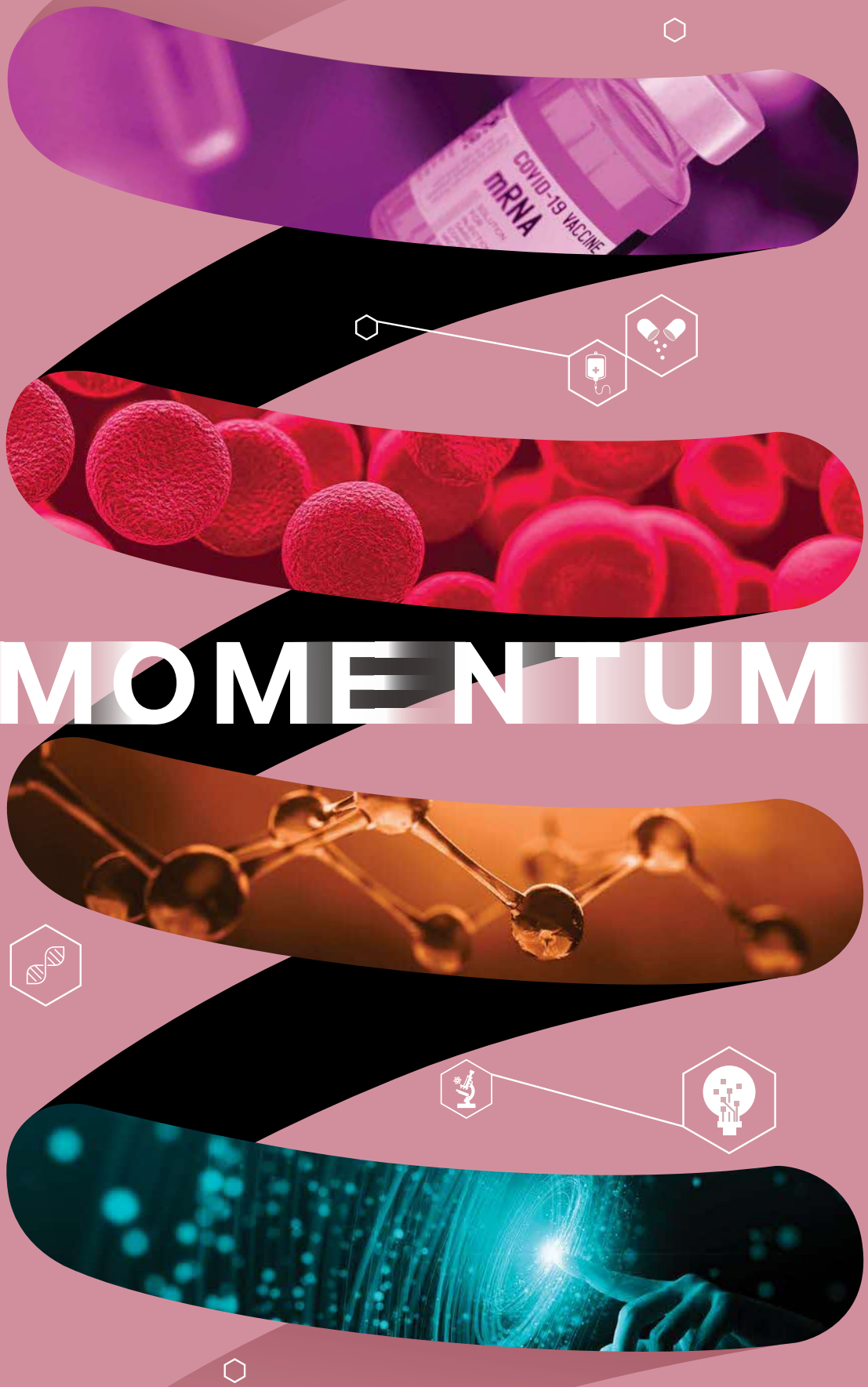
HEALTH SCIENCES AUTHORITY



MOMENTUM

Annual Report
2022/2023

HSA has built and gained **momentum** through our transformation initiatives in the past few years. With our new expertise, skills and ability to leverage technology and data, we continue on our transformation journey to build a more agile and adaptable workforce.

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 August 2018
ISO 9001:2015
Information Management Department
Corporate Headquarters

Since June 2018
ISO 9001:2015
Corporate Services Group

Since 2017
NS Mark (Gold) Accreditation

Since 2003
Community Chest Awards

Professional Excellence

HEALTH PRODUCTS REGULATION GROUP

Since January 2022
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
Vigilance & Compliance Branch

Since March 2008
ISO 9001:2015
Tobacco Regulation Branch

BLOOD SERVICES GROUP

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
The Joint Accreditation Committee ISCT-Europe & EBMT (JACIE)
Cell Therapy Facility was accredited for meeting global standards in the provision of quality laboratory practice in haematopoietic stem cell transplant and cellular therapy

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

December 2005
On-the-Job Centre Accreditation

Since 1992
World Health Organization Collaborating Centre for Transfusion Medicine

APPLIED SCIENCES GROUP

Forensic Medicine Division

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

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)

Pharmaceutical Division

Since June 2009
WHO Collaborating Centre for Tobacco Testing and Research

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 (WHO) Collaborating Centre for Drug Quality Assurance

Chemical Metrology Division

Since August 2013
Accredited as a Proficiency Testing Provider in compliance with ISO/IEC 17043 by SAC-SINGLAS

Memberships, Committees and Working Groups

HEALTH PRODUCTS REGULATION GROUP

WHO National Control Laboratory Network for Biologicals
Member

International Pharmaceutical Regulators Programme (IPRP)
Management Committee

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

International Medical Device Regulators Forum (IMDRF)
Management Committee

International Coalition of Medicines Regulatory Authorities (ICMRA)
Member

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

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

Global Harmonization Working Party (GHWP)
(formerly Asian Harmonization Working Party)
Member

BLOOD SERVICES GROUP

International Society of Blood Transfusion (ISBT)
Member

Asia Pacific Blood Network (APBN)
Founding Member

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

International Haemovigilance Network
Member

AABB
Member

Biomedical Excellence for Safer Transfusion (BEST)
Collaborative Member

OUR ACCOLADES

APPLIED SCIENCES GROUP

Forensic Medicine Division

MOH Biosafety Technical Committee
Member

MOH Workgroup for Biosafety Level 3 Requirements
Member

Royal College of Pathologists of Australasia Singaporean Committee
Member

Forensic Pathology of Specialist Accreditation Board, MOH
Chairman

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

International Association of Identification
Member

Association of Firearms and Toolmarks Examiners (AFTE)
Member

Institute of Traffic Accident Investigators (ITAI)
Member

Forensic Isotope Ratio Mass Spectrometry Network (FIRMS)
Institutional Member

International Association of Bloodstain Pattern Analysts (IABPA)
Member

The International Association of Forensic Toxicologists (TIAFT)
Committee Member

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

European DNA Profiling Group (EDNAP)
Associate Member

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

Asian Forensic Sciences Network (AFSN)
One of the founding members, Board Member and International Liaison Officer

International Forensic Strategic Alliance (IFSA)
Representative of AFSN

European Network of Forensic Science Institutes (ENFSI)

Associate Member of ENFSI Working Groups

ENFSI Forensic International Network for Explosives Investigation

ENFSI Expert Working Group for Road Accident Analysis

ENFSI Expert Working Group for Marks

ENFSI Textile and Hair Group

ENFSI Drugs Working Group

ENFSI European Network of Forensic Handwriting Experts

ENFSI Firearms and GSR Working Group

ENFSI Document Experts Working Group

ENFSI Paint, Glass and Taggants Working Group

ENFSI DNA Working Group

INTERPOL

INTERPOL DVI Workgroup Forensic Genetics Sub-Working Group
Member

INTERPOL DVI Workgroup Pathology and Anthropology Sub-Working Group

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

DNA Workgroup, Illicit Drugs Workgroup
Vice Chair

Crime Scene Investigation Workgroup, Digital Forensic Workgroup, DNA Workgroup
Secretary

Forensic Medicine Workgroup
Member

Chemical Metrology Division

ASEAN Reference Material Network
One of the founding members

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

Joint Committee for Traceability in Laboratory Medicine (JCTLM)
Member

Asia Pacific Metrology Programme (APMP)
Full Member

Pharmaceutical Division

General European Official Medicines Control Laboratories Network
Associate Membership

Observer to the European Pharmacopoeia Commission

WHO National Control Laboratory Network for Biologicals
Associate Membership

ASEAN Pharmaceutical Testing Laboratory Committee (APTLC)
Co-Chair

ASEAN Reference Substances Workgroup (ARS)
Member

European Pharmacopoeia Commission Group 10B (Organic Chemistry – synthetic and semi-synthetic products)
Member

ASEAN Cosmetics Testing Laboratory Committee (ACTLC)
Member

European Network of the Official Cosmetics Control Laboratories (OCCL)
Associate Membership

WHO Tobacco Laboratory Network (TobLabNet)
Chair

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

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

International Laboratories Forum on Counterfeit Medicines (ILFCM)

PROFESSOR
BENJAMIN ONG
Chairman

MESSAGE FROM THE CHAIRMAN

“In our pursuit of innovation, we reimagined solutions by leveraging digital technologies, embracing automation, and fostering a growth mindset that encourages lifelong learning and the acquisition of new technologies.”

The past year has brought tighter fiscal and resourcing challenges from significant global geopolitical and geoeconomic changes. Furthermore, the impact of an ageing population by 2030 presents additional challenges to the tight labour market.

We recognise that transformation, innovation, and digitalisation are crucial for HSA to not only succeed but thrive in this more challenging environment.

To adapt to these circumstances, we have reset our priorities and deployed our resources to support critical emerging needs, while deprioritising less critical tasks.

In our pursuit of innovation, we reimagined solutions by leveraging digital technologies, embracing automation, and fostering a growth mindset that encourages lifelong learning and the acquisition of new technologies.

We are also building a culture of collaboration and forging strategic partnerships to leverage each other's strengths and grow our capabilities.

At the core, it is our staff who are enablers. We will prioritise the well-being of our people, creating a supportive environment where they can flourish. We will continue to invest in the upskilling and growth of our people, to equip them with the necessary skills and tools to excel in their roles.

Leveraging digital technologies and embracing automation

We developed the "Vaccine Lot Release Track" app, which digitises and automates the processing and management of lot release notification data for imported vaccines. This app has not only alleviated laborious work processes but also enabled traceability and improved overall productivity. Furthermore, it has allowed us to analyse trends related to lot release status, enhancing our ability to make informed decisions.

We implemented various digital tools to enhance the surveillance and management of therapeutic product defects. These tools include an automated web-scraping program that employs machine learning to extract alerts related to product defects and recalls from overseas drug regulatory agency websites. We also developed filtering algorithms, machine learning models, and risk classification models to identify and prioritise the management of product defects. These initiatives have significantly enhanced our ability to ensure the safety and quality of therapeutic products.

In our commitment to uphold stringent quality standards, we introduced Robot Process Automation (RPA) to screen for adulterants in complementary health products. By automating the inter-quality control assessment and reporting outcomes, we have enhanced work efficiency and productivity while upholding the highest quality standards in accordance with ISO/IEC 17025:2017 requirements.

Culture of collaboration

Our achievements in our commitment to excellence would not have been possible without the culture of collaboration we have fostered. We have actively sought partnerships with local and overseas counterparts, exchanging experience and knowledge to enhance our capabilities.

Over the past year, HSA has issued regulatory approvals for 10 applications through Project Orbis, a global collaborative review program headed by the US FDA for cancer therapies; and completed six therapeutic product applications through Access Consortium, a coalition of five like-minded regulatory authorities that workshare to promote timely access to therapeutic products.

We are also now recognised by Australia's Therapeutic Goods Administration (TGA) as a Comparable Overseas Regulator (COR) for the review of medical devices, joining the European Union, United States of America, Canada, and Japan as one of five listed TGA COR regulators. With this recognition, companies can now leverage HSA's medical device approvals for faster entry into Australia.

Through a fruitful collaboration with clinicians from KK Women's and Children's Hospital and Singapore General Hospital, we utilised our Cell & Gene Therapy Facility as a manufacturing site for various CAR-T products. These CAR-T products were employed in clinical trials, offering innovative and more affordable salvage therapy for patients.

To strengthen the national emergency preparedness during mass fatality incidents, we conducted workshops with the Singapore Police Force to train police officers in the application of DNA kinship analysis for Disaster Victim Identification efforts. The knowledge and skills acquired can be applied both locally and internationally.

Investing in our people

In this ever-changing landscape, we need to instil a mindset of continuous learning, and provide the tools for our staff to upskill and develop new skills.

This year, the Blood Services Group (BSG) achieved a significant milestone by obtaining the certified On-the-Job Training accreditation from the Institute of Technical Education. Along with the Human Capital Management department, they developed a comprehensive blueprint for enhanced hands-on learning experiences. As a certified provider, BSG can now reward and acknowledge the efforts of staff with e-certificates upon completing the modules. This also serves as a source of motivation for our trainers to continually improve and develop better modules.

To ensure our staff are well-positioned to leverage data for data-driven decision-making, we have organised briefings, training courses, and data analytics clinics to provide them with the necessary digital skills, as well as equip them with tools to start them on their data analytics journey.

Recognition for our work

My heartiest congratulations to three HSA teams (Forensic Medicine and Histolab Team, Medical Devices Team, and Therapeutic Products Team) who received their National Awards (COVID-19) – the President's Certificate of Commendation (COVID-19) for their exceptional efforts which had a significant impact on Singapore's fight against COVID-19, and 118 of our colleagues who received the COVID-19 Resilience Medal.

As we reflect on the past year's accomplishments, we acknowledge the dedication, expertise, and passion of our staff and partners who have contributed to our success and helped set us apart as an organisation that continually strives to the highest standards in pursuit of our mission.

DR
CHOONG MAY LING, MIMI
Chief Executive Officer

MESSAGE FROM THE CEO

“I would like to extend my heartfelt gratitude to our stakeholders, our staff, healthcare professionals, industry partners, and the public, for their unwavering support and trust in our mission. Together, we will continue to navigate the challenges ahead and embrace change to shape the future of public health, regulatory and scientific excellence.”

HSA has embarked on a transformative journey in recent years. We have embraced transformation and innovation as a whole-of-HSA effort, where every HSAian has a vital role to play. We have gained significant momentum in building a more agile and adaptable workforce.

The transformative mindset pervades into how we view our mission of advancing and protecting public health. We see the wider impact of our work on the lives of people and our stakeholders, which spurs us ahead in our goals as an organisation.

Protecting and safeguarding the public's health

Our work does not stop at regulating health products. We facilitate access to safe, good quality and efficacious health products and medical devices.

Even as we have successfully transitioned to living with COVID-19, our work to protect the population against the pandemic continues. We granted interim authorisation under the Pandemic Special Access Route (PSAR) to three COVID-19 vaccines, two anti-viral therapeutics, and granted product registration for a paediatric vaccine.

The scope of our work has evolved with COVID-19. We are now leveraging data analytics to greatly enhance the safety monitoring of COVID-19 vaccines by developing and pioneering the Active Surveillance System for Adverse Reactions to Medicines and Vaccines (ASAR). ASAR analyses structured healthcare data and unstructured clinical notes from all public acute hospitals and this real-world data enables us to detect early safety signals and implement timely risk mitigation measures, inform COVID-19 vaccination policies, and enhance public health safety.

At the same time, we are taking steps to strengthen our regulatory system. We have launched phase 1 of the voluntary notification system (VNS) for complementary health products (CHPs), which enables companies dealing with these products to voluntarily submit relevant documents to demonstrate that their products meet the necessary safety and quality standards. The VNS aims to establish a local database of reliable CHPs that consumers can refer to, and facilitates regulatory actions by HSA should there be safety or quality issues.

We continue to make strides to ensure that medical devices are safe and of good quality in Singapore. I'm proud to share that the World Health Organization (WHO) has recognised HSA as a Stringent Regulatory Authority (SRA) for high-risk in vitro diagnostic medical devices (IVDs). This prestigious recognition places us alongside leading regulatory authorities worldwide, qualifying our high-risk IVDs for expedited listing. It opens doors to global markets and reinforces Singapore's position as a trusted authority in healthcare regulation.

Securing the nation's blood supply and saving lives

We are not just securing the nation's blood supply. We are saving lives.

To ensure that we have a sustainable blood supply, we are using data analytics to generate real-time reports for blood collection and supporting operations. To make blood donation more convenient for donors, we have also analysed footfall data to optimise the opening hours and closure days for the upcoming Bloodbank@One Punggol.

With the goal to ensure that patients have access to blood when they need it, we developed an action plan to prioritise the usage of red cells and platelets based on patients' medical conditions and urgency of surgeries, in the event of blood inventory shortages. With this plan, the most crucial patient groups will receive priority for blood transfusions during blood shortages.

To support physicians conducting haematopoietic stem cell transplants, our laboratory has broadened our capabilities to offer killer-cell immunoglobulin-like receptor genotyping which improves survival in Human Leukocyte Antigen-haploidentical haemopoietic stem cell transplants, greatly benefitting patients who need stem cell transplants.

Uncovering the truth and discovering solutions

At HSA, we are not merely serving the administration of justice, we are uncovering the truth and discovering solutions. This mindset has guided our endeavours and fuelled our pursuit of excellence.

In our unwavering commitment to protect public health, we established a new Biologics Lab dedicated to testing the efficacy of vaccines. This state-of-the-art facility will play a pivotal role in ensuring the safety and effectiveness of vaccines, further enhancing our ability to safeguard the health of our citizens.

We are always developing new capabilities to better meet the needs of our stakeholders, and optimising our processes to enhance our efficiency.

We have developed a new and novel method to enable long-term body tissue preservation without refrigeration in the event of a mass fatality incident. This enables proper preservation of bodily remains which is critical for maximising DNA recovery for victim identification. This preservation technique was recognised at the annual INTERPOL Disaster Victim Identification conference.

We undertook a comprehensive optimisation and re-engineering of our work processes to enable faster processing of sexual offence samples. This enables our laboratory to meet the substantial increase in our analysis work without additional manpower or resources.

Fostering a learning and supportive work environment

We take active care to create a supportive work environment, to continue to develop our people, while taking care of their overall well-being.

At our organisation, we prioritise continuous learning. We held our inaugural Learning Week, an event which featured bite-sized learning sessions on relevant topics to help our staff stay future-ready and adapt to the fast-moving and ever-changing external environment. To provide a diverse range of perspectives, we also invited speakers from the public, private sector, and academia.

HSA also recognises the growing importance of self-care and mental wellness. We held regular workshops and activities to equip our staff with such knowledge and life skills. We have also appointed wellness ambassadors who are equipped to offer basic mental and emotional support to fellow staff. We are confident that prioritising the well-being of our staff and creating a positive work culture will continue to drive the success of our organisation.

Embracing change for the future

As a whole, HSA is not just striving for organisational excellence. We are changing the way we work.

I would like to extend my heartfelt gratitude to our stakeholders, our staff, healthcare professionals, industry partners, and the public, for their unwavering support and trust in our mission. Together, we will continue to navigate the challenges ahead and embrace change to shape the future of public health, regulatory and scientific excellence.

HSA BOARD

As at August 2023

01
Professor Benjamin Ong
Chairman
Health Sciences Authority

02
Mr Jimmy Phoon
Chief Executive Officer
Seviora Holdings Pte Ltd

03
Professor Tai Lee Siang
Head of Pillar, Architecture and Sustainable Design
Singapore University of Technology and Design

04
Mr Lionel Yee Woon Chin
Deputy Attorney-General
Attorney-General's Chambers

05
Mr Dileep Nair
Independent Director
Keppel DC REIT Management Pte Ltd

06
Mr Alok Mishra
Chief Executive Officer
Value Addition

07
Ms Aileen Tan
Group Chief People and Sustainability Officer
Singtel

08
Mr Lin Qinghui
Senior Director, Policy Development Division
Ministry of Home Affairs

09
Mr Robert Chew
Managing Partner
iGlobe Partners

10
Professor Chen Tsuhan
Deputy President, Innovation and Enterprise
National University of Singapore

11
Professor Lim Chwee Teck
NUS Society Professor
Department of Biomedical Engineering

Director, Institute for Health Innovation and Technology (iHealthtech)
National University of Singapore

Founding Director
Singapore Health Technologies Consortium

HSA BOARD COMMITTEES

As at August 2023

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
Mr Lin Qinghui
Mr Robert Chew
Professor Chen Tsuhan
Professor Lim Chwee Teck

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
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 Low Chian Siong
Director
Infrastructure Planning & Policy
Ministry of Health

Mr Hoong Bee Lok
Visiting Consultant
Health Sciences Authority

BOARD UPDATES

We would like to express our deepest appreciation to Professor Freddy Boey and Professor Leong Tze Yun, who retired from the Board on 31 March 2023.

Professor Boey's professional expertise had been invaluable in charting HSA's strategic direction, driving innovation and improving performance. With his guidance, HSA had strengthened our scientific and regulatory standing and expanded our capacity in supporting the health and biomedical innovations and development in Singapore.

Professor Leong had provided great support to HSA's digital transformation journey and her advice had guided our adoption of digitalisation initiatives and had enhanced our IT systems and data protection and risk management systems.

We welcome Professor Chen Tsuhan and Professor Lim Chwee Teck who joined the Board on 1 April 2023. Both bring with them rich experience in their areas of expertise. We look forward to their guidance as we continue on our transformation journey.

HSA EXECUTIVE COMMITTEE (EXCO)

As at August 2023

01
Dr Choong May Ling, Mimi
Chief Executive Officer

02
Assoc Professor Chan Cheng Leng
Group Director
Health Products Regulation Group

03
Dr Ang Ai Leen
Group Director
Blood Services Group

04
Mr Jeffrey Wong
Group Director
Corporate Services Group

05
Dr Christopher Syn
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 2023

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

KEEPING UP OUR VIGILANCE

Health Products Regulation Group

We strike a fine balance between facilitating access to safe and efficacious health products, and developing regulations that support innovation.

COVID-19 RELATED WORK

HSA continued to support the nation in its fight against COVID-19.

AUTHORISATION OF COVID-19 VACCINES AND THERAPEUTICS

Over the past year, we granted interim authorisation under the Pandemic Special Access Route (PSAR) for the following:

Vaccines	Anti-viral Therapeutics
• Pfizer-BioNTech Comirnaty Bivalent (Original/Omicron BA.4-5) • Moderna Spikevax Bivalent (Original/Omicron BA.1) • Paediatric Moderna Spikevax (0.1mg/ml)	• Evusheld • Lagevrio

We also granted product registration for a paediatric vaccine (Pfizer-BioNTech Comirnaty 3mcg/dose).

FACILITATION OF ACCESS TO MEDICAL DEVICES FOR COVID-19

As of March 2023, 323 COVID-19 diagnostic tests were granted interim authorisation under the PSAR.

ENHANCED SAFETY MONITORING OF COVID-19 VACCINES

From the start of the pandemic, we have been conducting enhanced safety surveillance of COVID-19 vaccines through:

- Expedited reporting of serious adverse events (SAE) by healthcare professionals
- Consumer self-reporting of adverse events (AE)
- Implementing an active surveillance system which utilises real-world data for signal detection

As the vaccination strategy expanded to include new COVID-19 vaccines, booster doses, bivalent vaccines, and vaccination for children, so did the scope of our surveillance activities. We promptly evaluated AE reports of COVID-19 vaccines to identify new safety concerns, as well as held consultations with clinical expert panels in different disciplines to discuss the SAE reports received after vaccination.

We also communicated the latest safety findings to keep the public apprised on latest developments. These included topics such as the safety profile of the Nuvaxovid COVID-19 vaccine, as well as the incidence of AEs for the bivalent mRNA vaccines and paediatric vaccinations.

REGULATORY UPDATES AND REVIEWS

Our role as a regulator is to ensure that health and medical products remain safe for consumers in Singapore.

IMPLEMENTATION OF HEALTH PRODUCTS (COSMETIC PRODUCTS – ASEAN COSMETIC DIRECTIVE) (AMENDMENT) REGULATIONS 2023

In February 2023, HSA made several key amendments including:

- Prohibition of wholesale and retail supply of cosmetic products that are not notified with HSA
- Deletion of obsolete provisions on existing cosmetic products
- Updates to the list of regulated cosmetic ingredients (in accordance with the ASEAN cosmetic ingredient list)

REGULATORY UPDATES FOR THERAPEUTIC PRODUCT REGISTRATION

Revised Checklists for Post-approval Minor Variations (MIV-1 and MIV-2):

- **MIV-1:** Clarified eligible conditions and documentary requirements
- **MIV-2:** Re-categorised a list of chemistry, manufacturing & controls (CMC) variations from "MIV-2 Notification" to "Do-and-Tell"
- **MIV-2:** Introduced new "Do-and-Tell" checklists

The expansion of the "Do-and-Tell" changes aims to reduce regulatory submission burden and enable timely implementation of administrative and minor CMC changes that do not have any impact on the product's safety, efficacy and quality.

Extension of Verification Evaluation Route to Biological Products

We extended the verification evaluation route to biological and biosimilar products to enable greater reliance on reference agencies' assessments and to minimise duplication of efforts.

LAUNCH OF PHASE 1 OF VOLUNTARY NOTIFICATION SYSTEM FOR COMPLEMENTARY HEALTH PRODUCTS

As of August 2022, companies dealing with commonly purchased complementary health products (e.g., vitamin and mineral supplements) and products at higher risk of adulteration (e.g., weight loss, pain relief and male vitality products) can voluntarily submit their notifications.

The Voluntary Notification System aims to establish a local database of reliable complementary health products for consumers to refer to when making their purchases, and facilitates traceability and regulatory actions by HSA when there are safety or quality issues.

Companies that participate in this initiative are required to submit relevant documents to demonstrate that their products meet the necessary safety and quality standards. Only products that are compliant with these standards will be published on the HSA database.

ACTIVE SURVEILLANCE SYSTEM FOR ADVERSE REACTIONS TO MEDICINES AND VACCINES (ASAR)

HSA has developed the first nation-wide application – ASAR – that analyses structured healthcare data and unstructured clinical notes from all public acute hospitals. This real-world data is then used to detect and quantify the risk of AEs of interest, as well as determine the overall benefit-risk balance of medicines and vaccines used in Singapore.

ASAR pools millions of de-identified patient records from multiple sources of diagnoses, medications, vaccination records, laboratory test results and AE reports, and applies them to epidemiological studies to confirm or refute safety concerns relating to medicines and vaccines.

ASAR has enabled HSA to detect early safety signals and implement timely risk mitigation measures. The evidence generated through these analyses have also been used to inform MOH's COVID-19 vaccination policies, relevant regulatory actions and public communications aimed at safeguarding public health.

ENFORCEMENT ACTIVITIES

We worked together with local enforcement agencies to crack down on illegal health products and tobacco-related activities.

ENFORCEMENT ACTIONS AGAINST ILLEGAL HEALTH PRODUCTS IN GEYLANG

We worked closely with different agencies including the Criminal Investigation Department (CID) of the Singapore Police Force (SPF), Central Narcotics Bureau (CNB), Immigration & Checkpoints Authority (ICA), Singapore Customs, Ministry of Manpower (MOM) and Singapore Food Agency (SFA) to conduct multi-agency enforcement operations in targeted areas such as Geylang.

Conducted
163 joint operations

Seized an estimated
$456,000
worth of illegal health products

Investigated
26 suspects

Prosecuted and sentenced 10 peddlers
to imprisonment terms of up to
6 months

COMBATTING CYBERCRIME TO SAFEGUARD PUBLIC HEALTH

Through the deployment of robotic process automation technology and collaboration with various stakeholders, HSA has been able to enhance the detection and removal of illegal product listings on local e-commerce platforms.

In FY22/23:

We removed a total of
5,418 illegal health product listings
from online e-commerce platforms.

Issued 982 warnings
to sellers

OPERATION PANGEA

In June 2022, we participated in Operation Pangea, an annual exercise coordinated by the International Criminal Police Organisation (INTERPOL) to target the online sale of illegal health products, such as prescription medications, adulterated sexual enhancement products and unregistered medical devices.

HSA has participated in Operation Pangea for
15 consecutive years.

94 countries
took part in Operation Pangea 2022

Around 800 listings
of illegal health products were removed

ENFORCING THE ILLEGAL SALE OF ELECTRONIC VAPORISERS

Raid on Supplier

In June 2022, together with SPF officers from Geylang Neighbourhood Police Centre, we nabbed a seller of e-vaporisers in a mobile shop in Geylang. This allowed us to gain information which led to a larger raid on the supplier.

Prohibited products with a street value of more than
$50,000 were seized.

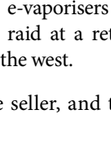
Nabbing E-vaporiser Seller who Sold to Students

In January 2023, acting on a tip-off about a seller who allegedly sold e-vaporisers to students, HSA conducted a raid at a retail store in a shopping centre in the west.

This led to an arrest of the seller, and the discovery of:

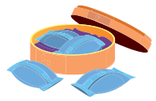
More than
400 e-vaporisers
and **350 related components**
in the seller's home and store

These were worth a total market value of more than
$11,000.



CHEWING TOBACCO SEIZED IN LITTLE INDIA

In April 2022, HSA conducted a joint raid with the SPF and CNB at Little India. A total of six premises were raided, of which four were found to contain prohibited tobacco products. This is the largest-ever chewing tobacco haul in a Little India raid.



A total of
660kg
of chewing tobacco, worth a street value of around
$130,000
were seized.

STAYING VIGILANT

Ensuring the health and safety of the public is one of our priorities.

LOCAL THERAPEUTIC PRODUCT DEFECT CASES

In FY22/23, **219 defect cases** were reported through various sources.

Of these, the top 3 issues related to:

Manufacturing	Product contamination	Product packaging
66 cases	**50 cases**	**23 cases**

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

Types of regulatory action taken:

21
Amendments to product registration (e.g. variation submission)

27
Issuance of communications (e.g. Dear Healthcare Professional Letter [DHCPL], Dear Purchaser Letter, press release)

16
Product recalls

SINGAPORE-SPECIFIC RISK MANAGEMENT PLANS (RMP)

29 RMPs
were evaluated as part of the registration of therapeutic products and cell, tissue and gene therapy products (CTGTP).

5 new RMPs
covering actions such as provision of educational materials, and submission of periodic benefit-risk evaluations reports (PBRER) were implemented.

The new RMPs included **1 enhanced RMP** for a CTGTP (Yescarta®), which required the product registrant to implement a controlled distribution programme, and submit long-term safety studies to manage the safety of this novel class of products.

SAFETY SIGNALS

Therapeutic Products and CTGTPs

- **238 safety signals** were assessed as part of post-market pharmacovigilance activities
- Notable regulatory actions taken included:
  - Publication of an article in HSA's Adverse Drug Reaction (ADR) News Bulletin to remind healthcare professionals on the risk of suicidality associated with selective serotonin reuptake inhibitors
  - Issuance of a DHCPL and publication in HSA's ADR News Bulletin on the risk of major cardiovascular events, malignancies, thrombosis, and death associated with Janus Kinase (JAK) inhibitors, identified from a large post-authorisation clinical study
- We also amended local package inserts to include newly emerging safety warnings, and communicated product safety information to healthcare professionals through safety alerts on HSA's website.

Evolving COVID-19 Vaccines

In light of the evolving safety profile of COVID-19 vaccines, we:

- Reviewed **18 monthly and bimonthly safety summary reports**
- Reviewed **4 PBRERs**

Adulterated Health Products

- **6 risk assessments** were conducted on adulterated products detected through post-marketing surveillance

Subsequently, press releases were issued to warn the public about these products.

ADVISORIES ISSUED

- Issued 12 press releases, covering safety advisories on 16 products
- Reviewed 9 company DHCPLs
- Issued 2 DHCPLs
- Disseminated 3 HSA ADR news bulletins to registered healthcare professionals
- Published 3 Safety Updates on the HSA website

MEDICAL DEVICE POST-MARKET SURVEILLANCE AND VIGILANCE SYSTEM

ADVERSE EVENTS

In FY22/23, a total of **702** AEs were reported locally.

The top 3 medical specialty areas were:

Cardiovascular:
319
Devices under this specialty include implantable cardioverter-defibrillators/pacemakers and cardiovascular stents

General Hospital:
113
Devices under this specialty include infusion pumps, patient monitors and ventilators

General and Plastic Surgery:
81
Devices under this specialty include breast implants, dermal fillers and surgical staplers

FIELD SAFETY CORRECTIVE ACTION (FSCA)

HSA also worked with companies to ensure that appropriate corrective and preventive actions were taken to ensure the safety and quality of current and future batches of medical devices.

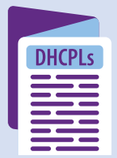
Total number of FSCAs
528

50 Recalls

192 Safety corrective actions

286 Dissemination of additional safety information

ADVISORIES ISSUED



DHCPLs
27

Safety alerts and updates
4

STREAMLINING OUR PROCESSES

By optimising our work processes, we can achieve higher efficiency and deliver greater value to stakeholders.

REGULATORY GUIDELINES AND FRAMEWORK (PRODUCTS)

Revised Guidelines for Standalone Medical Mobile Applications and Clinical Decision Support Software

We came up with new guidelines to provide clarity on:

- Risk classification of standalone medical mobile applications based on:
  - Significance of information provided to healthcare decision
  - State of healthcare situation or condition
- Qualification of Clinical Decision Support Software (CDSS) as a medical device

Guidelines for Software Medical Devices – A Life Cycle Approach

The guideline for software medical devices was refined to include evolving developments in cybersecurity considerations, software functionalities and artificial intelligence (AI) features.

Strengthening of Regulatory Oversight on High-risk Unregistered Medical Devices Intended for Local Clinical Use

The Special Access Routes (SAR) allow qualified practitioners and local medical facilities to bring in unregistered medical devices. As of April 2022, to further protect patient health and safety, applications from public healthcare institutions that have Class D implants and new technologies or state-of-the-art medical devices are now required to have their clinical justifications reviewed by the Ministry of Health.

Unique Device Identification (UDI) Framework

We published the 2nd edition of the UDI guideline, which included instructions (via video guide and FAQ) on how to submit UDI information for registered devices under MEDICS.

Subsequently, in November 2022, Singapore implemented Phase 1 of the UDI framework, which seeks to enhance patient safety by increasing the efficiency of tracking and identifying high-risk implantable medical devices such as coronary stents, orthopaedic joint replacement implants and intraocular lenses.

Regulatory Guidelines for Laboratory Developed Tests (LDTs)

We published new guidelines to provide an overview of the scope of LDTs and the regulatory requirements for local clinical laboratories, covering product, quality and post-market controls.

More Seamless Change Notification (CN) Submission Process in MEDICS

To make the MEDICS CN submission process more seamless, a separate Safety and Performance declaration documentation is no longer required for submissions from March 2023.

REGULATORY GUIDELINES AND FRAMEWORK (DEALERS)

Reverting to Standard Regulatory Controls

At the start of the COVID-19 pandemic, we implemented an Exemption Order to allow access to low-risk medical devices such as surgical masks. As Singapore embarked on the endemic phase, we revoked the Order and resumed standard regulatory controls.

New Approach for Local Standalone Dental Laboratories

We adopted a simplified risk-calibrated approach that continues to ensure quality oversight for dental laboratories that manufacture custom-made Class A or Class B dental devices. As of January 2023, manufacturers of these low-moderate risk custom-made devices no longer require HSA Manufacturer's Licences, and will only be required to:

- Have a Quality Management System in place for their manufacturing site (no certification required)
- Submit a notification to HSA on their activities (no fees imposed)

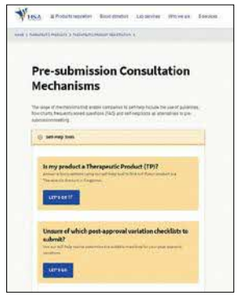
TECHNOLOGY AND INFRASTRUCTURE

We constantly adopt new technologies to improve our service and enhance our overall productivity.

PRE-SUBMISSION CONSULTATION MECHANISMS

We added the following industry self-help mechanisms on our website:

- Therapeutic Product Classification Tool and Post-approval Variation Classification Tool
- Guidance for Therapeutic Products Registration
- Frequently Asked Questions (FAQs)



If specific issues cannot be addressed by the self-help mechanisms, procedures for email or meeting consultations are available.

ENHANCING REGULATORY TRANSPARENCY BY PUBLISHING REGULATORY ACTIONS

We published a comprehensive range of information on regulatory actions relating to therapeutic products on our website to enhance transparency and accessibility to regulatory updates. Actions covered include New Approvals, Reclassifications, Transfers and Cancellation of Product Registrations, and Product Recalls.

AUTOMATING THE APPLICATION AND PROCESSING OF FREE SALE CERTIFICATES FOR MEDICINAL PRODUCTS

Previously, requests from companies for free sale documentation as evidence of their regulatory status for exempted medicinal products were received via email and manually processed.

In March 2023, to improve efficiency, we set up a new end-to-end digital process leveraging technological tools such as FormSG and GovTech (Digital) Workflow to streamline the internal processing and facilitate communication across branches for product verification.

Industry stakeholders can now enjoy a more expedient application process for export of such medicinal products by following a set of simplified instructions on FormSG.

ENHANCED SURVEILLANCE AND MANAGEMENT OF THERAPEUTIC PRODUCT DEFECTS USING DIGITAL TOOLS

We developed and implemented digital tools for managing therapeutic product defects:

- An automated web-scraping programme that uses machine learning to extract alerts relating to product defects and recalls from overseas drug regulatory agency websites
- A filtering algorithm based on machine learning and keyword-based approach to identify alerts relating to substandard medicines
- A combined machine learning algorithm with keyword-based model to classify quality issues using text relating to substandard medicines *(CISTERM)*
- A risk classification model for prioritising management of product defects (Regulatory Risk Impact Prioritisation Model for Product Defects – *RISMED and stat-RISMED*)

We shared our experience at the following local and international conferences:

- **July 2022** – Singapore Pharmacy Congress
- **November 2022** – 11th Asia Regulatory Conference
- **February 2023** – DIA Middle East Conference

SHARING OUR KNOWLEDGE

We strive to raise the overall standard of health products regulation in Singapore through continuous knowledge sharing.

GUIDANCE FOR LOCAL RETAIL PHARMACIES

In August 2022, we published a set of FAQs for e-pharmacy operators on our webpage. The FAQs assist the industry in understanding the regulatory requirements when setting up an e-pharmacy service, including the need for a closed loop computerised system to ensure proper transmission of information from the prescriber to the e-pharmacy.

STAKEHOLDER ENGAGEMENT SESSION ON NEW ACTIVE PHARMACEUTICAL INGREDIENTS (API) REGULATIONS

In March 2023, we held industry stakeholders' engagement sessions to share updates on the new regulations for API, including the transition approach for existing API manufacturers and dealers.

At the sessions, stakeholders were able to provide feedback on issues such as the helpfulness of the proposed API licensing regime towards managing manufacturing risk, and dealing with API.

PHARMACOVIGILANCE AND MEDICAL DEVICES EDUCATION INITIATIVES

We collaborated actively with local and international working groups and organisations.

- **September 2022** – Facilitated group discussions on the Fundamentals of Health Products Regulation for Graduate Certificate in Health Products Regulation, Duke-NUS CoRE
- **September 2022** – Engaged professionals on "Translating Regulatory Agility into Actions in a Post Pandemic APAC" at the APACMED MedTech Forum
- **October 2022** – Represented in panel for the CoRE Annual Scientific Conference, in the session "Communication in Safety and Healthcare Delivery"
- **November 2022** – Facilitated discussions on the Regulation of IVD Devices for Executive Certificate and Graduate Certificate in Health Products Regulation, Duke-NUS CoRE
- **November 2022** – Engaged professionals on "Navigating the Pathway to Commercialisation" at the AI Health Summit, Singapore
- **November 2022** – Engaged healthcare professionals on "Safety assessment of COVID-19 vaccines and ART kits" during a toxicology webinar organised by the Toxicology Society of Singapore (TOXSSIN)
- **February 2023** – Engaged healthcare professionals on "Detection of adulterants in complementary health products" during an annual scientific meeting organised by the Society for Emergency Medicine Singapore (SEMS)

SUSTAINING EDUCATIONAL OUTREACH TO SINGHEALTH PROFESSIONALS THROUGH DIGITALISATION

In July 2022, we collaborated with SingHealth Pharmacy & Therapeutics Council Office to reach out to healthcare professionals for continuous education. This comprised a virtual lecture for healthcare professionals on the importance of pharmacovigilance and AE reporting, and the development of an e-module on AE reporting in SingHealth's e-learning system.

The lecture was attended by:

280 participants coming from **4 hospitals, 5 specialist centres, 3 community hospitals and 9 polyclinics.**

INTERNATIONAL COLLABORATIONS

Beyond our shores, we also collaborated with global counterparts to widen our knowledge base.

INTERNATIONAL MEDICAL DEVICE REGULATORS FORUM (IMDRF)

AE Working Group

In the second year as Chair of the IMDRF AE Terminology Maintenance Working Group, we continued to improve, harmonise and expand the terminology used to code information relating to medical device AEs.

Good Regulatory Review Practices (GRRP) Working Group

The GRRP Working Group develops good review practices for regulatory authorities and their conformity assessment bodies. As co-chair, we reviewed and published a report relating to preparing medical device regulatory review reports, such as the collection of key information and documents that can improve the pre-marketing review process.

RECOGNISED BY AUSTRALIA AS A COMPARABLE OVERSEAS REGULATOR (COR) FOR MEDICAL DEVICES

In September 2022, Australia's Therapeutic Goods Administration (TGA) recognised HSA as a COR for the review of medical devices. With this recognition, companies can leverage HSA's medical devices approvals for faster entry into Australia. Singapore joins the European Union, United States of America, Canada and Japan as one of five listed TGA COR regulators.

GLOBAL HARMONIZATION WORKING PARTY MEETING

In February 2023, we were invited to speak at the 26th Annual Meeting on "Benefits of Regulatory Reliance". We shared with fellow regulators and regulatory professionals about our experience in regulatory reliance (using WHO's Good Reliance Practice model), steps towards regulatory convergence and resource optimisation.

ASEAN JOINT SECTORAL COMMITTEE ON GMP (GOOD MANUFACTURING PRACTICES) INSPECTION OF MANUFACTURERS OF MEDICINAL PRODUCTS MUTUAL RECOGNITION AGREEMENT (JSC GMP MRA)

In November 2022, we were appointed as Vice Chair of the ASEAN JSC GMP MRA. A key focus area of this committee is on expanding the scope of MRA beyond pharmaceutical products in finished dosage form to include biopharmaceuticals and APIs.

PROJECT ORBIS

We continued our collaborations with US FDA Oncology Centre of Excellence (OCE), ANVISA, Health Canada, Israel Ministry of Health, Swissmedic, TGA and UK MHRA through Project Orbis. Project Orbis provides a framework for concurrent submission and review of oncology products among international regulatory health authorities.

Over the past year, HSA has issued regulatory approvals for **10 applications** through Project Orbis.

ACCESS CONSORTIUM

Access Consortium is a coalition of regulatory authorities that aim to provide patients with timely access to high quality, safe and effective therapeutic products in the member countries.

Providing Timely Access to Safe and Efficacious Therapeutic Products

Over the past year, HSA has completed six therapeutic products applications through Access Consortium.

Collaborations to Assess New COVID-19 Safety Issues

As part of our COVID-19 safety monitoring efforts on vaccines and therapeutics, we actively collaborated with Access Consortium COVID-19 Vaccine & Therapeutics Working Group via participation in the Pharmacovigilance Subgroup Meetings.

Statement on GMP Inspections Reliance and Recognition

A collective statement was issued by the Access Heads of Agencies to solidify the Consortium's commitment to demonstrate greater inspection reliance and acceptance of one another's GMP inspection outcomes.

By relying on the review of inspection reports for GMP inspections conducted by Access members within their territories, it reduces the regulatory burden on stakeholders, and facilitates consumer access to high-quality, safe and effective pharmaceutical products.

HSA RECOGNISED BY WHO AS A STRINGENT REGULATORY AUTHORITY (SRA)

HSA has been recognised by the World Health Organization (WHO) as an SRA for high risk in vitro diagnostic medical devices (IVDs). With this recognition, any high risk (Class C or Class D) IVD registered with HSA will qualify for the abridged prequalification assessment by WHO. Manufacturers of such IVDs can now leverage HSA's SRA status to obtain expedited listing under the WHO prequalification programme, and gain access to various markets beyond Singapore. This recognition places Singapore alongside the United States of America, European Union, Canada, Australia and Japan as one of the six WHO SRAs for IVDs.

OUR INVOLVEMENT IN PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME (PIC/S)

Joint PIC/S-EMA-WHO Working Group

HSA participated in the Joint PIC/S-EMA-WHO Working Group on Revised Annex 1 GMP Guide on the manufacture of sterile products which will enter into force in August 2023.

What the Future Holds for Industry and PIC/S

In October 2022, we chaired Session 3 of the 50th Anniversary Symposium. This session consisted of two presentations followed by a panel discussion on "Ensuring GMP inspections are fit for purpose in the 21st Century".

Co-ordinating Committee of the PIC/S Expert Circle on GDP

We were involved in developing the PIC/S Aide-Memoire on the "Inspection of Good Distribution Practice (GDP) for Medicinal Products in the Supply Chain", and the Q&A document regarding the PIC/S GDP Guide. Both documents were published in February 2023.

COLLABORATION WITH HUNGARIAN SUPERVISORY AUTHORITY FOR REGULATORY AFFAIRS (SARA)

In March 2023, HSA hosted Dr Marcell Bíró, Chairman of SARA, together with Her Excellency Ms Judit Pach, Ambassador of Hungary to Singapore. During the meeting, we talked about collaborations with SARA to foster two-way cooperation and sharing of best practices on tobacco control.

NEW AWARDS AND ACCREDITATIONS

We received the following awards and achievements for our commitment to serving the public and stakeholders.

PUBLIC SECTOR TRANSFORMATION (PST) AWARDS 2022

The PST Awards is a Whole-of-Government (WOG) pinnacle platform to recognise and reward public officers and public agencies for excellence in their work and organisational practices.

This year, we were awarded:

The **Dare to Do Award**, for HSA's contribution, alongside A*STAR, to the assay development of COVID-19 vaccines.

The **Exemplary Leader Award**, for Group Director of the Health Products Regulation Group, Associate Professor Chan Cheng Leng's outstanding leadership in driving excellence, innovation and agility in health products regulation.

RE-CERTIFICATION OF ISO 9001:2015

In March 2023, the Enforcement Branch (EB), Vigilance & Compliance Branch (VCB) and Tobacco Regulation Branch (TRB) successfully completed the re-certification audit, a testament to our commitment to high standards.

OPENGOV ASIA RECOGNITION OF EXCELLENCE AWARD 2023

HSA's VCB and Integrated Health Information Systems jointly received this award for building ASAR in Singapore. Specifically, their efforts included enhancing the AE monitoring programme for COVID-19 vaccines, and shifting pharmacovigilance in Singapore towards a significantly more proactive paradigm.

EB AND TRB WERE RECOGNISED FOR THEIR EFFORTS WITH THE FOLLOWING AWARDS:

- **Ministry of Home Affairs (MHA) Team Award**
- **Community Policing Appreciation (CPA) Award**
- **Certificate of Appreciation by Minister of Home Affairs & Law**

MHA OPERATIONAL EXCELLENCE AWARD

In January 2023, TRB together with ICA were awarded:

3 MHA Operational Excellence awards.

This was for their efforts in detecting substantial amounts of chewing tobacco and e-vaporisers and their components at the checkpoints.

MINISTRY OF MANPOWER (MOM) CERTIFICATE OF APPRECIATION

In March 2023, TRB was awarded the MOM Certificate of Appreciation for its participation in International Migrants Day.

KEEPING PACE
WITH THE LATEST IN

BLOOD SERVICES

Blood Services Group

We are committed to improving efficiency and donor experience, whilst maintaining the safety of our nation's blood supply.

KNOWLEDGE AND INNOVATION

We strive to maintain world-class blood services by strengthening our knowledge base and utilising innovation.

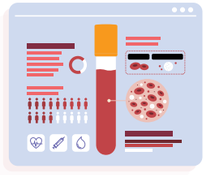
LEVERAGING DATA FOR BLOOD COLLECTION ANALYSIS AND PERFORMANCE OPTIMISATION

Footfall Analysis for New Bloodbank

Last year, we analysed footfall data to optimise opening hours and closure days for the upcoming Bloodbank@One Punggol. The use of data analytics proved to be a much more efficient approach than manually compiling data from surveys, which would have required significant expenditure on manpower and resources.

Supporting Decision-making and Performance Reporting

Starting from February 2023, we made use of Tableau to generate our blood collection data analysis report. The data available on the resulting interactive dashboard helps our Tableau data stewards to periodically evaluate and update blood collection and performance data, thereby supporting decision-making at the operations level. The performance reports also assist us in communicating relevant information to management and stakeholders.



IMPROVING SURVIVAL IN HAEMATOPOIETIC STEM CELL TRANSPLANT WITH KIR AND HLA GENOTYPING USING RT-PCR

Our Tissue Typing and Platelet Reference Laboratory supports physicians conducting haematopoietic stem cell transplant. We achieve this by performing Human Leukocyte Antigen (HLA) and killer-cell immunoglobulin-like receptor (KIR) genotyping, which are vital for a successful transplant.

If a full HLA-matched donor is not feasible, physicians may consider haplo-identical transplants. KIR genotyping helps to identify the most suitable donor, which improves the survival rates for HLA-haploidentical haematopoietic stem cell transplants.

Our Real-time Polymerase Chain Reaction (RT-PCR) methodology combines the ability to test in batch or individual samples with the assurance of timely results reporting.

TECHNOLOGY AND INFRASTRUCTURE

We embrace technology that helps us to raise efficiency in our work processes.

NEW FEATURES IN OUR DONATEBLOOD APP

January 2022:
Recruitment module was upgraded

We added an advanced search feature to identify and assign donor lists to tele-recruiters from the Blood Donor Programme. The new upgrade also allows staff to key in tele-recruitment related information and generate reports for data analysis.

May 2022:
Faster and more seamless log-ins

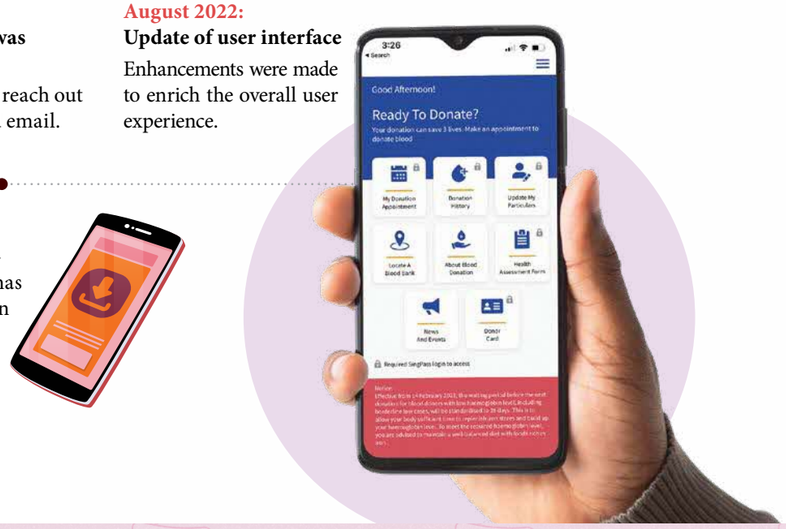
Staff can now log in easily and securely to the DonateBlood intranet system using the Whole-of-Government Active Directory authentication.

November 2022:
Mass notification feature was introduced

It enables staff to efficiently reach out to donors through SMS and email.

August 2022:
Update of user interface

Enhancements were made to enrich the overall user experience.



As of March 2023, our well-received DonateBlood app has been downloaded more than **39,000 times**.

IMPLEMENTING RFID IN OUR NATIONAL BLOOD PROGRAMME

In February 2023, we implemented real-time location tracking of blood and blood products by incorporating RFID chips in our blood labels. This transformation initiative significantly improves inventory management and reduces the time taken to retrieve blood products for distribution to hospitals.

PRIORITISATION OF BLOOD USAGE DURING NATIONAL BLOOD INVENTORY SHORTAGES

We developed an action plan last year to prioritise the usage of red cells and platelets based on patients' medical conditions and urgency of surgeries. This plan will enable clear communication to hospitals on which patient groups will receive priority for blood transfusions during blood shortages. The plan will also allow hospitals to better manage and prioritise medical procedures.

EVALUATION OF AUTOMATED SYSTEM FOR ANTIBODY IDENTIFICATION AND PHENOTYPING

Antibody identification result interpretation is mostly a manual process which requires a certain level of expertise for interpretation.

We will be implementing two automated systems to improve the process to make it more reliable. The adoption of these automated systems allows us to optimise our workforce by reallocating staff to other areas of need.

PEOPLE AND VALUES

Our people are the cornerstone of our organisation. Hence, we are committed to investing in their growth and development to help them realise their full potential.

CERTIFIED ON-THE-JOB TRAINING (OJT) CENTRE BY INSTITUTE OF TECHNICAL EDUCATION (ITE)

In August 2022, we successfully obtained the Certified OJT Centre accreditation by ITE. In this accreditation exercise, the Blood Services Group and HSA's Human Capital Management department developed the OJT blueprint that outlined the training requirements, skills and knowledge, and standards. The blueprint also included training guides, processes, and a structure to facilitate a more hands-on OJT learning approach.

As a certified OJT provider, we can award our staff an e-certificate when they complete their OJT module. This programme seeks to recognise our staff while motivating our trainers to develop better OJT modules.

NEW LOCAL PARTNERSHIPS

We continued to build capabilities by forging new partnerships locally.

Manufacturing In-house CAR-T Products

In July 2022, we collaborated with clinicians from KK Women's and Children's Hospital and Singapore General Hospital to use our Cell & Gene Therapy Facility as a manufacturing site for various CAR-T products.

Our in-house CAR-T products were employed in clinical trials, providing innovative and more affordable salvage therapy for patients with haematological malignancies such as lymphoma and leukaemia, who are unresponsive to conventional chemotherapy treatment.

NEW OVERSEAS PARTNERSHIPS

We collaborated with overseas counterparts, exchanging experience and knowledge to enhance our capabilities.

May 2022: In collaboration with SCG Cell Therapy Pte Ltd, we successfully completed the validation for the generation of a genetically modified cell product, SCG 101. The validation of SCG 101 processes was performed at our Good Manufacturing Practice (GMP)-certified facility in accordance with GMP requirements.

This has led to the commencement of Phase I clinical trial for treating patients with Hepatitis B virus-related Hepatocellular Carcinoma.

September 2022: We partnered with University of Hong Kong (HKU) and partner hospitals (Prince of Wales Hospital and Queen Elizabeth Hospital) to develop an implantable tissue engineered structure for autologous knee repair.

October 2022: We welcomed visitors from the Malaysia Transplant Programme to our laboratories. Together with the Singapore General Hospital Transplant Team, we are helping them to establish their National Transplant Programme.

AWARDS AND ACCREDITATIONS

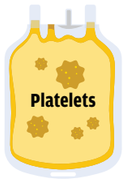
The efforts of our Blood Services Group were validated through the following awards and accreditations in FY22/23.

AWARDED DEFENCE TECHNOLOGY PRIZE FOR BREAKTHROUGH METHOD TO PRESERVE PLATELETS

In October 2022, HSA, DSO National Laboratory, Singapore Armed Forces Army Medical Service and Singapore General Hospital, jointly received MINDEF's most prestigious defence technology award, the Defence Technology Prize.

This award was given in recognition of our joint work to extend the shelf life of platelets through a cryopreservation technique. Through this breakthrough, we will be able to achieve a more stable supply of platelets to be used by patients with massive bleeding, or patients who suffer from low platelet counts due to various medical reasons. This is especially critical for stockpiling of platelets for civil emergencies and to meet the special clinical requirements of patients who need specific types of platelets.

The team successfully extended the shelf life of platelets from **7 days to 2 years**.



GOOD MANUFACTURING PRACTICES (GMP) CERTIFICATION

Our Gene Therapy Facility successfully achieved GMP certification while our Cell Therapy Facility renewed its certification last year. The facility was audited based on HSA's new guidelines for Cell, Tissue and Gene Therapy products.

NURSES' MERIT AWARD 2022

Ms Joanna Hiok, Senior Staff Nurse at Blood Resources, received the Nurses' Merit Award for exceptional performance and contribution to nursing.

It was awarded to 125 nurses by Minister for Health, Mr Ong Ye Kung in July 2022.

NATIONAL AWARDS (COVID-19)

Ms Noorhayati Rahamat, Blood Resources' Head of Planning & Controls was honoured with the Commendation Medal for her outstanding contributions.

The award ceremony recognised individuals and teams that made significant contributions in the fight against the COVID-19 pandemic.

SINGAPORE HEALTH QUALITY SERVICE AWARDS 2023

The Singapore Health Quality Service Awards (SHQSA) Ceremony was held in February 2023 at the University Cultural Centre, with President Halimah Yacob as the Guest of Honour.

SHQSA is Singapore's first dedicated platform for honouring outstanding healthcare professionals who have delivered quality care and excellent service to patients and the public.

We took home **two Gold Awards and five Silver Awards**.

RIDING THE WAVE OF PROGRESS

Applied Sciences Group

Our innovative and technology-driven outlook has enabled us to stay agile to enhance our techniques and capabilities.

KNOWLEDGE AND INNOVATION

We are constantly developing new capabilities and techniques to better serve our stakeholders.

QUALITATIVE AND QUANTITATIVE ANALYSIS OF HYDROGEN PEROXIDE

Hydrogen peroxide (H_2O_2) solution is commonly used as an antiseptic solution and can be easily purchased from pharmacies. H_2O_2 solution with concentration of more than 20% weight in weight is regulated in Singapore.

We developed a workflow to screen for hydrogen peroxide using commercial test strips and Raman spectroscopy, and for quantitative analysis using titration methods adapted from the American Society for Testing and Materials. This workflow was successfully applied to real samples, demonstrating its feasibility to be used in laboratories for the purpose of regulating hydrogen peroxide in Singapore.

METHOD DEVELOPED FOR DETERMINING BOW DRAW WEIGHT

Under the current Arms and Explosives (Arms) Notification 2020, a bow with a draw weight of more than 27.215kg is classified as a controlled item in Singapore.

At the request of the Police Licensing & Regulatory Department, an in-house method was developed in October 2022 to measure and determine the draw weight and measurement uncertainties for two common types of bows – compound and non-compound bows.

PRESERVATION OF BODY TISSUE SAMPLES

In mass fatality incidents, proper preservation of bodily remains is critical for maximising DNA recovery for victim identification. We developed a method using common table salt as a preservative. This method allows for long-term body tissue preservation without refrigeration, while at the same time maintaining compatibility with existing DNA processing workflows.

The preservation technique was recognised at the annual INTERPOL Disaster Victim Identification (DVI) conference in Lyon, France. The Forensic Genetics Sub-working Group has also suggested that the technique be incorporated into the INTERPOL DVI guide.

NEW CAPABILITY FOR FUTURE PANDEMICS

We developed multiple Reverse Transcription (RT)-digital polymerase chain reaction (dPCR) assays for the quantification of SARS-CoV-2 RNA in copy-based units. It has traceability to the International System of Units, as well as superior precision and reproducibility as compared to RT-quantitative PCR. The knowledge gained from developing these RT-dPCR assays would enable us to offer External Quality Assessment Programmes and certified reference materials in future pandemics.

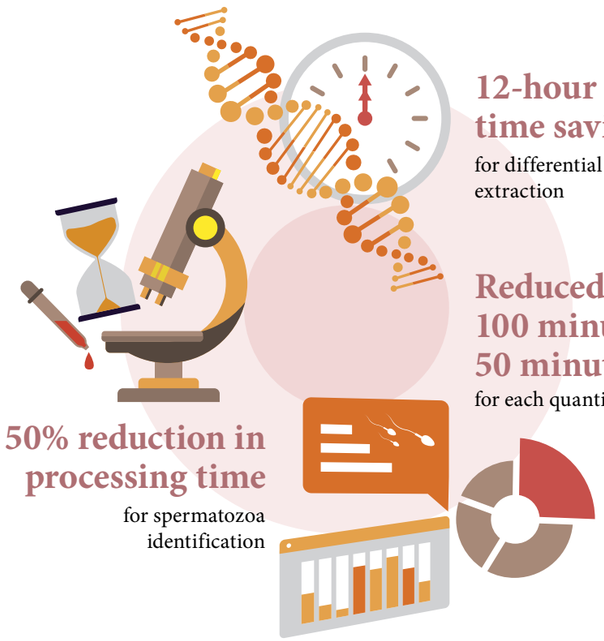
ENHANCING OUR EFFICIENCY

We leverage the latest in science and technology to ensure maximum efficiency.

ENHANCED PROCESSING OF SEXUAL OFFENCE SAMPLES

From 2015 to 2020, submissions of sexual offence samples increased by 370%. To manage the increased load, we optimised and re-engineered our work processes, which resulted in significant time savings.

These process improvements have enabled us to process samples within targeted turnaround times, without additional manpower or resources.



12-hour time savings
for differential DNA extraction

Reduced from 100 minutes to 50 minutes
for each quantitation assay

50% reduction in processing time
for spermatozoa identification

SEMI-AUTOMATION OF DNA QUANTITATION AND CAPILLARY ELECTROPHORESIS

DNA quantification and capillary electrophoresis are important processing steps that precede the generation of a DNA profile. To enhance laboratory productivity, we integrated the use of an automated liquid handling workstation to semi-automate the setting-up of these processes.

Consistent performance was achieved along with a

30-45% reduction in man-hours

ENHANCED SCREENING WITH ROBOTIC PROCESS AUTOMATION (RPA)

We introduced RPA to screen for adulterants in complementary health products. By using RPA to automate the inter-quality control assessment and reporting outcomes, we were able to enhance work efficiency and productivity. It minimises the need for staff oversight, and upkeeps the stringent quality in accordance with ISO/IEC 17025:2017 requirements.

AUTOMATED PROCESSING OF LOT RELEASE NOTIFICATION DATA FOR IMPORTED VACCINES

We developed a “Vaccine Lot Release Track” app to digitalise and automate the processing and management of lot release notification data submitted by companies for imported vaccines. The app alleviated laborious work processes, enabled traceability and improved overall work productivity. It also allowed us to conduct data analysis to analyse trends relating to lot release status.

OUR LOCAL COLLABORATIONS

We place great emphasis on forging strong partnerships with local organisations to add value and build synergy.

SINGAPORE POLICE FORCE (SPF)

To enhance emergency preparedness for DVI in mass fatality incidents (MFI), we conducted workshops together with SPF on the application of DNA kinship analysis in DVI. Participants included the United Nations Peacekeeping Force (UNPKF), who perform policing duties in overseas peacekeeping missions.

We also conducted a table-top exercise with SPF in January 2023 where we shared our international knowledge and experience on MFI.

FORENSIC DIVISION OF SPF

In April 2022, we formed a Crime Scene Workgroup with SPF's Forensic Division, which would enable us to:

- Maximise DNA recovery of bloodstains at scenes
- Prioritise and triage case exhibits
- Reduce turnaround time by conducting joint examinations
- Streamline forensic examination involving multiple evidence types (e.g. DNA, fingerprints and trace materials) by having more frequent discussions on past scenes

SINGAPORE JUDICIAL COLLEGE AND THE ATTORNEY-GENERAL'S CHAMBERS (AGC)

We gave a series of lectures to the Singapore Judicial College and the AGC on DNA analysis, updates on the New Psychoactive Substances situation, different drug sampling approaches, evaluative reporting and holistic assessment of evidence.

SINGAPORE CIVIL DEFENCE FORCE (SCDF)

In April 2022, we held an exercise to share with SCDF the emergency response procedures for our Biosafety Level-4 Autopsy Suite – "Blue Box 2". Our objectives included:

- Allowing SCDF to familiarise themselves with Blue Box 2 should they need to perform emergency evacuation of staff who collapse in the facility
- Giving our staff a chance to practise emergency response procedures in a simulated emergency
- Ensuring our liaison processes are kept up-to-date

CLINICAL LABORATORIES

We collaborated with the National University Hospital, Ng Teng Fong General Hospital, Khoo Teck Puat Hospital and Parkway Laboratories to conduct an extensive commutability study on three new clinical certified reference materials (CRMs). These included:

- HRM-3007A: Creatinine, glucose, urea and uric acid in human serum
- HRM-3008A: Total cholesterol, HDL-cholesterol, LDL-cholesterol, and total glycerides in human serum
- HRM-3004A: Albumin and creatinine in human urine

The CRMs have been demonstrated to be closely similar to real patient samples on multiple mainframe analysers and are thus suited for use in calibration or as quality control for routine clinical assays.

INTERNATIONAL PARTNERSHIPS

We continued to work closely with our international partners to set best practices and produce reference standards for greater accuracy.

EUROPEAN NETWORK OF FORENSIC SCIENCE INSTITUTES (ENFSI)

March 2022: Actively participated in the revision of the ENFSI Guidelines for the training of staff in forensic DNA laboratories. The guidelines were successfully published for use by European forensic laboratories.

November 2022: As part of the ENFSI European Paint, Glass and Taggants Working Group, we worked on the revision of the Best Practice Manual for the Forensic Examination of Paint and its related guidelines.

ASIAN FORENSIC SCIENCES NETWORK (AFSN)

From 2019 to 2022, HSA served as the president of AFSN, implementing many initiatives and uniting member institutes to continue to advance amidst the challenges brought by the COVID-19 pandemic.

March 2022: Hosted a Journal Club for the AFSN Questioned Document Workgroup.

July 2022: We organised the first AFSN Bloodstain Pattern Analysis (BPA) collaborative exercise, and an online session on Chemical Analysis of Unknowns/Materials.

November 2022: Together with the local organising committee from the Indonesian National Police, we hosted the 14th Asian Forensic Sciences Network Annual Meeting & Symposium in Jakarta, Indonesia.

EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE (EDQM)

June 2022 – Official Medicines Control Laboratories (OMCL) Annual Meeting in Strasbourg, France

The 28th Annual Meeting of the European Network of OMCLs provided an effective platform for technical exchange and work-sharing, with the objective of maintaining coverage and depth of competence while remaining flexible and responsive in an evolving environment.

Attended by
>230 participants from
36 countries, representing
60 OMCLs and national competent authorities

March 2023 – European Committee for Cosmetic and Consumer Health Meeting, and Official Cosmetics Control Laboratories Meeting

The meetings covered recent technical advances and developments in cosmetic product testing.

ASEAN ACTIVITIES

3rd ASEAN Pharmaceutical Testing Laboratory Committee (APTLC) Meeting

November 2022 – We chaired the 3rd Virtual APTLC Meeting to discuss and revise the activities under the 5-year APTLC Work Programme, including:

- Conducting surveys on testing and training needs, proficiency testing and collaborative study needs
- Compilation of test methods and guidelines adopted by all ASEAN member states in 2023

ASEAN Reference Substances Project on Chlorpropamide

The ASEAN Reference Substance Project, establishes ASEAN secondary drug reference standards for use in ASEAN member countries.

Singapore led the establishment of an ASEAN Reference Substance (PARS) – Chlorpropamide, through an inter-laboratory collaborative study. Through this project, the inter-laboratory study of Lumefantrine PARS, led by Indonesia, was also completed.

ASEAN Cosmetics Testing Laboratory Committee (ACTLC)

In March 2023, we were tasked to conduct a technical training session on "sample preparation on spray-type aerosol cosmetic products" coordinated by the ASEAN Secretariat.

WORLD HEALTH ORGANIZATION (WHO)

We continued to actively support WHO activities under its Terms of Reference as its Collaborating Centre.

WHO Collaborating Centre for Drug Quality Assurance

Our Monograph Development Work for the International Pharmacopoeia included:

- On-going development of the draft monograph on 1-nitroso-4-methyl piperazine (MeNP) in Rifampicin products
- Supporting WHO to set up a test strategy, as well as evaluate an alternative high performance liquid chromatography (HPLC) methodology for the determination of diethylene glycol and ethylene glycol in liquid preparations for oral use
- Working on a draft monograph on Clofazimine, for inclusion into the International Pharmacopoeia

Meetings

- 56th Virtual WHO Expert Committee Meeting on Specifications for Pharmaceutical Preparations (April and May 2022)
- 4th Regional Forum of WHO Collaborating Centres in the Western Pacific (November 2022) in Siem Reap, Cambodia
- Hosted a WHO Collaborating Centres Meeting to explore new opportunities for better serving countries and regions, and increase the impact of the Centres' work, and held a training session to build technical capacity among WHO member states
- Hosted the 7th Plenary Meeting of WHO Tobacco Laboratory Network in Singapore

WHO Collaborating Centre for Tobacco Testing and Research

We were invited to lead a WHO Global Method Validation study on smokeless tobacco products. This effort culminated in the publication of three WHO Standard Operating Procedures (SOP) in April 2022. The SOPs fill a very important regulatory void, especially in countries where smokeless tobacco products are prevalent and regulated.

ASEAN REFERENCE MATERIAL NETWORK (ARMN) PROFICIENCY TESTING AND OUTREACH

In April 2022, ARMN metrology institutes co-organised a virtual forum-discussion session to conclude the joint Proficiency Testing (PT) programme on Toxic Elements in Lipstick Material.

The material was converted into the first cosmetic reference material produced as a joint effort between ARMN institutes.

INTERNATIONAL PILOT STUDY ON HBA1C MEASUREMENT

Together with national metrology institutes in China, France and Republic of Korea, we initiated the first international pilot study on HbA1c measurement based on the isotope dilution mass spectrometry reference method. Our involvement included providing participating metrology institutes with purified signature hexapeptides as calibrators for the measurements.

PROVIDING DRUG-RELATED TRAINING FOR INTERNATIONAL COUNTERPARTS

We conducted training programmes for foreign officials from 17 countries to share on Singapore's comprehensive drug control strategies, drug analysis methodologies and to provide a platform for participants to share and exchange best practices.

- **July 2022 & February 2023:** Virtual trainings on drug analysis and identification for law enforcement officers and forensic practitioners from African countries
- **October 2022:** Laboratory visit from law enforcement officers from African, East and Southeast Asian countries

INTERNATIONAL ENGAGEMENTS

APEC Project SCSC-01 2021, Building Laboratory Capabilities to Assure Water Quality in Asia Pacific Economies

March 2022 & March 2023: This project saw us joining metrology institutes and accreditation bodies to co-organise two workshops aimed at building laboratory capabilities in the measurement of water quality in Asia Pacific economies.

Visit to the National Board of Forensic Medicine & National Forensic Centre in Linköping, Sweden

May-June 2022: The deep insights gained from visiting the DNA section of the Swedish forensic laboratories in Linköping, has provided ideas for implementation here.

International Society for Forensic Genetics (ISFG) Conference

August-September 2022: Invited as a panelist to share on our approaches to dealing with mixture profiles from high volume crimes, Y chromosomal testing, and activity level reporting.

9th International Conference on New Psychoactive Substances (NPS)

October 2022: Invited by the International Society for the Study of Emerging Drugs (ISSED) to share our workflow and strategies for identification of NPS.

Training on General Requirements for the Competence of Reference Material Producers (ISO 17034:2016)

November 2022: Co-conducted a virtual training on ISO 17034:2016 together with the National Institute of Metrology, Thailand and Department of Science Service, Thailand.

20th Standing Committee Meeting of Western Pacific Regional Forum for the Harmonization of Herbal Medicines (FHH)

February 2023: Two of our scientists presented on determination and analysis of substances using mass spectrometry.

9th FHH International Symposium

February 2023: The meeting and symposium covered topics relating to the regulation of Chinese medicines, Chinese proprietary medicines, updates on pre- and post-market activities, risk management strategies for new traditional Chinese medicine safety, and quality control and test method development for herbal drugs.

SHARING OUR EXPERTISE

In the spirit of learning and fostering closer professional ties, we endeavour to share our knowledge and experience with counterparts both locally and overseas.

INVITATIONS TO CONDUCT PEER REVIEWS AND TECHNICAL ASSESSMENTS

HSA was invited by established metrology institutes, the Korea Research Institute of Standards and Science, and the Government Laboratory (Hong Kong, China) to conduct peer reviews.

These reviews were done following the requirements of the International Committee for Weights and Measures Mutual Recognition Arrangement (CIPM MRA).

We were also invited by Australia's National Association of Testing Authorities to conduct technical assessments for its national metrology institute, the National Measurement Institute.

REVISION OF SINGAPORE ACCREDITATION COUNCIL (SAC) TECHNICAL GUIDE

We provided our expertise towards the major revision of the *SAC Technical Guide 2: A Guide on Measurement Uncertainty in Chemical & Microbiological Analysis*. The guide provides clear guidance and updated examples on the evaluation of measurement uncertainty (required under ISO/IEC 17025).

PARTNERING WITH UNODC ON CANNABIS ANALYSIS

We contributed to the revised manual, *Recommended Methods for the Identification & Analysis of Cannabis and Cannabis products*, which was published by the United Nations Office on Drugs and Crime (UNODC) in March 2022.

SUPPORTING SINGAPORE'S BUNKERING SECTOR

HSA was a member of an industry expert group co-chaired by the Maritime and Port Authority of Singapore (MPA) and the Singapore Shipping Association (SSA) to strengthen fuel quality assurance measures and to establish a comprehensive list of chemical compounds to be tested.

In April 2022, together with representatives from MPA and marine offshore testing bodies, we conducted a technical workshop on organic contaminants in marine fuel oil.

The workshop was attended by **50 representatives** from **15 fuel oil testing laboratories** in Singapore.

HYBRID EXTERNAL QUALITY ASSESSMENT (EQA) PROGRAMME SYMPOSIUM

The symposium saw staff from local clinical laboratories and clinics discussing the results of a voluntary programme in clinical chemistry comprising 17 clinical makers, and the national programme for HbA1c testing.

BENCHMARKING OF MEASUREMENT CAPABILITIES

Benchmarking plays an important role in ensuring the reliability of our measurement results.

BENCHMARK COMPARATIVE STUDY ON UNKNOWN PHARMACEUTICAL PRODUCT

In a comparative study organised by European Directorate for the Quality of Medicines & Healthcare (EDQM), we successfully identified controlled drug methylcodeine as the unknown ingredient of the product provided. The study outcome reaffirms our proficiency in structural elucidation of unknown chemical substances.

The study comprised
26 members
from the General European Official Medicine Control Laboratories Network (GEON).

PROFICIENCY TESTING (PT) SCHEME STUDIES

We achieved excellent results in the following benchmark PT programmes:

Pharmaceutical Laboratory

- Screening and quantitation of suspicious unknown Active Pharmaceutical Ingredients by European Directorate for the Quality of Medicines & HealthCare (EDQM)
- Assay of Cimetidine tablets by UV-VIS Spectrophotometry by Bureau of Drug & Narcotic (BDN)
- Assay of Atenolol Tablets by Liquid Chromatography by EDQM
- Determination of N-nitroso-dimethylamine (NDMA) in valsartan tablets by liquid chromatography tandem mass spectrometry by EDQM
- Assay of Heavy metals by inductively-coupled plasma mass spectrometry (ICP-MS) by Laboratory of the Government Chemist (LGC)
- Assay of Cannabidiol by Liquid Chromatography by LGC
- Assay of Sildenafil in Supplements by Liquid Chromatography by LGC
- Potentiometric determination of pH in Ciprofloxacin injection by BDN

Cosmetics Laboratory

- Identification of Hydroquinone, Mercury Compounds and Retinoic Acid in cream by Liquid Chromatography ICP-MS by ASEAN

Cigarette Testing Laboratory

- Assay of Nicotine, Propylene Glycol, Glycerol in e-Liquids by Gas Chromatography with flame ionisation detection (GC-FID) by Laboratory of the Government Chemist (LGC)

AWARDS AND ACHIEVEMENTS

Our awards and achievements reflect our commitment to excellence.

PHARMACEUTICAL DIVISION (PD)

ISO/IEC 17025:2017 Assessment

PD achieved full compliance to ISO/IEC 17025:2017 in its Singapore Accreditation Council (SAC) SINGLAS renewal assessment. In this latest assessment, the laboratory expanded its scope of accreditation to include three new tests: (1) Identification of common drugs by LTQ XL Linear Ion Trap Mass Spectrometry, (2) Identification of common drugs by LC-HRMS and (3) Identification of Artemisinin in health products by LC-MS/MS.

In recognition for PD's consistent performance and demonstration of excellence in Quality Management System, they were granted Extended Surveillance. This means that the labs will only be assessed by SAC SINGLAS every one-and-a-half years.

CHEMICAL METROLOGY LABORATORY (CML)

ISO/IEC 17025:2017 and ISO 17034:2016 Peer Review

In February and March 2023, CML successfully completed a remote peer review by SAC, as well as an on-site peer review by a team of experts from the international chemical metrology community.

Accreditation as a Proficiency Testing (PT) Provider

In April 2022, CML also completed a surveillance assessment by SAC and maintained its accreditation as a PT/External Quality Assessment (EQA) Provider in accordance with the requirements of ISO/IEC 17043:2010. CML remains the only SAC-accredited Provider of PT/EQA Programmes in 2022.

CROSS-AGENCY PUBLIC SECTOR TRANSFORMATION AWARD

In July 2022, the HSA Biologics Team and Bioprocessing Technology Institute (BTI) Project Team jointly won the "Dare to Do Award" (Public Service Transformation Awards) for their Rapid Development and Implementation of COVID-19 Vaccine Lot Release Testing Platform.

They overcame extreme challenges and successfully developed assays for certain COVID-19 vaccines at an unprecedented pace. This experience is invaluable to building up Singapore's resilience in the fight against COVID-19 and future diseases.

NATIONAL COVID-19 AWARDS

- Dr Paul Chui – Public Administration Medal (Silver) (COVID-19)
- Dr Lee Chin Thye and Dr Wu Jia Hao – Public Administration Medal (Bronze) (COVID-19)
- Mr Abdul Kalai Mony, Mr Ravi Subramaniyan and Mr Sevugan Subbiah – Commendation Medal (COVID-19)
- Forensic Medicine Division – President's Certificate of Commendation (COVID-19)

ROCHE LABORATORY MEDICINE (TECHNICAL) AWARD BY SINGAPORE SOCIETY OF PATHOLOGY

Mr Balakrishnan Periathamby Nagan was awarded the Roche Technical Award 2022, for his significant contributions to the practice of pathology.

GEARING UP FOR GREATER PRODUCTIVITY

Corporate Services Group

We continue to adapt and innovate in the fast-evolving world to bring forth greater efficiency.

CELEBRATING OUR ACHIEVEMENTS

In recognition of our commitment to safeguarding public health, we received numerous awards during the year-in-review.

WINNING AWARDS FOR SERVICE EXCELLENCE

HSA won several awards for excellent service to customers and stakeholders, leadership and assay development of COVID-19 vaccines. The Corporate Services Group managed the administration for the following awards by shortlisting, collating and submitting the nominations.

Public Sector Transformation Awards 2022
2 Awards

Singapore Health Quality Service Awards 2023
2 Gold and
7 Silver Awards

HSA Outstanding Service to Customers Award (OSCA) 2022

Staff across the various HSA Groups have won the OSCA 2022, which will be presented during the National Day Observance Ceremony in August 2023.

PEOPLE AND VALUES

As one big family, we are committed to caring for each other and engaging the community around us.

HSA WELLNESS DAY

HSA's Wellness Day, which fell on 27 October 2022, aimed to create awareness and strengthen the support of mental well-being among HSAians.

Revolving around the theme of self-care, activities at the event included:

1. Workshop on Mindfulness for Self-care

2. Fun Walk in Support of the Purple Parade

3. Chit-chat Session with HSA Wellness Ambassador

A series of pre-event initiatives were also organised in the month of October. These included:

- Masterclass on Mindful Compassion Art Therapy
- Sharing by the senior management on personal self-care tips
- Staff appreciation through distribution of handwritten cards and snack packs by directors and supervisors

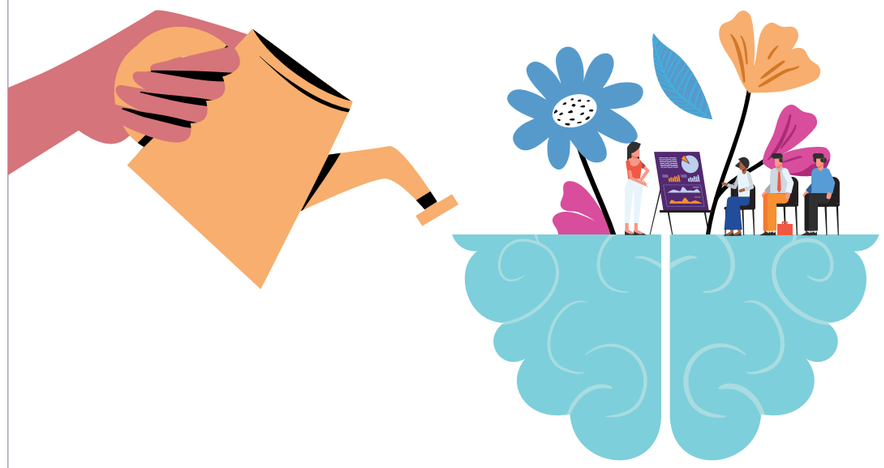
WECARE INITIATIVES

HSA continued to strengthen the emotional well-being of our staff through a series of WeCARE initiatives that seek to create a more caring culture, as well as build a healthier and more resilient HSA. These initiatives included workshops on mental health and wellness, and appointing Wellness Ambassadors (WA) to facilitate staff outreach as well as to provide basic mental and emotional support.

11 masterclasses and workshops
were conducted on topics such as Mental Health First Aid, Finding Your Ikigai, Power of Likeability and Wellness in Transition for Supervisors

Close to **500 staff**
attended these sessions

Our expanded WA Network now consists of
10 ambassadors
across the four Professional Groups



CORPORATE SOCIAL RESPONSIBILITY (CSR) ACTIVITIES – HSA CARES

At HSA, our commitment towards the needy and the environment is expressed through our Corporate Social Responsibility (CSR) Framework called **CARE** – "**C**ommunity **A**ction, **R**esponsible for our **E**nvironment". Through active volunteerism in CSR initiatives over the years, our staff have developed skills in helping the needy, as well as built up a sense of empathy and kindness to society.

Here are some of our CSR highlights for FY22/23:

MOH-HPB-HSA Hair for Hope 2022

Since 2013, HSA has been an active supporter of "Hair for Hope", the Children's Cancer Foundation's flagship fundraiser programme. In June 2022, HSA joined efforts with our colleagues from the Ministry of Health (MOH) and Health Promotion Board (HPB) to hold a One-MOH Family Hair for Hope Satellite Event to raise awareness and funds.

23 volunteers
from MOH, HPB and HSA shaved their heads to show solidarity with children with cancer, and their families

Together as a One-MOH family, we raised a total of
$88,715

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 contribute to a good cause.

This was done through a special "Read for Books" charity initiative, which saw books being donated to the National Library Board's selected beneficiaries for 2022 – WondeRead and the Migrant Worker Library. For every **10 persons** that came together to read for **15 minutes, 1 book** was donated.

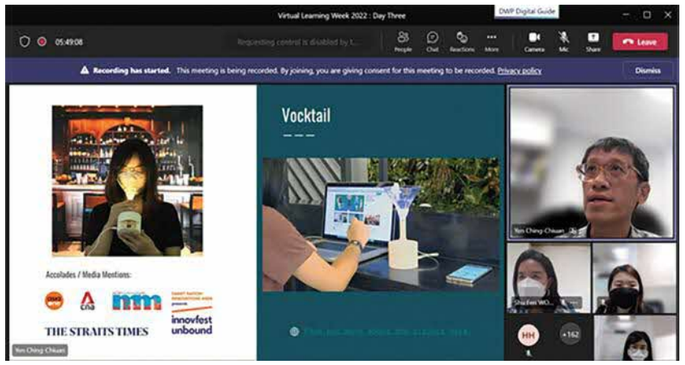
In August 2022,
1 onsite and **2 virtual reading sessions**
were held over lunchtime

68 staff
came together to support this meaningful initiative

DEVELOPING OUR PEOPLE

HSA places great emphasis on learning and innovation to equip our staff with relevant skills.

LEARNING IN HSA



Continuous learning is a key enabler for our people to be future-ready in a fast-moving and changing landscape. From 28 March to 1 April 2022, we held our inaugural Learning Week, which was aimed at strengthening the culture of continuous learning.

Features of the virtual event included:

Bite-size learning sessions on topics such as the Use of Virtual Realities in Healthcare, Healthcare Analysis, Decision-making in a VUCA World and Agile Leadership

Talks by speakers from the public and private sector, as well as academia, to expose our people to different perspectives, and the developments in other sectors

DIGITAL TRANSFORMATION EFFORTS

We continued to make strides in our efforts to raise our efficiency through digital transformation.

AUTOMATING AND STREAMLINING WORK PROCESSES

To raise productivity, we leveraged Robotics Process Automation (RPA) to free up our staff for higher value work. To improve awareness of RPA, external speakers were also invited to share on the technology and its applications.

HARNESSING DATA

To support data-driven decision making, we set up and implemented the HSA Tableau Server. In the initial rollout phase, we conducted training courses for our staff on data wrangling and data visualisation. Additionally, our Data Analytics Core Team had organised informal data analytics clinic sessions to address Tableau-related queries.

MEDIA ENGAGEMENT AND BRANDING

To build trust and inform the public, we work closely with the media to keep them apprised of the latest health and safety developments.

OUR EFFORTS TO SAFEGUARD PUBLIC HEALTH

To ensure the public stayed well-informed, we issued press releases on product alerts, authorisation of COVID-19 vaccines and treatments, and enforcement against illegal health products and e-vaporisers. For the first time, we also published an annual summary of HSA's enforcement and vigilance activities for safeguarding the public from illegal health products.

To highlight HSA's enforcement efforts, we hosted the media on a trip to Tuas South Incineration Plant to observe the disposal of seized e-vaporisers and components on World No Tobacco Day.

MAINTAINING BLOOD STOCKS

It has been challenging to keep blood stocks healthy due to various factors related to COVID-19. In response, we strategically pushed out stories and updates to appeal for blood donations when we observed a downward trend in blood collection. These stories on blood donors and beneficiaries, as well as updates on blood donation trends helped to reinforce the importance of blood donation.

SHOWCASING OUR FORENSIC EXPERTISE

We garnered good coverage on various media platforms through pitching stories to showcase our forensic advancements and scientific capabilities, as well as the work of our scientific experts.

We published **4 HSA updates** and **24 press releases,** as well as managed **252 media queries,** contributing to **1,839 media articles.**

We created a total of **135 marketing collaterals** and **21 event collaterals.**

TECHNOLOGY AND INFRASTRUCTURE

By harnessing technology, we can create a world-class infrastructure that better serves our stakeholders.

As part of our digitalisation efforts, we rolled out the following initiatives in FY22/23:

1. Enhanced HSA Helpdesk support with expanded operating hours and services
2. Increased mailbox size from 2GB to 8GB
3. Enhanced SPICE document search capability
4. Improved service levels from IT support vendors through review of resource levels, competencies of key personnel and resolution of critical issues
5. Expedited technology refresh of 380 laptops with enhanced performance and reliability

OUR WORK IN FIGURES

BLOOD SERVICES GROUP

Key statistics as at end-December 2022

74,154
Blood donors

386,317
Blood components processed

117,967
Whole blood donations

1,413,086
Laboratory tests conducted

9,100
Apheresis donations

APPLIED SCIENCES GROUP

Key statistics as at end-March 2023

	Analytical Cases	Analytical Tests
Pharmaceutical Division	1,719	3,001

	Forensic Cases	Forensic Exhibits
Analytical Toxicology Division	18,855	31,225
Biology Division	13,851	22,234
Forensic Science Division	297	1,318
Illicit Drugs Division	1,802	6,199

	Coroner's Cases	Coroner's Autopsies
Forensic Medicine Division	5,119	1,145

HEALTH PRODUCTS REGULATION GROUP

Key statistics as at end-March 2023

Medicinal Products Pre-market Cluster

28
Therapeutic Products Containing New Chemical/ Biological Entities Approved

293
Therapeutic Products Registrations Approved (New Drug Applications and Generic Drug Applications)

5,194
Therapeutic Products Variation Applications Approved

5,427
Approved Products on the Register of Therapeutic Products

278
New Chinese Proprietary Medicines Listed

12,229
Chinese Proprietary Medicines Listed

51,084
New Cosmetic Products Notified

170,194
Cosmetic Products Notified

15
New Class 1 and Class 2 Cell, Tissue and Gene Therapy Applications Approved

9
New Class 1 and Class 2 Cell, Tissue and Gene Therapy Products Variation Applications Approved

50
Class 1 and Class 2 Cell, Tissue and Gene Therapy Applications Approved

146
New Clinical Trial Applications Processed

138
New Clinical Trials Applications Approved

Medical Devices Cluster

1,198
Medical Device Product Registrations Approved

77,728
Medical Device Product Listings Notified

2,981
Medical Device Change Notification Applications Approved

1,380
Licences for Importers of Medical Devices

1,331
Licences for Wholesalers of Medical Devices

19,511
Approved Products on the Singapore Medical Device Register

410
Applications for Import of Medical Devices for Personal Use Processed

269
Licences for Manufacturers of Medical Devices

258
Certificates for Exporters of Medical Devices

Vigilance, Compliance and Enforcement Cluster

383
Licences/Certificates for Manufacturers of Health Products*

1,744
Licences/Certificates for Importers of Health Products*

692
Licences/Certificates for Wholesalers of Health Products*

370
Registration of Retail Pharmacies

416
Licences/Certificates for Exporters of Health Products

376
Site Audits Conducted for Good Manufacturing & Good Distribution Practices and Pharmacies

8,246
Applications and Enquiries for Import of Medicinal Products for Personal Use Processed

2,570
Medical Advertisement Permits Approved

18,366
Spontaneous Adverse Drug Reaction Reports Captured

4,196
Post-market Feedback Received (Relating to Potential Contravention of Health Product Legislation)

381
Tobacco Retail Licences Approved

4,313
Licensed Tobacco Retail Outlets

4,793
Electronic Vaporiser Cases Handled by HSA

* except medical devices

FINANCIAL HIGHLIGHTS

Statement of Financial Position

	FY22/23	FY21/22	Increase / (Decrease)	
	$'000	$'000	$'000	%
Property, Plant & Equipment	78,983	78,914	69	0.1
Intangibles	10,716	10,693	23	0.2
Right-of-Use Assets	17,083	13,297	3,786	28
Current Assets	263,486	245,740	17,746	7
Total Assets	**370,268**	**348,644**	**21,624**	**6**
Equity	265,863	246,497	19,366	8
Non-Current Liabilities	16,073	14,022	2,051	15
Current Liabilities	88,332	88,125	207	0.2
Total Equity and Liabilities	**370,268**	**348,644**	**21,624**	**6**

Statement of Comprehensive Income

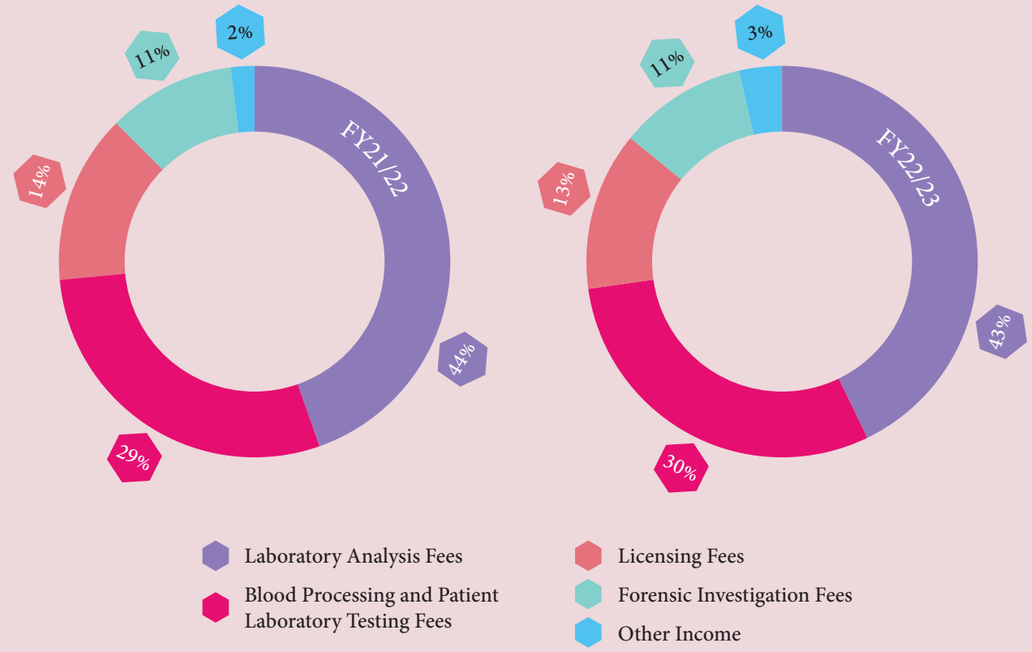
The Authority achieved an overall net surplus of $17.8m for FY22/23.

	FY22/23	FY21/22	Increase / (Decrease)	
	$'000	$'000	$'000	%
Operating Income	158,414	147,496	10,918	7
Operating Expenditure	(241,709)	(231,850)	9,859	4
Deficit before Government Grants	**(83,295)**	**(84,354)**	**(1,059)**	**(1)**
Government Grants	104,917	100,654	4,263	4
Surplus before Contribution to Consolidated Fund	**21,622**	**16,300**	**5,322**	**33**
Contribution to Consolidated Fund	(3,676)	(2,771)	905	33
Net Surplus	**17,946**	**13,529**	**4,417**	**33**
Other Comprehensive Income	(131)	243	(374)	(154)
Net Surplus and Comprehensive Income for the Year	**17,815**	**13,772**	**4,043**	**29**

Operating Income

The Authority earned a total operating income of $158.4m in FY22/23, an increase of $10.9m (7%) from FY21/22's revenue of $147.5m.

	FY22/23	FY21/22	Increase / (Decrease)	
	$'000	$'000	$'000	%
Laboratory Analysis Fees	67,691	65,858	1,833	3
Blood Processing and Patient Laboratory Testing Fees	47,722	42,588	5,134	12
Licensing Fees	20,666	20,511	155	1
Forensic Investigation Fees	16,840	15,793	1,047	7
Other Income	5,495	2,746	2,749	100
Total Operating Income	**158,414**	**147,496**	**10,918**	**7**

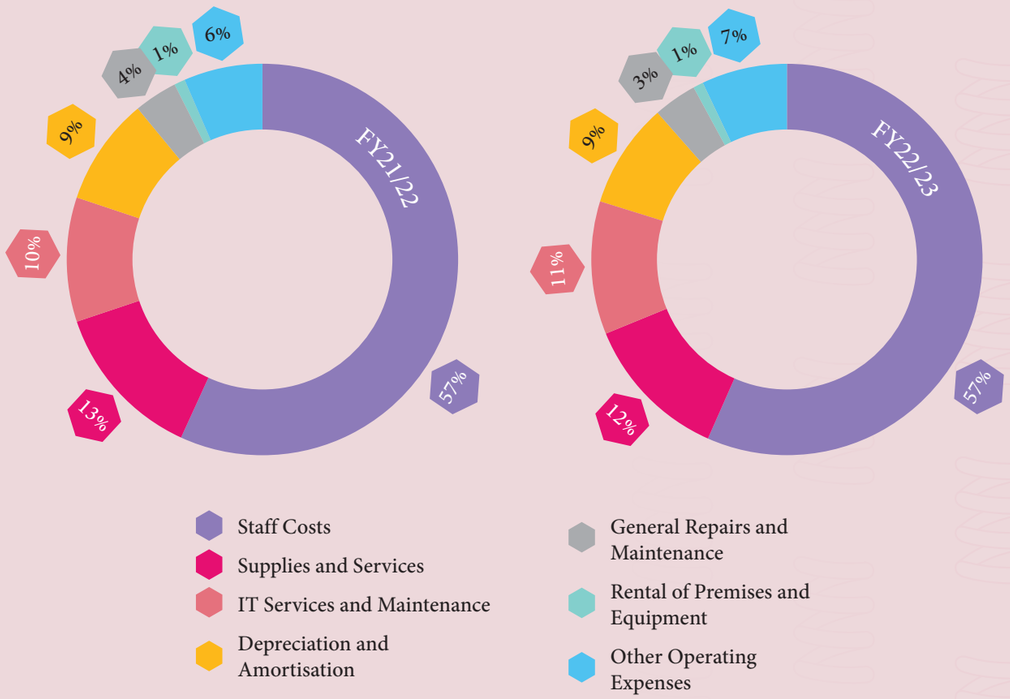


FINANCIAL HIGHLIGHTS

Operating Expenditure

The Authority incurred a total operating expenditure of $241.7m in FY22/23, an increase of $9.9m (4%) from FY21/22's expenditure of $231.9m.

	FY22/23	FY21/22	Increase / (Decrease)	
	$'000	$'000	$'000	%
Staff Costs	136,766	131,609	5,157	4
Supplies and Services	29,563	30,486	(923)	(3)
IT Services and Maintenance	26,461	23,585	2,876	12
Depreciation and Amortisation	21,178	20,596	582	3
General Repairs and Maintenance	8,625	8,572	53	1
Rental of Premises and Equipment	2,193	1,843	350	19
Other Operating Expenses	16,923	15,159	1,764	12
Total Operating Expenditure	**241,709**	**231,850**	**9,859**	**4**



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