
HEALTH SCIENCES AUTHORITY
ANNUAL REPORT 2021/2022
ADAPT
EVOLVE
ADVANCE

ADAPT, EVOLVE, ADVANCE

In the past year, HSA continued to navigate the challenges brought along by the pandemic. Put to the test with the ever-changing situation, we grew stronger as an organisation.

By being agile and adaptable, we adopted new ways of working, to continue to advance, transform and deliver.

As we move forward, we are confident that we can overcome the challenges that come our way with what we have built and learnt.

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.

CONTENTS

OUR ACCOLADES

Organisational Excellence

Since April 2019
Singapore Quality Class Star
with People and Service Niche Standards

2014 to March 2019
Singapore Service Class

2003 to March 2019
Singapore Innovation Class
First public healthcare agency to be endorsed

2002 to March 2019
People Developer
Certification

Since August 2018
ISO 9001:2015
Information Management Department
Corporate Headquarters

Since June 2018
ISO 9001:2015
Corporate Services Group

2014
The Public Service
Achievement Award

2012
Singapore H.E.A.L.T.H.
Platinum Award

2010
The Public Service
Milestone Award

Since 2008
Meritorious Home Team
Partner Award

2006
Public Service Award for
Organisational Excellence

Since 2005
Meritorious Defence
Partner Award

2004
Singapore Family Friendly
Employer Award

Since 2003
Community Chest Awards

Professional Excellence

HEALTH PRODUCTS REGULATION GROUP

Since January 2022
Attainment of Maturity Level 4 status for Advanced Medicines Regulatory System – awarded by the World Health Organization

Since November 2018
ISO 9001:2015
Audit & Licensing Division

Since March 2017
ISO 9001:2015
Enforcement Branch
Tobacco Regulation Branch
Vigilance & Compliance Branch

BLOOD SERVICES GROUP

2021
Singapore Health Quality Service Awards
Commendation Award

Since August 2014
Compliance with PIC/S Good Manufacturing Practice Standard
Cell Therapy Facility was audited to acceptable GMP standard jointly by HPRG and Swissmedic

Since July 2013
International Society for Cellular Therapy and European Blood and Bone Marrow Transplantation (JACIE)

Since August 2008
American Society for Histocompatibility and Immunogenetics (ASHI)
First transplant testing laboratory in the Western Pacific Region to be accredited

Since May 2006
AABB Accreditation
First national blood service in Asia to be accredited

Since 1992
World Health Organization Collaborating Centre for Transfusion Medicine

APPLIED SCIENCES GROUP

Forensic Medicine Division

2021
Singapore Health Quality Service Awards
Commendation Award

Since September 2005
National Association of Medical Examiners (NAME)
First agency outside North America to be accredited

March to May 2003
Commendation for Significant Contribution in Helping Singapore Overcome SARS

Since 1999
Accreditation of Laboratory for Pathology Training by The Royal College of Pathologists of Australasia

Analytical Toxicology Division, Biology Division, Forensic Science Division, Illicit Drugs Division

Since 2017
ANSI National Accreditation Board (ANAB)
Forensic Science Testing Accreditation

1996 to 2017
Forensic Science Testing Accreditation under American Society of Crime Laboratory Directors/ Laboratory Accreditation Board (ASCLD/LAB)

1999
Excellence for Singapore Award

Forensic Science Division

2021
Ministry of Home Affairs (MHA)
Operational Excellence Award

Illicit Drugs Division

2021
Ministry for Home Affairs
National Day Awards
(MNDA Team Award)

2018 to 2020
Ministry of Home Affairs
Operational Excellence Award

Chemical Metrology Division

Since August 2013
Accredited as a Proficiency Testing Provider in compliance with ISO/IEC 17043 by the Singapore Accreditation Council

Pharmaceutical Division

Since February 2012
Observer to the European Pharmacopoeia Commission

Since June 2009
World Health Organization Collaborating Centre for Tobacco Testing and Research

July 2003
Public Service Award for Organisational Excellence

Since August 2002
Singapore Quality Class

Since 1997
ISO/IEC 17025:2017 Accreditation under Singapore Accreditation Council — Singapore Laboratory Accreditation Scheme (SAC-SINGLAS)

Since February 1993
World Health Organization Collaborating Centre for Drug Quality Assurance

OUR ACCOLADES

Memberships, Committees and Working Groups

HEALTH PRODUCTS REGULATION GROUP

Since September 2021
WHO National Control Laboratory Network for Biologicals
Member

June 2018 to June 2021
International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)
Management Committee

Since January 2018
International Pharmaceutical Regulators Programme (IPRP)
Management Committee

Since November 2017
International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)
Regulatory Member

Since September 2016
International Medical Device Regulators Forum (IMDRF)
Management Committee

Since 2013
International Coalition of Medicines Regulatory Authorities (ICMRA)
Member

Since 2007
Australia-Canada-Singapore-Switzerland-United Kingdom (Access) Consortium
Consortium Member

Since January 2000
Pharmaceutical Inspection Co-operation Scheme (PIC/S)
Participating Authority

BLOOD SERVICES GROUP

Since 2012
International Society of Blood Transfusion (ISBT)
Rare Donor Working Party Member

Since 2006
Asia Pacific Blood Network (APBN)
Founding Member

Since 2006
International Council for Commonality in Blood Banking Automation (ICCBBA)
Asia Pacific Technical Advisory Group Member

APPLIED SCIENCES GROUP

Analytical Toxicology Division, Biology Division, Forensic Science Division, Illicit Drugs Division

Since September 2021
International Association of Identification
Member

Since February 2021
Association of Firearms and Toolmarks Examiners (AFTE)
Member

Since October 2020
Institute of Traffic Accident Investigators (ITAI)
Member

Since January 2020
Forensic Isotope Ratio Mass Spectrometry Network (FIRMS)
Institutional Member

Since May 2017
International Association of Bloodstain Pattern Analysts (IABPA)
Provisional Member

Since July 2016
The International Association of Forensic Toxicologists (TIAFT)
Committee Member

Since 2016
National Mirror Working Group for ISO Technical Committee, ISO/TC272

Since April 2013
European DNA Profiling Group (EDNAP)
Associate Member

Since January 2011
Scientific Working Group for the Analysis of Seized Drugs (SWGDRUG)

Since October 2010
International Forensic Strategic Alliance (IFSA)
Representative of AFSN

Since 2008
Asian Forensic Sciences Network (AFSN)
One of the founding members

European Network of Forensic Science Institutes (ENSFI)

Associate Member of ENSFI
Working Groups

Since April 2018
ENSFI Expert Working Group for Marks

Since June 2017
ENSFI Textile and Hair Working Group

Since May 2017
ENSFI Drugs Working Group

Since January 2016
ENSFI European Network of Forensic Handwriting Experts Workgroup

Since November 2015
ENSFI Firearms and GSR Working Group

Since October 2015
ENSFI Document Experts Working Group

Since September 2013
ENSFI Paint and Glass Working Group

Since April 2013
ENSFI DNA Working Group

INTERPOL

Since July 2018
INTERPOL DVI Workgroup
Forensic Genetics Sub-Working Group
Member

Since May 2017
INTERPOL DVI Workgroup
Pathology and Anthropology Sub-Working Group

Since May 2016
INTERPOL DNA Monitoring Expert Group
Member

Asian Forensic Sciences Network

Crime Scene Investigation Workgroup, Questioned Document Workgroup, Toxicology Workgroup, Trace Evidence Workgroup, Quality Assurance & Standards Committee
Chair

Illicit Drugs Workgroup
Vice Chair

Digital Forensic Workgroup, DNA Workgroup
Secretary

Chemical Metrology Division

Since July 2016
ASEAN Reference Material Network
One of the founding members

Since November 2014
Consultative Committee for Amount of Substance: Metrology in Chemistry and Biology (CCQM)
Member

Since December 2013
Joint Committee for Traceability in Laboratory Medicine (JCTLM)
Member

Since July 2008
Asia Pacific Metrology Programme (APMP)
Full Member

Pharmaceutical Division

Since September 2021
WHO National Control Laboratory Network for Biologicals
Associate Membership

Since October 2020
ASEAN Pharmaceutical Testing Laboratory Committee (APTLC)
Co-Chair

Since May 2014
General European Official Medicines Control Laboratories Network
Associate Membership

Since November 2012
ASEAN Cosmetics Testing Laboratory Committee (ACTLC)
Member

Since September 2012
Official Cosmetics Control Laboratories (OCCL)
Member

World Health Organization

Since May 2016
WHO Tobacco Laboratory Network (TobLabNet)
Chair

Since November 2013
WHO Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations
Member

Since 2013
Western Pacific Regional Forum for the Harmonization of Herbal Medicines (FHH)

Since 2004
International Laboratories Forum on Counterfeit Medicines (ILFCM)

MESSAGE FROM THE CHAIRMAN

The past year was no doubt intense, but at the same time productive and fulfilling. With the progress we have made in going digital, forging closer ties through greater collaboration, and adopting a stakeholder-centric approach, I am confident that HSA is poised to continue growing and reaching greater heights.

PROFESSOR BENJAMIN ONG
Chairman

This is my first year as Chairman of HSA and I am honoured to be part of the mission to secure public health and safety, especially during this challenging period when Singapore has been busy battling the COVID-19 pandemic.

Since I joined the HSA Board in 2020, I have been impressed by HSAians' professionalism and passion in their pursuit of scientific excellence and rigour.

Building Strategic Collaborations

Recognising the value of partnerships, we have continued to grow our strategic collaborations to enable knowledge exchange between HSA and our counterparts.

Building on the Memorandum of Understanding signed with Korea's Ministry of Food and Drug Safety (MFDS) on Good Manufacturing Practices (GMP) for Pharmaceutical Products in 2019, we embarked on a one-year pilot project to establish mutual confidence in each country's GMP inspection regulatory framework.

The project was successfully completed in July 2021, paving the way for MFDS and HSA to recognise GMP certificates issued by either side without the need for any additional inspections, thereby enhancing regulatory efficiency. We are now working towards formalising the arrangement through a Mutual Recognition Agreement.

Another noteworthy collaboration was with NUS Pharmacy Department to boost our capabilities in detecting designer drugs abuse, such as synthetic cannabinoids. In August 2021, we developed a new testing approach that identifies unique urinary biomarkers to prove consumption of the new synthetic cannabinoids.

HSA has also begun trialling an automated e-commerce surveillance tool developed by the Home Team Science and Technology Agency. Using robotic process automation and artificial intelligence to trawl through listings of illegal drugs, health products and cosmetics, as well as unauthorised COVID-19 test kits and vaccines, we have managed to shorten the detection process from weeks to just a matter of hours.

Enhancing the Safety of Blood Products through Continuous Research

A key focus of HSA is the National Blood Programme, and we are always looking to enhance the safety and quality of our blood products for patients.

This year, we have validated the extension of the shelf life of our platelets from five to seven days. This extended shelf life allows us to better manage our platelet inventory, while continuing to ensure the safety and quality of platelets for use in transfusion therapy.

We also completed a collaborative study with DSO National Laboratories and Singapore General Hospital on the preparation and use of frozen whole blood derived pooled platelets for transfusion therapy. The frozen platelets are effective in preventing bleeding among patients with very low platelet counts, and have the advantage of a significantly longer shelf life of at least two years.

Another significant breakthrough we have made is to validate and optimise the process of removing excess plasma to produce plasma-reduced platelets. Such platelets have proven to be particularly useful for patients who develop allergic reactions from the standard platelets.

Our Digital Transformation Strategy

In our drive towards greater efficiencies, we continued to embrace digital transformation. Our digital transformation strategy leverages the capabilities of our staff to better serve the different needs of our stakeholders.

To ensure HSAians have the right digital mindset, we rolled out various initiatives including digitalisation seminars, digital work tools for knowledge building, and even specialised training programmes for senior staff.

We also enhanced our Data Analytics Strategy to enable more effective use of data in developing insights, and decision making in the organisation. Specifically, we appointed Data Champions to drive and initiate strategic data analytics projects across HSA, organised a Data Arcade Tournament (DATx@HSA) to promote the use of data analytics across departments, and onboarded GovTech's Workflow Management System to automate our internal work processes.

One of the most important milestones in our digitalisation journey so far is the launch of our Audit Management System (AMS) for Good Distribution Practice (GDP) and retail pharmacy inspections in January 2022.

This AMS digitalises GDP and pharmacy audit-related work processes, by using technology to facilitate the entire workflow from inspection scheduling, to communicating with companies on inspection findings, to closing out of inspections. Indeed, such technology enablement has significantly streamlined the inspection processes and improved connectivity with our stakeholders.

A Positive Outlook

The past year was no doubt intense, but at the same time productive and fulfilling. With the progress we have made in going digital, forging closer ties through greater collaboration, and adopting a stakeholder-centric approach, I am confident that HSA is poised to continue growing and reaching greater heights.

MESSAGE FROM THE CEO

Through the many challenges that we have had to face, we have learnt that the world is ever-changing and that we must be agile and adaptable. At HSA, we strive to learn, unlearn and relearn new skills. As we advance, we will continue to hone our professional and scientific expertise, and embrace new digital skills that will enable us to transform to become even more efficient and ready for the journey ahead.

DR CHOONG MAY LING, MIMI
Chief Executive Officer

These past two years have been a challenging period – one which continuously tested us but also taught us many valuable lessons.

We demonstrated our agility, adaptability and resilience by quickly developing and embracing new working methods. As an organisation, we continued to evolve and advance our transformation journey.

Fighting COVID-19

In December 2021, following the first-in-Asia interim authorisation of the Pfizer-BioNTech and Moderna vaccines in 2020 and 2021, HSA approved Pfizer-BioNTech's Comirnaty, transiting it to full registration, and extended its use to children aged 5 to 11 years old. We continued to expedite the review of other vaccine types to facilitate the diversification of Singapore's COVID-19 vaccine portfolio, as well as COVID-19 treatments, via the Pandemic Special Access Route (PSAR). PSAR has allowed us to evaluate data from clinical studies as and when they are ready, allowing for faster, yet thorough reviews.

Under PSAR, we were able to grant interim authorisation for two COVID-19 vaccines – CoronaVac and Nuvaxovid in October 2021 and February 2022, two monoclonal antibody therapies for the treatment of COVID-19 (Sotrovimab, and a combination of Casirivimab and Imdevimab), and Singapore's first oral medicine for COVID-19 treatment – PAXLOVID™.

Additionally, we also put in place the Special Access Route (SAR) in June 2021 to enable healthcare institutions to bring in World Health Organization Emergency Use Listing (WHO-EUL) vaccines, not authorised under PSAR, to vaccinate eligible doctor-supervised patients. As of 31 March 2022, we have approved 521 applications for WHO-EUL vaccines and 47 applications for COVID-19 therapeutics through SAR.

To ensure that safety is not compromised, HSA came up with a vaccine safety monitoring framework for COVID-19 vaccines. Our most intensive effort to date, this framework ensures that emerging public health and safety concerns associated with vaccines are promptly detected and managed, and the public are kept informed through regular Safety Update Reports.

We also worked with key stakeholders, including the Ministry of Health and the Health Promotion Board, to leverage electronic medical records and the National Immunisation Registry records for the active surveillance of COVID-19 vaccines. With these data points, we were able to detect potential safety concerns more effectively, using data analytics and epidemiology studies.

Putting Our Blood Donors First

Even in the midst of the COVID-19 pandemic, we were heartened by the support of warm-hearted donors who continued to altruistically give their time and blood to patients in need. We continued to have enough blood to meet patients' needs throughout the pandemic.

To ensure a constant and safe supply of blood, we looked at ways to make it more conducive for donors to donate blood regularly. In September 2021, we launched our first-ever DonateBlood mobile app, which was jointly created with the Singapore Red Cross, to give donors easier access to blood donation-related services anytime and anywhere.

To accommodate more donors at our centrally-located Bloodbank@DhobyGhaut (BB@DG), whose daily blood collection has almost doubled since it opened in 2012, we embarked on a renovation project. The new BB@DG features a more spacious donor waiting area and refreshment area for improved donor experience.

Developing New and Improved Techniques

To enable us to deliver top tier scientific services, we focused on innovation to raise our efficiency.

In April 2021, HSA was alerted by overseas regulatory counterparts to the potential of azidomethyl-biphenyl-tetrazole contamination in angiotensin II receptor blocker products. As there were no existing test methods internationally for such analysis, we swiftly moved to develop our own testing methodologies. This initiative enabled our health products regulation arm to take timely and appropriate regulatory actions to safeguard public health.

In another example of innovation at work, we developed a novel DNA testing method to detect cannabis plant material to complement existing methods comprising physical examination and chemical analysis. Using this method, we were able to obtain >99% match to known cannabis references, which is particularly useful in identifying highly fragmented cannabis samples.

Garnering Recognition for Our Contributions

HSA's prompt, proactive facilitation and regulatory agility have enabled Singapore to swiftly roll out essential COVID-19 diagnostic testing and ensure that we are amongst the earliest in the world to access critical vaccines, therapies and medical devices to combat the pandemic. For our efforts, we were awarded a total of three Public Service Transformation awards – two "One Public Service Awards" for building capacity and capability for COVID-19 testing and securing access to vaccines; and the "Agility Award" for our role in supporting Singapore's fight against COVID-19.

I am also extremely proud of HSA achieving WHO's Maturity Level 4 (ML4) – the highest recognition for an advanced medicines regulatory system. HSA is the first agency out of 194 member states to achieve ML4. This achievement comes after a rigorous and comprehensive assessment by a team of WHO-appointed international assessors who looked at over 250 indicators across the entire regulatory lifecycle spanning medicines from clinical trials, marketing authorisation, post-market safety monitoring, audit and licensing of manufacturers and dealers, and laboratory testing of medicines.

Over the year-in-review, we put our scientific expertise to good use by participating in a multi-agency study led by the Singapore Civil Defence Force to investigate the cause of vegetation fires along expressway road dividers. Through our two-year study to analyse mulch samples to determine the volatile organic compounds emitted and the particle size of the samples, we managed to help decrease the number of vegetation fires on our expressways, as well as pick up a Ministry of Home Affairs Ops Excellence Award for our efforts.

I trust that all these external validations will enhance the Singapore public's confidence and trust in HSA's role to protect and advance public health and safety.

Transforming to Advance

Through the many challenges that we have had to face, we have learnt that the world is ever-changing and that we must be agile and adaptable. At HSA, we strive to learn, unlearn and relearn new skills. As we advance, we will continue to hone our professional and scientific expertise, and embrace new digital skills that will enable us to transform to become even more efficient and ready for the journey ahead.

HSA BOARD

AS AT AUGUST 2022

Professor Benjamin Ong
Chairman
Health Sciences Authority

Mr Dileep Nair
Independent Director
Keppel DC REIT Management Pte Ltd

Mr Alok Mishra
Chief Executive Officer
Value Addition

Mr Jimmy Phoon
Chief Executive Officer
Seviora Holdings Pte Ltd

Professor Tai Lee Siang
Head of Pillar, Architecture and Sustainable Design
Singapore University of Technology and Design

Ms Aileen Tan
Group Chief People and Sustainability Officer
Singtel

Professor Leong Tze Yun
Professor of Computer Science (Practice), School of Computing

Director, NUS Artificial Intelligence Laboratory
National University of Singapore

Professor Freddy Boey
Deputy President (Innovation & Enterprise)
National University of Singapore

Mr Lionel Yee Woon Chin
Deputy Attorney-General
Attorney-General's Chambers

Mr Lin Qinghui
Senior Director, Policy Development Division
Ministry of Home Affairs

Mr Robert Chew
Managing Partner
iGlobe Partners

HSA BOARD COMMITTEES

AS AT AUGUST 2022

Board Executive Committee

Chairman
- Professor Benjamin Ong

Members
- Mr Alok Mishra
- Mr Lionel Yee Woon Chin
- Ms Aileen Tan

Audit and Risk Committee

Chairman
- Mr Jimmy Phoon

Members
- Professor Freddy Boey
- Professor Leong Tze Yun
- Mr Lin Qinghui
- Mr Robert Chew

Building Development Committee

Chairman
- Professor Tai Lee Siang
  Head of Pillar, Architecture and Sustainable Design
  Singapore University of Technology and Design

Co-Chairman
- Dr Choong May Ling, Mimi
  Chief Executive Officer
  Health Sciences Authority

Members
- Mr Dileep Nair
  Independent Director
  Keppel DC REIT Management Pte Ltd
- Mr Jeffrey Wong
  Group Director
  Corporate Services Group
- Dr Christopher Syn
  Acting Group Director
  Applied Sciences Group
- Assoc Professor Chan Cheng Leng
  Group Director
  Health Products Regulation Group
- Dr Ang Ai Leen
  Group Director
  Blood Services Group
- Mr Loke Mun Sing
  Director
  Healthcare Infrastructure Projects Division
  Ministry of Health Holdings
- Mr Hoong Bee Lok
  Visiting Consultant
  Health Sciences Authority

BOARD UPDATES

We would like to express our sincerest appreciation to Professor Satkunanantham S/O Kandiah, who has retired as Board Chairman. Under Professor Satkunanatham's visionary leadership for almost eight years, HSA has further developed and strengthened our scientific rigour, capacity and infrastructure. Through his guidance, HSA has established itself as a well-respected scientific and regulatory authority nationally and internationally, and forged strong professional ties with partner agencies. Under his leadership, HSA was able to put in place a responsive manpower strategy focused on attracting, retaining and developing the best and right talents to be future ready.

Professor Benjamin Ong, who joined us as Deputy Chairman in 2020, stepped up as the new Chairman of the HSA Board on 1 October 2021. With his steady leadership and extensive experience, Assoc Professor Ong will lead HSA in our continued mission to safeguard public health and safety.

We welcome Mr Robert Chew, who joined the Board on 1 October 2021. With his rich experience and expertise in IT, we look forward to his insights and wise counsel.

HSA EXECUTIVE COMMITTEE (EXCO)

AS AT AUGUST 2022

Dr Choong May Ling, Mimi

Chief Executive Officer

Assoc Professor Chan Cheng Leng

Group Director

Health Products Regulation Group

Dr Ang Ai Leen

Group Director

Blood Services Group

Mr Jeffrey Wong

Group Director

Corporate Services Group

Dr Christopher Syn

Acting Group Director

Applied Sciences Group

CORPORATE GOVERNANCE STATEMENT

The HSA Board and Senior Management Team are committed to maintaining a high standard of corporate governance and complying with the recommendations set out by the Code of Corporate Governance. The Board believes that good governance is essential in enhancing corporate performance and accountability, ensuring transparency and protecting stakeholders' interests at all times. Our stakeholders include the Ministry of Health, Ministry of Finance, other government agencies, the healthcare industry, our clients, our suppliers and the public at large.

This statement outlines the main corporate governance practices of the organisation that are in place.

The Board

The Board comprises the Chairman and its members, who are appointed by the Minister for Health for a two-year or three-year term. It aims to meet every two to three months to set strategic directions, assume the role of monitoring and reviewing of policies leading to HSA's improved management and performance.

Board Members' Remuneration

HSA follows the Government's Directorship and Consultancy Appointments Council (DCAC) guidelines in determining the remuneration of the Board Members.

Notice and Declaration of Directorships and Interest in Shares and Debentures

Board Members are required to declare their directorships in various organisations and their interests in shares and debentures in various corporations. Board Members deemed to have any such interests during the meetings are required to declare them. They are to refrain from any deliberations made when such an interest has been declared.

Accountability and Audit

HSA's Senior Management Team is accountable to the Board. In turn, the Board is accountable to the Minister for Health. To allow the Board to discharge its duties adequately, Senior Management and staff are required to provide periodic updates and answer any queries that the Board may have on the operations and planning of the organisation.

For accountability purposes, the Board has established the following Board Committees:

A. Board Executive Committee

This Committee assists the Board to review and make recommendations on manpower-related issues. These include assessing the adequacy of manpower numbers to meet operational needs.

B. Audit and Risk Committee

This Committee assists the Board to review and assess the adequacy of internal controls, provide guidance on financial matters, as well as to have oversight of significant organisational risks. It meets quarterly with the Management and auditors to determine the scope of the external and internal audits, review audit findings, and to provide oversight of financial budgets.

C. Building Development Committee

This Committee assists the Board to review and provide guidance on matters related to the new HSA building project. These include having oversight of the project delivery milestones, ensuring compliance with corporate governance guidelines as well as putting forth recommendations for the various approval aspects of the project.

Communication with Stakeholders

The Professional Groups conduct regular consultations with the industry and their clients, seeking to keep them informed of new directions and regulations, and to listen to their concerns. HSA publishes an annual report to meet statutory requirements and provide information to our stakeholders. In addition, regular updates on matters of interest to our stakeholders are posted on our website. Our Quality Service Manager ensures that the organisation's professional quality standards are maintained.

Code of Business Conduct

The Board, officers and employees are required to observe and maintain high standards of integrity, and be compliant with the law, government regulations, organisation policies, and best corporate practices.

Risk Management

The Management is continually reviewing and improving business and operational activities to identify and manage areas of significant risks with appropriate measures and controls. The Management also reviews all significant control policies and procedures, and highlights significant matters to the Board, the Board Executive Committee, and the Audit and Risk Committee as necessary.

ORGANISATION CHART

AS AT AUGUST 2022

HSA BOARD

CHIEF EXECUTIVE OFFICER

- Quality Service Manager
- Internal Audit

HEALTH PRODUCTS REGULATION GROUP

Medicinal Products Pre-Market
- Therapeutic Products
- Complementary Health Products
- Innovation Office & Clinical Trials
- Advanced Therapy Products

Vigilance, Compliance & Enforcement
- Vigilance & Compliance
- Enforcement
- Tobacco Regulation
- Audit & Licensing

Medical Devices
- Therapeutic Devices
- Diagnostic Devices
- Digital Health
- MD Quality Systems, Adverse Events & Compliance

Group Director's Office

Stakeholders Engagement Office

APPLIED SCIENCES GROUP

Analytical Science
- Chemical Metrology
- Pharmaceutical

Forensic Science
- Analytical Toxicology
- Biology
- Illicit Drugs
- Forensic Science

Forensic Medicine

Group Director's Office

Quality Assurance Unit

BLOOD SERVICES GROUP

Professional
- Clinical Services
- Quality Management
- Capability Development and International Collaboration

Operations
- Patient Services
- Blood Supply Management
- Blood Resources

Admin
- Blood Service Support

CORPORATE SERVICES GROUP

Compliance

Corporate Communications & Service Quality

Engagement, Innovation & Professional Development

Facilities Management

Finance

Human Capital Management

Information Management

Legal

Risk Management & Emergency Planning & Data Governance

Safety & Quality

Strategy & Business Transformation

01.

HEALTH PRODUCTS REGULATION GROUP

We have in place a robust framework for regulating health products, to ensure the highest standards of safety, quality and efficacy.

REGULATORY DEVELOPMENTS AND REVIEWS

We review our regulatory processes regularly to ensure they remain updated and relevant to the latest developments.

OUR WORK DURING THE COVID-19 PANDEMIC

Interim Authorisation via Pandemic Special Access Route (PSAR)

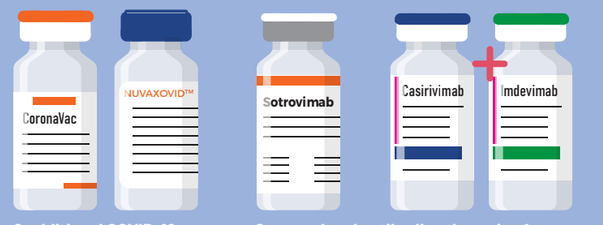
Following the interim authorisation of the first two mRNA COVID-19 vaccines in December 2020 and February 2021, HSA continued to expedite the review of other vaccine types to facilitate diversifying Singapore's vaccine portfolio. This included inactivated and protein subunit COVID-19 vaccines, as well as PAXLOVID™, Singapore's first oral medicine for COVID-19 treatment.

As a condition for interim authorisation under PSAR, companies are required to submit data from ongoing clinical studies for HSA's continual benefit-risk assessment.

In December 2021, HSA also approved the New Drug Application by BioNTech Pharmaceuticals Asia Pacific Pte Ltd for the COVID-19 mRNA vaccine, Comirnaty, to transit from PSAR interim authorisation to full registration.

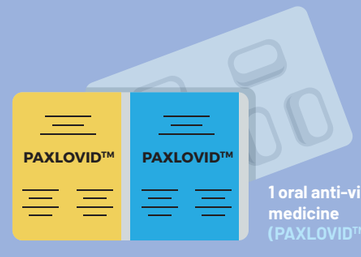
Concurrently, the authorisation of Comirnaty COVID-19 vaccine by Pfizer-BioNTech was extended to children of ages 5 to 11 years.

OVER THE PAST YEAR, HSA GRANTED INTERIM AUTHORISATION FOR:



2 additional COVID-19 vaccines (CoronaVac and Nuvaxovid)

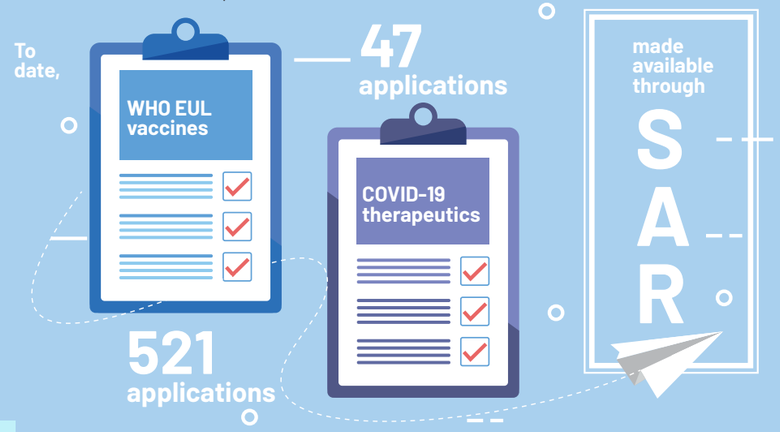
2 monoclonal antibodies therapies for the treatment of COVID-19 (Sotrovimab, combination of Casirivimab and Imdevimab)



1 oral anti-viral medicine (PAXLOVID™)

Facilitating Access to WHO Emergency Use Listing (EUL) Vaccines and Therapeutic Products (TP)

To facilitate access to WHO EUL vaccines which have not been authorised under the PSAR by HSA, the Special Access Route (SAR) was put in place in June 2021. This SAR allows healthcare institutions to bring in unauthorised vaccines as an alternative to PSAR-authorised vaccines to cater to the needs of their patients.



Expediting Clinical Trials

We continued to play a critical role in providing early regulatory guidance and following up closely with companies that are developing COVID-19 vaccines in response to emerging SARS-CoV-2 variants.

Through prioritising and expediting the review of COVID-19 clinical trials, we helped to bolster Singapore's capabilities to develop vaccines and therapeutics quickly and efficiently to manage the global pandemic.

Piloting Remote Good Clinical Practice (GCP) Inspections

As COVID-19 safe management measures meant that physical GCP inspections could not be carried out, we successfully piloted and conducted remote virtual GCP inspections in 2021.

With the virtual inspections, we were able to ensure that the safety and well-being of trial participants were safeguarded, and that the clinical trial data was credible.

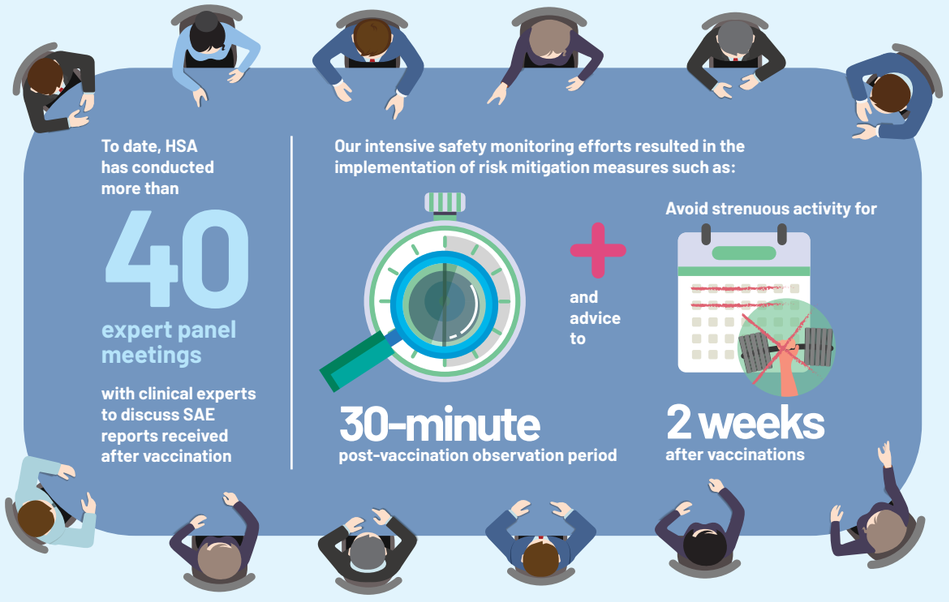
Active Safety Monitoring of Vaccines

HSA initiated its most intensive vaccine safety monitoring effort to date with an enhanced safety monitoring framework for COVID-19 vaccines. The aim of this exercise was to ensure that any emerging safety concerns associated with vaccines could be detected and managed promptly to protect public health. This in turn ensured that the benefits of vaccines continue to outweigh any known risks.

Initiatives that were rolled out under this framework included:

- Expedited reporting of serious adverse events (SAE) by healthcare professionals
- Consumer self-reporting of adverse events (AE)
- Appointment of clinical experts in the different disciplines of neurology, cardiology, rheumatology, haematology and nephrology to adjudicate SAEs of interest received locally

We also worked with key stakeholders including the Ministry of Health and the Health Promotion Board to leverage electronic medical records and the National Immunisation Registry records for the active surveillance of COVID-19 vaccines. With these data points, we were able to enhance our detection of potential safety concerns, using data analytics, as well as epidemiology studies.



Ensuring Regulations Remain Relevant and Responsive

To safeguard the rights, safety and well-being of trial participants, the Health Products (Clinical Trials) Regulations was amended in October 2021. Updates included:

- New requirements to inform trial participants whenever human tissue is collected
- Enabling appropriately qualified and trained pharmacists to be principal investigators of clinical trials that involve locally registered TPs, subject to safeguards and requirements

Facilitating Access to Medical Devices

As of 31 March 2022, we granted marketing authorisation for 273 COVID-19 diagnostic test kits.

Enhancing Consumer Safety Awareness

To enhance consumer safety awareness when purchasing masks, we published a list of locally manufactured medical masks that meet 95% Bacterial Filtration Efficiency on the HSA website for easy reference.

Enhancing Communications to Healthcare Professionals and Public

Given the speed at which COVID-19 vaccines and treatments are being developed and made available to the public, rapid communication of information on newly authorised COVID-19 vaccines and treatments to healthcare professionals is crucial.

Accordingly, HSA has published monthly safety updates on COVID-19 vaccines on our website since April 2021. Rare SAEs identified with the COVID-19 vaccines that have been highlighted in these safety updates include anaphylaxis and myocarditis.

STREAMLINING AND ENHANCING OUR PROCESSES

To ensure regulatory efficiency, we are always looking for new ways to streamline and enhance our work processes.

FINALISED GUIDANCE ON E-LABELLING OF TPs

In April 2021, after consultation with industry and healthcare professionals, HSA finalised and implemented the guidance for the e-labelling of approved package inserts and patient information leaflets for prescription-only TPs.

E-labelling not only allows for efficient and timely dissemination of the latest approved product information, it is also eco-friendly. Our next step would be to review the feasibility of extending e-labelling to non-prescription TPs.

To date, e-labelling has been implemented for over

400

prescription-only TPs

NEW AND UPDATED GUIDELINES

Updating of Guidelines for Traditional Medicines (TM) and Heath Supplements (HS)

In March 2022, the updated safety, quality, labelling and claims guidelines for TM and HS were finalised and published on our website. These guidelines provide good practices for the industry to level up relevant standards and ensure that the products that companies deal with are of good and consistent quality.

The guidelines were published after HSA held discussions with and solicited feedback from industry experts and relevant associations.

New and Refined Guidelines for Medical Devices

a. *3D-Printed Medical Devices (Jul 2021)*

We came up with a guideline and accompanying Frequently Asked Questions on HSA's regulatory perspectives and risk-based approach for the control of medical devices manufactured using 3D-printing technology.

b. *Unique Device Identification (UDI) Framework (Aug 2021)*

To support Singapore's adoption and implementation of UDI used internationally to enhance patient safety and streamline the tracking and identification of medical devices, we:

- Published guidance documents to provide clarity on the regulatory requirements and framework for UDI implementation, and
- Enhanced our systems to cater for UDI and ease of device information record keeping

c. *MD Product Classification Guide (Nov 2021)*

We refined this guide to provide greater clarity on a list of commonly enquired products, and to present their classifications clearly.

d. *Regulatory Reference Agency Approvals (Jan 2022)*

We updated the list of medical device reference regulatory agencies that HSA recognises for abridged, expedited or immediate review. The updated list now includes US FDA's De Novo, the updated EU Medical Device Regulations (MDR) and IVD Regulations (IVDR).

Guidance for Local Manufacturers and Distributors

May 2021

We published a new Guidance Note with a list of Frequently Asked Questions and interpretation of Good Manufacturing Practice (GMP) guidelines to clarify the regulatory requirements for companies performing secondary packaging for therapeutic and medicinal products.

Oct 2021

We delivered two presentations to 15 Chinese Proprietary Medicines manufacturers at the Complementary Health Products Industry Training Workshop 2021. These presentations provided updated guidance and expectations on regulatory requirements.

Dec 2021

We published the results of our monitoring and trend analysis of deficiencies observed during GMP and Good Distribution Practice (GDP) inspections of licensed and certified manufacturers and distributors. Through the sharing of the results, the industry will be better able to focus on key improvement areas.

Jan 2022

Leveraging feedback from the industry, we published a comprehensive Guidance Note on the licensing, GMP certification and inspection of TP manufacturers. This Guidance Note seeks to facilitate the industry's understanding of regulatory processes and requirements.

TAPPING ON TECHNOLOGY

We tapped on technology to better serve our stakeholders and improve our efficiency.

FORMSG FOR SPECIAL CONSIGNMENT

In January 2022, we used FormSG to launch a user-friendly web-based form to simplify the application process for special consignments. The purpose of this process is to allow companies to divert stock from other markets to mitigate potential stock-out situations in Singapore, and to ensure the continued availability of registered TPs.

LAUNCHING OF AUDIT MANAGEMENT SYSTEM (AMS)

We launched the AMS for GDP and retail pharmacy inspections in January 2022. The AMS digitalises GDP and pharmacy audit-related work processes such as arranging for inspections, scheduling and communicating with companies on inspection findings.

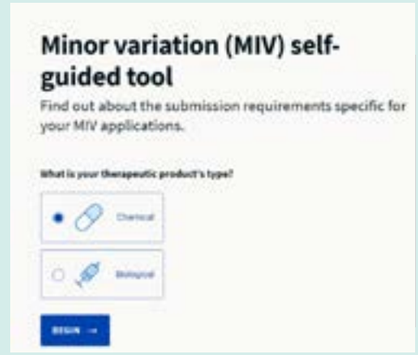
Inspectors can now use handheld devices to review company information and document findings in the AMS, thereby enhancing the inspection processes and improving our connection with stakeholders.

To ensure a smooth transition to the new process, we will continue to monitor the system and engage with stakeholders on a regular basis.

SELF-HELP TOOLS

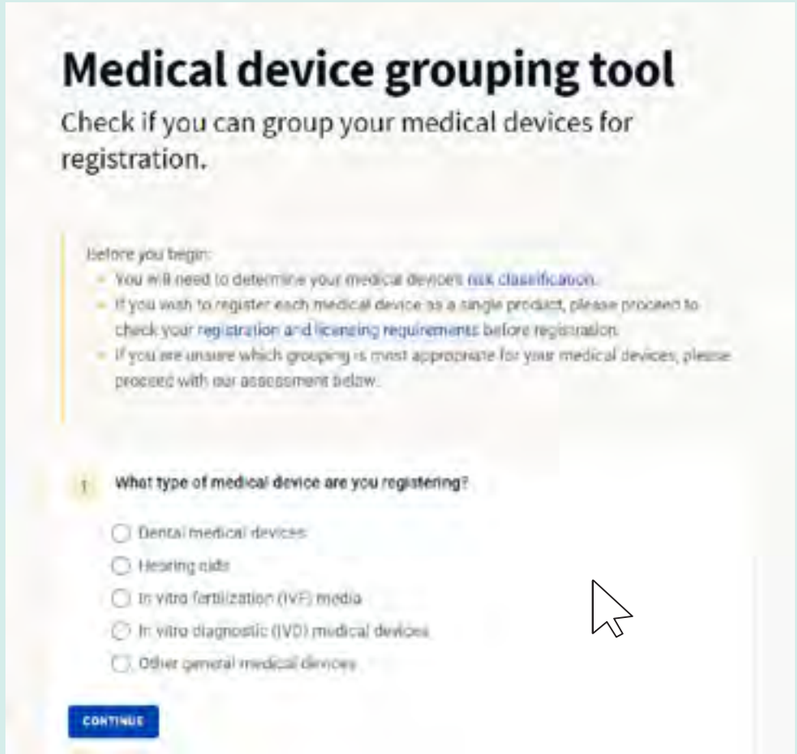
TP Post-approval Minor Variation (MIV) Tool

The MIV tool enables applicants to quickly determine the correct application type, variation category and documentary requirements for their TP MIV applications in just a few clicks. By gaining a better understanding of the regulatory process for good quality submissions, stakeholders can benefit from a more expedient application process.



Medical Device Grouping Tool

We launched a new medical device grouping tool in February 2021 for users to quickly and easily ascertain which medical devices can be grouped together for pre-market registration preparation. Grouping allows certain medical devices to be included in a product registration submission to reduce cost and effort.



STAYING VIGILANT

To ensure public safety, we are committed to staying vigilant at all times.

LOCAL THERAPEUTIC PRODUCT DEFECT CASES

In FY21/22, a total of:

213 local defect cases were received from various sources

Of these, the top 3 issues reported were related to:

- Product packaging **60** cases
- Manufacturing **52** cases
- Product contamination **38** cases

HSA worked with the companies to ensure that appropriate corrective and preventive actions were taken to mitigate the impact on the safety and quality of the defective products as well as their future batches.

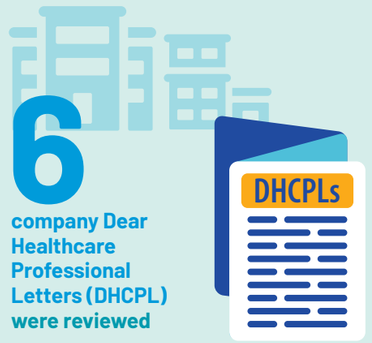
Regulatory actions taken included

- **27** amendments to product registration
- **24** communications issued
- **22** product recalls

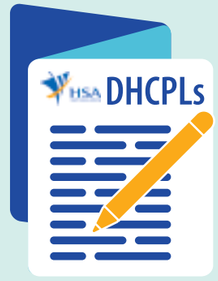
ADVISORIES ISSUED

9 press releases were issued including safety advisories on **18** products

6 company Dear Healthcare Professional Letters (DHCPL) were reviewed



5 DHCPLs were issued by HSA



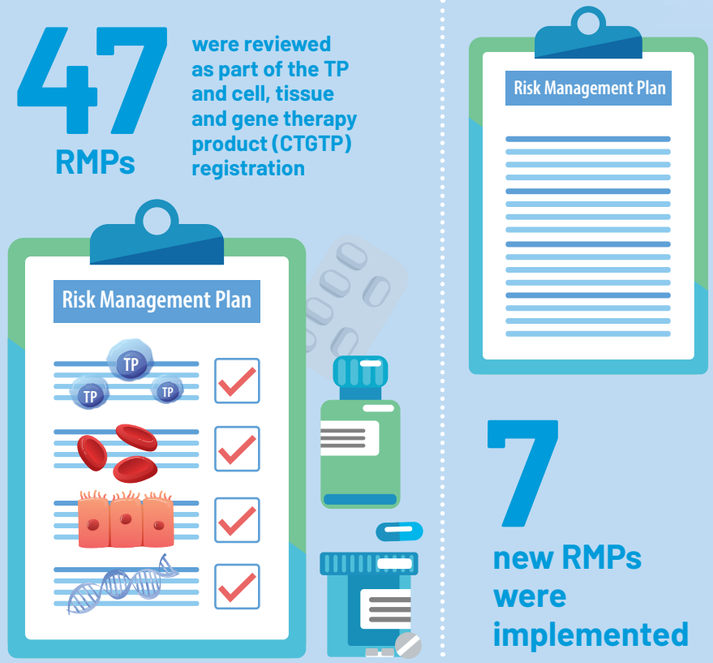
3 HSA ADR News Bulletins were published and disseminated to registered healthcare professionals

12 safety updates were published on the HSA website

UPDATE ON PRODUCT RISK MANAGEMENT

Singapore-Specific Risk Management Plans (RMP)

47 RMPs were reviewed as part of the TP and cell, tissue and gene therapy product (CTGTP) registration



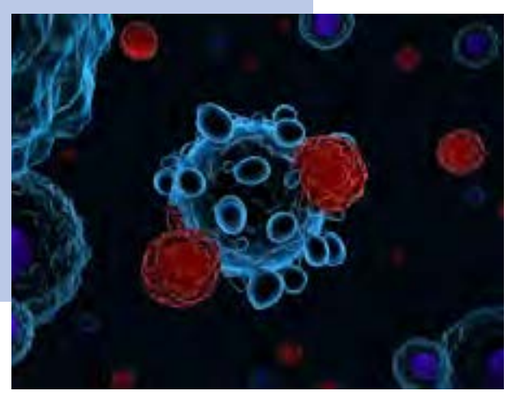
7 new RMPs were implemented

Enhanced RMPs for CTGTPs (Kymriah® and Luxturna®)

Enhanced RMPs were put in place to manage safety concerns, such as cytokine release syndrome, neurotoxicity, and infections associated with the first two CTGTPs approved locally.

This resulted in:

- A controlled distribution programme and site qualification at treatment centres
- Provision of educational materials for healthcare professionals, patients, and product administration personnel
- Close monitoring of the products' safety profile through submission of long-term safety studies and periodic benefit-risk evaluation reports



Safety Signals

TP and CTGTP

157 safety signals were assessed as part of post-market pharmacovigilance activities

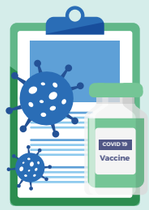
This resulted in:

- Amendment of local package inserts to reflect newly emerging safety concerns
- Communication of product safety information in the form of DHCPLs, HSA's Adverse Drug Reaction (ADR) News Bulletin, and product safety alerts on HSA's website

COVID-19 Vaccines and Therapies

Enhanced safety monitoring of COVID-19 vaccines and therapies, and their evolving safety profiles resulted in:

21 monthly safety summary reports on COVID-19 vaccines reviewed



6 monthly safety summary reports for COVID-19 therapies reviewed

Adulterated Health Products

7 risk assessments were conducted on adulterated products, resulting in the issuance of press releases to warn the public

MEDICAL DEVICE POST-MARKET SURVEILLANCE AND VIGILANCE SYSTEM

Adverse Events

In FY21/22, a total of

778

local reporting of adverse events were received

Top 3 medical speciality areas from which the reports were received

Cardiovascular:

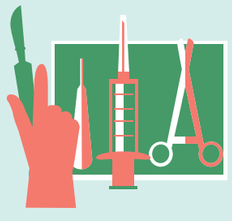
308

Devices under this specialty include implantable cardioverter-defibrillators/ pacemakers, external defibrillators, cardiovascular stents

General Hospital:

134

Devices under this specialty include infusion pumps, patient monitors, ventilators



General & Plastic Surgery:

79

Devices under this specialty include breast implants, dermal fillers, surgical staplers

Field Safety Corrective Action (FSCA)

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

Total number of FSCAs:

593

Recalls: **66**

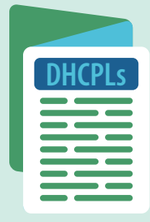
Safety corrective actions: **222**

Dissemination of additional safety information: **305**

Advisories Issued

DHCPL

35



Press release

1

Safety alerts and updates

9

SHARING OUR KNOWLEDGE

To raise the standards of health products regulation in Singapore, we share our knowledge and expertise with our partners and stakeholders.

TALK ON REGULATION OF IVDs AND PRECISION MEDICINE PRODUCTS AT DUKE-NUS CENTRE OF REGULATORY EXCELLENCE (CORE)

We were invited to deliver a talk on the regulatory developments and advancements on In Vitro Diagnostics (IVD) regulations for the DUKE-NUS' CoRE Graduate Certificate in "Health Products Regulation: In Vitro Diagnostics and Precision Medicine" programme. The topics we spoke on included total product lifecycle, international and ASEAN frameworks, as well as post-market and regulatory requirements for next generation sequencing-based IVDs and companion diagnostics.

CONTINUING PHARMACOVIGILANCE EDUCATION INITIATIVES

We collaborated with the following local and international working groups and organisations on various pharmacovigilance education initiatives:

Local

Date	Collaborators / Event	Topic
Jan 2021	Duke-NUS CoRE	Regulation of CTGTPs
Apr 2021	Saw Swee Hock School of Public Health	Risk communications training
Oct 2021	Duke-NUS CoRE	Principles and framework for pharmacovigilance
Nov 2021	Roadshows for Nanyang Technological University graduates in Double Degree in Bachelor of Sciences in Biomedical Sciences and Bachelor of Chinese Medicine	Raise awareness among the Traditional Chinese Medicine community on HSA's adverse event monitoring efforts

International

Date	Collaborators / Event	Topic
Sep 2021	Duke-NUS CoRE: World Health Organization (WHO) Uppsala Monitoring Centre (UMC) -HSA Inter-regional Pharmacovigilance Training Workshop	Enhancing preparedness for pharmacovigilance
Oct 2021	Coalition to Accelerate Patient Engagement in Asia-Pacific (CAPE) Regional Multi-stakeholder Roundtable	Patient engagement
Nov 2021	WHO UMC's Medsafety week	Importance of reporting vaccine adverse effects

NEW LOCAL PARTNERSHIPS

We are committed to building up our partnerships with local agencies and companies.

COLLABORATING WITH HOME TEAM SCIENCE AND TECHNOLOGY AGENCY (HTX) ON CONTRABAND PRODUCT SURVEILLANCE

In a bid to crack down on contraband products sold online in a more accurate and effective way, and to further safeguard public health, HSA began trialling an automated e-commerce surveillance tool developed by HTX.

The use of robotic process automation and artificial intelligence to trawl through listings of illegal drugs, health products and cosmetics, as well as unauthorised COVID-19 test kits and vaccines has shortened the process to a matter of hours, instead of weeks taken previously. The automated process also helped to free up manpower as enforcement officers had to manually sift and analyse one listing at a time prior to this initiative.

ENGAGING HEALTHCARE PROFESSIONALS ON COVID-19 VACCINE SAFETY SURVEILLANCE

In August 2021, we participated in the Pharmaceutical Society of Singapore's Continuous Professional Education Session to share on the topic of "Regulatory Updates on COVID-19 Vaccines in Singapore", which included HSA's Pandemic Special Access Route and the safety surveillance of COVID-19 vaccines. A total of 351 pharmacists attended and we received positive feedback that participants had benefitted from the session.

PUBLISHING OUR ADR NEWS BULLETIN ON AGENCY OF INTEGRATED CARE'S (AIC) WEBSITE

In our efforts to ensure effective communication of health products safety information to healthcare professionals, we collaborated with AIC to publish our ADR News Bulletin and relevant AE Guides on their website regularly. This will enhance our drug safety communications to General Practitioners in over 1,000 CHAS clinics island-wide.

INTERNATIONAL COLLABORATIONS

Beyond our shores, we collaborate with various organisations to strengthen our knowledge base.

COMPLETION OF PILOT PROJECT WITH KOREA MFDS

Building on the Memorandum of Understanding signed with Korea's Ministry of Food and Drug Safety (MFDS) on GMP for Pharmaceutical Products in November 2019, we embarked on a one-year pilot project to establish mutual confidence in each party's GMP inspection regulatory framework.

The pilot project was successfully completed in July 2021, with both parties concluding on the equivalency of the frameworks. This paves the way for MFDS and HSA to rely on the GMP certificates issued by either side without the need for any additional inspections on local manufacturers, and thereby enhance regulatory efficiency.

MFDS and HSA are now working towards formalising the arrangement through a Mutual Recognition Agreement.

SINGAPORE REGISTERED MEDICAL DEVICES ELIGIBLE FOR ABRIDGED REGISTRATION PROCESS IN THE PHILIPPINES

As of November 2021, under the Philippines Food and Drug Administration's (FDA) regulatory reliance programme, medical devices (Class B, C or D) approved by HSA using the Common Submission Dossier Template are now eligible for the abridged registration process. Companies can leverage HSA's medical device approvals for faster entry into the Philippines market.

HSA-NATIONAL PHARMACEUTICAL REGULATORY AGENCY (NPRA) COLLABORATION

In June 2021, we approved the first application under our ongoing collaboration with Malaysia's NPRA on the evaluation of generic medicines.

PROJECT ORBIS

Project Orbis is a collaborative effort that seeks to provide a framework for concurrent submission and review of oncology products among international regulatory health authorities. Collaborators include the Brazilian Health Regulatory Agency, Health Canada, Israel's Ministry of Health, Swissmedic, Australia's Therapeutic Goods Administration, US FDA's Oncology Centre of Excellence, and UK's Medicines and Healthcare Products Regulatory Agency.

Through Project Orbis, HSA has issued regulatory approvals for

7
applications

INTERNATIONAL MEDICAL DEVICE REGULATORS FORUM (IMDRF)

Medical Device Single Audit Programme (MDSAP)

In April 2021, we were recognised as an Affiliate Member of the IMDRF MDSAP, paving the way for future full-fledged membership. This programme recognises the Auditing Organisation's regulatory audit of medical device manufacturers as a single requirement for multiple member jurisdictions.

AE Working Group

In September 2021, we chaired the IMDRF AE Working Group meetings. Our objective was to improve, harmonise and expand the terminology used to code information relating to medical device AEs.

WHO MEMBER STATE MECHANISM RISK COMMUNICATION WORKING GROUP

We continued to work with the WHO to enhance the ability to run effective risk communication campaigns for substandard and falsified medical products in WHO member states.

ACCESS CONSORTIUM

Access is a coalition of like-minded regulatory authorities, whose aim is to provide patients with timely access to high quality, safe and effective TPs in the member countries.

Through Access, we:

Published
4
joint statements

on Access' regulatory position on COVID-19 vaccines and therapeutics

Completed review of
9
TP applications

through work sharing collaborations

CLAMPING DOWN ON ILLEGAL ACTIVITIES

We embarked on various enforcement operations to clamp down on illegal health products and tobacco-related activities.

COMBATTING CYBERCRIME TO SAFEGUARD PUBLIC HEALTH

We collaborated with various stakeholders to detect the illegal sale of health products on local e-commerce platforms.

Through our efforts, a total of:

6,054
illegal health product listings were removed

2,759
advisories were issued

REVOCATION AND SUSPENSION OF TOBACCO RETAIL LICENCES

We took action against stores selling cigarettes to those below the Minimum Legal Age (MLA)

and suspended the licences of

2 offending retail outlets

ILLEGAL HEALTH PRODUCTS

Multi-agency Enforcement Operation

In October 2021, we participated in a multi-agency enforcement operation led by Bedok Police Division and supported by the Criminal Investigation Department, Central Narcotics Bureau (CNB), Immigration & Checkpoints Authority, Singapore Customs and Singapore Food Agency.

Through this operation:

3
men between the ages of 32 and 43

were rounded up for investigation

Cough syrups, assorted brands of sexual enhancement medicines and other illegal medicines worth a street value of about:

$16,000
were seized

OUR OVERALL ENFORCEMENT RESULTS

426
joint operations with Singapore Police Force and CNB

were conducted

An estimated $572,993

worth of health products were seized

33
suspects

were rounded up for investigation

OPERATION PANGEA

In May 2021, we participated in Operation Pangea – an enforcement operation by the International Criminal Police Organisation (INTERPOL) targeting the online sale of illegal pharmaceutical products. In the intensive one-week operation, HSA stepped up its surveillance of local e-commerce platforms.

Over **700** listings of illegal health products (prescription medicines, adulterated weight loss, sexual enhancement and cosmetic products) were removed

14th year that HSA has been involved in Operation Pangea

92 countries took part

SMUGGLING OF ELECTRONIC VAPORISERS (E-VAPORISERS)

May 2021

An illegal seller caught using four different social media platforms to advertise and sell e-vaporisers and related components was sentenced on 31 May 2021 with a fine of $53,500.

OUR OVERALL E-VAPORISER ENFORCEMENT RESULTS

30 e-vaporiser peddlers prosecuted

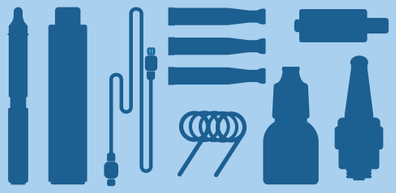
Youngest offender: **18** years old (sentenced to 24-month probation)

Range of fines meted out:
$1,500 – $40,500

Total amount of fines:
$283,100

June 2021

We carried out investigations following the detection of illegal smuggling of e-vaporisers and related components at Tuas Checkpoint by ICA officers. In this case, e-vaporisers and related components were found to be concealed in the seats of lorries used to transport live chickens.



54,392 units of e-vaporisers and related components were seized

Street value

~$700,000

Suspects involved:

14 drivers and attendants

Ages of smugglers:

22 to 54 years

Sentencing terms:

up to 2 months

October 2021

Acting on a tip-off, HSA raided a storage facility in Boon Lay. The successful operation marks the largest-ever seizure of e-vaporisers and related components by HSA, in terms of the volume and street value. It also disrupted the operations of an illegal e-vaporiser supply chain.

Total street value of seized items

Over **$2.2 million**

AWARDS AND ACHIEVEMENTS

Our efforts were validated through the following awards and achievements.

ACHIEVING WHO ML4 STATUS

With effect from 17 January 2022, HSA became the first national regulatory authority to be awarded the highest recognition of Maturity Level 4 for operating an advanced medicines regulatory system. This achievement comes after a rigorous and comprehensive assessment by a team of international assessors using WHO's Global Benchmarking Tool.

This external validation by WHO will enhance the Singapore public's confidence and trust in HSA as an innovative and effective medicines regulator working to protect and advance public health and safety.

PRO-ENTERPRISE INITIATIVE AWARDS 2021

Gold Award

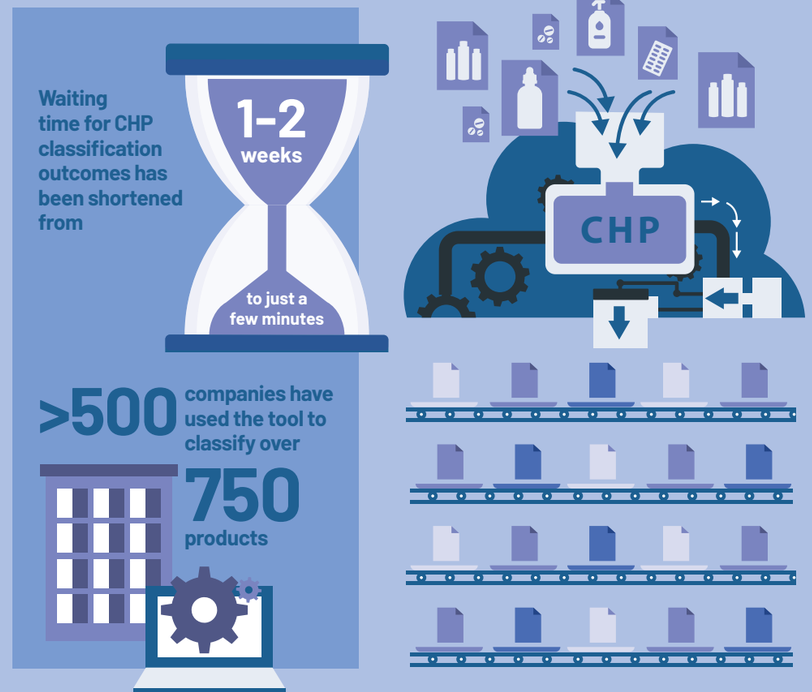
During the pandemic, HSA implemented various initiatives, including regulatory pathways, consultations and virtual audits to support our local businesses, as well as ensure continued and prompt access to critical therapies and medical devices.

For our efforts in ensuring that our population would be one of the earliest in the world to have access to critical COVID-19 vaccines, medicines and medical devices, we received the Gold Award at the Pro-Enterprise Initiative Awards 2021.

Bronze Award

For our efforts in coming up with the digital Complementary Health Products (CHP) Classification Tool to enable the industry to self-determine the classification of their products, we received the Bronze Award at the Pro-Enterprise Initiative Awards 2021.

Through our enhanced CHP Classification Tool:



HSA also won three Public Service Transformation (PST) Awards 2021, including the Agility Award 2021, for our regulatory agility and facilitation in supporting Singapore's fight against COVID-19, and ensuring that Singapore had timely access to diagnostic tests, medicines and vaccines. For more details, please refer to *page 80*.

02.

BLOOD SERVICES GROUP

We are committed to ensuring the safety and sustainability of the nation's blood supply, and engaging our donors regularly to improve their blood donation experience.

ENGAGING & COMMITTED

PEOPLE AND VALUES

We strive to develop, nurture and upskill our people, who are at the heart of the organisation.

CLINICAL NURSE LEAD PROGRAMME

With the implementation of our Clinical Nurse Lead (CNL) programme, qualified staff nurses can now take the lead for blood collection activities at our Bloodbanks.

The CNL role not only provides our staff nurses with additional professional development opportunities, but also solves the issue of medical screening personnel shortages. Many of the tasks that could previously only be done by medical screening professionals and doctors, can now be performed by our CNLs.

Such tasks include:

- Medical screening and medical care at Bloodbanks
- Clinical assessment of donors with adverse reactions
- Ensuring appropriate management is instituted in accordance with relevant guidelines and standards
- Counselling of deferred donors and donors with low haemoglobin levels

To ensure the highest standards of donor safety and blood collected, only experienced, knowledgeable and qualified staff who meet the training and competency requirements will be allowed to take on the CNL role.

As of Q1 2022,

we have **3 fully trained CNLs**

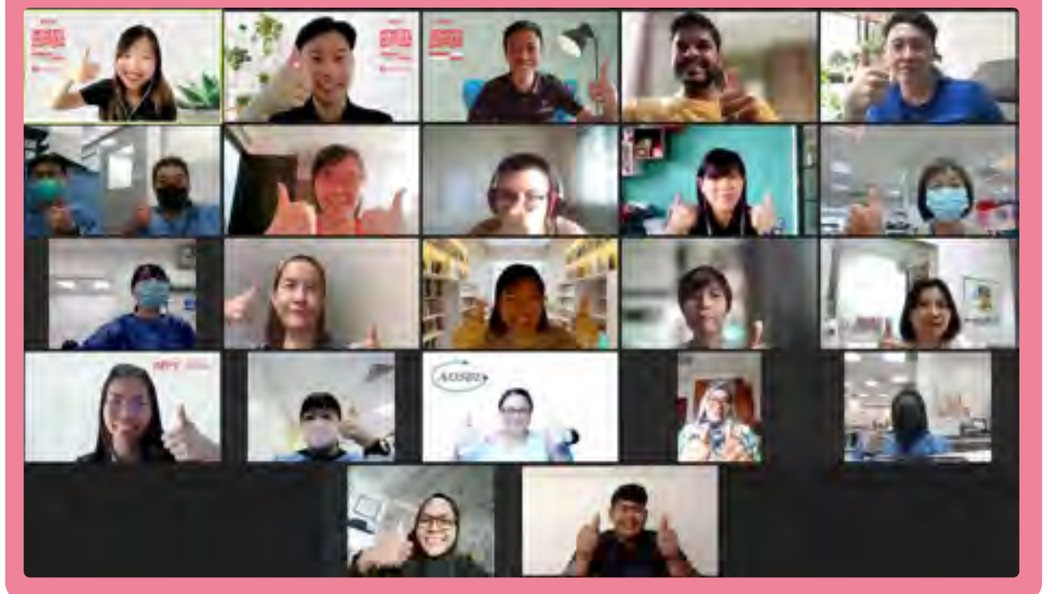
To train a total of 6 CNLs

OPERATION & TECHNOLOGY ROADMAP WORKSHOP

From September to November 2021, we collaborated with the NTUC Industry Training & Transformation team to conduct a virtual workshop, titled "Operation & Technology Roadmap".

In line with our objective to build a sustainable workforce that will be able to support the transformation of our blood supply operations through automation, the workshop focused on instilling in our staff a greater sense of ownership and a better understanding of the need for change. Through this workshop, our staff got the chance to co-create ideas and identify gaps in skillsets, as well as explore new job functions for process automation.

The next step will be to roll out a training roadmap to prepare our team to be ready for these newly identified processes.



FOR OUR DONORS

We endeavour to make the blood donation experience comfortable and convenient for our donors.

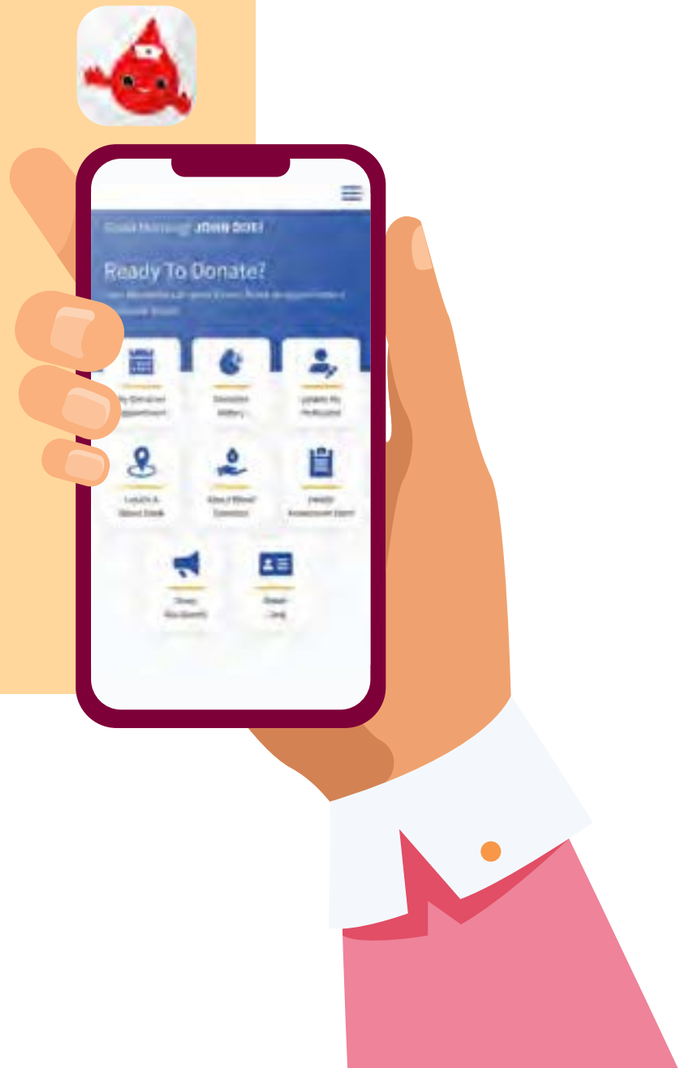
DONOR MOBILE APP

In September 2021, HSA launched our first-ever DonateBlood mobile app, which was jointly created with the Singapore Red Cross (SRC). This is part of a series of digital initiatives aimed at making the blood donation process more convenient. The DonateBlood app allows donors to easily access blood donation-related services anytime and anywhere with their mobile phone.

Such services include:

- Donation appointment
- Donation history (including their milestones, total number of donations)
- Updating their particulars
- Health Assessment Form
- Digital Donor Card
- Information about blood donation

To ensure relevance of the app, HSA and SRC gathered donors' inputs on the user experience via focus group discussion during the app development phase. Moving forward, we will continue to gather feedback to further enhance and improve the app.



EXPANSION OF SATELLITE SITE AT DHOBY GHAUT EXCHANGE

Ever since its launch in 2012, Bloodbank@DhobyGhaut's (BB@DG) average daily blood collection has jumped 87%, from 47 units in 2012 to 90 units in 2021. Last year, BB@DG's collection accounted for 26% of our total blood collection.

In response to BB@DG's growth, we embarked on an expansion project to accommodate more donors at the site. Completed in 2022, the new BB@DG features a more spacious donor waiting area and refreshment area for improved donor experience.

Enhancements at the newly renovated BB@DG

An increased floor area from

264 square metres → 299 square metres

Increased daily collection capacity of

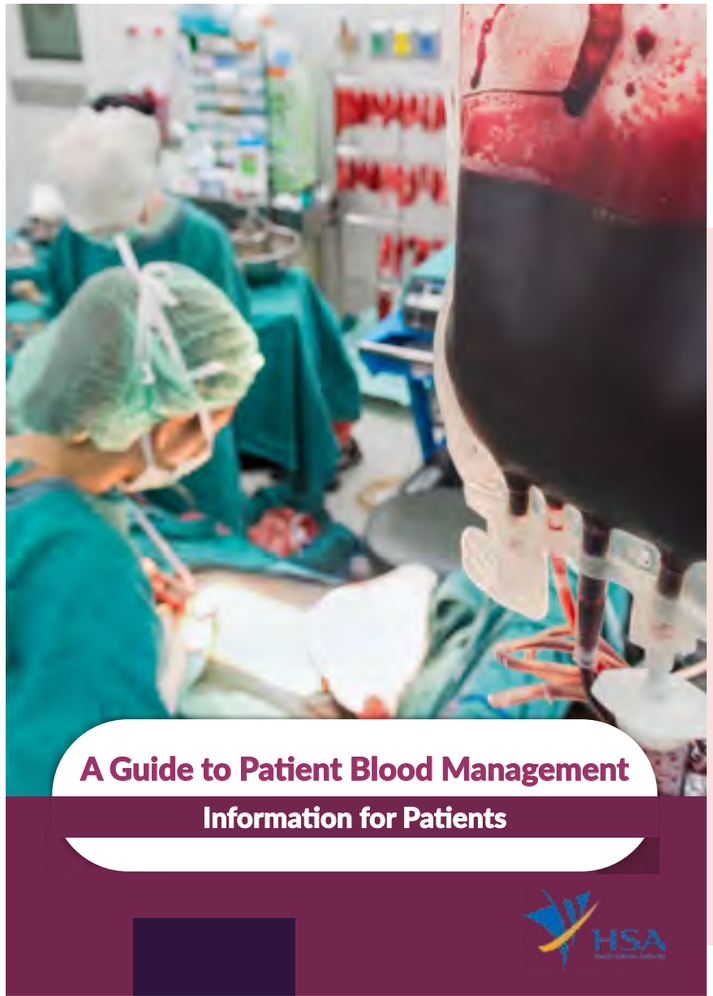
98 units

Larger waiting area for donors

Additional room for medical screening

KNOWLEDGE AND INNOVATION

In our efforts to maintain a best-in-class blood services outfit, we are constantly building our knowledge base and innovating new processes.



IMPROVING PATIENT BLOOD MANAGEMENT (PBM) KNOWLEDGE

In addition to our regular audits and sharing of good practices on PBM with the public hospitals in Singapore, we came up with a patient information leaflet on PBM.

The leaflet contains useful information about PBM as well as strategies to enhance red blood cell production and minimise blood loss. The leaflet also provides advice for patients to discuss with their doctors about PBM, with the aim of optimising their haemoglobin level and reducing transfusion requirements.

This brochure has been distributed to all hospitals as well as made available on our website.

IMPROVED SAFETY AND ADEQUACY OF BLOOD PRODUCTS

In July 2021, we implemented two new initiatives to enhance the safety and adequacy of our blood supply.

Extension of platelet shelf life from five days to seven days

Leading up to the implementation, we conducted extensive time-based bacterial contamination detection studies, as well as monitored quality control indicators of both apheresis and whole blood derived pooled platelets to ensure safety and quality of platelets for use in transfusion therapy over the extended seven-day period.

This extended shelf life allows us to better manage our platelet inventory, as well as reduce product wastage.

Provision of plasma-reduced platelets

Plasma is the main media used for storing platelets for transfusion therapy. However, in rare situations, plasma proteins can lead to allergic reactions in patients who cannot tolerate large volumes of plasma.

To cater to the needs of such patients, we validated and optimised the process of removing excess plasma from platelet units to produce plasma-reduced platelets.

HELPING PRIVATE HOSPITALS DEVELOP PRE-TRANSFUSION TESTING CAPABILITIES

As private hospitals started to manage their own plasma and platelet inventory, they have also developed their own pre-transfusion testing capabilities. This will ensure that they are able to supply compatible blood and blood products to their patients in a timely manner.

To assist them with their transition, we conducted on-site training for our private hospital counterparts on how to set-up their crossmatching laboratories.

INTRODUCING NEW TESTING SERVICE AND METHODOLOGY TO IMPROVE TRANSPLANT OUTCOMES AND TEST TURNAROUND TIME

The upcoming introduction of a new testing service – killer cell immunoglobulin-like receptors (KIR) genotyping, will assist clinicians in selecting the most suitable donors for haplo-identical haematopoietic stem cell transplants, thereby improving transplant outcomes when full matched donors are not available.

The use of the new real-time Polymerase Chain Reaction (PCR) methodology in human leukocyte antigen (HLA), human platelet antigen (HPA) and KIR genotyping, coupled with an automated analysis software, will significantly reduce the need for manual post-PCR procedures and interpretation of results, thus freeing up man hours and hence improving test turnaround times.

To enhance efficiency and better synergise our efforts, we made several infrastructural changes.

INFRASTRUCTURAL CHANGES

CONVERSION OF CELL PROCESSING LAB TO CELL & GENE THERAPY FACILITY

To better reflect our current work and direction, the Cell Processing Lab that was built as a prototype in 2006 has been renamed to the Cell & Gene Therapy Facility (CGTF).

In addition to the name change, the lab has also undergone infrastructural modifications to incorporate new capabilities, such as viral-related and genetically modified cell manufacturing.

Among the reasons for this change was a growing interest and patient demand for the use of Chimeric Antigen Receptor (CAR)-T Cells for relapsed leukaemia and lymphoma. Hospitals needed a facility that could support the piloting of gene modified viral vector work.

The launch of CGTF is exciting as it gives us the capability to not only manufacture CAR-T cells locally, but also enables us to translate and scale up other viral vector-based cell therapy works.

To better serve our stakeholders, we worked with partners on various blood-related clinical trials and studies.

OUR COLLABORATIONS

VALIDATION WORK FOR LENTIVIRAL-BASED GENE THERAPY PRODUCTS

We collaborated with SCG Cell Therapy Pte Ltd to evaluate and validate the cell therapy manufacturing process for SCG101 – an autologous T-cell receptor (TCR) T cell therapy for patients with Hepatitis B virus (HBV) related hepatocellular carcinoma (HCC).

This process is performed in our renovated CGTF in full compliance with current GMP requirements.

Our validation results will be able to support globally TCR T cell therapy clinical trials in Singapore and the US, and hopefully improve treatment outcomes for HCC patients.

STUDY ON THE SAFETY AND EFFICACY OF CRYOPRESERVED PLATELETS IN HYPOPROLIFERATIVE THROMBOCYTOPENIC PATIENTS

In August 2021, we completed our collaborative study with DSO National Laboratories and Singapore General Hospital on the preparation and use of frozen whole blood derived pooled platelets for transfusion therapy.

Currently, platelets are stored in room temperature and have a short shelf life of seven days. Freezing of the platelets can significantly extend its shelf life to at least two years. Through this collaboration, we were able to study the safety and efficacy of the frozen platelets in preventing bleeding among patients with very low platelet counts.

PROVISION OF RESIDUAL PLASMA SAMPLES FOR DENGUE SERO-PREVALENCE STUDY

To support blood and public health safety, we collaborated with the National Environment Agency from July to September 2021 to provide de-identified residual plasma samples. These samples came from blood donors who consented to use their residual blood samples for research purposes. This study is conducted periodically to generate information on disease epidemiology and geospatial analysis of dengue immunity.

MANUFACTURING OF CD19-DIRECTED AND DUAL CD22/19-DIRECTED CAR-T CELLS

We worked closely with KK Women's and Children's Hospital to produce CD19-directed and dual CD22/19-directed CAR-T cells for children and adult patient trial participants.

In line with the newly released Cell, Tissue and Gene Therapy Products (CTGTP) regulatory framework, we ensured that we are in compliance with the new guidelines on GMP for CTGTP for manufacturers. New biosafety procedures to handle viral-related processing, which is carried out in our CGTF, were also drafted.

If the trials are successful, it will pave the way for the production of safe and effective locally made CAR-T cell products that can serve as alternatives to other commercial products, and provide access to potential life-saving treatment.

03.

APPLIED SCIENCES GROUP

We champion innovation, adopt a progressive mindset and develop new capabilities to deliver faster and better solutions.

KNOWLEDGE AND INNOVATION

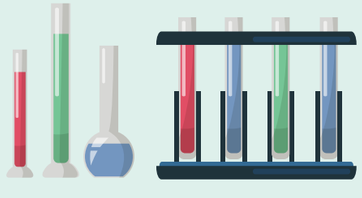
We harness scientific knowledge to bring about greater innovation in our work.

RESPONSIVE ANALYTICAL SUPPORT TO DETECT NITROSAMINE IMPURITY IN ARB PRODUCTS

In April 2021, HSA was alerted by overseas regulatory counterparts to the potential contamination of azidomethyl-biphenyl-tetrazole (AZBT) in angiotensin II receptor blocker (ARB) products. As there were no standard test methods for such analysis available internationally, we swiftly developed our own testing methodologies.

With strong commitment from our team, we successfully developed a Liquid Chromatography Q-Exactive Hybrid Orbitrap Mass Spectrometer (LC-HRMS) method in two weeks, to determine the amount of AZBT in ARB products. Our responsive analytical support enabled our colleagues in the Health Products Regulation Group to take timely and appropriate regulatory actions to safeguard public health.

A total of **38** ARB products



marketed locally in Singapore were analysed using our in-house developed testing methodology

DNA-BASED IDENTIFICATION OF CANNABIS

Traditional cannabis identification largely relies on a combination of physical examination and chemical analysis. To complement existing methods particularly for highly fragmented cannabis samples, we developed an innovative DNA testing method for forensic samples suspected to contain cannabis plant material.

With our new DNA testing method, we were able to obtain a

>99% match

to known cannabis references from samples tested

EXAMINATION OF DIGITAL-FORMAT DOCUMENTS

In today's world where digital technology is used widely, it is increasingly common that documents for examination are often available only as soft copies. The limitation of examining soft copies is that some handwriting features such as pen pressure cannot be determined.

However, digital files can contain traces of crucial information, such as authorship, and whether data has been manipulated.

Recognising the benefits of such examination techniques, we initiated a multidisciplinary approach incorporating digital evidence analysis in handwriting examination as part of our standard practice. This additional information identifying the subject and associated alteration activity will be beneficial for the court.

ENHANCING THE INTERPRETATION AND ANALYSIS OF BLOODSTAIN PATTERN THROUGH RESEARCH

Bloodstain pattern analysis aims to provide information on the deposition of blood at a crime scene by studying the number, shape, size and distribution of bloodstains.

The key to effective bloodstain pattern analysis lies in the classification of bloodstain patterns and understanding how the blood was deposited. In our efforts to develop an established classification criterion, we successfully constructed a device to study the characteristics of downward cast-off and cessation bloodstain patterns, as well as the formation and deposition of blood droplets.

Through the subsequent application of statistical methods, we were able to obtain and publish qualitative insights to enhance our interpretation of bloodstain patterns at crime scenes.

ENHANCING OUR EFFICIENCY

We continue to enhance our efficiency through the improvement and refinement of existing techniques.

AUTOMATED URINE BOTTLE UNSEALING DEVICE

Annually, we receive approximately

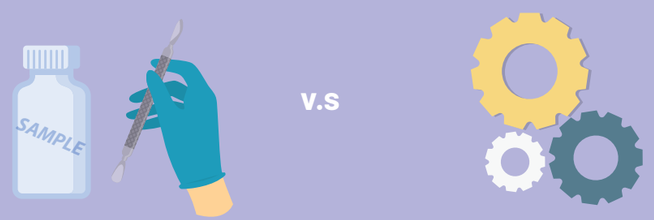
20,000 to 22,000
urine samples in sealed plastic bottles for testing of controlled drugs

Old Method

We needed to manually open the water resistant tamper-proof seal on these urine samples using a cutter, which was both labour intensive and posed a risk for injuries.

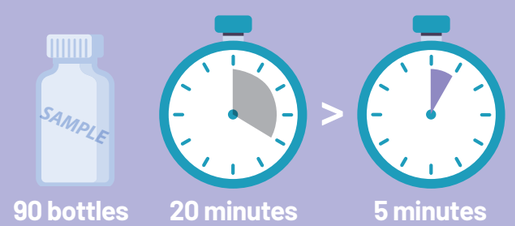
New Method

Working with a commercial company, a custom device was built to automate the unsealing of urine samples. The portable device is made up of a bottle feeder, a conveyor belt, an attached blade and a collection tray.



Efficiencies Achieved

With this automated device, we can now unseal 90 urine bottles in around 5 minutes, as compared to 20 minutes by hand previously. This has increased our efficiency and more importantly, reduced the risk of injuries when handling the biohazardous specimens.



SEMI-AUTOMATED TOOL FOR QUALITY CONTROL DATA MONITORING

To ensure our laboratory processes adhere to the highest standards, we regularly monitor quality control (QC) standards and data. To improve our efficiency, we developed a semi-automated tool to analyse QC data trends and quickly address potential issues before they arise.

At the 2021 Annual European Network of Forensic Science Institute (ENFSI) DNA Expert Working Group Meeting, we shared our practices and methods with other international laboratories that were also gearing towards monitoring their QC data.

AUTOMATED PROFICIENCY TEST SYSTEM

As part of our continual efforts to enhance productivity, we upgraded our manual proficiency test (PT) system into an automated one in 2021. This new e-PT system allows authorised users to create the annual PT masterplan and route for approval with tracked changes, among other functions.

The initiative has enhanced work productivity through effective management of PTs and upkeeping of stringent quality standards, in accordance with ISO/IEC 17025:2017 requirements.

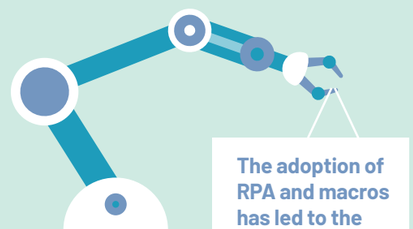
AUTOMATING PROCESSES FOR ILLICIT DRUGS ANALYSIS

We turned to Robotic Process Automation (RPA) to assist us in the daily autotuning process of all our Gas Chromatography - Mass Spectrometers (GC-MS) in the laboratory. The use of RPA has enhanced our work efficiency and prevents oversight which can occur during manual verification.

Additionally, to enhance users' experience when using the GC-MS, we have also implemented macros that allow users to:

- Automate library matching of sample peaks to databases to enhance efficiency of result interpretation
- Directly display method information on instrumental printouts for traceability
- Process data from instrument runs and generate PDF printouts of results for interfacing to the Laboratory Information Management System
- Extract ion chromatograms to look for trace amounts of commonly searched drugs

As a result, it eliminates the need for manual documentation, thereby reducing human errors and improving process productivity.



The adoption of RPA and macros has led to the total estimated time savings of:

84 man-days/year

OUR LOCAL COLLABORATIONS

We continue to actively collaborate with our local partners on various projects.

ASSESSING THE QUALITY AND SAFETY OF COSMETIC PRODUCTS

To assess the quality and safety of cosmetic products sold in Singapore, we assisted the Consumer Association of Singapore (CASE) to conduct a heavy metals (lead and cadmium) consumer survey on 30 popular lipsticks sold in physical and e-commerce platforms in May 2021.

The results of the survey revealed that the levels of toxic metals in most of the lipsticks sold were generally within regulatory limits, and CASE issued a statement on the findings.

Photo credit: NUS

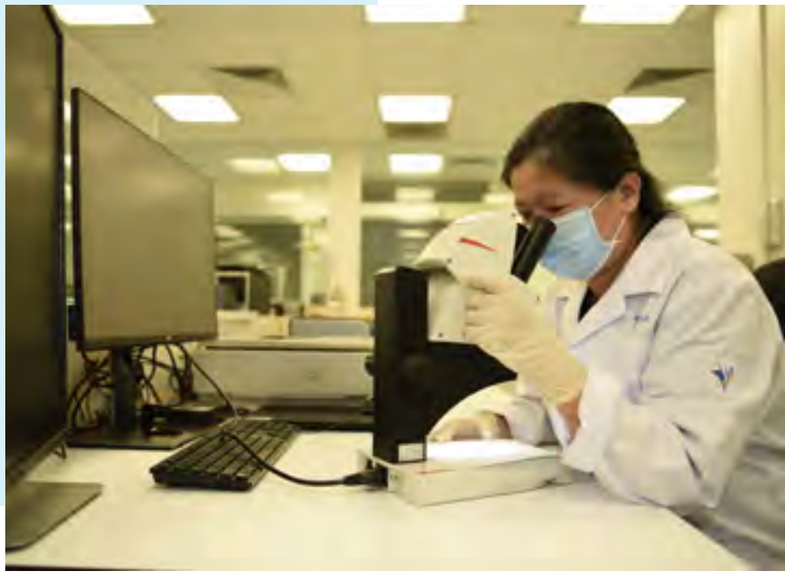
DETECTING THE ABUSE OF EMERGING SYNTHETIC CANNABINOIDS

To boost the detection of designer drug abuse such as synthetic cannabinoids, we partnered with the NUS Pharmacy Department to develop a new testing approach in August 2021 that employs the concepts of drug metabolism and pharmacokinetics to identify unique urinary biomarkers of new and prevalent synthetic cannabinoids.

PATTERNS OF CHANGES IN HANDWRITING PRECEDING SEVERE CAR-T CELL RELATED NEUROTOXICITY

Even as CAR-T cell therapy continues to advance for relapsed or refractory acute lymphoblastic leukaemia, there remains a major concern of CAR-T cell related neurotoxicity or CAR-T cell related encephalopathy syndrome (CRES) occurring in patients. Early recognition and management of such toxicities is key in minimising complications related to the therapy.

In August 2021, our document examiners collaborated with the NUH Department of Paediatrics in a project to help determine if changes in the patterns of handwriting in patients that preceded major seizure events could be a sign of more severe neurotoxicity.



PLAYING OUR PART IN THE COVID-19 PANDEMIC

In our continued fight against the pandemic, we worked closely with the Coroner's Court and the Singapore Police Force to safely transfer and handle deceased persons who were suspected to have or diagnosed with COVID-19.

In line with the roll out of the national COVID-19 vaccination programme, we also assisted with autopsy findings relevant to the investigation of deaths that occurred after COVID-19 vaccinations.

SHARING OUR EXPERTISE

To maximise the positive impact of our work, various knowledge sharing and exchange sessions were held both here and abroad.

APMP FOCUS GROUP ON FOOD SAFETY PROJECT ON MEASUREMENT CAPABILITIES FOR TOXIC ELEMENTS IN SEAFOOD

In May and June 2021, we partnered with the National Institute of Metrology (Thailand) and Government Laboratory (Hong Kong SAR, China) to organise a series of virtual training workshops under the Asia Pacific Metrology Programme (APMP). Joining as speakers and moderators were experts from HSA's Chemical Metrology Laboratory; Thailand Food and Drug Administration; National Measurement Institute, Australia; National Institute of Metrology, China; Government Laboratory, Hong Kong SAR, China; and Korea Research Institute of Standards and Science.

As part of the post-training activity, the organisers tested the measurement capabilities of participating institutes for toxic elements in a fish sample.

TRAINING SESSIONS FOR ENFORCEMENT OFFICERS

In November 2021, we held a virtual training session for Singapore Police Force officers on the preservation and submission of evidence, the laboratory processes, and the interpretation of results. We also shared about our new test services, namely Y-STR testing, mitochondrial testing, and age/ancestry prediction. These key learning points provided attendees with a better understanding of DNA evidence and the role that HSA plays in investigations.

In March 2022, we conducted an exhibit processing refresher training programme for Forensic Response Team (FORT) officers from the Central Narcotics Bureau. The programme was specifically tailored to their current work processes and needs, with a special focus on swabbing techniques in exhibit processing, exhibit integrity preservation and contamination prevention. Through this programme, both parties gained a better understanding of the mutual challenges faced, thereby facilitating better support for future casework.

PROVIDING OUR EXPERTISE TO THE HONG KONG LABORATORY ACCREDITATION SCHEME (HOKLAS)

In March 2022, our scientists from the Illicit Drugs Division and the Analytical Toxicology Division were invited as technical experts to assist in the online reassessment of the Hong Kong Government Laboratory under the HOKLAS.

SHARING OUR KNOWLEDGE AT THE ASIAN FORENSIC SCIENCES NETWORK (AFSN)

Gaining Insight on Secondary DNA Transfer

In recent years, a common question in court trials has been around the likelihood and frequency of secondary DNA transfers; whereby a person's DNA is transferred onto an object through an intermediate object or person.

During the AFSN DNA Workgroup meeting, we delivered a presentation on factors associated with such transfers. These findings would allow fellow scientists from the region to gain more insight on secondary transfers.

Workshop on Forensic Analysis of Paint

As part of the AFSN symposium, we conducted a workshop titled "Forensic Analysis of Paint Evidence". Our key objective was to share about common practices in forensic paint examination and the challenges in the interpretation of paint evidence.

Through our sharing, participants were equipped with the requisite knowledge on how to make an informed decision when selecting methods for paint examination.

Analysis of Explosives

Another session that we hosted at the AFSN symposium was on the challenges faced by regional forensic scientists in analysing explosives. We touched on the difficulties of analysis brought about by the sheer diversity of explosive types, as well as which techniques were the most suitable for analysing each explosive type.

BENCHMARKING OF MEASUREMENT CAPABILITIES

To ensure the reliability of our measurement results, we benchmark our measurement capabilities.

INTERNATIONAL AND REGIONAL COMPARATIVE STUDIES PARTICIPATED/CO-ORGANISED

International Comparisons Participated

Topic	Organising Metrology Institutes
Toxic elements in seafood	Government Laboratory (Hong Kong SAR, China)
Elements in rice	Korea Research Institute of Standards and Science (Republic of Korea); and National Metrology Institute of Japan (Japan)
Elements in yerba mate	Laboratorio Tecnológico del Uruguay (Uruguay)
Amino acids in human plasma	LGC Limited (United Kingdom)
Zearalenone in maize and anions in seawater	National Institute of Metrology (China)

International Study Co-organised

Topic	Co-organising Metrology Institute
Pilot study on HbA1c measurement	Health Sciences Authority (Singapore), Laboratoire national de métrologie et d'essais (France), Korean Research Institute of Standards and Science (Republic of Korea), and National Institute of Metrology (China)

Establishment of International Chemical Reference Substances (ICRS)

We also participated in an inter-laboratory collaborative study organised by the European Directorate for the Quality of Medicines and HealthCare (EDQM) to establish the reference substance for Dexamethasone Phosphate for the WHO International Pharmacopoeia.

PROFICIENCY TESTING (PT) PROGRAMMES & SCHEMES

HSA participated in the following international pharmaceutical PT programmes to benchmark our performance standards.

Topic	Organisation
Assay of cimetidine tablets by UV-VIS spectrophotometry	Bureau of Drug & Narcotic (BDN)
Assay of esomeprazole magnesium trihydrate by liquid chromatography	EDQM
Determination of methylisothiazolinone (MI) and methylchloroisothiazolinone (MCI) in bubble bath, shower gel and hair conditioner	EDQM
Assay of maleic acid and glycine by titration	EDQM
Assay of ascorbic acid by titration	Laboratory of the Government Chemist (LGC)

We organised the following accuracy-based PT Schemes:

- PT Programme on Organic Contaminants in Marine Fuel Oil, comprising two analytes in the quantitative scheme and eight analytes in the qualitative scheme, for local and overseas oil testing laboratories
- PT Scheme on Toxic Elements in Lipstick Material, in partnership with the National Institute of Metrology (Thailand), for local and regional cosmetic testing laboratories

EXPANDING OUR CHEMICAL METROLOGY SERVICES

We are constantly expanding our metrology services and adding new substances to expand our Certified Reference Materials.

CERTIFIED REFERENCE MATERIALS (CRM) PRODUCED

This past year, we expanded our list of CRMs to include:

April 2021

- HRM-2015A: Trace Elements (Al, Sb*, As, Ba*, Cd, Ca, Cr, Cu, Pb, Mn*, Mo, Ni and Se*) in Water

May 2021

- HRM-2014A: Elements (As, Cd*, Hg and Pb) in Lipstick Material
- HRM-2016A: Mercury* in Water

February 2022

- HRM-1029A: N-nitrosodimethylamine (NDMA*) in methanol

*New additions

KEEPING THE STAKEHOLDERS OF OUR CHEMICAL METROLOGICAL SERVICES UP-TO-DATE

We kept our stakeholders and partners updated through the following outreach initiatives:

- Launched HSA CheMetrology News, which presents recent and upcoming metrological activities
- Partnered with the Singapore Accreditation Council to conduct training courses for local testing laboratories on basic statistical tools, method validation and measurement uncertainty
- Launched an online measurement uncertainty course for professionals working in clinical laboratories
- Partnered Eurachem and Cooperation on International Traceability in Analytical Chemistry (CITAC) to co-organise four sessions of online workshop on Assessment of Performance and Uncertainty in Qualitative Chemical Analysis. The workshop was attended by more than 500 individuals based in over 60 economies.

INTERNATIONAL COLLABORATIONS

Close ties with the international community allow us to keep expanding our knowledge base.

WHO NATIONAL CONTROL LABORATORY (NCL) NETWORK FOR BIOLOGICALS

As part of our efforts to stay connected with global vaccines development, HSA successfully joined the WHO NCL Network for Biologicals as an associate member in September 2021. Through this membership, HSA will now be able to share and access information pertaining to lot release of vaccines within the WHO databases.

ACTIVE SUPPORT OF WHO ACTIVITIES

WHO Collaborating Centre for Drug Quality Assurance

- Redesignation of WHO Collaborating Centre

  Our Pharmaceutical Laboratory was redesignated by WHO as its Collaborating Centre for Drug Quality Assurance for another four-year term (March 2022 to February 2026). This is an important milestone for us as it marks a continued recognition of our professional and technical excellence.

- Monograph Development Work for the International Pharmacopoeia

  In addition, WHO also invited our Pharmaceutical Laboratory to support and develop a nitrosamine test monograph (1- nitroso-4-methyl piperazine (MeNP) in Rifampicin products) for inclusion into the International Pharmacopoeia.

- Participation in other WHO Events:

Event
• WHO consultation meet on quality control laboratory tools and specifications for medicines
• Follow-up consultation meet on screening technologies, laboratory tools and pharmacopoeial specifications for medicines

TOBACCO TESTING-RELATED ACTIVITIES

WHO Collaborating Centre for Tobacco Testing and Research

In view of Singapore's contribution and achievements to the field of tobacco regulation, WHO formally invited Cigarette Testing Laboratory's Laboratory Director in September 2021 to chair TobLabNet for a further two years. The role of chair involves providing strategic and operational direction to advance tobacco product regulations.

Speaking at a Virtual Workshop Organised by Australia's McCabe Centre for Law and Cancer

Representing WHO TobLabNet, we were invited to speak on the science and regulation challenges of emerging tobacco products.

PARTICIPATION IN PHARMACEUTICAL AND COSMETICS-RELATED INTERNATIONAL EVENTS

European Directorate for the Quality of Medicines and Health Care (EDQM)

- 26th Annual Meeting of the European Network of Official Medicines Control Laboratories (OMCLs)
- 9th joint session of the European Network of Official Cosmetics Control Laboratories (CD-P-COS) and the European Network of Official Cosmetics Control Laboratories (OCCLs)

ASEAN Meetings

- 2nd ASEAN Pharmaceutical Testing Laboratory Committee (APTLC) Meeting
- Workshop on ASEAN Australia New Zealand Free Trade Agreement (AANZFTA), on cooperation in international standards engagement in cosmetics
- Western Pacific Regional Forum for the Harmonization of Herbal Medicines (FHH)
- 8th FHH International Symposium

ASEAN Laboratory Studies

- Established ASEAN Reference Substance (PARS), Chlorpropamide with five other countries, namely Brunei, Indonesia, Laos, Malaysia and Myanmar through an inter-laboratory collaborative study
- Joined an inter-laboratory study of Lumefantrine PARS, led by Indonesia
- Provided support on the methodology on the identification and determination of 1,4-Dioxane in cosmetic products by headspace GC-MS with ASEAN Cosmetic Scientific Body (ACSB) members for reference purposes

AWARDS AND ACHIEVEMENTS

We received the following awards in recognition of our scientific contributions to the community.

MNDA TEAM AWARD

The HSA team received the Minister for Home Affairs National Day Awards (MNDA) Team Award in recognition of our contribution to Singapore's campaign against Cannabis Rescheduling at the United Nations Commission on Narcotic Drugs (CND).

We were part of an inter-agency committee, which also comprised representatives from the Ministry of Home Affairs (MHA), Central Narcotics Bureau, Attorney-General's Chambers, Ministry of Foreign Affairs and Ministry of Health. We provided technical advice to the committee and was part of the delegation representing Singapore at the CND meetings.

MHA OPS EXCELLENCE AWARD

We were awarded the MHA Ops Excellence Award in 2021 for our role in analysing mulch samples to reduce vegetation fires.

In 2019, the Singapore Civil Defence Force (SCDF) spearheaded a multi-agency study involving the Home Team Science and Technology Agency, National Parks, National Environment Agency and HSA. The purpose of this study was to investigate the cause and come up with solutions to reduce vegetation fires along expressway road dividers.

We analysed mulch samples submitted by SCDF to determine the volatile organic compounds emitted and the particle size of the samples.

ISO/IEC 17025:2017 ASSESSMENT

We achieved full compliance to ISO/IEC 17025:2017 at the Singapore Laboratory Accreditation Scheme (SAC-SINGLAS) annual assessment.

Pharmaceutical Laboratory (PL)

PL's scope of accreditation has now been expanded to include two new tests:

1. Determination of Sennosides in health products by HPLC-DAD
2. Determination of Cannabinoids in health products by LC-MS/MS

Cigarette Testing Laboratory (CTL)

CTL expanded its scope of accreditation to include the Determination of Nicotine Content in Smokeless Tobacco Products – WHO TobLabNet Official Method SOP12.

Cosmetics Laboratory (CL)

CL's scope of accreditation has now been expanded to include two new tests:

1. Screening and Determination of Parabens in Cosmetic Products by HPLC-DAD
2. Screening of Hair Dyes "(2,2'-[(2-Nitro-1,4-phenylene) diimino]bis[ethanol]" and "2,6-Bis[(2-hydroxyethyl) amino]toluene)" by HPLC-DAD

04.

CORPORATE SERVICES GROUP

We approach our work and processes with dynamism and agility to support and respond to evolving needs.

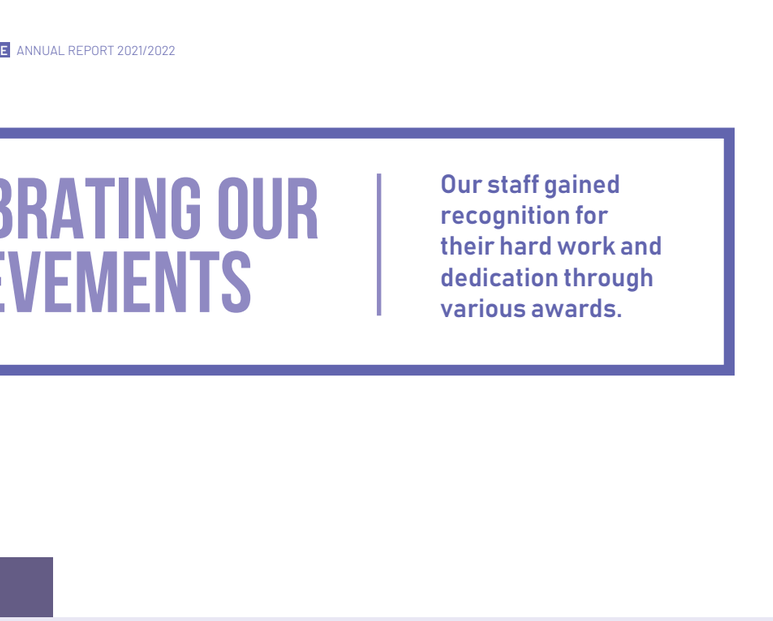
CELEBRATING OUR ACHIEVEMENTS

Our staff gained recognition for their hard work and dedication through various awards.

PUBLIC SECTOR TRANSFORMATION AWARDS 2021

The Public Sector Transformation (PST) Awards recognises and rewards public officers and public agencies for excellence in their work and organisational practices.

HSA won a total of 3 team awards for the nation's fight against COVID-19:



Through our prompt, proactive facilitation and regulatory agility, HSA was able to ensure that Singapore had timely access to diagnostic tests, medicines and vaccines, while ensuring their safety, quality and efficacy.

SINGAPORE HEALTH QUALITY SERVICE AWARDS 2022

The Singapore Health Quality Service Awards (SHQSA) honours and celebrates the exemplary efforts of healthcare professionals in improving patient experience. This past year, our staff were recognised for their service excellence and contributions to the COVID-19 fight. This is the third time HSA has participated in this award.

There were a total of 24 individual winners from HSA:

- 3 Star
- 8 Gold
- 13 Silver

HSA OUTSTANDING SERVICE TO CUSTOMERS AWARD (OSCA) 2021

This award is given to staff who exemplify excellent customer service in HSA.

There were

47

OSCA 2021 winners:

- 6 Gold
- 8 Silver
- 28 Bronze
- 5 Team

PEOPLE AND VALUES

HSAians take pride in having a strong sense of purpose that extends beyond the workplace. We took part in activities which allowed us to give back to the community.

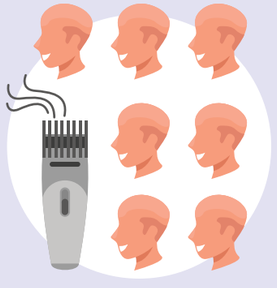
HSA CAREs – Corporate Social Responsibility (CSR) Activities

We are committed to giving back to society through our Corporate Social Responsibility (CSR) Framework, known as CARE – "Community Action, Responsible for our Environment". Over the years, our staff have actively volunteered in CSR initiatives which have helped them to develop skills for helping the needy, as well as build up a sense of empathy and kindness to society.

Hair for Hope

The Children's Cancer Foundation's flagship fundraiser, Hair for Hope, returned after being suspended for a year due to the COVID-19 pandemic. HSA has been an active supporter of the programme since 2013.

Between June and July 2021, various activities were held to create awareness of childhood cancer, garner support from families and friends, and raise funds for children with cancer.



As a sign of solidarity to children with cancer and their families, **7 of our staff shaved their heads**

Through generous contributions from our staff, a total of **$11,620 was raised**

Reading Together for Charity

In support of the National Reading Movement, HSAians came together to nurture their love of reading while at the same time contributing to a good cause.

This was done through a special "Read for Books" charity initiative, where

1 book would be donated by the National Library Board

every time **10 persons came together to read for 15 minutes**

To support the good cause, HSA organised **3 virtual reading sessions** over lunch in July 2021

We were very encouraged by the strong support despite the challenges of team segregation and hybrid work arrangements that were part of COVID-19 safe management measures.

COVID-19 Vaccination Buddy Programme

In April 2021, a number of HSAians spent a day volunteering for the COVID-19 Vaccination Buddy Programme. Organised as part of the Public Service (PS) Cares Day, each volunteer was paired up with a Silver Generation Ambassador from the Silver Generation Office.

Together, they went door-to-door reminding seniors to stay safe during the pandemic, sharing information about COVID-19 vaccinations, and gathering feedback from those already vaccinated. They also offered their assistance in booking appointments online and accompanying seniors to vaccination centres.

DEVELOPING OUR PEOPLE

As one big HSA family, we are committed to caring for our staff both professionally and for their personal well-being.

HSA WELLNESS AMBASSADORS INITIATIVE

To better support our fellow officers' well-being, we onboarded the Public Service Division's Wellness Ambassador Initiative in March 2021. As part of this initiative:

- Wellness Ambassadors (WAs) are trained to identify signs of distress, provide non-professional basic mental and emotional support, encourage help-seeking behaviour, and recognise and escalate cases where fellow colleagues pose immediate danger to themselves or others

- We strive to create a more caring culture within HSA, and at the same time, build a healthier and more resilient HSA

We trained **8 staff**, who are now actively playing the role of **mental well-being ambassadors**. More WAs will be trained to better serve the needs of all HSAians.

HSA PROFESSIONAL PERSONAL MASTERY PROGRAMME – "LEADERSHIP REIMAGINED"

To better drive leadership transformation and serve our stakeholders, HSAians need to build their capabilities and grow capacity to lead more effectively in the rapidly changing landscape of scientific and technological advancement.

With this aim, the inaugural HSA Leadership Reimagined programme was launched in January 2022. Designed in collaboration with Civil Service College's consultants, this programme provides our senior professionals with the necessary tools to lead effectively, build their personal and team resilience, and lay the foundation to grow together as a learning community.

INAUGURAL HSA FORENSIC ODONTOLOGY SCHOLARSHIP

Forensic Odontology is an interdisciplinary field where dental expertise is applied to law, forensic medicine and forensic science. It is one of the specialist disciplines employed in Singapore's criminal justice system to determine the identity of perpetrators and victims through the examination and evaluation of dental evidence.

To ensure a pipeline of qualified specialists, HSA launched the inaugural HSA Forensic Odontology scholarship in 2021. Our first-ever scholarship recipient, Dr Dennis Heng, is currently pursuing his Masters in the University of Dundee, where he is being trained in a broad spectrum of topics within the discipline of Forensic Odontology. He will also gain practical experience through post-mortem dental identification casework at a working mortuary.

HSA'S DIGITAL TRANSFORMATION EFFORTS

Our staff gained recognition for their hard work and dedication through various awards.

OUR DIGITAL STRATEGY

HSA's Digitalisation Framework

Why

To transform how HSA operates and how it interacts with its stakeholders by digitalising our operations, service delivery and insights

What

DIGITALISE CORE BUSINESS

Digitalises Insights

Leveraging data to anticipate and respond to the stakeholders' needs

Digitalises Operations Management

Digitalising, automating, and streamlining key work processes

Digitalises Service Delivery

Digitalising to make transactions easy, seamless and secure for our stakeholders

How

PEOPLE & PARTNERS	PROCESS	DATA & TECHNOLOGY
Develop People, Organisation and Culture	Employ User-Centric Design	Leverage Data
Leverage Ecosystems	Adopt Agile Practices	Leverage Smart Tech

SCIENCE, INNOVATION AND TRANSFORMATION FIESTA

In October 2021, we organised an online Science, Innovation and Transformation (SIT) Fiesta. The theme was "We ADAPT", which highlighted the need for HSAians to adapt fast and be future-ready.

Highlights of the fiesta included:

- Showcase of research, innovation and transformation projects by HSAians
- Laboratory workshops and virtual laboratory tours
- Keynote speeches by Dr Zhou Lihan from MiRXES and Ms Sarah Espaldon from GovTech's Open Government Products Unit on their organisation's approach to agility and innovation
- A celebration of HSA's 20th Year Anniversary with a video featuring the collective achievements of our four Professional Groups

Catering to Our Stakeholders

In consideration of our diverse stakeholders with different digital maturity levels, we have built a holistic digitalisation strategy that serves varying needs. We have leveraged data analytics to help us make better decisions to meet stakeholders' needs. We also streamlined and automated work processes to make all transactions easy and secure for all stakeholders.

Shifting away from a waterfall model to agile methodologies, our digital solutions now embrace UX Design, customer journey mapping and beta-testing of solutions.

Driven by Data

We updated our Data Analytics Strategy to enable more effective use of data in developing insights, and decision making in the organisation. Data Champions were also appointed to drive and initiate strategic data analytics projects across HSA.

Other initiatives included organising a Data Arcade Tournament to promote the use of data analytics across departments, as well as onboarding of GovTech's Workflow Management System to automate our internal workflows and processes.

Equipping Our People

To ensure effective management of our digitalisation projects, we equipped our people with the necessary skills such as agile methodology and UX Design. We also made continuous efforts to effect change and instil in HSAians the right digital mindset.

We employ a variety of channels to raise the capabilities of our staff, including digitalisation seminars, a digitalisation microsite, roll out of primers to facilitate knowledge building, development of a digital skills framework, and specialised training for scientific staff.

MEDIA ENGAGEMENT AND BRANDING

To ensure transparency and inspire the public's confidence, we work closely with the media to share our scientific and regulatory efforts and achievements.

We engaged with various media platforms including print, broadcast and online media to highlight HSA's authorisation of COVID-19 vaccines and medication, product safety alerts and various enforcement activities.

We also profiled our forensic experts on TV programmes such as Inside Crime Scene, Crimewatch and Mind Blown. Through the CNA documentary – Singapore in Red, Green and Blue, the public got to hear more about the story of blood donation through the years, both in terms of the challenges and progress.

We published

27 press releases

7 HSA Updates

resulting in **678** media articles

We also created a total of

207 marketing collaterals

36 event collaterals

In the pursuit of greater efficiency, we are constantly reviewing and adopting new technologies to enhance our workflow and processes.

TECHNOLOGY AND INFRASTRUCTURE

We made the following enhancements to our IT infrastructure:

- Launched Microsoft SG-Teams to transform the digital workspace in line with the demands of remote working brought about by COVID-19. HSAians benefited from using tools such as chatrooms, video conferencing, content collaboration and file sharing
- Expanded Wi-Fi coverage for the laboratories in our Outram building and the Synapse office to bring about more reliable and faster network connectivity
- Onboarded HSA application systems to GovTech's Operations and Management Tools. This has enabled us to have better visibility of our vulnerabilities, and to take prompt remedial action on security lapses, anomalies, and misconfigurations
- Promoted and increased cybersecurity knowledge amongst HSAians through sharing on topics such as phishing, Cyber Supply Chain Risk, and Remote Working Risk
- Accelerated the modernisation of IT infrastructure by adopting cloud computing for scalability of computing resources and efficiency in managing systems. The applications implemented include the National Blood Supply Management system and budget planning software

OUR WORK IN FIGURES

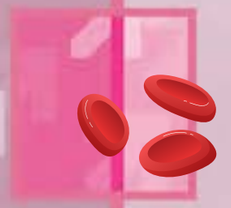
BLOOD SERVICES GROUP

Key statistics as at end-December 2021

69,032
Blood Donors

114,471
Whole Blood Donations

9,946
Apheresis Donations



379,501
Blood Components Processed

1,310,103
Laboratory Tests Conducted

APPLIED SCIENCES GROUP

Key statistics as at end-March 2022

PHARMACEUTICAL DIVISION

2,366
Analytical Cases

3,948
Analytical Tests

ANALYTICAL TOXICOLOGY DIVISION

16,591
Forensic Cases

27,582
Forensic Exhibits

BIOLOGY DIVISION

13,107
Forensic Cases

21,709
Forensic Exhibits

FORENSIC SCIENCE DIVISION

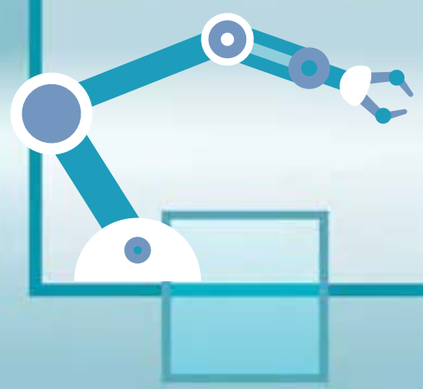
360
Forensic Cases

1,772
Forensic Exhibits

ILLICIT DRUGS DIVISION

1,896
Forensic Cases

6,649
Forensic Exhibits



FORENSIC MEDICINE DIVISION

5,040
Coroner's Cases

1,163
Coroner's Autopsies

HEALTH PRODUCTS REGULATION GROUP

Key statistics as at end-March 2022

32
Therapeutic Products Containing New Chemical/Biological Entities Approved

316
Therapeutic Products Registrations Approved (New Drug Applications and Generic Drug Applications)

5,334
Approved Products on the Register of Therapeutic Products

12,042
Chinese Proprietary Medicines Listed

5,069
Therapeutic Products Variation Applications Approved

1,158
Medical Device Product Listings Approved (Class B, C & D)

18,996
Approved Products on the Singapore Medical Device Register

241
New Chinese Proprietary Medicines Listed

593
Field Safety Corrective Action Reporting for Medical Devices Received

778
Adverse Events (Local) Reporting for Medical Devices Received

2,790
Medical Device Change Notification Applications

158,775
Cosmetic Products Notified

2,119
Applications for Import of Medicinal Products for Personal Use Processed

35
New Class 1 and Class 2 Cell, Tissue and Gene Therapy Products Notified and Registered, Respectively

4,425
Licensed Tobacco Retail Outlets

438
Tobacco Retail Licences Approved

7,196
Electronic Vaporiser Cases Handled by HSA

35,696
New Cosmetic Products Notified

143
New Clinical Trials Applications Approved

39
Class 1 and Class 2 Cell, Tissue and Gene Therapy Products on the Notified List and Register

2,517
Medical Advertisement Permits Approved

34,553
Spontaneous Adverse Drug Reaction Reports Captured

3,947
Post-market Feedback Received (Relating to Potential Contravention of Health Product Legislation)

389
Site Audits Conducted for Good Manufacturing & Good Distribution Practices and Pharmacies

148
New Clinical Trials Applications Processed

6
New Class 1 and Class 2 Cell, Tissue and Gene Therapy Products Variation Applications Approved

APPLICATIONS APPROVED

613
Licences/Certificates for Manufacturers of Health Products

3,110
Licences/Certificates for Importers of Health Products

2,215
Licences/Certificates for Wholesalers of Health Products

265
Certificates of Medical Devices

361
Registration of Retail Pharmacies

347
Licences/Certificates for Exporters of Health Products

FINANCIAL HIGHLIGHTS

STATEMENT OF FINANCIAL POSITION

	FY21/22	FY20/21	Increase / (Decrease)	
	$'000	$'000	$'000	%
Property, Plant & Equipment	78,914	77,060	1,854	2
Intangibles	10,693	13,009	(2,316)	(18)
Right-of-Use Assets	13,297	13,626	(329)	(2)
Current Assets	245,740	218,574	27,166	12
Total Assets	**348,644**	**322,269**	**26,375**	**8**
Equity	246,497	232,077	14,420	6
Non-Current Liabilities	14,022	14,662	(640)	(4)
Current Liabilities	88,125	75,530	12,595	17
Total Equity and Liabilities	**348,644**	**322,269**	**26,375**	**8**

STATEMENT OF COMPREHENSIVE INCOME

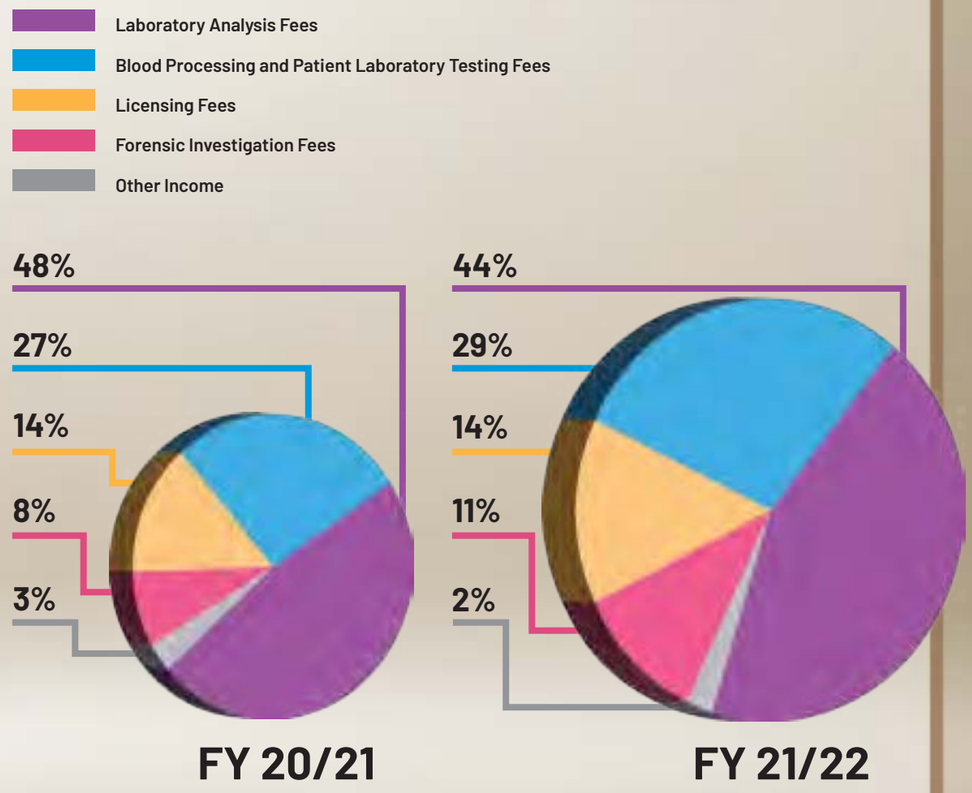
The Authority achieved an overall net surplus of $13.8m for FY21/22.

	FY21/22	FY20/21	Increase / (Decrease)	
	$'000	$'000	$'000	%
Operating Income	147,496	149,866	(2,370)	(2)
Operating Expenditure	(231,850)	(208,943)	22,907	11
Deficit before Government Grants	**(84,354)**	**(59,077)**	**25,277**	**43**
Government Grants	100,654	87,620	13,034	15
Surplus before Contribution to Consolidated Fund	**16,300**	**28,543**	**(12,243)**	**(43)**
Contribution to Consolidated Fund	(2,771)	(4,854)	(2,083)	(43)
Net Surplus	**13,529**	**23,689**	**(10,160)**	**(43)**
Other Comprehensive Income	243	41	202	493
Net Surplus and Comprehensive Income for the Year	**13,772**	**23,730**	**(9,958)**	**(42)**

OPERATING INCOME

The Authority earned a total operating income of $147.5m in FY21/22, a decrease of $2.4m (2%) from FY20/21's revenue of $149.9m.

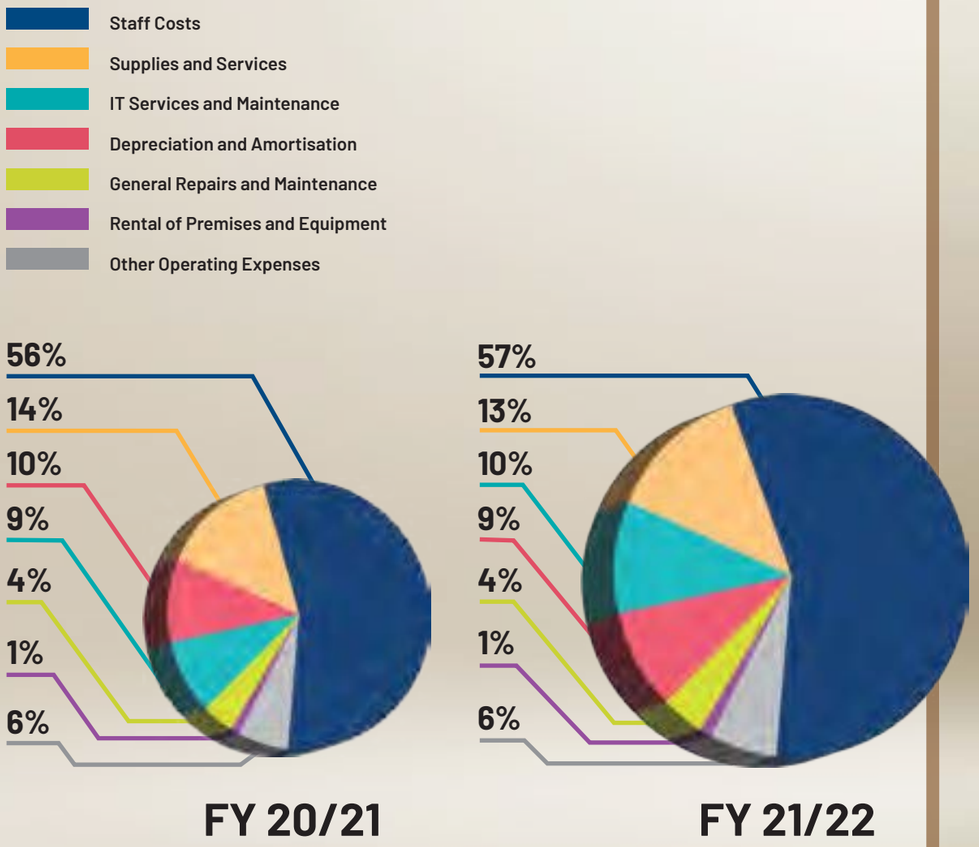
	FY21/22	FY20/21	Increase / (Decrease)	
	$'000	$'000	$'000	%
Laboratory Analysis Fees	65,858	72,583	(6,725)	(9)
Blood Processing and Patient Laboratory Testing Fees	42,588	40,492	2,096	5
Licensing Fees	20,511	20,267	244	1
Forensic Investigation Fees	15,793	12,702	3,091	24
Other Income	2,746	3,822	(1,076)	(28)
Total Operating Income	**147,496**	**149,866**	**(2,370)**	**(2)**



OPERATING EXPENDITURE

The Authority incurred a total operating expenditure of $231.8m in FY21/22, an increase of $22.9m (11%) from FY20/21's expenditure of $208.9m.

	FY21/22	FY20/21	Increase / (Decrease)	
	$'000	$'000	$'000	%
Staff Costs	131,609	117,481	14,128	12
Supplies and Services	30,486	29,035	1,451	5
IT Services and Maintenance	23,585	18,853	4,732	25
Depreciation and Amortisation	20,596	20,876	(280)	(1)
General Repairs and Maintenance	8,572	8,341	231	3
Rental of Premises and Equipment	1,843	2,195	(352)	(16)
Other Operating Expenses	15,159	12,162	2,997	25
Total Operating Expenditure	**231,850**	**208,943**	**22,907**	**11**



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