

SAMED 
advancing patient care through MedTech

ANNUAL REPORT



20
22/23



SAMED VALUES

The SAMED Values encapsulate the ethos of the association and underpin its strategy, operations and engagements. They position SAMED in a deliberate and authentic manner and serve to protect and grow SAMED's reputation.



TRUST is at the heart of successful relationships. It is the glue that binds industry parties, so they spend less time protecting themselves and more time on collaboration. Trust is the natural result of a myriad thoughts, intentions, words and actions.



RESPECT is about showing humility and being sensitive. Being treated respectfully promotes a collaborative culture which motivates engagement, support and performance, making it easier to achieve common goals. Respect requires introspection – thinking about how our words or actions affect our environment and the reputation of others. A lack of respect undermines the value all parties bring to the table and can erode relationships.



TRANSPARENCY is a core strength that speaks to one's authenticity and confidence. Sharing ideas and information allows industries to get new and often deeper perspectives, opinions and ideas. Problems are solved faster and more efficiently if one is open and honest. Transparency builds trust, fosters shared accountability and raises ethical standards.



INTEGRITY means honouring our commitments and acting with honour regardless of whether actions are public. It's about nurturing an ethical culture that permeates the entire organisational ecosystem. Having integrity leads to smarter, more sustainable decisions and practices.



INCLUSIVITY and diversity go hand-in-hand to allow meaningful opportunities for all stakeholders to contribute to our industry. Inclusivity entails the involvement of diverse companies and people and the sharing of abilities and experiences. Inclusivity boosts innovation, skills and creativity.



STEWARDSHIP refers to the responsibility to understand and manage the impact SAMED has on our members and their operational environment. Our role is to uphold the best interests of our members and the broader medtech sector. We are custodians of our members' concerns, guardians of their sustainability and curators of their growth.



UNITY. SAMED is the voice of the medtech industry. We use a united voice to address common matters. Our industry has a far greater reach and impact when our representatives, individual member companies and their employees speak with a united voice.

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CHAIRPERSON'S MESSAGE

Purpose-driven medtech

In the period May 2022 to April 2023, SAMED made a concerted effort to galvanise new energy and infuse interactions with members, the industry and stakeholders with confident leadership and sound strategies.

Our intention was to shake things up and rejuvenate our association so it could be the bold voice of medtech – medical devices, medical technologies and in-vitro diagnostics (IVDs) – and to unleash our sector's potential to become intensely purpose-driven. For me, this meant driving greater access to medtech, partnering with others to reform healthcare, and building economic activity within our industry and South Africa more broadly.

Working with the board, members and the secretariat, we charted an exciting four-pronged vision to re-engineer SAMED into an association that elevates medtech, partners with key stakeholders, provides value to members, and is equitable, diverse and inclusive.

This mindset shaped how we engaged this year with members, the rest of the medtech industry, the South African Health Products Regulatory Authority (SAHPRA), other policy makers, funders, our peers and partners, healthcare professionals, patient interest groups and many others who provide or support health service delivery.

An association that elevates medtech

Partly as a result of the COVID-19 pandemic, there has been a growing appreciation of the value of medtech, the industry responsible for it, and SAMED as its primary representative in South Africa.

SAMED leadership developed interventions to maximise this opportune time to elevate medtech or raise the profile of the sector, the association and our members. It meant shifting gears in how SAMED presents itself and pursues its mandate to ensure a sustainable, transformed and ethical medtech industry.

SAMED shed its sometimes-introverted personality and embedded a resolve to speak up, putting forward a clear case for medtech to be prioritised in the planning and delivery of healthcare. This industry needs to be ambitious and courageous if we are to withstand the harsh trading conditions, disruptions due to the energy crisis, and broader economic impacts.

The first intervention that assumed this attitude was the initiation of the Captains of Industry forum in September 2022. This new platform strives to strengthen engagement



Peter Mehlahe,
SAMED Chairperson

between SAMED leadership and the CEOs and other senior representatives of member companies.

The inaugural event provided insights and ideas for:

- Taking our industry and the association forward in relation to stakeholder interaction.
- Rolling out an effective mechanism for collecting data from members.
- Building capacity within the SAMED secretariat.
- Developing processes for mentorship and transformation.

Peter Mehlahe, *SAMED Chairperson*

We held several fruitful forums and the latest, in March, was a partnership-building success.

It helped marshal greater collaboration, and drove conversations about the industry's diversity, woman-led businesses, and the powerful role played by small and medium enterprises.

The platform enabled major progress towards collaboration with the SAHPRA in defining and developing an elevated medtech industry. In her remarks at our Captains of Industry event, SAHPRA CEO Dr Boitumelo Semete-Makokotlela stated: “This partnership with SAMED is critical for us – there are insights that you have in the sector that are important for us to have sight of.”

We sought to take the annual SAMED conference in September up a notch and the event was a resounding hit. It was smoothly held together by television presenter Tania Habimana who filled the role of programme director. Business Unity South Africa (BUSA) president Professor Bonang Mohale opened the event with a passionate assertion that “South Africa will work if business makes it work”. SAMED’s partnership with the Youth Employment Service (YES) was central to a session on harnessing the power of our youth, while Setlhare Bakhane of the National Department of Health (NDOH) affirmed the significance of medtech in the delivery of universal healthcare.

Mr Bakhane, who is the Director for Health Technology at the NDOH, said: “The National Department of Health is looking forward to working with SAMED as we reform our health sector into becoming one system serving people in an equitable manner.”

SAMED’s Data with Integrity initiative went live early in 2023. Its ability to promote the medtech industry lies in producing reliable and increasingly detailed information to position our industry more strategically in terms of its contribution to economic growth and the transformation of the health system. I cannot overemphasise how essential it is for all SAMED members, big and small, to help us succeed with this initiative. In the current environment, data is king: it lies at the heart of the success and sustainability of our sector and individual companies.

During the year we undertook various activities to



Dr Boitumelo Semete-Makokotlela,
SAHPRA CEO

professionalise and elevate the SAMED brand. We harnessed personal relationships of board members to help secure prominent speakers – for example, the Director General of Health, Dr Sandile Buthelezi, was the keynote speaker at our 2023 annual general meeting – and to unlock collaboration with entities such as Webber Wentzel, Werksmans, Deloitte and the Gordon School of Business Science (GIBS) on hosting of events, strategy development, women’s empowerment, and learning from best practices in other sectors.

As every business leader knows, a solid business strategy is key to staying ahead of challenges, maximising opportunities and sustaining successes. The board engaged Professor Adrian Saville of GIBS to facilitate sessions aimed at refreshing SAMED’s strategy. In the coming period, our focus will be on membership, “ownership” of sector data, constructive contribution to regulatory and policy matters, reputation building, thought leadership, our international role, and strengthening our provision of certified training.

SAMED’s LinkedIn profile is proving to be a cost-effective tool to communicate these exciting stories to our members and stakeholders and to create new connections. I invite every member company to get involved in expanding the use of this platform.





Chairperson's Message (continued)

‘Quality of care cannot happen without medical technology . . . Universal health coverage, through National Health Insurance Fund, cannot be achieved without the South African Medical Technology Industry Association and its members equipping the country’s health system with appropriate equipment.’ Dr Sandile Buthelezi, Director General of Health, SAMED 2023 AGM

An association that partners with key stakeholders

The first Captains of Industry Forum sensitised SAMED to the importance of appreciating the needs of our key stakeholders in order to achieve constructive two-way dialogue. It is not always possible to be on the same page as other organisations, but it is necessary to express disagreements respectfully and preserve working relationships.

Peter Mehlape, SAMED Chairperson

For instance, our narrative did not have to be entirely rewritten in order to convey more effectively our willingness to ensure that medtech increasingly reaches beyond well-resourced urban areas to benefit more South Africans living in rural areas and to engage with them in the language they understand.

This approach appears to have achieved more for SAMED in certain respects than the industry-centric slant that characterised many SAMED stakeholder interactions in the past. For example:

- SAHPRA has been keen to participate in our events and there are open channels of communication between us.
- Invitations have been extended by the NDOH, the Department of Trade, Industry and Competition (the dtic), Discovery Health and the Council for Scientific and Industrial Research (CSIR) for SAMED to participate in various regulatory, market access and localisation initiatives.
- A SAMED video, focusing on our partnerships, was used on the website of Invest SA, an agency of the dtic.

- SAMED leaders had numerous opportunities to contribute at events organised by: the Advanced Medical Technology Association (Advamed), the Medical Technology Association Middle East and Africa (Mecomed), Medtech Europe, World Health Organization (WHO), BUSA, the Chemical Industries Education and Training Authority (CHIETA), Global Medical Technology Alliance (GMTA), Africa Health Business, the Medical Device and Diagnostic Innovation Cluster (MeDDIC) of the SA Medical Research Council (SAMRC), and foreign trade missions.

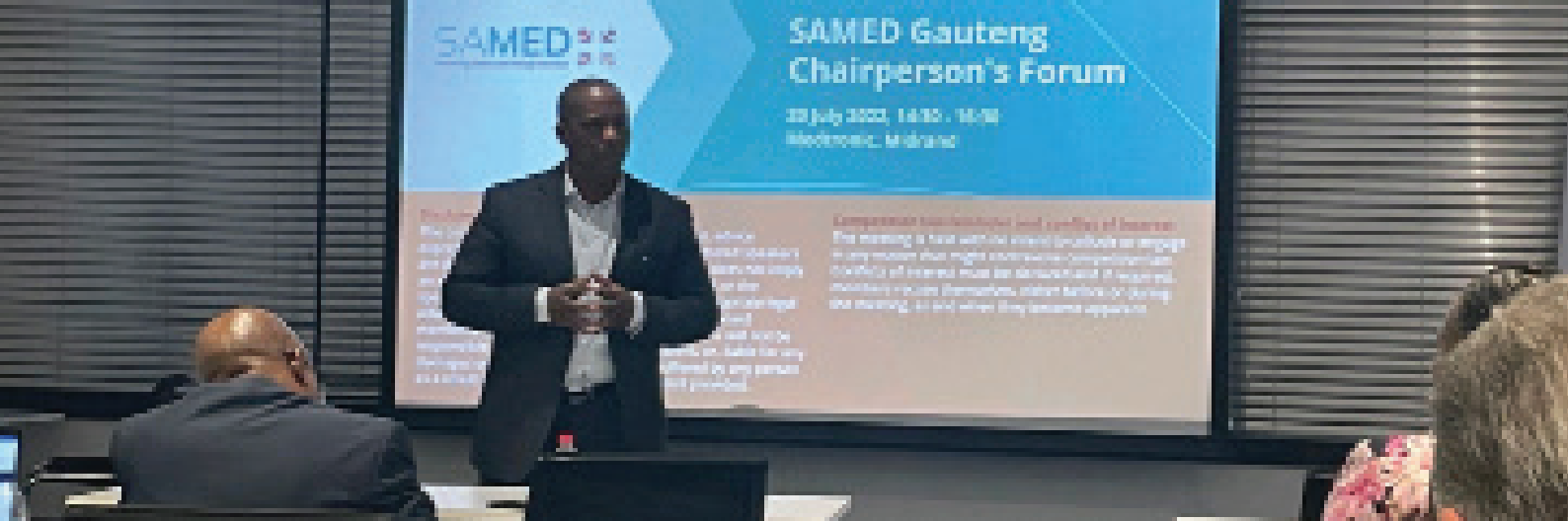
An association that provides value to members

Apart from confidently and meaningfully representing member interests during interactions with various external parties, SAMED offers its members a series of relevant and informative meetings each year. In 2022/23, SAMED organised 42 member events most of which provided members with practical information they could use to enhance their businesses. Two-thirds of events were organised by SAMED committees and the active participation of members speaks to the value of these meetings.

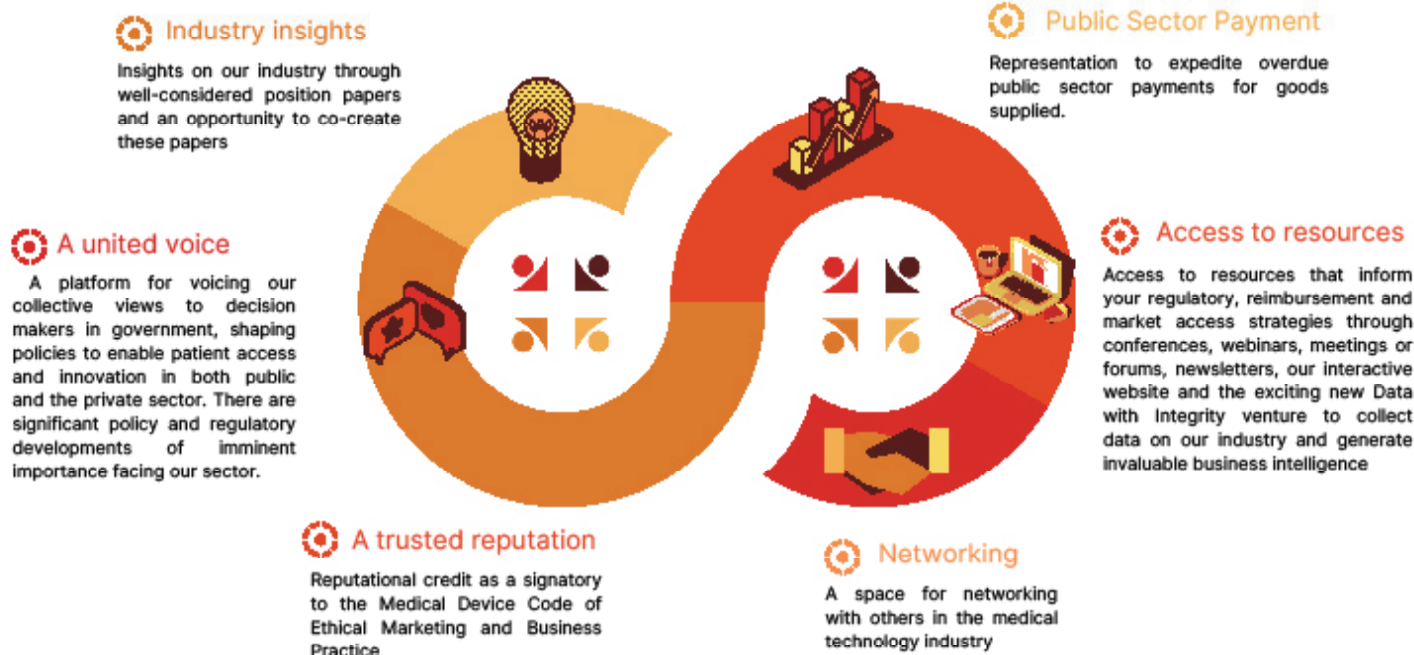
SAMED understands that a major pain point for our members is the persistent issue of outstanding debt owed to them by the public sector. The association continued to collate information from members and communicate the extent of outstanding payments to stakeholders in government. After taking this a step further by writing to the Office of the President, we made progress with some of the provinces. SAMED will continue to support members in this regard.

Under the guidance of the Code Committee, SAMED provided 18 non-binding advisory opinions regarding the Medical Device Code. This service is offered at no cost to members and exemplifies SAMED's leadership on issues of governance, integrity and the promotion of ethical marketing and business practices to our members and the industry.

To ensure that the SAMED office continues to support the organisation's mandate, respond to members' growing needs, and manage its work efficiently, some changes and capacity building have been instituted. SAMED has registered as a YES partner and looks forward to recruiting



SAMED Membership Benefits



An association and industry that are equitable, diverse and inclusive

According to the International Labour Organization (ILO), high levels of equality, diversity and inclusion are associated with greater innovation, productivity and performance, talent recruitment and retention, and workforce wellbeing. SAMED has taken to heart the advice of Manuela Tomei, Director at ILO's Conditions of Work and Equality Department: "An equal, diverse and inclusive workplace is a key driver of resilience and recovery."

SAMED's current board is the most diverse since the organisation's inception in 1985 and we have seen the benefits of increasing diversity over the past few years. There has been a broadening of our collective mindset and a change in the temperature of discussions with some key stakeholders. This kind of transformation is also happening within individual medtech companies.

However, we can do even better and the board, with enthusiastic support from the secretariat, has sought to maximise equity, diversity and inclusivity (EDI) in every SAMED structure and to introduce initiatives, such as Women in Medtech forums and a Women's Empowerment Index.

Closing remarks

SAMED will continue to elevate medtech in South Africa, representing the breadth of players in the sector – large and small entities with diverse product portfolios. Every one of our members is crucial to delivering care to patients and expanding access. I am grateful to SAMED members for their support and participation, and to my board colleagues and Executive Officer Tanya Vogt and her dedicated staff for ensuring that SAMED is recognised as the voice of medtech and that together, we achieve systemic change and progress.

Peter Mehlape
 Chairperson



The year at a glance

During 2022/23, SAMED continued to grow and implement strategies across five central pillars.

Safeguarding, promoting and representing our members' shared interests

Much work was done during the year to strengthen SAMED's **governance**, prioritise the value and benefits of SAMED for **ordinary members** and find ways to advance **localisation**. These factors fed into strategic planning by the board. SAMED's **refreshed business strategy** identified ownership of sector data, our contribution to regulations and policy, reputation building, thought leadership and provision of certified training as areas of particular importance.

Promoting access to medtech for better patient outcomes

This area of our work featured a busy schedule of in-person meetings and the submission of comments on different policies such as sections **18A and 18B** of the Medicines and Related Substances Act, health technology assessments (**HTA**) and matters related to the running of medical schemes including annual statutory returns for 2022 and low-cost benefit options. SAMED had valuable opportunities to promote the efforts of **patient interest groups**, including those dedicated to women's health and diabetes.

Supporting growth for sustainability

SAMED engaged with members and local and international stakeholders **to promote South Africa** as a valuable investment and trade destination in Africa and a gateway into the rest of the continent.

Specifically, SAMED focused on the **attractiveness and sophistication of the South African medtech landscape** and the potential growth of the sector.

In these deliberations we collaborated with foreign trade missions, Africa Health Business, the Coalition on Women's Health in Africa, provincial development agencies in Gauteng and the Western Cape, the CSIR and others.

Shaping best practice in standards, policies and regulatory requirements

SAMED remained committed to the development and implementation of **appropriate policy** and fit-for-purpose **standards**, and the progressive **harmonisation of regulatory frameworks**. In pursuing these objectives, we engaged with local and international stakeholders including SAHPRA, the NDOH, the African Medical Device Forum, and our peers in the United States, Europe and the Middle East, namely Advamed, Medtech Europe and Mecomed.

Driving adherence to ethical principles and business practices

We continued to assert the central role of ethical marketing and business practices in individual supplier and industry sustainability, to promote the value of self-regulation, to implement and improve **Medical Device Code** compliance, and support third-party initiatives including the **Health Sector Anti-Corruption Forum**.

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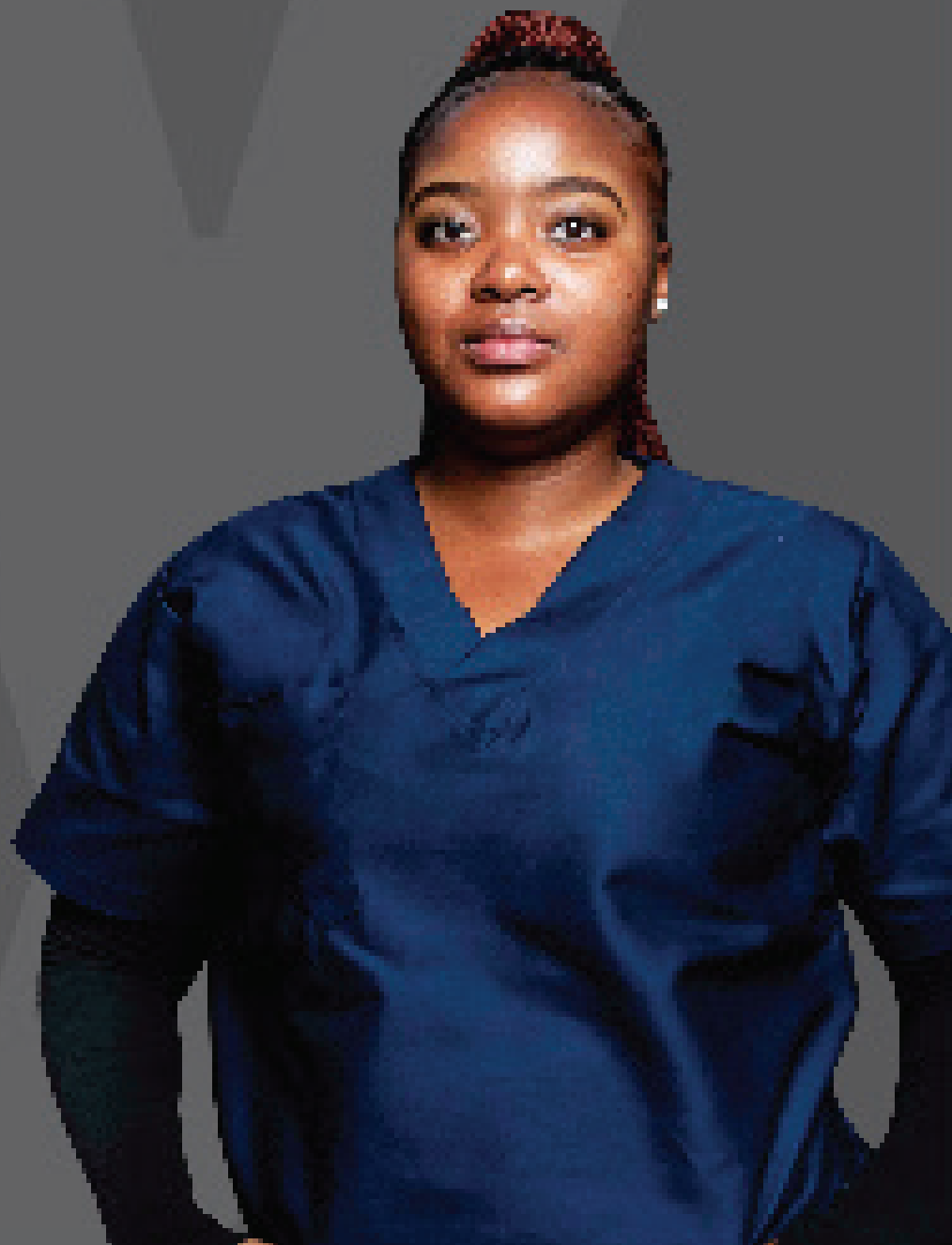
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Gain up to two levels on your B-BBEE scorecard and/or integrate YES into your ESG strategies.

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EXECUTIVE OFFICER'S REPORT

Medtech with a mission

This was a year of change, during which SAMED, our members and other medtech companies strove – through our actions – to change perceptions of our industry. We drove the theme of medtech with a mission, which highlighted the multidimensional good the industry delivers to patients and the health system and contextualised the commercial aspects of the sector and its economic role.

SAMED leadership, led by our dynamic chairperson and a committed and diverse board, worked with the secretariat to enhance our ability to interact productively with members and external stakeholders. This made for a jam-packed year that demanded we be more visible and more responsive.

Factors which impacted positively on us included:

- The enhanced agility and productivity that accompanied the COVID-induced virtual way of working.
- More frequent meetings of SAMED committees, which facilitated better delivery to members and stakeholders. This required increased administrative support that was willingly provided by the SAMED office.
- An encouraging response to our deliberate efforts to more “out there”. SAMED saw a marked increase in invitations to participate in diverse health-related discourses and initiatives.

Global and local economic crises inevitably impacted on the medtech industry, but we endeavoured to maximise opportunities that speak to Africa's growing importance to multinational manufacturers and other global medtech role players.

Instruments such as the African Continental Free Trade Agreement are beginning to facilitate cross-border trade. There has been enthusiastic participation in forums, symposia and exhibitions that seek to put Africa on the global medtech map by the dtic and its partners in Africa, continental health regulators including the African Medical Device Forum and SAHPRA, international agencies, national programmes in developed markets, and the private sector.

Some of these engagements were directed at short-term commercial results, while others envisaged long-term returns. These included collaborative processes aimed at regulatory harmonisation and the adoption of international standards and other best practices that will strengthen African health systems and benefit medtech suppliers on the continent.



Tanya Vogt

Executive Officer

SAMED has witnessed the rise of health as a national priority. Senior officials in government, including the Presidency, have become more responsive to health-related issues in the last year. Their presence and energy have created a positive ripple effect on other stakeholders, including BUSA, the CSIR and MeDDIC.

What is the value of medtech?

Most simply, the value of the South African medtech market can be presented in monetary terms. It is estimated to be worth about R22.5 billion in 2023 (Quelle: Department of Trade, Industry and Competition, 2022).

An alternative and deeper definition of the value of medtech considers every life that is saved and changed for the better. The premature baby in an incubator, breathing through an oxygen apparatus. The accident survivor living a full life because of a prosthetic leg. The breadwinner whose regular dialysis for chronic kidney disease enables him to work and support his family. The individual spared a day in hospital for a colonoscopy by swallowing a pill-sized recording device that can take and transmit quality images to the doctor.

Part of the value of medtech lies in the innovative nature of this sector. Medtech innovations save patients time and inconvenience, deliver better clinical outcomes, make more efficient and effective use of health resources, and benefit the entire health system.



OUR MEMBERS – THE BEATING HEART OF SAMED AND THE MEDTECH INDUSTRY

SAMED's mission and vision extend to the entire medtech sector in South Africa. The interests of members and non-members are similar and we gain more when we act in unity with the rest of the industry. However, we are essentially a membership association, providing value primarily for our members in order to remain strong as an organisation and to continue to serve as the solid core of industry initiatives.

In the past year we assessed our membership, digging deep to understand who our members are, why they are members, what value we need to deliver to them, and the criteria for membership that will best serve the association and the broader medtech sector. These processes led to the reshaping and consolidation of our membership constituency.

- After careful deliberation and consultation with the South African Laboratory Diagnostics Association (SALDA) and the Medical Device Manufacturers of South Africa (MDMSA), the SAMED board discontinued the category of association membership as from 1 January 2023. This approach centres on the principles of good governance, consistency and fairness. Our core membership base

comprises ordinary members – individual companies, of all sizes that manufacture, import, export and distribute medical technology and in vitro diagnostics. Our ordinary members pay full membership fees and should be the primary beneficiaries of SAMED services.

- We respect the independence of SALDA and MDMSA and will continue to collaborate with them on initiatives that require alignment for a united sector.
- As part of our ongoing strengthening of ethics and compliance, SAMED enforced the Medical Device Code certification as a mandatory requirement of SAMED membership, with ongoing monitoring of compliance with certification processes. Seven companies had their membership terminated because of failure to complete certification.
- We reluctantly terminated the membership of eight companies that were unable to pay their annual fees. This step was taken after efforts to help with payment terms and the possible sourcing of partnership-based funding. However, payment of fees is a material issue related to governance, compliance and fairness, and SAMED needs to give effect to it. The affected companies were all small or medium-sized and retaining the involvements of SMEs will remain a strategic focus area for the association in the coming year.



Executive Officer's Report (continued)

As a result of the above developments, SAMED ended the year with fewer members than the previous year. A breakdown of this year's membership and how the companies realised their membership benefits provides greater insight into the relationship between SAMED and its members and pointers for next year's priorities and strategies.

TABLE 1:

Examples of how members realised benefits of SAMED membership

	Total members	Ordinary members	SMMEs	Number participating in committees	Total attendance at events	Requests for Code opinions
2021/22	216	192	160 (83%)	112	2 746 (33 events)	10
2022/23	174	152	120 (80%)	119	2 328 (42 events)	18

Data with Integrity opens new possibilities

The long-awaited initiative to generate our own primary data on our industry went live in early 2023. The chosen name of the programme, Data with Integrity, emphasises our concern to provide reliable, trustworthy information. However, the quality and usefulness of our data depends on member support and veracity.

launch date in focus. Short training workshops were tailor-made for different sections of the initial questionnaire, namely company details, employment figures, financial data, and information on import/export activities,

Tanya Vogt, Executive Officer of SAMED

SAMED members will be able to use the information to establish baselines, benchmarks and goals, to support procurement and reimbursement discussions, and to take evidence-based decisions and actions.

The initiative has already been commended by key stakeholders including the SAHPRA CEO Dr Boitumelo Semete-Makokotlela who said such accurate, current information would assist SAHPRA in regulatory policy and process development.

Before Data with Integrity went live, SAMED developed and executed an information and capacity-building campaign that entailed targeted communication to company CEOs and senior personnel directly involved in data gathering and submission. A series of "countdown" mailers kept the

Data with Integrity

Building a detailed and reliable picture of medtech sector



Establish baselines, benchmarks and goals



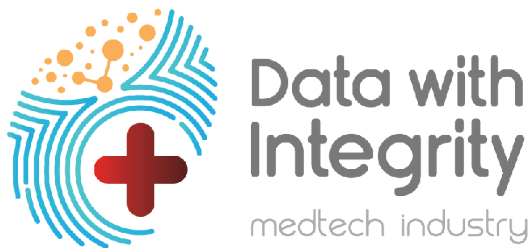
Support procurement and reimbursement discussions



Take evidence-based decisions and actions



Substantiate medtech industry contribution to economy and transformation



LUCKY DRAW

time
IT IS EASY TO ENTER



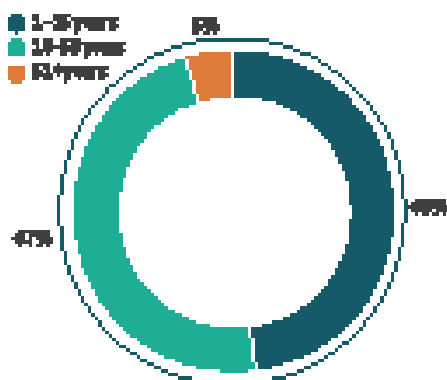
regulatory affairs, local manufacturing, and research and development.

Of the 157 ordinary member companies, 21 participated in the first round of information gathering conducted in January-March, and not every participating company responded to all the questions. Despite these limitations, preliminary information is helping us get a clearer view of our membership.

I cannot over-emphasise how crucial the success of Data with Integrity is to our sector's credibility. Our capacity to form new stakeholder relationships and strengthen longstanding ones, to shape the agenda on regulatory and policy matters, and to take up other issues that impact your business, depend on how well we work together to produce solid data.

SAMED will work closely with the members to improve the data gathering process. Starting with the next data collection round, which is planned for November 2023, we want every SAMED member to participate in order to obtain more accurate and comprehensive data. The secretariat will intensify hands-on support to members through regular communication and small-group or even individualised training sessions to address members' challenges.

FIGURE 1:
SAMED member companies age breakdown



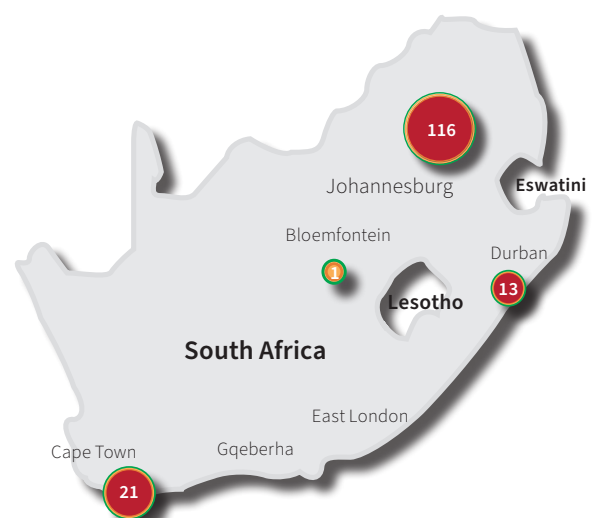
Company information: age, location and type of business

SAMED's membership continues to feature companies of varying age, sizes and types. We are encouraged by the strong representation of newer companies, which speaks to SAMED's relevance in this segment. Networking them with some of the more established members ensures sharing of different views and enriches discussions within

FIGURE 2:
Member composition by type of business



FIGURE 3:
SAMED member companies by location



Executive Officer's Report (continued)

Events and forums: expanding a key service offering


Events and forums are a valued element of the comprehensive service we offer to members. Our objective is to empower members with current and relevant business intelligence and develop skills they can use to enhance their businesses. These gatherings also provide a platform for airing concerns and asking questions.

A novel forum, introduced this year, is SAMED's Women in Medtech initiative. This highlights the role of women in medtech and the potential for the industry to provide opportunities to women. Through sharing of inspirational case studies at two events, we recognised, supported, and celebrated female leadership and service in the medtech sector. We appreciate the support for this venture shown by men in leadership in some of our member companies.

SAMED intends to introduce a Women's Empowerment Index which will allow the sector to set goals and track progress in creating corporate environments which value diversity and afford women inclusivity and equity.

Some events were externally directed, designed to inform partners or other role players or advocate for specific SAMED and sector positions. This helps to build relationships and trust with these stakeholders and share their knowledge and experience with the members.

Videos, presentations, reports and other documents related to events are circulated to assist members take relevant actions to improve their operations. Attendance at some events was higher than the number of delegates who pre-registered, which reflects the secretariat's tireless efforts to promote events.

 See appendix on pages 36–39 for details on events, topics and speakers.

SAMED events during the year

- 20** events hosted by SAMED committees: Code and Ethics, Market Access, Regulatory and Compliance, Public Sector Procurement and Outstanding Payments, and Transformation
- 3** Captains of Industry Forums
- 2** Women in Medtech Forums
- 3** Chairperson Forums: two in the Western Cape and one in Gauteng
- 2** Major events: the annual general meeting and the annual conference
- 12** information or training sessions

Total attendance at **42** events exceeded
2 000 participants



Helping members manage matters of material significance

SAMED assisted members to address outstanding public sector payments and medical inflation, two issues that critically affect companies' business performance.

Outstanding public sector payments

For several years, SAMED has tracked outstanding debt accrued as a result of delayed payments to members by customers in the public sector.

This debt and extended payment timelines pose manifold risks. They impact on the sustainability of supplier companies, cause disruptions to supply chains and service delivery, and affect patient access to care. They also reduce competition, weaken the medtech industry, and diminish its contribution to the economy.

Previously our attempts to resolve this problem were largely directed at provincial departments of health. But these approaches yielded very limited results.

This year the debt escalated to record levels and SAMED changed course. We took seriously President Cyril Ramaphosa's promise to cut red tape and make it easier for all types of organisations to do business with government. We wrote to the President, advising that "over R1.7bn in outstanding payments over the 30-day legal requirement is due to SAMED members by various government health institutions" and appealed for "urgent intervention at the highest levels of national and provincial government to ensure immediate payment" and find a long-term solution to this longstanding matter.

Our appeal was well received: the President instructed the Director General of Health to intervene and expedite engagements with chief financial officers of provincial

departments. This facilitated problem-solving meetings with departments in KwaZulu-Natal and the Western Cape.

- The KZN Health Department embarked on a project "Pay on Time" and invited SAMED to collaborate in designing an efficient consignment stock process which would reduce payment backlogs for walking implants. The aim is to share outcomes and learnings with other provinces.
- The Western Cape team shared the departmental procurement vision and processes with SAMED members and implemented initiatives at facility level to improve payment timelines.

We hosted Public Sector Payment Forums to help member companies understand and follow correct processes.

Medtech inflation

Medtech price inflation is a complex matter that affects SAMED members, other suppliers, health service providers and patients. The COVID-19 pandemic and the Russia-Ukraine conflict combined to take medtech inflation to new levels as a result of currency fluctuations, increased costs for energy, raw materials, logistics, and regulatory processes.

Like its peers in Europe and Asia, SAMED acted by **researching the causes and effects and communicating these** to funders, customers, government and other stakeholders with the aim of sensitising them to the issues for purposes of their financial planning.





Executive Officer's Report (continued)

Elevating SAMED's governance

SAMED's governance needs to stand up to the sternest scrutiny if it is to play its role in elevating the medtech industry effectively. The organisation needs to be fit for this purpose and our administration protected from a variety of risks. In the past year SAMED devoted time and resources to reviewing our governance structures and practices and addressing matters that need attention.

Legal experts from Webber Wentzel assessed the board's effectiveness in terms of its structure, balance of skills and experience, proceedings, risk management procedures, and resilience and sustainability. They identified areas for improvement and made recommendations. A similar assessment will be done in two years to establish progress against these recommendations.

A review of the SAMED Constitution was undertaken to identify gaps and necessary changes. These included adjusting the nomination and election of board members in line with the principles of equity, diversity and inclusion (EDI), amending decision-making processes, providing for electronic voting, and strengthening financial operating procedures, independent financial audits and records of meetings. This review was done by legal experts Michael Judin, Neil Kirby, and Mlu Mahlangu and Ashford Nyatumba of Webber Wentzel and a task team appointed by the board. The revised Constitution was approved at the 2023 annual general meeting.

The composition of the current board reflects SAMED's commitment to diversity and inclusion.

 See Governance Report – Our Board on page 23.

Environmental, social and governance (ESG) matters have been added to the board's responsibilities. We discussed these during the annual conference and plan to work with Deloitte, the ESG exchange and Chapter Zero to train, guide and support members on responding to climate change.

The secretariat's resources have been strengthened with the appointment of a new staff member, Ntokozo Dlamini, who will provide administrative support and coordinate projects including Data with Integrity, the Medical Device Code, and outstanding public sector payments.

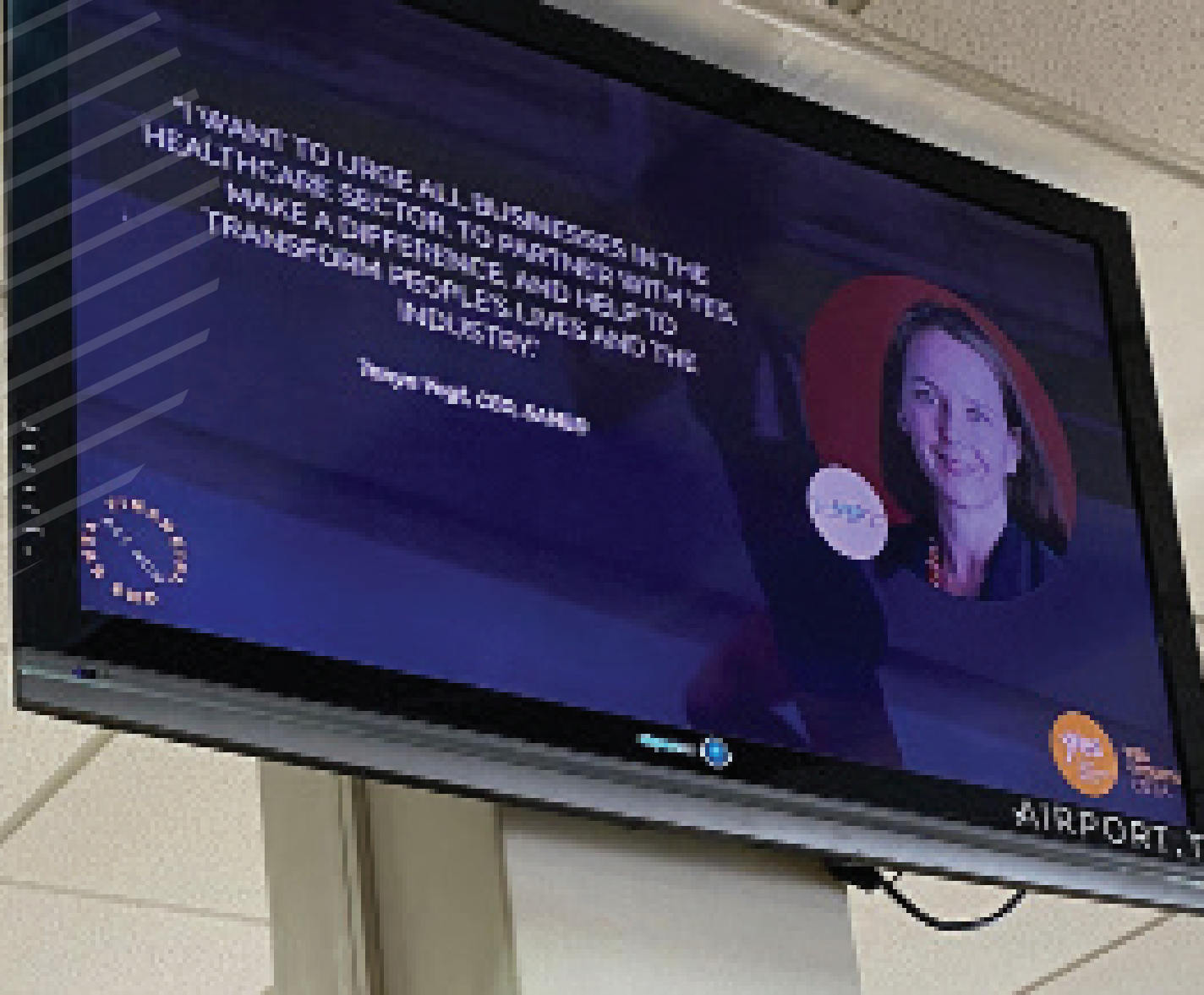
Work to enhance governance also entailed strengthening of compliance with Competition Law and the Protection of Personal Information Act, and sanctions against members who were unable to comply with payment of membership fees and certification in terms of the Medical Device Code.

Acknowledgements

It gives me great pleasure to announce that Rob Millar has become the first honorary member of SAMED. This tribute is only paid to individuals who have rendered exceptionally valuable services to SAMED and the medtech industry. Rob is a renowned medtech and healthcare industry expert with 45 years' service that spans pharmaceuticals, device manufacturing, capital equipment and specialised technology products. Rob has been committed to the progress of the medtech industry in South Africa, sensitive to the changing environment, and unwavering in his efforts to achieve the objectives of SAMED since its inception in 1985. He has provided leadership while serving, variously, as chairperson, vice-chairperson, treasurer and chair of the Code Committee.

Rob was central to the development of the Medical Device Code which is the foundation of self-regulation of the industry. He has been a mentor and friend to the SAMED secretariat, generously giving his time to strengthen our skills and capacity. Although recently retired, Rob remains dedicated to SAMED and has been co-opted onto SAMED's Code Committee. In this role, Rob will continue to lead SAMED's work in relation to sections 18A and 18B of the Medicines Act, as well as Project 18C.

I am grateful to the Chairperson and the entire SAMED Board for their courageous and inspiring leadership, support and passionate dedication to SAMED and our industry. Special thanks go to Vitor Ferrão, who completed his tenure as a nominated board member, and to Reiner Gabler, our Treasurer, for his unfailing support and guidance on all matters monetary.



I wish to express appreciation to the chairs and members of SAMED committees who volunteer time, expertise and energy to the association.

Thank you to the Treasurer and others who assisted in managing the raising of monies owing to the South African Revenue Service (SARS) and to those members who have already contributed.

My special thanks go to the SAMED secretariat – Communications and Events Management Officer Caroline Scott, Office Assistant Emily Mehtlape and Projects Coordinator and Admin Support Ntokozo Dlamini. Our Office Manager, Nicky Tamboer, who served SAMED for 10 years, left during the year but was invaluable in the earlier months. A special thank you to Amanda Jane Wilde who stepped in to assist with administration during the period of staff transition. The recovery of a large portion of monies

owing to SARS was largely due to her tireless efforts. Our team is small, but its members are exceptionally diligent and always there for our members, the board, the committees and partners.

Finally, I would like to thank our members for your support and participation. This energy and interest are what makes SAMED the genuine voice of the medtech industry.

Tanya Vogt
Executive Officer





PURPOSEFUL STAKEHOLDER RELATIONS

Elevate medtech and reform healthcare

As indicated in the reports of the Chairperson and Executive Officer, SAMED invested thought and energy to elevate medtech through purposeful engagements with stakeholders. Some of these entailed an exchange of information with a view to raising awareness about our sector and the value of medtech in a broader sense. More often, we engaged with a deliberate agenda:

- To contribute constructively to regulatory and policy developments.
- To positively influence factors impacting on market access to medtech.
- To strengthen collaborations that advance localisation.

Advocacy for regulatory strengthening, convergence and harmonisation

SAMED represented the medtech industry's interests and advocated for regulatory strengthening, convergence and harmonisation in multiple domestic, African and international forums.

The context for this interaction was favourable. The elevation of medtech's role – by the COVID-19 pandemic and our response to it – stimulated increasing interest in medical devices and in vitro diagnostics and issues of quality, safety and value among stakeholders, including the regulator, the health department, organised business and other private health stakeholders. SAMED has experienced a genuine desire to understand the workings of our industry and respect for the expertise vested in it. We have also been able to address historical misunderstanding and mistrust of the medtech industry.

For example, the Executive Officer represented SAMED on a selection panel to fill medtech-related NHI posts (a process that is led by the NDOH) and on the dtic committee responsible for the Health Sector Masterplan. Provincial departments of health, hospital groups and funders have already begun to ask suppliers for information similar to that likely to be included in regulations on product registration.

SAMED believes that robust and appropriate medtech regulation, backed by a widely recognised and enforceable Medical Device Code, are the means to reform the health system's procurement and utilisation of medtech. SAMED has used all suitable occasions to educate stakeholders on effective regulatory models and international best practice.

Our earlier advocacy secured a three-year postponement in the introduction of regulations under sections 18A and 18B of the Medicines and Related Substances Act. The postponement will end on 10 December 2024. In the past year, we **engaged with SAHPRA and the Pricing Committee** on timelines for the finalisation of relevant regulations, and explored options for a further exemption. This approach is consistent with SAMED's attempts, through Project 18C, to have the Medical Device Code apply to the entire sector.

Building on the cordial SAMED-SAHPRA relationship and the supportive stance of SAHPRA CEO Dr Boitumelo Semete-Makokotlela on Project 18C, we expect to have opportunity to submit further comment to the Minister in due course. During the SAMED Captains of Industry Forum, we welcomed Dr Semete-Makokotlela's undertaking that product registration will be managed by a team comprising individuals versed in medtech, as opposed to pharmaceuticals.

Exciting developments took place this year in the area of medical device regulatory convergence:

- SAMED participated in meetings and workshops hosted by Advamed/USAID on convergence and good regulatory practices. These events presented opportunities to collaborate and strengthen our relationship with SAHPRA.
- We played a leadership role, in collaboration with Advamed, Mecomed and Medtech Europe, in the formation of a GMTA Africa working group that is cochaired by SAMED and Mecomed. The working group:
 - Commented on the AMDF draft guidelines dealing with labelling, promotion and advertising, public health emergency authorisation, field safety corrective actions, registration and listings, and clinical investigations.
 - Presented at workshops on good regulatory practice and technical barriers to trade with Kenyan and South African regulators and the industry.
 - Conducted initial mapping of conformity assessment, manufacturing site inspection and labelling with a report on the industry impact of non-harmonisation.
 - Participated in the Med Dev Reg Afri Summit, a gathering of national regulatory affairs agencies and industry to discuss medical device and IVD regulations and market access in Africa.



Market access: HTA, working with funders, patient interest groups and more

SAMED has long advocated that HTAs must form part of value assessments conducted when bringing medical technologies to market. This applies both to the private sector that is largely funded by medical aids and to the NHI framework.

As part of this work, we drafted an **HTA position paper** on the need for an independent, institutionalised body as part of NHI implementation. SAMED has shared this paper with the newly formed HTA NDOH task team and plans to engage with key stakeholders on the arguments and research underpinning the paper.

The association submitted comments on two circulars issued by the Council for Medical Schemes (CMS):

- Circular 25 of 2022 on the performance of HTAs, proposing:
 - The creation of a national HTA system with a separate function from the duties imposed by legislation on individual medical schemes and ways to ensure this structure was independent, free from stakeholder bias and conflicts of interest.

- Ways of dealing with concerns about how funders apply criteria of cost-effectiveness and affordability under the Medical Schemes Regulations.

- Circular 39 of 2022 dealing with annual statutory returns for 2022 and the proposal for low-cost benefit options to be offered by medical schemes.

Other activities aimed at ensuring easier market access were:

- Helping SAMED members understand the role and influence of medical aids on market access, and keeping them abreast of developments related to HTA, procurement, reimbursement, NHI and the CMS.
- Working with Discovery Health on product approval and pricing processes.
- Supporting the launch of the Coalition on Women's Health in Africa and the work of the Rare Diseases Access Initiative.
- Engaging with a leading diabetes patient interest organisation, Sweetlife, to identify the most pressing needs of diabetic patients in relation to medical devices and linking them with relevant SAMED members.



Purposeful stakeholder relations (continued)

Medtech as a player in the national economy

Localisation of lifesaving and life-changing medtech is a priority for SAMED. During the year, the association helped investors and commercial partners understand the South African healthcare environment and acted as a link between them and members who can fulfil various roles, such as distribution, manufacturing and maintenance.

Other initiatives to strengthen localisation included:

- Championing SMMEs which constitute the majority of our members. SAMED compiled a **web index** of initiatives and entities which provide support to local manufacturers and SMMEs.
- Hosting a localisation session at the annual conference. Panel members included representatives of key partners: the dtic, SA Medical Research Council, Gauteng Small Enterprise Development Agency and CSIR.
- Participation by our Executive Officer in MeDDIC steering committee meetings and the CSIR Manufacturing Industry Advisory Panel. These platforms enable SAMED to share insights about the medtech sector and provide guidance on research, development and innovation (RDI) activities in alignment with our industry priorities.
- Engaging with sector education and training authorities (SETAs) – including those for health and manufacturing and engineering – to educate them about the medtech sector and role they could play to grow the sector. SAMED is collaborating with CHIETA, the SETA for chemical industries, with a view to gaining recognition for individuals conducting medtech regulatory functions. This would entail creating a new occupational category, health regulatory affairs assistants, and a certified course. The intention is to encourage young people to enter our industry.
- Inviting provincial development organisations, the Gauteng Growth and Development Agency and Wesgro in the Western Cape, to participate in SAMED Chairperson Forums to update members on strategies, programmes and incentives that enable investment in medtech.

- Attending and presenting at numerous events and meetings hosted by:
 - Foreign trade missions: Austrade, KOTRA, Taipei Liaison Office, High Commission of Canada, Germany Trade and Invest and SA-Belgium trade event.
 - Africa Health Business, where we highlighted the value of medtech innovation in supporting women's health.

Amplifying stakeholder relations through communication

SAMED's communication and events team has had a full and dynamic calendar, endeavouring to keep members informed of relevant developments through a multimedia approach that includes SAMED News, From the Desk of the EO and other written and video mailers, website upgrades and updates and alerts on how member companies can help elevate medtech through their participation in our own and third-party initiatives.

The team was instrumental in the organisation of the annual conference and 41 other SAMED events, preparation of presentations for stakeholders and driving the Data with Integrity initiative.

The solid efforts of the secretariat and purposeful contributions by the board and many members have this year grown our LinkedIn audience from 360 followers to over 2 000. This five-fold increase is particularly noteworthy because it is organic, driven by interest in our posts rather than paid boosting.



SUPPORTING HEALTHY TRANSFORMATION

SAMED regards transformation as an economic and social imperative. We are committed to transformation and believe we can drive meaningful and sustainable change as an industry body.

Inclusivity – one of the seven values of SAMED – along with diversity and equity are the building blocks of transformation within SAMED, our industry and South Africa.

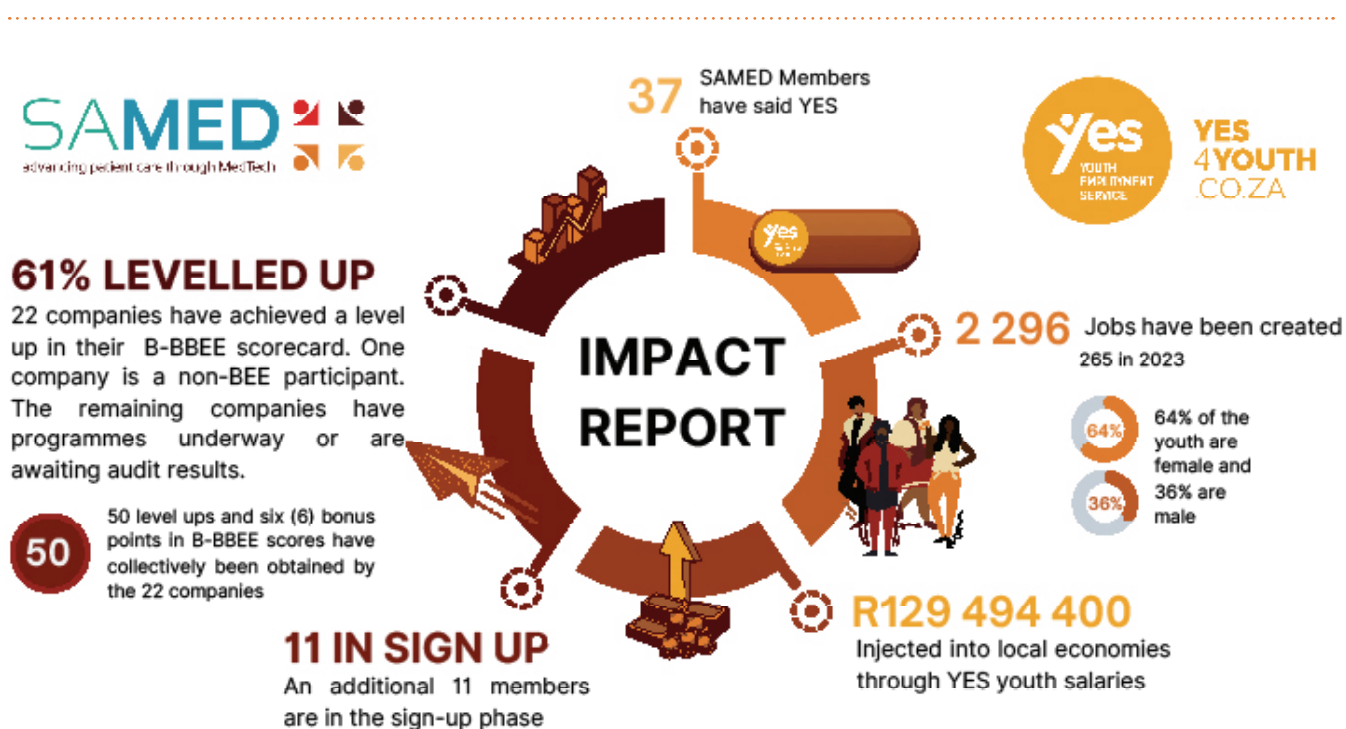
SAMED and the Youth Employment Service (YES) celebrated the first anniversary of our partnership that contributes both to youth employment and empowerment and to organisational and sector transformation. The YES programme builds youth confidence and employability through workplace skills development and social and networking experiences, and facilitates work placements. Giving learners experience and skills in critical medtech areas like regulatory

affairs, compliance, reimbursement, quality control and manufacturing, builds more sustainable businesses.

Among the implementation partners with YES are Asili Risk Management, Blossom Care Solutions, CiTi, HIVSA, IT Varsity, Liquid Intelligent Technologies, National Financial Literacy Association, Witkoppen Clinic and Youth Health Africa.

SAMED salutes YES, SAMED member companies and others who have taken on this challenge to make South Africa better, one YES youth at a time.

Youth and SAMED members transforming South Africa one YES at a time



Supporting healthy transformation (continued)

YES has created an astounding 100 000 jobs for young people since its inception. Thus far, **37 participating SAMED members** have created 2 296 jobs, injecting nearly R130 million into local economies through youth salaries. In return, 22 companies improved their B-BBEE scorecard by one or more levels. These achievements deserve to be lauded – especially in tough trading conditions.

The SAMED Alumni Project is a database of youth who participate in YES in the medtech industry but were not immediately absorbed and are eager to find permanent work in the sector. Interested companies can access this database. In partnership with YES, SAMED will develop an online resource where youth who are completing their programme can upload their CV and make it available to members to simplify talent sourcing and recruitment. SAMED supported Rays of Hope, a non-profit that uplifts the Alexandra community through education, healthcare and career building. Several SAMED members volunteered to mentor secondary school learners and provide guidance on careers in our sector, and they earned B-BBEE points in the process.

The 2022 B-BBEE Landscape Analysis enabled SAMED to track trends, highlight improvements and identify gaps with regard to members' transformation journey. Several achievements are worth celebrating.

- The number of B-BBEE-compliant members increased from 52 out of 86 participating members in 2019 to 155 out of 203. Compliance was based on an examination of certificates and affidavits submitted. In addition to an increase in absolute numbers, the percentage of

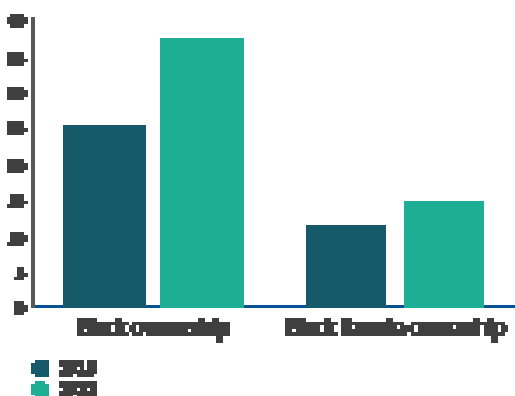
compliant participants rose from about 60% to 76%.

- The data shows an improvement in members' B-BBEE levels. In 2019, 23 members attained level 1 and this rose to 54 members in 2022. The average level in 2019 was level 5 for those with a valid certificate and level 2 for those with a valid affidavit. In 2022, this improved to level 4 and level 2 respectively.
- There were fewer members with certificates in 2022 compared to 2019, possibly due to the COVID-19 pandemic and related factors, and more relied on affidavits.
- In 2019, the average score for members with certificates was level 8, with a marked improvement to level 6 in 2022. This indicates that on average members have moved up two B-BBEE levels on their scorecards.

We are encouraged by the increase in black ownership (25.20% in 2019; 37.32% in 2022) and especially black female ownership (11.25% in 2019; 14.69% in 2022).

FIGURE 4:

SAMED member black/black female ownership



ELEVATING ETHICS

SAMED has long championed the highest standards of ethical behaviour in the marketing, procurement and utilisation of medtech, maintaining a focus on the interest of patients. We stand unequivocally for zero tolerance of fraud, corruption and perverse business and marketing activities that serve the self-interest of parties in the supply chain at the expense of patients, the health system and our country.

The effects of corruption during the COVID-19 pandemic remain with us. Fortunately, such difficult experiences have advanced transparency, gradually changing how we view, own and drive accountability not just in the sphere of medtech but healthcare more broadly. SAMED wholeheartedly embraces this shift.

By raising awareness of good governance and ethical marketing and business practices and using available means to clamp down on transgressions, we contribute to a more prosperous South Africa – something that we all yearn for.

SAMED therefore continues to promote and strengthen the Medical Device Code, which is an instrument for self-regulation of the medtech industry. The key principle is that signatories to the Code will not offer inappropriate inducements to healthcare providers and healthcare professionals in order to sell or lease their products. SAMED is the custodian of the Code.

During the year, the Code underwent a robust review that included assessment against the Advamed Code in the United States and the Medtech Europe Code. Changes were made to provisions relating to the value of promotional items, and a final version awaits SAMED board ratification.

SAMED strengthened compliance through rigorous enforcement of the certification process including the requirement that the Code declaration must be signed by compliance officers of every member company. We terminated the membership of seven members who were unwilling to comply.

The Code is also the basis for lodging complaints on the 24/7 anonymous **Medical Device Code Hotline** which SAMED continued to promote. Two new complaints are being investigated by the appointed independent chairperson and one is likely to be reported to the Competition Commission.

Play your part in building ethical, corruption-free health services

Be informed: access [the Code and training manuals](#) and [advisory opinions](#)

Report transgressions of the Code: call 0800-00-04-68

Complete the online CPD-accredited [Code certification course](#)

Although fewer complaints were lodged this year, SAMED received more requests for non-binding Code advisory opinions, provided free of charge by the Code Committee. This suggests that suppliers, their customers and professional societies, such as the Vascular Society of Southern Africa (VASSA), have a desire to comply with the Code. Opinions are not only sent to parties requesting them but are circulated to compliance officers of all SAMED members and stored in the **[SAMED library](#)**.



Elevating ethics (continued)

Medical Device Code advisory opinions

Activity	Outcome
Wheelchair donation to patient	Non-compliant
Sponsorship of a registry	Compliant
Skills development at congresses	Compliant
Donation of a TV to a children's hospital ward	Non-compliant
Mugs as a promotional item	Compliant
Loan of fridge	Compliant
Consumer competition	Declined advisory process
Free equipment placement at customer in exchange for scripts	Non-compliant
Sponsorship and display of products	Compliant
Sponsorship of registrars for branded headset	Compliant
VASSA Congress sponsorships and satellite symposia	Compliant
Conference venue compliance: Sun City	Declined advisory process
Catering in return for slot at journal club	Non-compliant
Conference venue compliance	–
Overnight stay at bed-and-breakfast as a competition prize	Non-compliant
International employee certification	Not governed by Code
Rebate model for supply of certain devices or services to healthcare organisation	Compliant
Sponsorship of nurses to attend congress	Compliant

SAMED continued to build support for its efforts to extend the Code to all medtech suppliers.

- The **Compliance Officers' Toolkit** is a practical resource that compliance officers can use to train their staff and suppliers so they can follow best ethical practices.
- We engaged with professional societies to enlist their assistance in making healthcare professionals aware of the Code and applaud those who have acquired Code certification. SAMED's joint statement with Prof Mmampapatla Thomas Ramokgopa, head of orthopaedic surgery at Wits University, on **opportunities for training** offered to registrars is an example of our work in this area. The statement addressed the rights and wrongs of medtech companies approaching registrars, consultants and specialists in public health institutions regarding company-arranged and third-party events and disbursement of educational grants.

Ensuring a fair and objective access to continued education opportunities also supports equity, diversity and inclusion that SAMED is actively driving across all areas of our work.

- Work on Project 18C to secure recognition of the Medical Device Code has progressed. SAHPRA initially advised us to pursue this matter through the Industry Task Group (ITG). However, the ITG proposed a more inclusive consultation involving all parties with a vested interest, including NDOH, SAHPRA, retailers, manufacturers and importers. Work is underway to initiate this.

SAMED continued to support the Health Sector Anti-Corruption Forum (HSACF) and, as a member of its steerco, to participate in the forum's efforts to uncover and root out corruption in healthcare. The forum has received and investigated nearly 30 allegations of fraud and corruption since 2018.

GOVERNANCE REPORT

SAMED is a not-for-gain voluntary industry association. In terms of its constitution, the majority of board members are elected by the members each year at the annual general meeting. The executive committee – comprising, at a minimum, the chairperson, the vice-chairperson and the treasurer – is chosen by the board at its first meeting after the AGM. The board may also nominate a maximum of four members.

The board is diverse not only in terms of gender and ethnicity but in its representation of many facets of our sector: medical devices, medical equipment, in-vitro diagnostics, SMMEs, multinational corporations, local manufacturers and distributors.

2022/23 Executive Committee members

Peter Mehlape SAMED Chairperson Managing Director: Southern Africa Medtronic	Avanthi Govender Bester SAMED Vice-Chairperson Associate Director – Regulatory Affairs & Quality Alcon Laboratories
Reiner Gabler SAMED Treasurer Managing Director Gabler Medical	Donata Kubheka SNR Reimbursement Manager & Market Access Manager Medtronic
Monica Lucas General Manager Werkomed	Neil Venter Managing Director SA Biomedical
Dr Vitor Ferrão Independent Consultant	

2022/23 Elected Board members

Avanthi Govender Bester Associate Director – Regulatory Affairs & Quality Alcon Laboratories	Bulelwa Maponya Head Market Access & Government Affairs Boston Scientific
Dave Roberts General Manager for Southern Africa Johnson & Johnson Medtech	Donata Kubheka SNR Reimbursement Manager & Market Access Manager Medtronic
Madeleine Pearce Senior Quality & Regulatory Systems Manager Philips Healthcare	Marlon Burgess Commercial Manager GE Healthcare
Monica Lucas General Manager Werkomed	Neil Venter Managing Director SA Biomedical
Sabashini Naicker Managing Director Smith & Nephew	Sello Malete Head of Regulatory Affairs, Quality Assurance, SHE and Facilities Roche Diagnostics

2022/23 Nominated Board members

Ian Wakefield General Manager, Africa BD (Becton Dickinson)	Dr Vitor Ferrão Independent Consultant
Reiner Gabler Managing Director Gabler Medical	



MEDTECH: THE GOOD NEWS

We celebrate the life-changing impact that SAMED members are making every day in the lives of patients who use their products and through their social investment programmes.

We share these stories below in the knowledge that they represent fraction of the good work undertaken across the sector.

Medtech that restores the joy of living

Below are testimonies provided to SAMED member **Abbott/Ariste Health** by patients whose unbearable suffering was banished by the correct technology.

“ Last year I decided to take a year off school as I was suffering from severe depression and anxiety. I decided to try transcranial magnetic stimulation (TMS therapy) as an option as the medication I had been prescribed hadn't quite done what I would've liked, and I was still not feeling ok. I was quite nervous for TMS, being a shock treatment on the brain so to speak, but I was really pleasantly surprised as it was not sore at all. Since having my treatment, I have gone back to school. I'm getting the marks I used to get before I got depressed and all in all I'm feeling much better. I'm very grateful to have found TMS as it has really changed my life for the better. ”

– Anonymous

“ For four years, I have been battling with unbearable nerve pain and have been on strong medication for pain that is chronic and debilitating. My normal life has been uprooted. It is something that you can't describe to anyone who hasn't experienced nerve pain. You are robbed of a normal life with joy and happiness. Then I was introduced to Spinal Cord Stimulation (SCS). This device has changed my life. From being in constant pain to a life without pain and without taking any meds. The SCS has made such a huge impact on my life. I can stand in a queue in a supermarket. The best part is that I'm pain free. I have my life back. I can enjoy things again. I have a new zest for life ”

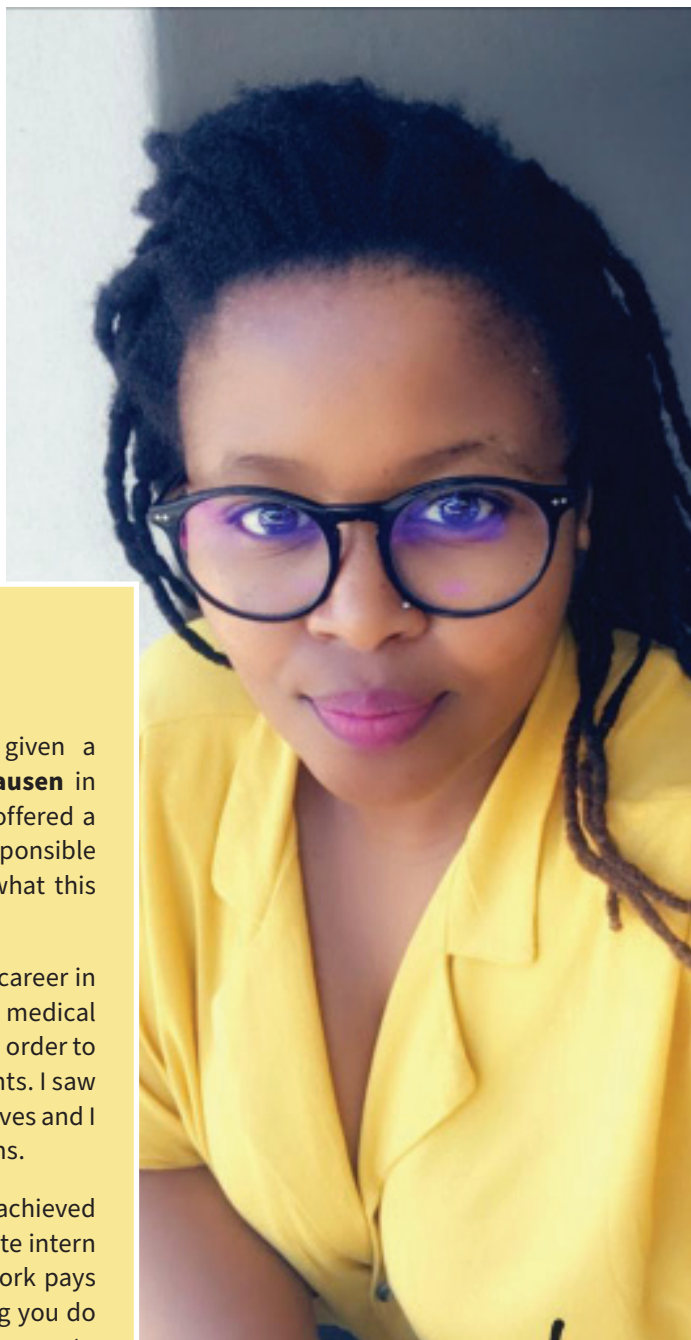
– Anonymous



Healing the wounds of people and planet

SAMED member **BSN Medical** has found a sustainable use for waste generated at its elastic adhesive bandage factory. Selvage trim from the bandage cloth used to be taken to landfill – adding to the mountain of waste and costing the company for its disposal. BSN Medical gave this problem some thought and got together with a carpet manufacturer to turn this waste into a resource for making hard-wearing carpets which are sold to game reserves.

BSN Medical believes it has found an enduring way to help protect the environment. Carpets, like bandages, are not likely to go out of fashion any time soon.



From a graduate intern to a provincial sales rep

Phelo Duma, one of two university graduates given a time-limited internship at SAMED member **Dahlhausen** in 2022, made such a great impression that she was offered a permanent position as a medical sales rep – responsible for the entire province of KwaZulu-Natal. Here is what this experience has meant to Phelo.

“This position gave me an opportunity to begin my career in medtech. It allowed me to learn the importance of medical devices and equipment for doctors and caregivers in order to provide better care and improve conditions of patients. I saw how important medtech was in improving people’s lives and I decided to be part of an industry that brings solutions.

“When I look back, I also can’t believe what I have achieved and learnt in such a short time, from being a graduate intern to a permanent employee. This proves that hard work pays off and if you put your mind and heart in everything you do you can achieve anything, you just need that one person to believe in you. And for me that ‘person’ was Dahlhausen.”



Medtech: The good news (continued)

Sanitary pads help keep girls in school

Millions of adolescent girls and women cannot afford sanitary products and resort to unhygienic materials which put them at risk of infection. The lack of safe sanitary protection causes many girls to miss up to four days of school every month – about 20% of the school year – and contributes to the school drop-out rate.



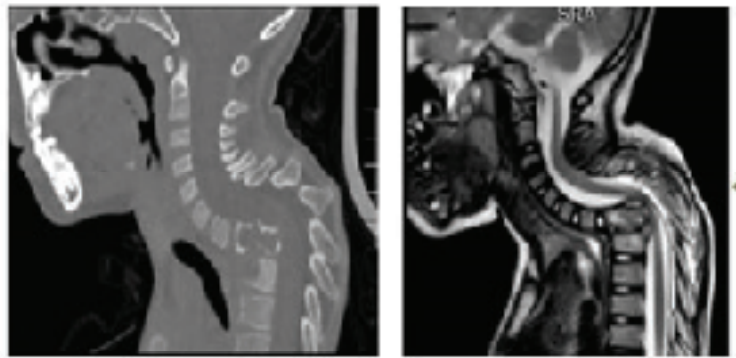
Keamogetse Totwe and Delicia Machabe of SAMED member **HemoCue** did not hesitate when their customers approached them to support a Pharmacy Month initiative to address period poverty.

Kea donated 100 packs of sanitary pads to the North West Pharmaceutical Depot to be distributed to grade 8 and 9 schoolgirls. She also attended a fun walk in a village in the province which concluded with a health fair offering screening tests, vaccination and free health products. Delicia donated sanitary products to the value of R1 000 to the pharmacy at Tintswalo Hospital in Mpumalanga for distribution to girls in nearby schools.

Saving a young patient's life through urgency and ubuntu

SAMED member **J&J MedTech** moved with speed to deliver a key medical device for spinal surgery in order to save the life of a six-year-old with pulmonary tuberculosis which was affecting her proximal thoracic spine.

A team of surgeons was challenged by the large deformities present in the patient's small anatomy. The procedure needed a specific spinal repair kit that suited this particular case. They reached out to Johnson & Johnson MedTech for the EXPEDIUM® 4.5 Spinal System, a DePuy Synthes rod-hook-and-screw solution that is specifically designed for small patients. Product availability, tight time frames and COVID-19 travel restrictions combined to make this a complicated request, but one the company was determined to make happen. Surgery was a huge success and recovery feedback has been outstanding.



Medtech: The good news (continued)

YES harnesses the power of young South Africans

Boitumelo Ketlhapile joined YES and was sponsored by SAMED member **Medtronic** to work at the Aurum Institute as a lay counsellor. She gained great experience, sharpening her interpersonal skills as she helped to manage HIV and TB patients in a healthcare facility. Boitumelo spoke at SAMED's annual conference, sharing her dream of helping to build a better healthcare system where she could serve and work with people from different backgrounds.

Dimakatso Maitisa, *Field REP YES Youth*

Vutomi Mongwe, *Field REP YES Youth*



#RuralHealthMatters: Closing the care gap in Limpopo

When Limpopo Health MEC Dr Phophi Ramathuba issued a call to action to ease the surgical backlog in the province some highly skilled surgeons were listening . . . and ready to act. Under the rallying call of #RuralHealthMatters, distinguished surgeons and international urogynaecologists conducted hands-on skills transfer workshops at Pietersburg Hospital to develop the ability of local doctors to conduct pelvic floor surgery. SAMED members **Sure Medical** and **Vertice** provided financial support and participated in skills sharing for this initiative which promises to provide life-changing surgery for many women. With the backing of Dr Dakalo Muavha, Head of Obstetrics and Gynaecology at Pietersburg Hospital, plans are already in place for a Women's Drive 2023.



Limpopo Health Department fights urology backlog

Limpopo Health Department gets surgical backlog up to date





Special dolls ease childhood cancer treatment

Meet Thoso and Nandi, the huggable dolls created to help children with cancer understand chemotherapy and find some comfort during the trials of treatment. The dolls have removable ports similar to those used to administer chemo to children. They are made by a non-profit organisation in KwaZulu-Natal for SAMED member **Zebra Medical** in an income-generating initiative that extends the



FINANCIAL REPORT

For most SAMED members, 2022 represented the “new normal” in trading conditions after the COVID-19 pandemic. There was a general easing of restrictions and members had ready access to hospitals, and both these factors had a positive impact on the business environment. However, aftereffects of the pandemic were still felt in terms of supply chain issues, substantial increases in freight costs, and other inflationary pressures.

Thanks to the support of members, SAMED ended 2022 in a healthy financial position. Our total surplus amounted to R1 591 112, comprising an operating surplus of R890 457 and net interest earned of R700 655. Equity, in the form of an accumulated surplus, grew to R12 236 000.

The operating surplus was primarily due to underspending against budget by some committees.

Despite the surplus, cash reserves dropped by R1 100 468, with cash and cash-equivalents amounting to R9 962 852 at year end. This reduction in cash reserves can be ascribed to a significant VAT arrears payment of R3 174 524.88 that was made in December 2022.

Previous financial reports explained how SAMED became exposed to a substantial VAT liability, interest charges and possible penalties. We are pleased to report that considerable progress was made this year in resolving this issue.

We issued debit notes for the arrears VAT to members and by end May 2023, an amount of R2 596 908.22 had been recovered from members against a total amount of R3 633 939. This means 28% of the VAT amount still needs to be collected and we urge members who have not yet contributed to do so.

Only the interest charges and penalties are outstanding and SARS has assessed these at R1.8 million. Our tax consultants are engaging with SARS to keep these charges to a minimum.

In view of SAMED’s substantial reserves, this situation does not threaten SAMED’s financial position as a going concern.

The statement of financial position as at 31 December 2022 indicates the positive state of the association’s financial affairs. The income statement reflects total revenue of R7 669 187 which comprises members’ subscriptions, conference fees and other income.

Major expenditure items were:

- Employee costs – R2 707 657.
- Advertising expenses – R702 830, comprising communications services, association rebranding and website costs.
- Consulting and professional fees – R514 849. These related to strategic development and guidance for SAMED and members (R135 000), professional consulting and training services relating to CMS submissions, procurement and NHI (R117 176.75), and legal counsel and training on competition and contract law (R93 627.50).
- Code Compliance costs – R131 126, mainly for independent legal review services.
- BUSA membership – R341 038.
- Data with Integrity – R750 833.
- Event costs – R201 202.
- Subscriptions for MDMSA – R496 262.

The above items comprise 86% of the association’s expenditure. The remaining 14% includes office rental, other office expenses, and outsourced specialist services. Our personnel costs increased by 4.5%, which is a modest increase.

The SAMED 2023 budget projects a deficit of R2.6 million. Once-off projects account for R825 000 of this. The balance of the deficit pertains to committee expenditure. All projects funded within the 2023 budget were carefully considered by the board, which weighed their strategic and operational value for SAMED, the members and the broader medtech sector. SAMED reserves will offset the deficit without compromising SAMED’s strong financial position.

The association had suspended membership fee increases for two years, but decided to implement a modest 3.5% fee increase for 2023.

Reiner Gabler

Treasurer



Summary of income and expenditure

Income January to December 2022

	2022	2021
Member subscriptions	7 526 403	7 271 487
Conference fees	109 268	32 650
Other income	33 516	708 031
Interest income	700 689	391 818
Total income	8 369 876	8 403 986

Expenditure January to December 2022

	2022	2021
Employee costs	2 707 657	2 591 558
Office and other expenses	1 475 173	1 560 022
Subscription fees to MDMSA	496 262	1 221 050
Advertising	702 830	461 955
Consulting and professional fees	514 849	161 065
Code compliance costs	131 126	286 807
Data with Integrity initiative	750 833	98 320
Total expenditure	6 778 730	6 380 777

LIST OF SAMED MEMBERS

Ordinary members
3M South Africa
Abbott Rapid Diagnostics
Abex Pharmaceutica
Acino Forensic
Advanced Orthopaedic Solutions
Africoncur Medical
AHG Health Solutions
Akacia Medical
Alcon Laboratories
Allenco Medical and Dental Supplies
Alltech Healthcare
Anstem Medical
Ariste Health
Arjo Huntleigh South Africa
Arterial Medical
Ashanti Medical
B Braun Medical
BCC Pharmaceuticals
BD (Becton Dickinson)
Beier Drawtex Healthcare
BioTech Africa
Bloemed Medical Supplies and Services
BMG Orthopaedic Solutions
Bone SA
Boston Scientific South Africa
BSN Medical
Carl Zeiss
Centre for Tissue Engineering
Chairman Industries
Cherrymed Enterprises
Clinipro
Coloplast
Continuous Oxygen Suppliers T/A VitalAire
Convatec South Africa
Corin SA

Ordinary members
Cossni Medical
Creatori Health
Dahlhausen
Demant South Africa
Dimela Health
Dr Temp
Dräger South Africa
Duzane-Africa Medical
Edwards Lifesciences
Elegant Line Trading T/A Health Armour
Elekta
Endosurgical
Ethitech
Fluorovizion Holdings
Fresenius Medical Care
Gabler Medical
GE Healthcare Technologies
Grobir Medical Supplies
Guerbet South Africa
Hartmann Vitamed
H.A.S.S. Southern Africa
HemoCue South Africa
Hi Care Surgical
Imperial Market Access Healthcare SA
Implantcast SA
Imvula Healthcare Logistics
Isifuba Medical
JaLo Enterprise
Johnson & Johnson MedTech
K2 Medical
Karl Storz Endoscopy SA
Kiara MedTech
Klinikka
Langamedics
LDK Intertrade



List of Samed members (continued)

Ordinary members

Lechoba Medical Technologies

Ligamed SA

Lorumir D

Lukatit Investments 14 T/A Unitron SA

Maars Medical

Maisha Medical

Maquet Southern Africa

Marcus Medical

MED-EL Distribution

MED-EL Implant Systems South Africa

Medhealth Supplies

Medical International Orthopaedics

Medical Plant Africa

Medtronic Africa

Meducat Medical

Melemo Medical

Merck Life Sciences

Meril SA

Merit Medical South Africa

Mezotrix

Modiro Medical

Morgan Joshua Innovation

National Bioproducts Institute

Neurophysics

Nipro Medical South Africa

NuAngle Solutions

O&M Halyard South Africa

Obsidian Health

OMS Medical

Optimum Orthopaedics

Ordinary members

Ortho-Design

Orthomedics Pharmaceuticals

Ortho-Xact

Osteologix SA

Paragon 28 Medical Devices

Patient Medical Care T/A Zebra Medical

Perryhill International Trading

Philips South Africa

Phoenix Neomed

Pinnacle Innovations

Pointer Medical

Population Service International, South Africa

PrimeSafe T/A SteriTech

PrionGuard

Prism Inter Africa CC

Procter & Gamble South African Trading

Professional Orthopaedics

Progress Medical Supplies

Q-Surgical

Responsive Orthopaedics

Roche Diagnostics

SA Biomedical

Safarmex

Safmed

Sea 4 Medical Logistics

Selective Surgical

Siemens Healthcare

Smith + Nephew

Soflens T/A Bausch + Lomb

Southern Ear Nose and Throat

Ordinary members

Southern Implants
Staar Surgical
Stieglmeyer Africa
Stryker South Africa
Supra Healthcare
Sure Medical
Surgical and Ophthalmic Supplies
Surgical Innovations
SXS Surgical Solutions
Synthecon Sutures Manufacturing SA
Tara Healthcare
Teleflex Medical
The Scientific Group
Umsebe Healthcare
Vertec Scientific SA
Vertice Healthcare
Viking BCT
Viking Cardiovascular
Welch Allyn South Africa
Werkomed
WS Audiology South Africa
Zimmer Biomet South Africa

Associate members

AfriPharm SA
Austrade
BRANDTECH Health Technology Consulting
CEASA
CSIR
DI Medicine Regulatory Consultants
Diverse Conversations
DSV Solutions T/A DSV Healthcare
Enterprise Ireland
Institute of Bio Research Auditing and Training in Southern Africa (IBRATSA)
Intellectus Campus
IQuad Integrated Management Systems
JPJ Medical
KOTRA
Mark Banfield & Associates
Masoom Training Solutions
Mawele Investments T/A Twinz Pharmaceutical Regulatory Affairs Consultants
MC Pharma Consulting
MedInc SA
NGL Logistic Solutions
Progressus Digital
Regulatory For Africa



APPENDIX

Events and expertise on offer to members 2022/23

Date	Event and topic	Speakers and highlights
11 May 2022	SAMED-SALDA Regulatory Forum: SAHPRA communications and Ghana medtech regulations	Lydia Motlogelwa , Manager Registration, Medical Device Regulation, SAHPRA Khanyisile Nkuku , Pharmacist, SAHPRA Emmanuel Nkrumah , Director, Medical Devices, Cosmetics and Household Chemicals, Ghana Food and Drug Administration
11 May 2022	SAMED Chairperson's Forum in Western Cape: Opportunity for members to engage with SAMED leadership	Mandi Swanepoel , HealthTech Ecosystem Manager, Wesgro Tanya Vogt , Executive Officer, SAMED Marlon Burges , Chairperson, SAMED
17 May 2022	SAMED Market Access Forum: Discovery reimbursement and HTA processes and Mediclinic procurement process	Dr Noluthando Nematswerani , Head: Centre for Clinical Excellence, Discovery Health Kershnee Chetty , Head: Surgical Risk, Discovery Health Niri Bhimsan , Head: Health Technology Assessment, Discovery Health Paul Wijtenburg , Capital Procurement Manager, Mediclinic South Africa
26 May 2022	SAMED Annual General Meeting: Our first in-person event since onset of COVID-19	Cas Coovadia , CEO, BUSA
7 June 2022	SAMED Market Access Forum: Addressing public sector debt	Linda Lombard , Market Access Chairperson, SAMED Tanya Vogt , Executive Officer, SAMED
23 June 2022	SAMED Medical Device Code Forum: The rise of extortion of businesses in South Africa	Wayne Malgas , Partner, Control Risks Michael Judin , Judin Combrinck Attorneys
29 June 2022	SAMED Transformation Forum: Capacitating healthcare through youth opportunities	Danai Nyagani , Programme Manager, Youth Health Africa Farai Mubaiwa , Business Development Lead, YES Tracy Pepler , Business Development Leader, Rays of Hope
6 July 2022	SAMED Regulatory Forum: Middle East & Africa update and unpacking Global Medical Device Nomenclature (GMDN)	Rana Chaloub , Regulatory Affairs, Mecomed Dr Barry Daniels , Clinical Lead, GMDN
12 July 2022	SAMED Market Access Forum: Medscheme reimbursement and HTA processes	Christine Keyter , Advanced Specialist: HTA, Medscheme
20 July 2022	SAMED Chairperson's Forum in Gauteng: Focus on industrial and innovation hubs and adverse impact of public sector debt on SMME sustainability	Amanda Tshaya , Senior Manager: Investment Facilitation and Promotion, Gauteng Growth and Development Agency (GGDA) Peter Mehlahe , Chairperson, SAMED

Date	Event and topic	Speakers and highlights
21 July 2022	Overview of the South African Orthopaedic Registry (SAOR)	Dr Odette Koch , Registry Lead, SAOR
3 August 2022	SAMED Chairperson's Forum in Western Cape: Chance for members to engage with SAMED leadership and discuss local opportunities	Dr Neshaad Schruder , Head of General Specialist Service: Medicine, Tygerberg Hospital Peter Mehlae , Chairperson, SAMED
19 August 2022	SAMED Transformation Forum: Women in Medtech Expanding the participation of women at all levels of the industry	Dagmar Kahn , Business Development Manager, Witkoppen Health Daniel Nhemavhena , Multi-disciplinary Healthcare Service Delivery Lead, Witkoppen Health Panel: Abigail Boikhutso , Managing Director, Isifuba Medical Bongi Mageushe , Managing Director, Sysmex South Africa Dave Roberts , General Manager, Johnson & Johnson Medtech Jackie Pretorius , Director, Jalo Enterprise Natasha Naidoo , Managing Director, VitalAire Peter Mehlae , Managing Director, Medtronic Moderator: Tania Habimana , CNBC Africa host
23 August 2022	SAMED Medical Device Code Forum: Compliant grant management	Jaco Kleynhans , Code Committee Member, SAMED Sada Volk , Code Committee Member, SAMED Oriane Chetty , Code Committee Member, SAMED
1 September 2022	Captains of Industry Forum: Inaugural forum, held at Deloitte's new facilities in Midrand, discussed strategies for taking SAMED and the industry forward	Panel: Abigail Boikhutso , Managing Director, Isifuba Medical Avanthi Govender Bester , Vice chairperson, SAMED Dave Roberts , General Manager, Johnson & Johnson Medtech Ian Wakefield , General Manager, Beckton Dickinson Peter Mehlae , Chairperson, SAMED Moderator: Tania Habimana , CNBC Africa host
6 September 2022	SAMED Market Access Forum: Public sector payments – update and new approaches to government	Linda Lombard , Market Access Chairperson, SAMED John Prevost , Market Access Committee Member, SAMED Tanya Vogt , Executive Officer, SAMED
7 September 2022	SAMED Regulatory Forum: Compliance in conduct of clinical trials	Khanyisile Nkuku , Medical Device Licencing Unit, SAHPRA



Appendix (continued)

Date	Event and topic	Speakers and highlights
21–22 September 2022	SAMED Annual Conference: Purpose-driven medtech: partnering to reform healthcare Special youth input included	14 sessions, 45 speakers and 144 participants on day 1 and 109 on day 2
28 September 2022	CRICE Forum: Equipping company representatives with knowledge and skills for ethical business conduct	Fatima Amod , Managing Director, Masoom Training Solutions
6 October 2022	SAMED Market Access Forum: Life Healthcare procurement, update on competition law and World Bank financing and debt insurance	Heather Irvine , Partner, Bowmans Ilhaam Solomons , Group Procurement and Clinical Engineering Manager, Life Healthcare Shuichi Hayashida , Head: West and Central Africa, World Bank
13 October 2022	SAMED Medical Device Code ethics panel training	Michael Judin , Judin Combrinck Attorneys Tanya Vogt , Executive Officer, SAMED
20 October 2022	SAMED Medical Device Code Forum: Fair market value, HPCSA ethics booklet and hotline	Veronique Monjardet , Global Compliance Director, IQVIA Kabeer Uddin , Associate Principal: Strategy Life Science, IQVIA Valentine Ngobeni , Business Development Manager, Deloitte Mpho Mbodi , Head: Professional Practice Division, HPCSA
2 November 2022	SAMED Regulatory Forum: Sub-Saharan Africa update and managing risk within ISO 13485	Frangelina Letsoalo , Regulatory Committee Member, SAMED Simone Rudolph-Shortt , Regulatory Committee Member, SAMED
8 November 2022	Captains of Industry Forum: Medtech building brilliant and cybersecurity in healthcare	Adrian Saville , Economics Professor, GIBS Leishen Pillay , Cyber Privacy Leader, Deloitte Moderator: Pabi Moloi , radio and television presenter
16 November 2022	SAMED Market Access Forum: CMS, reimbursement and diagnostics	Elsabe Klinck , Partner, Elsabe Klinck & Associates Bridget McNulty , Co-Founder, Sweet Life Rosanna Peeling , Professor and Chair: Diagnostics Research Director, International Diagnostics Centre, London School of Hygiene and Tropical Medicine
17 November 2022	SAMED Transformation Forum: Strategies for 2023 and ESD complexities	Kealeboga Mokobolote , Associate Director, Transcend Leanne Emery-Hunter , COO, Youth Employment Service Kebalepile Matlhako , Transformation Consultant, BEE Chamber

Date	Event and topic	Speakers and highlights
7 February 2023	Data with Integrity training session	Caroline Scott , Communication and Events Management Officer, SAMED Launch event overviewing the platform and call for primary and alternative contacts
7 February 2023	Regulatory Forum: Middle East and Africa regulatory landscape	Rana Chalhoub , Mecomed
8 February 2023	SAMED Market Access Forum: Western Cape tender and procurement process	Santie Roy , Director of Supply Management, Western Cape Department of Health
14 February 2023	SAMED Transformation Forum: B-BBEE and procurement regulations	Kebalepile Matlhako , Transformation Consultant, BEE Chamber
23 February 2023	SAMED Medical Device Code Forum: Third-party events, advisory opinions and whistleblowing hotline	Sada Vlok , Code Committee Member, SAMED Caroline Scott , Communication and Events Management Officer, SAMED Michael Judin , Judin Combrinck Attorneys
27 February 2023	Data with Integrity Forum: Technical skills-building for data gathering	Caroline Scott , Communication and Events Management Officer, SAMED
1–2 March 2023	Data with Integrity: Practical sessions for operational personnel	Caroline Scott , Communication and Events Management Officer, SAMED Seven training sessions on the first call for member inputs
3 March 2023	Women in Medtech Forum: SAMED Women's Empowerment Index and broader issues of empowerment and equity	Prof Ncoza Dlova , Dean, School of Clinical Medicine, UKZN Nyimpini Mabunda , CEO, GE Southern Africa and author "Take Charge: Life Lessons on the road to CEO" Moderator: Tania Habimana , CNBC Africa host
15 March 2023	SAMED-Deloitte Anti-Money Laundering legislation	Hannes van der Merwe , Senior Manager: A&AS, Deloitte Dean Chivers , Risk Advisory Lead, Deloitte
17 March 2023	Captains of Industry Forum: Engaging with SAHPRA and the SAMED-YES partnership	Dr Boitumelo Semete-Makokotlela , CEO, SAHPRA Dr Dimakatso Mathibe , Senior Manager: Medical Devices, SAHPRA Peter Mehlahe , Chairperson, SAMED Avanthi Govender Bester , Vice Chairperson, SAMED Scott de Olivera , Transformation Chairperson, SAMED Moderator: Pabi Moloji , facilitator, radio and television presenter





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