments.

NEW OVERSEAS PARTNERSHIPS

Close collaborations with international partners are instrumental for fortifying our knowledge base.

MUTUAL RECOGNITION AGREEMENT (MRA) SIGNED WITH REPUBLIC OF KOREA'S MINISTRY OF FOOD AND DRUG SAFETY (MFDS)

In February 2024, HSA entered into a MRA with the Republic of Korea's MFDS to establish Good Manufacturing Practice (GMP) requirements for Medicinal Products. The agreement was signed by Dr Choong May Ling, Mimi, Chief Executive Officer of HSA, and Dr Oh Yu-Kyoung, Minister of MFDS.

This MRA allows for the reciprocal acceptance of GMP certificates and inspection results for pharmaceutical manufacturers located in Singapore and South Korea, and minimises duplicative on-site GMP inspections and assessment of manufacturing facilities. It will also enhance trade and improve the accessibility of medicinal products in Singapore and South Korea.

Photo credit: Ministry of Food and Drug Safety of the Republic of Korea

INVOLVEMENT IN PIC/S ACTIVITIES

In 2024, HSA was appointed by the Pharmaceutical Inspection Co-operation Scheme (PIC/S) Committee to be part of the re-assessment team to assess the Republic of Korea's Ministry of Food and Drug Safety.

HSA will serve as the Chair of PIC/S Sub-Committee on Training and as Member of the PIC/S Executive Bureau from 1 January 2023 to 31 December 2024.

MEMORANDUM OF UNDERSTANDING (MOU) SIGNED WITH POLAND'S NATIONAL REGULATORY AUTHORITY

In May 2023, HSA signed an MOU with Poland's Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (URPL) to kickstart cooperation between the two regulatory authorities.

Both HSA and URPL are members of the International Medical Device Regulators Forum National Competent Authority Report (IMDRF NCAR) Exchange Programme, which facilitates the exchange of post-market safety information on medical devices of significant concerns or potential trends.

38th ASEAN COSMETIC COMMITTEE MEETING

From 20 to 23 November 2023, HSA hosted the 38th ASEAN Cosmetic Committee Meeting and its related meetings. This was the first in-person meeting since the COVID-19 pandemic.

The meeting provided a sharing platform for updates on the implementation of the ASEAN Cosmetic Directive, as well as harmonisation of the technical requirements and testing methods on cosmetic products.

ACCESS CONSORTIUM ESTABLISHES NEW WORKING GROUP

Access Consortium is a coalition of five regulatory authorities (Australia Therapeutic Goods Administration, Health Canada, Health Sciences Authority, Swissmedic, UK Medicines and Healthcare Products Regulatory Agency) that seeks to explore collaborative opportunities for optimising synergies among authorities and reducing duplicate efforts within industry.

A new working group for Advanced Therapy Medicinal Products was established in November 2023 to foster interdisciplinary scientific discussions on emerging innovative therapeutic concepts and technologies.

WORLD HEALTH ORGANIZATION (WHO) PILOT ASSESSMENT SESSIONS FOR NEW IN VITRO DIAGNOSTICS (IVD) PREQUALIFICATION MODEL

In June and December 2023, WHO's IVD Assessment Team organised joint sessions with invited assessors from various international agencies and institutions to pilot and trial new standardised assessment approaches for IVD prequalification.

HSA is a WHO-recognised Stringent Regulatory Authority for high-risk IVDs and four of our evaluators were invited to participate in these sessions. The sessions provided a good platform for enhancing assessment capacity and promoting knowledge sharing.

PERMANENT FORUM ON INTERNATIONAL PHARMACEUTICAL CRIME (PFIPC) AND INTERNATIONAL LABORATORY FORUM ON COUNTERFEIT MEDICINES (ILFCM)

From 25 to 29 September 2023, HSA hosted the PFIPC and ILFCM meetings in Singapore. These two events helped to forge closer ties between Singapore and global enforcement colleagues, as we work together to combat pharmaceutical crimes and safeguard public health.

HSA also took the opportunity to present on Singapore's regulatory framework of e-pharmacies and safeguards in place to ensure the safe supply of medicines.

INTERNATIONAL MEDICAL DEVICE REGULATORS FORUM (IMDRF) GOOD REGULATORY REVIEW PRACTICES (GRRP) WORKING GROUP

The IMDRF GRRP Working Group seeks to develop good review practices for regulatory authorities and their conformity assessment bodies.

In March 2024, the Working Group, co-chaired by US FDA and HSA, initiated an update of existing GRRP documents to achieve consistent terminology for development of a risk calibrated regulatory approach for innovations, and to harmonise pre-market review requirements for medical devices.

All **8 documents** that were tabled for updates were approved at the 25th IMDRF meeting.

BLOOD SERVICES GROUP

SECURING THE FUTURE

We constantly seek out the latest technologies and methodologies to ensure the sustainability and safety of our nation's blood supply.

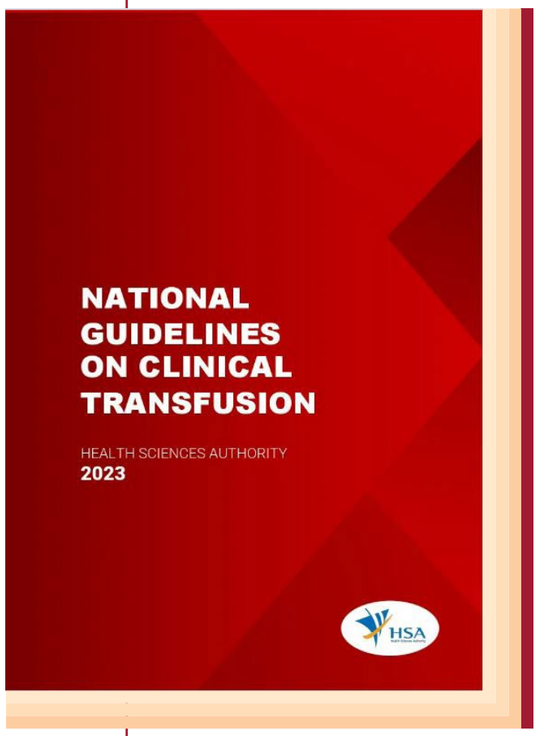
KNOWLEDGE AND INNOVATION

We maintain a high standard of blood services through our world-class knowledge base and commitment to innovation.

EASING OF RESTRICTION FOR DONORS FROM vCJD-RISK AREAS

We have revised our restrictions on donors who have previously lived in the vCJD-risk areas of France, Ireland and the United Kingdom. This is in light of recent international data indicating minimal risk of variant Creutzfeldt-Jakob Disease (vCJD) transmission through leucodepleted blood components. From October 2023, the easing of the restrictions only applies to apheresis donation which is able to remove the white blood cells during collection of specific blood components.

This allows us to accept donors who have lived in vCJD-risk areas, among whom a greater proportion are RhD negative, which is an uncommon blood type in Singapore.



PUBLICATION OF NATIONAL GUIDELINES ON CLINICAL TRANSFUSION

In collaboration with a multidisciplinary workgroup of specialists from various healthcare institutions, we published the National Guidelines on Clinical Transfusion. This provides significant updates to 2011's HSA-Ministry of Health (MOH) Clinical Practice Guidelines on Clinical Blood Transfusion.

The aims of these guidelines are to:

- Promote effective and safe clinical transfusion practices
- Enhance patient safety and effective utilisation of blood components among clinicians
- Harmonise indications for blood transfusion in Singapore

The guidelines were disseminated to all medical professionals via MOH Alerts and uploaded onto the HSA website in December 2023.

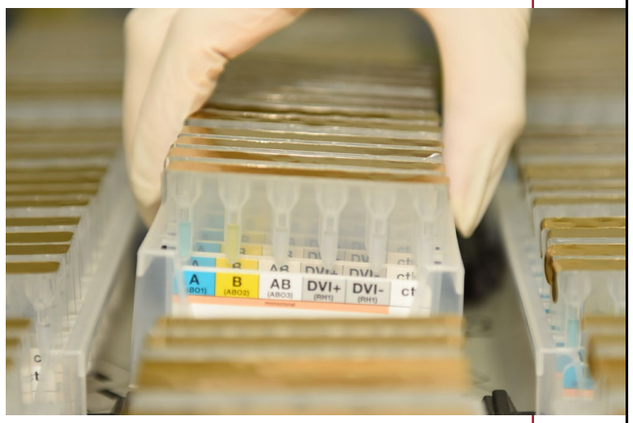
ONLINE HAEMOVIGILANCE REPORTING USING FORMSG

In March 2023, we piloted the online haemovigilance reporting of adverse events and transfusion-related incidents with two public hospitals. This was then rolled out to all other hospitals in October 2023. Benefits of online haemovigilance submission include timely reporting of incidents, secure data storage, removal of paper reporting and reduction in physical storage space requirements.

RIGHT-SITE PRE-TRANSFUSION TESTING BY PRIVATE HOSPITALS

Previously, our Crossmatch Laboratory performed centralised pre-transfusion testing of blood components for all private hospitals. In 2016, we began the preparation work to right-site pre-transfusion testing. This included training laboratory staff from private hospitals. The right-siting process started in January 2022, and concluded in January 2024.

Right-siting of pre-transfusion testing at the private hospitals shortens the turnaround time to supply compatible blood to patients.



- Enhanced patient safety
- Lower risk of errors
- Faster processing of patient samples
- Shorter waiting time for patients needing transfusion
- Better maintenance of cold chain

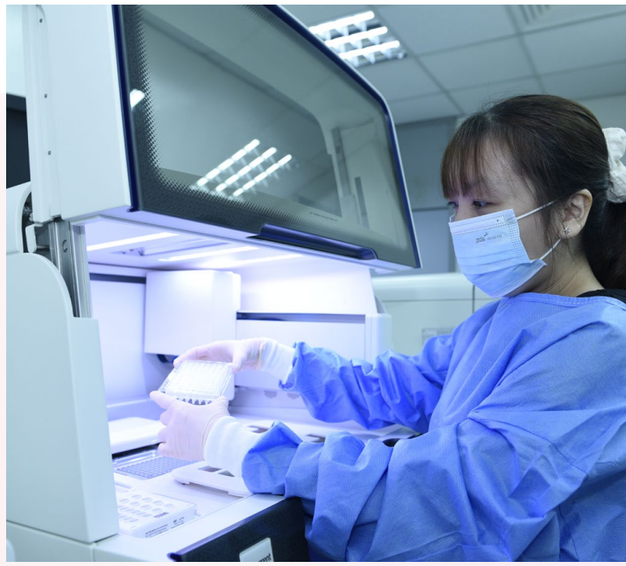
LAUNCH OF SECOND BLOOD COLLECTION TRAINING CENTRE

In addition to Bloodbank@HSA, we designated Bloodbank@Westgate Tower (BB@WT) as our second training centre to boost the training capacity for the National Blood Programme. This initiative seeks to ensure the organisation's long-term sustainability by providing a steady pipeline of skilled and knowledgeable staff, equipped to deliver quality services.

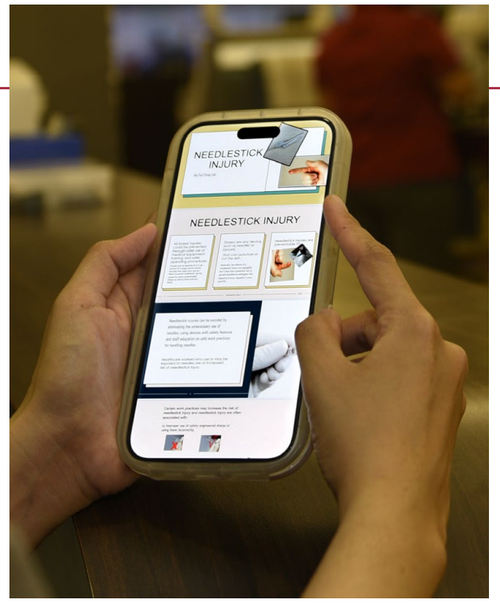
- Training capabilities of BB@WT include registration, haemoglobin testing, phlebotomy and capping procedures
- To date, 6 batches of internal and external staff have been successfully trained

INTRODUCTION OF NEXT GENERATION SEQUENCING FOR HLA GENOTYPING

In July 2023, our Tissue Typing and Platelet Reference Laboratory implemented Next Generation Sequencing (NGS) for HLA Genotyping, which will generate HLA high resolution typing results in a single system. NGS frees up technologists' hands-on time as this single higher throughput testing system replaces the need for running multiple tests. This initiative has also enabled us to provide higher quality and better resolution HLA tissue typing results for solid organ and haematopoietic stem cell transplant patients and donors, while reducing overall costs.



- Reduced fees
- Higher throughput capabilities
- Higher resolution capabilities
- Maintained competitive edge



NEW eLEARNING PLATFORM FOR BLOOD COLLECTION STAFF

To empower our staff to take control of their own training and skills development, we introduced a new flexible and accessible eLearning app. This platform offers a variety of learning content on topics related to blood collection, infection controls and blood safety. It also features assessment functions to evaluate staff's understanding and their degree of knowledge retention.

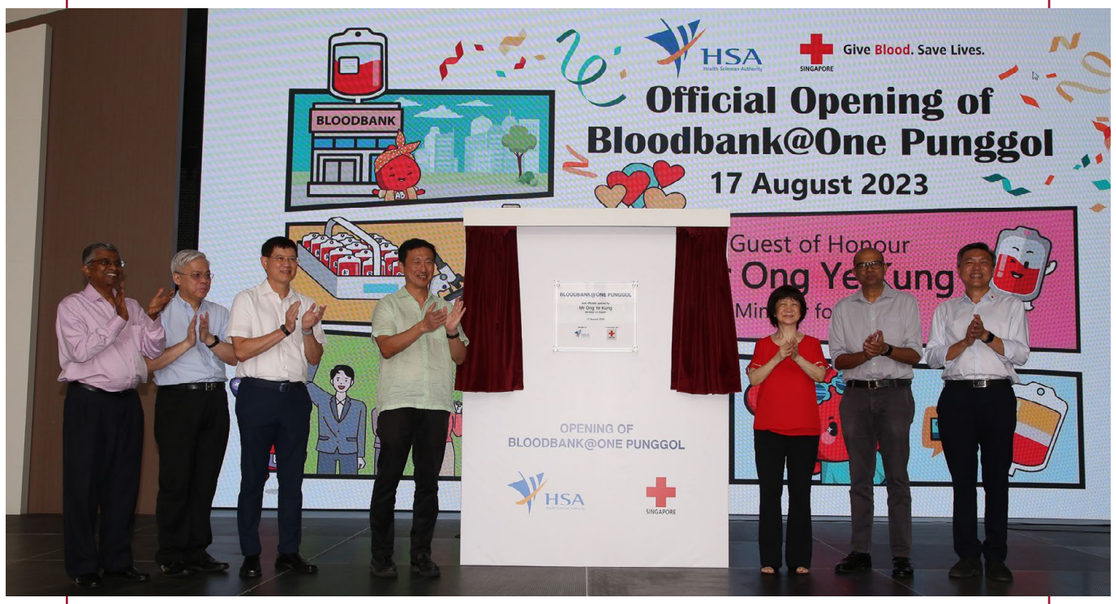
TECHNOLOGY AND INFRASTRUCTURE

To fully leverage the capabilities of our staff and optimise our operations, we are dedicated to establishing the appropriate technology and infrastructure for our Bloodbanks, ensuring safety and maintaining the highest quality standards.

SETTING UP OF BLOODBANK@ONE PUNGGOL

As part of our ongoing efforts to make blood donation more accessible, we launched our fifth Bloodbank, Bloodbank@One Punggol (BB@OP) in August 2023. Minister for Health, Mr Ong Ye Kung officiated the opening of BB@OP.

Situated within the One Punggol integrated community hub, BB@OP offers a convenient and accessible facility for our donors living, working and studying in Punggol and the North-East region. It features smart digital solutions, including self-help BMI machines, refreshment vending machines and an enhanced queue management system.



STREAMLINING PROCESSES AT OUR BLOODBANKS

Donor registration and haemoglobin testing are two critical checkpoints in the blood donation process. They help to ensure the safety of donors and recipients.

To improve the blood donation experience and to enhance the efficiency of our processes, we combined registration and haemoglobin testing into one station. This was first implemented in January 2023 at Bloodbank@Westgate Tower, and subsequently with the learnings gleaned, rolled out to our latest BB@OP.

Through positive and constructive feedback received from our donors, we will be embarking on phased improvement works to implement a combined registration and haemoglobin testing station for the rest of our Bloodbanks in 2024.

ENHANCING USER EXPERIENCE THROUGH TECHNOLOGY ADOPTION

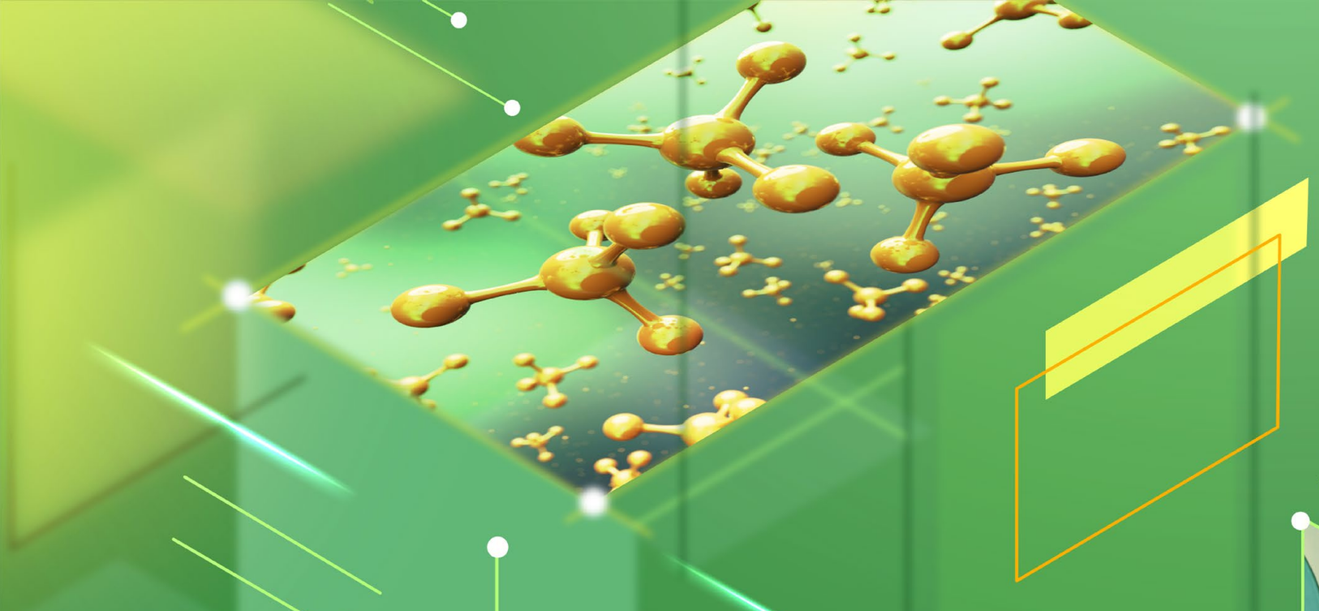
Over the past year, several technological solutions were introduced to enhance user experience and operational efficiency at our Bloodbanks.

Refreshment vending machines – Vendors can now utilise the vending machine inventory management system to track usage and efficiently arrange for the replenishment of refreshments, thereby reducing the need for extensive manpower oversight and management.

Self-service BMI machines – Through self-service BMI machines, donors can fast track the registration process by checking their own weight eligibility for blood donation. Donors are also able to monitor their BMI.

Enhanced Queue Management System (QMS) via Software as a Service (SaaS) – With SaaS, we have been able to:

- Reduce the amount of QMS equipment required in our IT Rack
- Remotely diagnose and quickly resolve QMS system issues, reducing the need for onsite technicians



APPLIED SCIENCES GROUP

WHERE INNOVATION LIVES

We leverage innovation to achieve greater efficiency in testing and analysis for our nation's health and safety.

KNOWLEDGE AND INNOVATION

We constantly innovate to create new testing capabilities, methods, and products to meet stakeholder needs.

NEW TESTING CAPABILITIES THROUGH OUR NEW BIOLOGICS LABORATORY

In May 2023, we began operations of our new Biologics Laboratory to safeguard public health by providing the following testing services:

- Lot release for locally manufactured vaccines
- Post-market surveillance testing of biologics in the local market
- Investigation of substandard and unsafe biological products

FIRST SET OF SIGNATURE HEXAPEPTIDE CRMS WITH METROLOGICAL TRACEABILITY LAUNCHED

We unveiled two first-in-the-world Certified Reference Materials (CRMs) designed for calibrating HbA1c measurement using the isotope dilution mass spectrometric (IDMS) method. The glycated VHLTPE Peptide Solution (HRM-3010A) and VHLTPE Peptide Solution (HRM-3011A) assigned by higher order IDMS method provide reference laboratories with an unbroken chain of traceability to the International System of Units (SI) from HSA.

EVALUATING ALTERNATIVE LDL-CHOLESTEROL EQUATIONS

We successfully used External Quality Assessment (EQA) programme data to evaluate alternative published equations for calculated LDL-cholesterol, including the Friedewald equation. We found an alternative equation that gave the least difference against HSA's traceable LDL-C reference values and fewer misclassifications, especially in samples with higher triglycerides and LDL-cholesterol levels associated with higher risk patients.

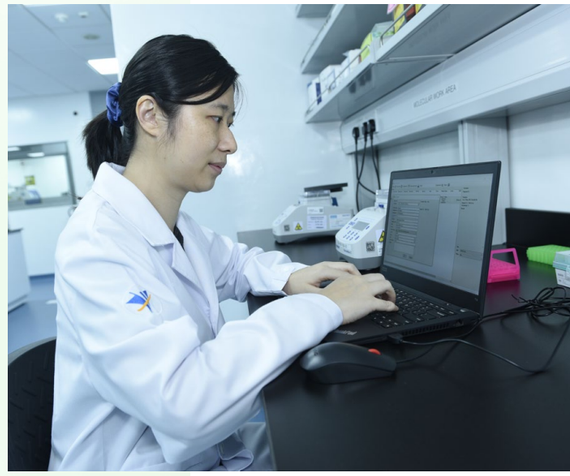
ENHANCING OUR EFFICIENCY

We embrace digitalisation, striving for greater efficiency and ways to enhance our workflow.

INTRODUCING DIGITALISED AND AUTOMATED LOT RELEASE PROCESSES FOR LOCALLY MANUFACTURED VACCINES

We developed a Lot Release App to streamline workflow and enhance efficiency, productivity and data management. Key features include:

- Automatic retrieval and population of lot release request data submitted by manufacturers via FormSG
- Real-time tracking of lot release status with a built-in alert system to trigger different roles for actions to ensure timely lot release
- Centralised sample information, test and evaluation results, and communication to facilitate seamless information exchange within HSA



DIGITALISATION OF DNA DATABASING TO ACHIEVE EFFICIENT, PAPERLESS WORKFLOW

By leveraging the new Laboratory Information Management System to digitise case data, our DNA Database Laboratory has reviewed and revised work processes to simplify report retrieval and reduce physical storage space required for hardcopy reports.

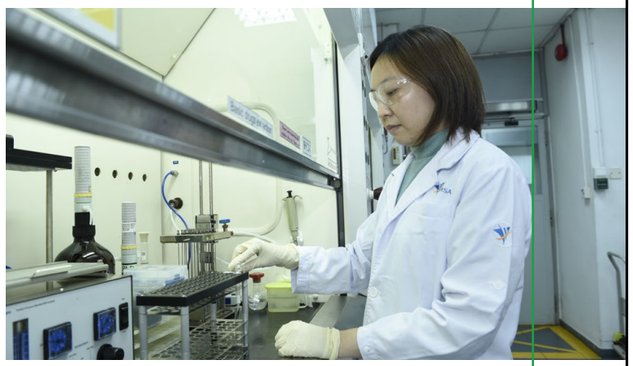
- **60%** less time required for preparation of reports
- **80%** reduction in paper usage

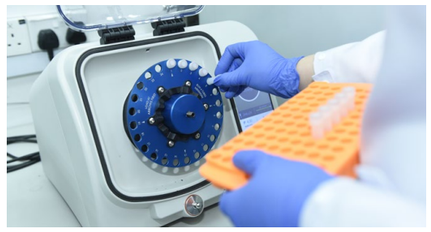
TOXICOLOGY AND DRUG TESTING INNOVATIONS

New workflow for acidic and neutral drugs

Our newly created workflow:

- Requires **5x** less amount of blood
- Supports quantitative analysis of **80 drugs** and qualitative screening for more than **300 drugs**
- Combines **5** separate workflows on **4** different instruments into **1** single process
- Reduces processing time by **62%**, **saving 680 man-hours a year**





Consolidation of hair confirmation lab workflows

The consolidation of four different workflows into one:

- Reduces analysis time from **6** to **2** days
- Requires **5x** less hair for analysis

Expanded testing scope for drugs

We expanded the scope of our urine testing service to encompass emerging drugs. We also achieved enhanced sensitivity in our testing of controlled drugs in a wide range of edible products, including medications.

- Number of drugs that we can test per run (timeframe): Up from **221** to **230**

Automated analysis of urine samples

By automating our laboratory processes, we have been able to do away with the laborious process of manually preparing urine samples. Our new method for cannabinoid analysis is capable of differentiating metabolites of delta-8-THC from delta-9-THC in a single run, as well as processing all samples significantly faster.

- Cannabinoid analysis reduced from **2 working days** to **4 hours**, **saving 350 man-hours a year**

Improvement works in our Illicit Drugs Laboratory

To better manage the increase in workload of our Illicit Drugs laboratory, we embarked on a project to relook at our laboratory space and work processes. This resulted in:

- An expansion of our laboratory space by **25%** to support better segregation and dedicated processing areas for various drug types. This expansion also accommodated the space needed for our new sample preparation automation system, with expected savings of **0.4 headcount** per year.

USING DIGITAL TOOLS TO INCREASE PRODUCTIVITY

Problem	Solution	Outcome
Difficulty in evaluating the uptake of Certified Reference Materials (CRMs)	Used Tableau dashboard to examine historical sales data and illustrate revenue from sales	Gained insights into which CRMs should be maintained or discontinued
Analysis of video evidence involving metadata retrieval is time consuming and prone to human error	Developed a Python script to automate the process	Savings of about 2 to 3 man-hours for a video with over 250,000 frames
Substantial time and effort are required to verify exhibit markings in the report drafting process	Created a check bot using Python script to automatically compare exhibit markings from reports with those obtained from the system and flag out errors	Improved efficiency and a higher degree of accuracy and consistency in reports
Tracking the laboratory's turnaround time and performance monthly on Excel is time-intensive	Created a Python script to automate the process and perform data cleaning. Tableau dashboard was also used to improve data visualisation	Latest statistics are updated within minutes and are free from human error
Manual monitoring of quality control data and trend analysis is labour and time-intensive	Leveraged Robotic Process Automation to monitor performance indicators for DNA laboratory processes	Early detection of systemic issues has enabled more effective management of risks

LEARNING FROM THE EXPERTS

We value constant learning to acquire new knowledge that strengthens our scientific capabilities.

IMPLEMENTED CODIS 11 TO ENHANCE DISASTER VICTIM IDENTIFICATION (DVI)

We became the first laboratory outside of the United States to implement CODIS 11 – the latest version of the DNA databasing software that was created by the US Federal Bureau of Investigation.

As part of the implementation process, we were trained on:

- Direct and familial DNA profile searches
- Pedigree tree construction
- Kinship determination

This has enabled us to:

- Process DNA profiles and perform kinship reconciliation from DVI incidents in-house
- Strengthen our capabilities for DVI in mass fatality incidents

VACCINE LOT RELEASE TRAINING BY EXPERT FROM BELGIUM

Dr Geneviève Waeterloos, Head of Quality of Vaccines and Blood Products at Sciensano, Belgium conducted a Vaccine Lot Release Training for HSA in July 2023.

As part of the training, she shared about Sciensano's experience in lot release of vaccines, current practices of the EU Official Control Authority Batch Release (OCABR) and WHO guidelines.

The session provided us with useful knowledge for improving our future workplans, quality management system and vaccine lot release workflow. It also established a foundation for potential collaborations with Sciensano.

LOCAL PARTNERSHIPS

We actively share knowledge to promote collaboration and cultivate a well-informed and engaged community.

SEPTEMBER 2023

Science Centre Singapore

Citizen Forensic Science Day – We provided members of the public with insights about modern-day forensic examination techniques, such as DNA and illicit drugs analyses and trace evidence examination, through a mock-up crime scene, and lectures.

Virtual CSI Game "ArenaX" – Upper primary and secondary students were introduced to concepts and scientific techniques of crime scene processing, bloodstain pattern analysis, firearms, fingerprint and DNA analysis through a virtual investigation of a murder.

OCTOBER 2023

CNB, MOH, HPB, ICA, SAF, NPARKS, Singapore Customs, MSF and NEA

To enhance the knowledge of public officers from various local agencies dealing with issues of vaping, we conducted a sharing session and a laboratory tour that offered insights into the local drug scene, the rising trend of vaping, legislative controls and potential health risks associated with vaping.

MARCH 2024

NTU Odyssey Programme and American Chemical Society NUS Student Chapter

HSA was invited to partner the NTU Odyssey Programme and American Chemical Society NUS Student Chapter to run the Forensic Science Workshop cum Competition 2024.

Our forensic scientists gave lectures on illicit drugs, DNA and bloodstain pattern analysis, and conducted workshops on fourier-transform infrared spectroscopy (FTIR) and handheld Raman spectrometer. The event connected us with over 200 STEM students from NTU and NUS.

INTERNATIONAL PARTNERSHIPS

We forge close ties with our overseas partners to leverage diverse expertise, resources and perspectives.

NATIONAL INSTITUTE OF METROLOGY (NIM), CHINA

In November 2023, HSA signed a Memorandum of Understanding (MOU) with NIM China virtually at the 39th Asia Pacific Metrology Programme General Assembly and Related Meetings.

The MOU provides a framework for the exchange of knowledge and personnel to increase both HSA and NIMs' scientific and technical capabilities in addressing measurement issues related to clean water, infectious diseases and clinical diagnostic markers. It also covers advanced techniques for nuclear magnetic resonance spectroscopy.

2023 ANNUAL PERMANENT FORUM ON INTERNATIONAL PHARMACEUTICAL CRIME & INTERNATIONAL LABORATORY FORUM ON COUNTERFEIT MEDICINES

Through these two forums held in Singapore in September 2023, HSA shared invaluable insights on identifying trends associated with new drug analogues, testing of novel nitroso-impurities in health supplements, and pharmaceutical counterfeiting and adulterated health products.

ASEAN PHARMACEUTICAL TESTING LABORATORY COMMITTEE (APTLC) MEETING

As the Chair of the 4th APTLC Meeting which was held in the Philippines in November 2023, HSA focused on key initiatives to strengthen and enhance the APTLC framework, as well as commemorated the completion of the compilation of test methods and adoption of guidelines by all ASEAN member states.

ASEAN REFERENCE SUBSTANCES PROJECT

HSA continued its active involvement in the ASEAN Reference Substance Project, establishing secondary drug reference standards for reliable use across ASEAN member countries.

Highlights over the year included spearheading the establishment of an ASEAN Reference Substance (PARS) – Gemfibrozil, together with Brunei, Indonesia and the Philippines, and participation in the Vietnam-led inter-laboratory study of Tobramycin PARS.

ASEAN COSMETICS TESTING LABORATORY COMMITTEE (ACTLC)

Updates this year included the development of a concept and framework for a harmonised approach on cosmetics method review together with Thailand and Brunei.

We were also joint organisers of the 21st ACTLC meeting in November 2023, which saw members agreeing to harmonise the technical review framework on cosmetic testing, and renew their pledge to strengthen collaborative efforts in improving regulatory compliance and product safety.

WORLD HEALTH ORGANIZATION

June 2023 – Our Cigarette Testing Laboratory was redesignated as the WHO Collaborating Centre for Tobacco Testing and Research for another four-year term.

October 2023 – The monograph on 1-Nitroso-4-Methyl Piperazine (MeNP) in Rifampicin Products that we developed was accepted at the 57th WHO Expert Committee Meeting on Specifications for Pharmaceutical Preparations for inclusion in the International Pharmacopoeia.

October 2023 – Our support to help WHO set up a test strategy for determining "Diethylene Glycol (DEG) and Ethylene Glycol (EG) in liquid preparation for oral use" resulted in a new monograph being published in the International Pharmacopoeia.

PROBABILISTIC GENOTYPING WORKSHOP

We organised a training workshop on the use of Probabilistic Genotyping (PG) and Likelihood Ratios in crime casework. PG is a statistical method for the interpretation of complex DNA profiles and deconvolution of more contributors than currently available methods. It was attended by over 140 participants from HSA and Korea, Malaysia, Brunei, Philippines, Thailand and Indonesia.

ASIAN FORENSIC SCIENCES NETWORK (AFSN)

Approved Basic Blood Pattern Analysis (BPA) trainer

In June 2023, our Forensic Chemistry & Physics Laboratory was approved by the International Association of Bloodstain Pattern Analysts (IABPA) to conduct the 40-hour Basic BPA training course.

Only **59 agencies** worldwide are certified to conduct this course

Our first trainees were our AFSN counterparts

Regional trainer for forensic workshops

Over the year, we successfully conducted workshops for several AFSN workgroups, covering the following topics:

- Introduction to Traffic Crash Reconstruction
- Bloodstain Pattern Analysis
- Practical Vehicle Paint Analysis & Database
- Tape Analysis
- Hair Drug Testing
- Quality System and Method Validation
- Cannabis and NPS Analysis in Various Matrices
- Laboratory Information Management System

Inter-laboratory and collaborative exercises

We facilitated various inter-laboratory exercises, including one to evaluate the effectiveness of a newly released DNA amplification kit for detecting DNA degradation and inhibition.

We also organised collaborative exercises:

- Document Examination for AFSN Questioned Documents Workgroup
- Bloodstain Pattern Analysis for AFSN CSI Workgroup

ASIA PACIFIC METROLOGY PROGRAMME (APMP)

In November 2023, Dr Teo Tang Lin, Division Director of HSA's Chemical Metrology Division, became the first Singaporean elected to chair APMP's Technical Committee for Amount of Substance.

From end-2024 to 2027, Dr Teo's duties will include coordinating the review of all chemistry and biology calibration and measurement capability claims of APMP's member institutes to ensure compliance with requirements of the International Committee for Weights and Measures (CIPM) Mutual Recognition Arrangement (MRA).

EUROPEAN NETWORK OF FORENSIC SCIENCE INSTITUTES (ENFSI)

We were the sole Asian representative in the 20-member collaborative DNA Recovery and Activity (ReAct) Study aimed at building a probability repository for evaluating activity-related DNA transfer hypotheses, which are increasingly being raised in court.

We also organised a collaborative exercise on fibre examination for the European Textile and Hair Group.

ORGANISATION OF SCIENTIFIC AREA COMMITTEES (OSAC) FOR FORENSIC SCIENCE

In July 2023, Ms Nellie Cheng from our Forensic Chemistry & Physics Laboratory was appointed as an Affiliate Member of the Forensic Document Examination (FDE) Subcommittee, Physics/Pattern Interpretation Scientific Area Committee, OSAC for Forensic Science.

The appointment in OSAC acknowledges HSA's international forensic standing, providing an opportunity to influence FDE standards and best practices, while staying informed about emerging topics in the field.

BENCHMARKING OF MEASUREMENT CAPABILITIES

Our measurement results are benchmarked to established metrology institutes and reference laboratories.

PARTICIPATION IN INTERNATIONAL COMPARISONS AND STUDY

Comparisons	Organised by
CCQM Key Comparison on Measurement of Nanoparticle Number Concentration in Liquid Suspension	LGC, United Kingdom
IFCC External Quality Scheme for Reference Laboratory (RELA) for 17β-estradiol	Reference Institute for Bioanalytics (RfB), Germany
CCQM Key Comparisons on • Mass Fraction of Oxytetracycline in Oxytetracycline Hydrochloride Material • Mass Fraction of Oxytetracycline Hydrochloride Salt	International Bureau of Weights and Measures (BIPM)
CCQM Key Comparison on Polar Analyte in High Protein Food Matrix – Metronidazole in Porcine Muscle	The Federal Office of Consumer Protection and Food Safety (BVL), Germany
CCQM Pilot Study on Fire Drill Influenza RNA copy number quantification	LGC, United Kingdom and National Institute of Science and Technology (NIST), United States

2023 COLLABORATIVE STUDY FOR DPVS

We were invited by the United States Pharmacopoeia (USP) to contribute to the 2023 Collaborative Study for the Dissolution Performance Verification Standard-Prednisone (DPVS). This study aims to establish acceptance ranges for Prednisone Tablets in USP's Performance Verification Test.

ACCREDITATIONS/ INTERNATIONAL PEER REVIEW

We expanded our professional accreditations/peer review as part of our ongoing commitment to uphold international standards and best practices.

ISO/IEC 17043:2010

In August 2023, the Chemical Metrology Laboratory completed its surveillance assessment by the Singapore Accreditation Council (SAC), maintaining its status as the only accredited provider of Proficiency Testing (PT) and External Quality Assessment (EQA) programmes in Singapore for 10 years since 2013.

ISO/IEC 17025:2017

Pharmaceutical Division's chemical laboratories achieved full compliance in its SAC-SINGLAS extended surveillance assessment, with the following accomplishments:

Pharmaceutical Laboratory expanded its scope of accreditation to include three new tests:

- Determination of Dihydrocodeine, Codeine & Pholcodine by high-performance liquid chromatography with diode-array detection (HPLC-DAD)
- Analysis of Sodium Borate by inductively coupled plasma mass spectrometry (ICPMS)
- Determination of Six Nitrosamine Impurities in Western Medicines by liquid chromatography–mass spectrometry (LC-MS)/MS

Cosmetics Laboratory expanded its scope of accreditation to include the Identification and Determination of Climbazole in Cosmetic Products

Cigarette Testing Laboratory expanded its scope of accreditation to include the Determination of the pH of Smokeless Tobacco Products

INTERNATIONAL PEER REVIEW

From February to March 2023, Chemical Metrology Laboratory completed its peer review by SAC and international metrology experts from metrology institutes in South Korea, China and United Kingdom. HSA continued to demonstrate capability to disseminate traceability in organic and inorganic chemical measurements and peptide/protein measurements to customers through its metrological services, fulfilling Singapore's obligation towards the International Committee for Weights and Measures (CIPM) Mutual Recognition Arrangement (MRA).

CORPORATE SERVICES GROUP

REDEFINING EXCELLENCE

We build a workplace that is powered
for efficiency, productivity and sustainability.

PEOPLE AND VALUES

HSAians are dedicated to fostering a culture of care for one another and the community. Throughout the year, we actively participated in initiatives that enabled us to create positive impact to the community.

MOH-HPB-HSA HAIR FOR HOPE 2023

Started by the Children's Cancer Foundation, "Hair for Hope" seeks to raise funds and awareness for childhood cancer. 2023 marked the third time that HSA has partnered with the Ministry of Health (MOH) and the Health Promotion Board (HPB) to hold a joint Hair for Hope satellite event.

In May 2023, **21 staff volunteers** from the **3 agencies** shaved their heads to show their unwavering support for the fight against cancer.

More than of **$57,000** was raised.

BRINGING JOY TO THE SENIOR COMMUNITY

In October and November 2023, HSAians came together to support the Lions Befrienders by raising funds, as well as interacting with the seniors.

27 volunteers from HSA brought the seniors out for an excursion to Singapore's only crocodile farm, followed by a tea reception.

Over **$5,500** was raised for Lions Befrienders at Meiling Street.

READING TOGETHER FOR CHARITY

"Read for Books" is an annual book donation charity drive organised as part of the National Reading Movement to share the joy of reading with the less privileged. The donated books supported the beneficiaries under "The WondeRead initiative", "kidsREAD", and "Ready to READ @ NLB, *Starter kit & Programmes for Babies and Toddlers*".

For every **10 persons** who read for **15 minutes**, **1 book** was donated.

In July 2023, **106 HSAians** came together to read over 3 sessions.

CLEANING UP SINGAPORE'S WATERWAYS

In December 2023, we joined the Waterways Watch Society and embarked on a clean-up of the Marina Reservoir area. We also learnt more about the impact of trash on waters and wildlife, as well as reaffirmed our commitment to social responsibility and environmental sustainability.

Within just **1 hour**, **25 HSA volunteers** gathered around **20kg** of trash.

DEVELOPING OUR PEOPLE

HSA places great emphasis on creating delightful employee experiences for our staff.

MOMENTS@HSA

Moments@HSA is part of HSA's digital transformation journey and represents our efforts to improve employee experience at every stage of their career with us.

Launched in January 2024, Moments@HSA is a one-stop HR portal that was co-created with our employees through a series of engagements and focus groups. From Pay & Benefits to Career Development opportunities, employees now have easy access to a wide range of HR resources and tools to guide them on their professional development journey and help them excel in their roles.

HSA'S DIGITAL TRANSFORMATION EFFORTS

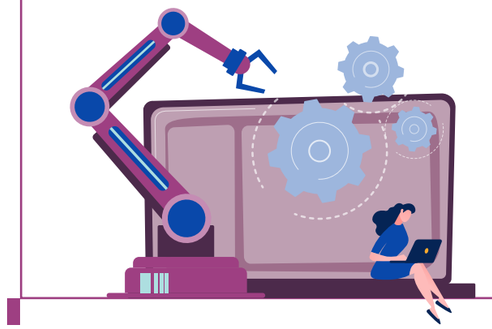
We continue to build digital capabilities within HSA and adopt digital solutions to raise work productivity and efficiency.

STRENGTHENING HSA'S CORE BUSINESS OPERATIONS THROUGH DATA ANALYTICS

We operationalised the data analytics platform, Tableau, to equip staff across the organisation with self-service data visualisation capabilities. This initiative helped empower users to extract valuable insights from data and enabled better and more proactive decision making on critical issues and challenges related to our core business operations.

BUILDING DIGITAL CAPABILITIES TO STREAMLINE PROCESSES

We came up with various initiatives to equip staff with the knowledge for automating work processes. These included an RPA Citizen Developer Workshop on performing task automation with zero to minimal use of code, as well as starting an RPA community on SG teams to encourage cross sharing and learning of RPA use cases.



ENHANCING LITERACY ON DATA AND ANALYTICS

To encourage staff to deepen their data analytics skills and embrace data-driven decision making, we collaborated with GovTech to organise an internal Data Arcade Tournament and participated in a whole-of-government Data Arcade Tournament.

The top three winning teams developed dashboards that offered valuable insights in three key areas:

- The Forensic Chemistry and Physics Laboratory highlighted significant trends in Singapore's **crime statistics.**
- The Vigilance and Compliance Branch presented data on **Severe Cutaneous Adverse Reactions (SCARs).**
- The combined team from the Health Products Regulation Group and Applied Sciences Group provided insights into **drug abuse trends** in Singapore.

We also received **GovTech's Platinum Tier Award** for our active participation in the tournament.

MEDIA ENGAGEMENT AND BRANDING

We leverage various media platforms to highlight the latest news and developments, as well as showcase HSA's capabilities.

MEDIA OUTREACH

We worked with the media to reach out to blood donors to address a shortage in group O blood stocks through targeted media appeals. As a result, we were able to restore the blood stock levels to a healthy state within three days following the appeal. Additionally, we garnered good publicity for the opening of the new Bloodbank@One Punggol which was graced by Minister for Health, Mr Ong Ye Kung.

In safeguarding public health, we issued alerts regarding adulterated products and profiled our vigilance and enforcement efforts in relation to illegal medicines and e-vaporisers. Additionally, we showcased our work in the administration of justice on social media and on screen, taking part in Season 2 of Inside Crime Scene.

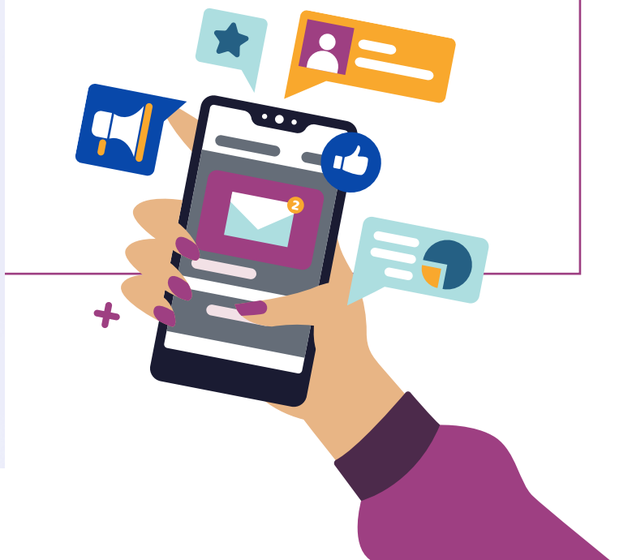
We published **4 HSA updates** and **32 press releases**, as well as managed **239 media queries**, contributing to **1,716 media articles**.

We created a total of **281 marketing collaterals** and **203 event collaterals** to support our outreach efforts.

BRANDING HSA AS AN EMPLOYER OF CHOICE

We enhanced our branding efforts on LinkedIn to elevate HSA's presence and interaction with prospective employees and industry partners. We increased the frequency and diversified the content of our posts, incorporating staff profiling and notable achievements.

Our online community experienced significant growth, with a **60% increase in the number of followers**.



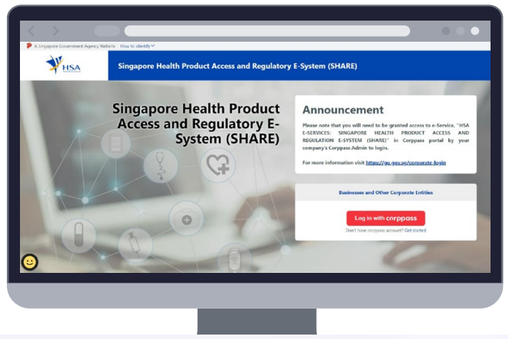
TECHNOLOGY AND INFRASTRUCTURE

We create a world-class infrastructure that leverages the latest technology to better serve our stakeholders.

ENHANCING NETWORK CONNECTIVITY FOR GREATER EFFICIENCY

Through upgrades to our network infrastructure, we managed to enhance network coverage and reliability to improve the productivity of our staff operating from HSA premises as well as at remote sites.

Our network coverage and reliability have been enhanced by up to **10X**.



EMBRACING TECHNOLOGY TO ACTIVELY ENGAGE AND ATTRACT BLOOD DONORS

We successfully implemented Queue Management System Software-As-A-Service (SaaS) and completed infrastructure setup for our new Bloodbank@One Punggol. This implementation supports the Blood Services Group's overall efforts to make blood donation more convenient for donors.

SUCCESSFUL IMPLEMENTATION OF SHARE TO ENSURE THE SAFETY OF HEALTH PRODUCTS

In December 2023, we launched the Singapore Health Product Access and Regulatory E-System (SHARE) Minimum Viable Product (MVP). SHARE serves as a unified platform, fostering collaboration among HSA staff, industry partners, and the public to ensure the safe delivery of health products in Singapore.

This MVP release encompasses a modernised architecture in Cloud and uses improved UX/UI design to enhance the way businesses and partners interact with HSA.

AWARDS AND RECOGNITION

INTERNATIONAL AWARDS

WHO LISTED AUTHORITY DESIGNATION

In October 2023, HSA was one of the first three regulatory authorities designated by WHO as a WHO Listed Authority (WLA). This accolade is a global recognition that HSA meets internationally recognised regulatory standards and practices, and is operating at the highest level of regulatory performance.

HSA'S FIRST TECHNICAL AWARD FROM THE REGIONAL METROLOGY ORGANISATION, THE ASIA PACIFIC METROLOGY PROGRAMME (APMP)

Dr Teo Tang Lin received this award for her contributions as an APMP Executive Committee Member from 2019 to 2023. It was the first APMP Technical Award to be presented to an HSA Officer.

NATIONAL AWARDS

MINISTER FOR HOME AFFAIRS, NATIONAL DAY AWARD (TEAM)

This award was presented to these teams who contributed to the safety and security of Singapore:

- Illicit Drugs Laboratory
- Enforcement Branch

NATIONAL AWARDS (COVID-19)

The President's Certificate of Commendation (COVID-19) was awarded to the:

- Forensic Medicine & HistoLab Team
- Medical Devices Team
- Therapeutic Products Team

HSA staff received awards for their significant contributions to Singapore's fight against the COVID-19 pandemic.

1
The Public Service Star (COVID-19)

6
The Public Administration Medal (Silver) (COVID-19)

11
The Public Administration Medal (Bronze) (COVID-19)

31
The Commendation Medal (COVID-19)

167
COVID-19 Resilience Medal

PUBLIC SECTOR AWARDS

MINISTRY OF HEALTH PS (HEALTH) TEAM AWARD 2023 FOR WHO GLOBAL BENCHMARKING OF MEDICINES REGULATORY SYSTEM

HSA demonstrated OLE! Desired behaviours (Openness, Learning, Empowerment and Innovation) as the first National Regulatory Authority in the world to achieve WHO's highest Maturity Level (ML4) for its regulatory system which placed it among one of the most trusted and advanced medicine regulators based on operational efficiency.

MINISTER FOR HOME AFFAIRS (MHA) OPERATIONAL EXCELLENCE AWARD

This award was presented to the Tobacco Regulation Branch for the efficient handling of checkpoint cases involving large quantities of prohibited tobacco products.

SINGAPORE HEALTH QUALITY SERVICE AWARDS (SHQSA) 2024

41 outstanding individuals from various departments in HSA were presented with the Silver, Gold, and Star awards at the SHQSA Ceremony for their exceptional service in the healthcare sector.

7 *Star* **28** *Gold* **6** *Silver*

PUBLIC SECTOR TRANSFORMATION (PST) AWARDS 2023

Mr Louis Koh was presented with the Exemplary SkillsFuture @ Public Service Award 2023. He is a senior forensic scientist who expanded his expertise to include video forensics, document metadata and computer forensics, and developed RPA workflows to automate manual checks for instruments for his laboratory.

IMMIGRATION & CHECKPOINTS AUTHORITY (ICA) COMMISSIONER'S COMMENDATION BRONZE

This award recognised the Tobacco Regulation Branch for their teamwork and operational efficiency that led to the detection of large numbers of prohibited tobacco products at the checkpoints.

HSA OUTSTANDING SERVICE TO CUSTOMERS AWARD (OSCA) 2023

HSA staff who demonstrated outstanding service standards were recognised for their efforts.

1 *Star* **5** *Gold* **9** *Silver*

27 *Bronze* **10** *Team*

OUR WORK IN FIGURES

BLOOD SERVICES GROUP

Key statistics as at end-December 2023

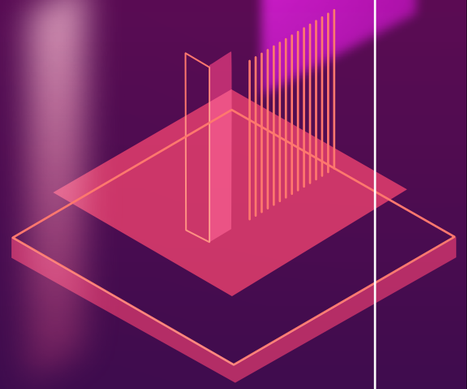
77,424 Blood Donors

122,668 Whole Blood Donations

8,378 Apheresis Donations

400,173 Blood Components Processed

1,413,287 Laboratory Tests Conducted



APPLIED SCIENCES GROUP

Key statistics as at end-March 2024

Pharmaceutical Division

2,017 Analytical Cases

3,792 Analytical Tests

Analytical Toxicology Division

17,226 Forensic Cases

28,185 Forensic Exhibits

Biology Division

13,914 Forensic Cases

21,619 Forensic Exhibits

Forensic Science Division

306 Forensic Cases

1,779 Forensic Exhibits

Illicit Drugs Division

2,014 Forensic Cases

7,800 Forensic Exhibits

Forensic Medicine Division

5,069 Coroner's Cases

1,110 Coroner's Autopsies

HEALTH PRODUCTS REGULATION GROUP

Key statistics as at end-March 2024

Medicinal Products Pre-market Cluster

31 Therapeutic Products Containing New Chemical/Biological Entities Approved

230 Therapeutic Products Registrations Approved (New Drug Applications and Generic Drug Applications)

5,133 Therapeutic Products Variation Applications Approved

5,475 Approved Products on the Register of Therapeutic Products

707 New Chinese Proprietary Medicines Listed

12,761 Chinese Proprietary Medicines Listed

49,851 New Cosmetic Products Notified

172,276 Cosmetic Products Notified

202 New Class 1 Cell, Tissue and Gene Therapy Products Notified

795 Class 1 Cell, Tissue and Gene Therapy Products Notification Updates

1,170 Class 1 Cell, Tissue and Gene Therapy Products Notified

3 New Class 2 Cell, Tissue and Gene Therapy Products Approved

12 Class 2 Cell, Tissue and Gene Therapy Products Variation Applications Approved

6 Approved Products on the Register of Class 2 Cell, Tissue and Gene Therapy Products

129 New Clinical Trial Applications Processed

118 New Clinical Trial Applications Approved

Medical Devices Cluster

1,139 Medical Device Product Registrations Approved

55,113 Medical Device Product Listings Notified

2,782 Medical Device Change Notification Applications Approved

1,480 Licences for Importers of Medical Devices

1,416 Licences for Wholesalers of Medical Devices

19,795 Approved Products on the Singapore Medical Device Register

531 Applications for Import of Medical Devices for Personal Use Processed

279 Licences for Manufacturers of Medical Devices

240 Certificates for Exporters of Medical Devices

Vigilance, Compliance and Enforcement Cluster

294 Licences/Certificates for Manufacturers of Health Products* Approved

1,709 Licences/Certificates for Importers of Health Products* Approved

747 Licences/Certificates for Wholesalers of Health Products* Approved

358 Licences for Retail Pharmacies Approved

412 Licences/Certificates for Exporters of Health Products* Approved

443 Site Audits Conducted for Good Manufacturing & Good Distribution Practices and Pharmacies

13,416 Applications and Enquiries for Import of Medicinal Products for Personal Use Processed

2,727 Medical Advertisement Permits Approved

29,901 Spontaneous Adverse Drug Reaction Reports Captured

4,351 Post-market Feedback Received (Relating to Potential Contravention of Health Products Act)

451 Tobacco Retail Licences Approved

4,352 Licensed Tobacco Retail Outlets

11,403 Electronic Vaporiser Cases Handled by HSA

**except medical devices*

FINANCIAL HIGHLIGHTS

Statement of Financial Position

	FY23/24 $'000	FY22/23 $'000	Increase / (Decrease) $'000	%
Property, Plant & Equipment	80,136	78,983	1,153	1
Intangibles	8,847	10,716	(1,869)	(17)
Right-of-Use Assets	12,879	17,083	(4,204)	(25)
Current Assets	287,967	263,486	24,481	9
Total Assets	**389,829**	**370,268**	**19,561**	**5**
Equity	281,285	265,863	15,422	6
Non-Current Liabilities	11,277	16,073	(4,796)	(30)
Current Liabilities	97,267	88,332	8,935	10
Total Equity and Liabilities	**389,829**	**370,268**	**19,561**	**5**

Statement of Comprehensive Income

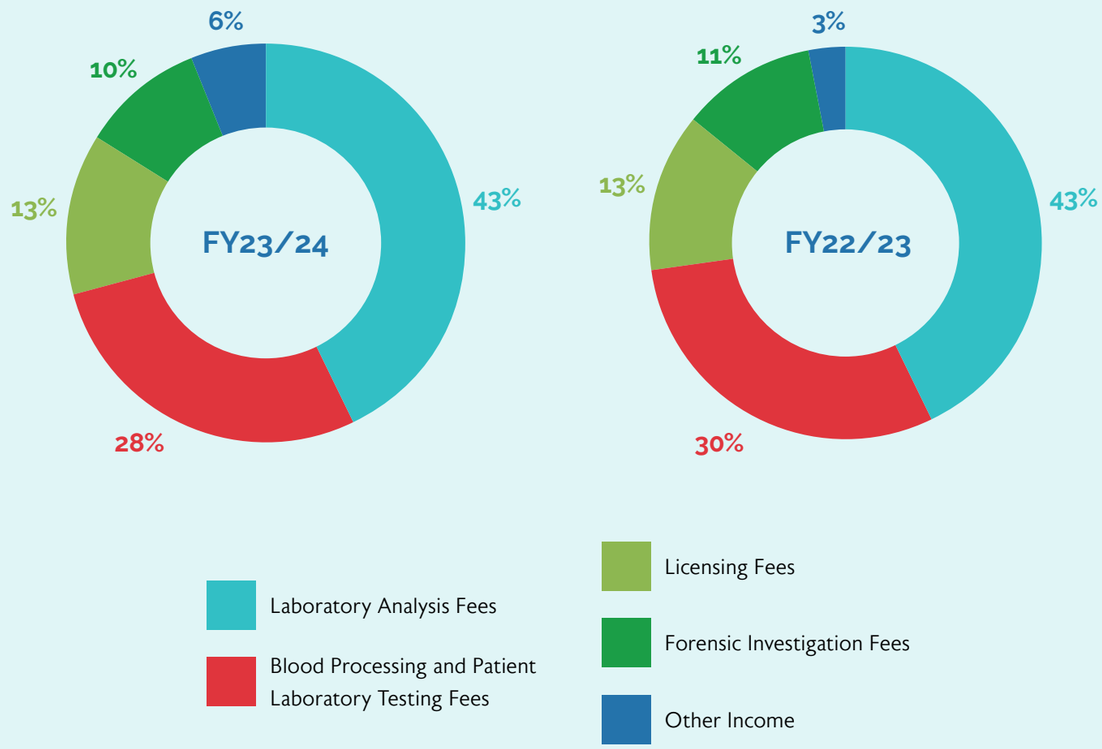
The Authority achieved an overall net surplus of $20.1m for FY23/24.

	FY23/24 $'000	FY22/23 $'000	Increase / (Decrease) $'000	%
Operating Income	167,247	158,414	8,833	6
Operating Expenditure	(267,493)	(241,709)	25,784	11
Deficit before Government Grants	**(100,246)**	**(83,295)**	**16,951**	**20**
Government Grants	124,442	104,917	19,525	19
Surplus before Contribution to Consolidated Fund	**24,196**	**21,622**	**2,574**	**12**
Contribution to Consolidated Fund	(4,115)	(3,676)	439	12
Net Surplus	**20,081**	**17,946**	**2,135**	**12**
Other Comprehensive Income	36	(131)	167	127
Net Surplus and Comprehensive Income for the Year	**20,117**	**17,815**	**2,302**	**13**

Operating Income

The Authority earned a total operating income of $167.2m in FY23/24, an increase of $8.8m (6%) from FY22/23's revenue of $158.4m.

	FY23/24 $'000	FY22/23 $'000	Increase / (Decrease) $'000	%
Laboratory Analysis Fees	72,086	67,691	4,395	6
Blood Processing and Patient Laboratory Testing Fees	46,077	47,722	(1,645)	(3)
Licensing Fees	21,216	20,666	550	3
Forensic Investigation Fees	17,580	16,840	740	4
Other Income	10,288	5,495	4,793	87
Total Operating Income	**167,247**	**158,414**	**8,833**	**6**

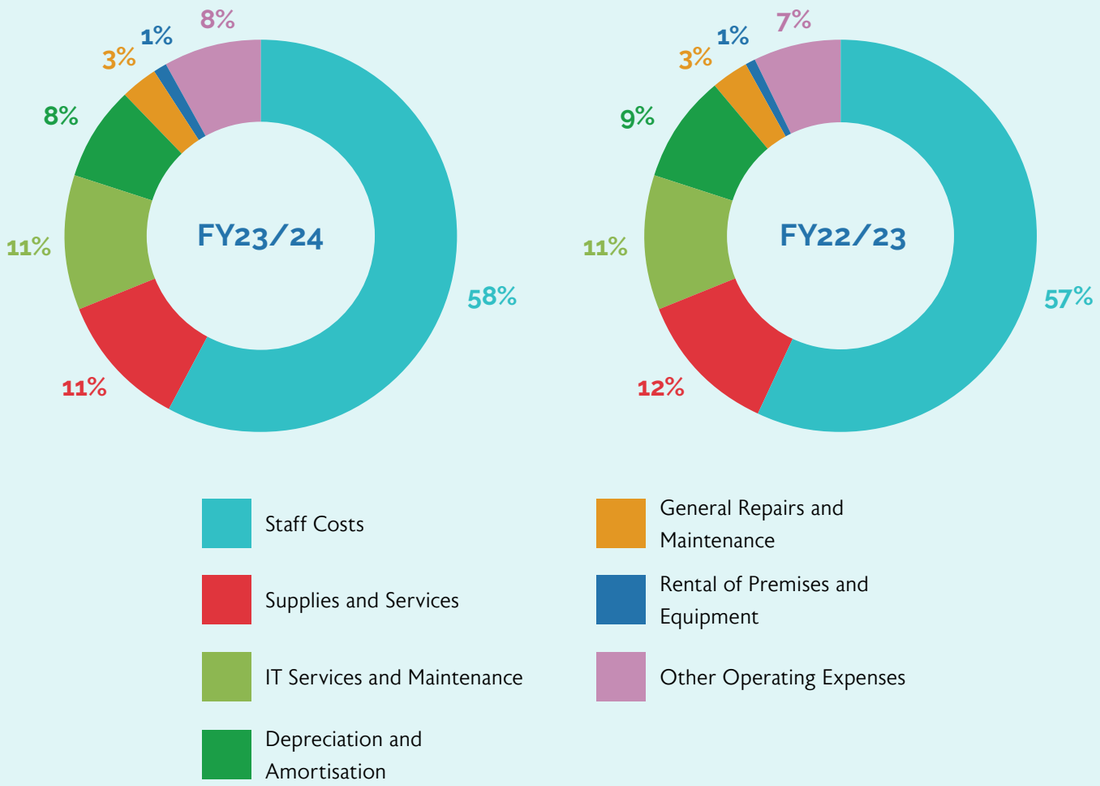


FINANCIAL HIGHLIGHTS

Operating Expenditure

The Authority incurred a total operating expenditure of $267.5m in FY23/24, an increase of $25.8m (11%) from FY22/23's expenditure of $241.7m.

	FY23/24 $'000	FY22/23 $'000	Increase / (Decrease) $'000	%
Staff Costs	155,757	136,766	18,991	14
Supplies and Services	28,365	29,563	(1,198)	(4)
IT Services and Maintenance	28,761	26,461	2,300	9
Depreciation and Amortisation	22,404	21,178	1,226	6
General Repairs and Maintenance	8,757	8,625	132	2
Rental of Premises and Equipment	2,284	2,193	91	4
Other Operating Expenses	21,165	16,923	4,242	25
Total Operating Expenditure	**267,493**	**241,709**	**25,784**	**11**



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