

THE SAMED BOARD REPORT MAY 2024 – MAY 2025

Presented by the Chairperson Scott de Oliveira

SAMED at 40: Breaking Barriers – Inclusive, Innovative and Impactful Medtech

This report to SAMED member companies is presented during the Association's 40th anniversary year.

Way back in 1985, the then Registrar of Medicines, Mr Johan Schlebusch advised that Act 101 was to be amended to include medical devices into the regulatory framework. Dr Roger Balding of Johnson & Johnson convened a meeting of local manufacturers to discuss the implications of such legislation, and it was decided to form SAMED – the South African Medical Device Industry Manufacturers' Association.

The early objectives of the Association were to engage with the regulatory authorities on impending registration of devices.

Our founding member “forefathers” were: Brittan Healthcare Group; Browning Medical cc; Marcus Medical (Pty) Ltd; Orthomedics (Pty) Ltd; Safmed (Pty) Ltd; Smith & Nephew (Pty) Ltd; Southern Implants (Pty) Ltd.

2024-25 SAMED SIGNIFICANT NUMBERS

- 141** Ordinary members
- 23** Associate members
- 10** New members
- 76** Registered Public Debt portal users
- 50** Member companies participating in public debt data collection
- 51** Registered Women Empowerment Index users
- 29** Member companies in Women Empowerment Index
- 1** New MOU – with Council for Medical Schemes on medtech matters
- 45** Medtech companies that said YES to youth employment
- 3 502** Youth jobs created by medtech companies, 62% are female
- R197 512 800** Paid out in YES youth salaries
- 184** Experienced youths' CVs on the SAMED-YES Alumni portal
- 11** Policy submissions
- 2** Major SAMED events – AGM and annual conference
- 18** Other events hosted by SAMED
- 1 794** Attendance at SAMED events
- 3 554** SAMED LinkedIn followers
- 3** Code hotline cases received and investigated | 21 since 2019
- 15** Code advisory opinions provided

The Association membership was restricted to local manufacturers for the initial seven years. Multinationals were excluded as they were de facto well advanced regarding regulatory compliance.

In 1990 the proposed changes to Act 101 were released and SAMED objected vehemently as the intent was merely to add the words ‘medical devices’ to legislation that was aimed primarily at pharmaceutical products. Since it was not created for medical devices, it would have been impossible for any device company to comply with such irrelevant legislation.

Due to the incredible efforts of SAMED, we finally have medical device-specific regulations today and SAMED continues to advocate that these be harmonised, fit-for-purpose and that they keep up with the times.

Who would have known 40 years ago that artificial intelligence would today be enhancing diagnostics, with remote monitoring technology transforming chronic disease management and telemedicine bringing consultations with HCPs to people who until recently might not have had access to healthcare?

This incredible 40th birthday milestone deserves to be acknowledged in this report.

As humans, we grow up observing and celebrating how we change each year. I believe that the same applies to an industry collective like SAMED where many exemplary individuals from different branches of our medtech sector and beyond worked together to define, defend, develop and realise the incalculable value of medtech in saving and improving lives.

As the 2025 SAMED chairperson, it is my honour to pay homage to my predecessors and the many colleagues and members who were part of our Association's journey.

Together, we have identified, developed, provided and shared expertise, research and resources with medtech suppliers, policy makers, funders, regulators, healthcare professionals and South African patients. This four-decade legacy has allowed SAMED to gain perspective and harness learnings and relationships to ensure that we can confidently look towards a prosperous future for the medtech sector and its vital role in patient care.

The high regard for SAMED in the market is reflected by the many local and international entities that approach SAMED for advice and assistance and shows that South Africa is an enticing place to be for the medtech industry. Despite its headwinds, South Africa provides one of the best routes into Africa.

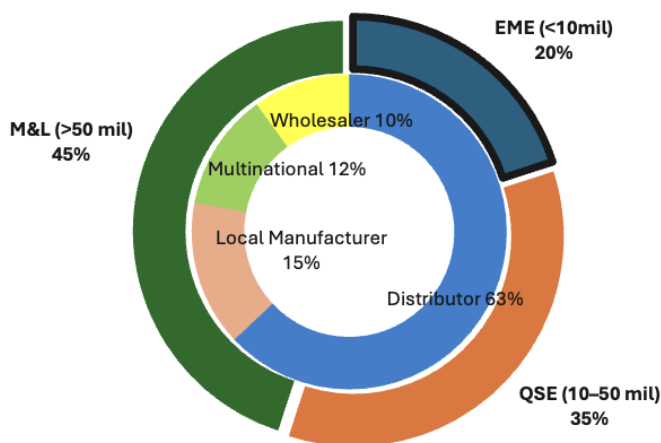
The strategy development process that the board initiated in November 2024 affirmed:

- SAMED's commitment to promoting an ethical, sustainable and globally competitive medtech sector that enhances patient care and health outcomes and advocates for data-driven healthcare solutions.
- That SAMED functions as an Institution For Collaboration (IFC) which relies on partnerships to achieve its mission to serve as the collective voice of the medtech industry. A crucial aspect of this function is to empower member companies with information and tools to help them navigate through the evolving regulatory and healthcare landscape.
- SAMED's role in shaping and enabling efficient industry policy and regulation, supporting its members and their commercial goals and addressing macroeconomic, regulatory and competitive challenges.

As SAMED turns 40, we ought to note significant dynamics that are part of today's context and tomorrow's trajectory for the medtech sector. South Africa and the African continent are at the same time home to recognised healthcare centres of excellence and some of the most unequal and under-served health systems worldwide. With her youthful population, Africa can rapidly adopt and optimise digitisation and other new technologies to improve healthcare, as well as other ESG (environment, society, governance) goals and indicators holistically. In addition, a fundamental common spirit of togetherness – in South Africa expressed as ubuntu – provides a foundation for uniting and thereby amplifying the value our diverse businesses and services bring to each patient across vastly different healthcare settings.

Specifically, the medtech industry faces various external challenges, including regulatory complexity, economic volatility, geopolitical risks, and technological disruption. Compliance with evolving South African Health Products Regulatory Authority (SAHPRA) regulations, procurement shifts, and EU Medical Device Regulation (MDR) requirements continue to add layers of complexity to business operations. Additionally, government debt, exchange rate fluctuations and shifting global trade conditions present further challenges for medtech businesses operating in South Africa. The industry must also navigate issues related to artificial intelligence, cybersecurity, digital transformation, and the growing influence of non-traditional players.

Graph 1: SAMED membership constitution



As illustrated by the membership constitution graph, SAMED represents companies of all sizes and both local and international role players. The growing number of small/medium-sized enterprises (SMEs) joining the Association demonstrates the benefits of being a member of SAMED and the valuable access this affords to business-essential information and assistance.

During the course of the year, three specific but deeply interconnected policies and market related challenges emerged:

- National Health Insurance: access SAMED's recently minted [10-point position paper on NHI](#).
- The MEDTECH Master Plan.
- Resolution of the government debt owed to members.

To address the current market dynamics and to fulfil its mandate to authentically represent the voice of its members, the Board has structured its functions into three key workstreams: Environmental, Social, And Governance (ESG). Each workstream is supported by a dedicated set of competencies, designed to deliver on the core performance areas within its domain. While the workstreams operate as distinct pillars, they are complementary, with each maintaining a clear focus on its respective ESG focus. To ensure strong leadership and accountability, Workstream Champions have been appointed for each area, tasked with overseeing implementation and encouraging cross-functional collaboration.

Environmental

- The Environmental workstream plays a vital role in advancing the strategic objectives of the MedTech Master Plan. A primary focus is the cultivation of a collaborative and aligned partnership with SAHPRA to develop a harmonised regulatory framework. This framework is intended to streamline processes, strengthen compliance, and promote sustainable practices across the sector. Through improved alignment and operational efficiency, the workstream seeks to drive meaningful progress that benefits all stakeholders—particularly in supporting the growth of local manufacturing.

Social

- The Social workstream focuses on public relations, diversity, and inclusion, aiming to elevate SAMED's visibility and relevance within the South African medtech sector through strategic, targeted PR campaigns. Advocacy efforts on the diversity and inclusion agenda will prioritise building partnerships between industry and educational institutions, fostering opportunities for internships, cooperative programmes and practical training. This approach will not only empower women within the sector but also contribute to the development of critical skills, essential for the industry's long-term growth.

Governance

- The Governance workstream is dedicated to driving the sustainable development of the MedTech industry, advocating for value-based funding models that emphasise long-term effectiveness, patient outcomes, and overall healthcare impact, rather than focusing solely on initial acquisition costs. It will also support the implementation of the National Health Insurance (NHI) system, in alignment with SAMED's position and the best interests of all sector stakeholders. The workstream will lead efforts to enforce the marketing code for medtech companies, championing its integration into SAHPRA's licensing processes. Additionally, it will focus on developing market intelligence to empower SAMED members in advancing their business objectives.

These narratives are reflected in SAMED's 40th anniversary theme, *Breaking Barriers – Inclusive, Innovative and Impactful Medtech*.

Breaking Barriers is a rallying call to identify and overcome systemic and operational challenges that constitute many of the pain points of SAMED members – such as the outstanding government debt. In addition:

- The medtech industry has the responsibility to be **inclusive** – to assist health systems in all their forms and varieties to provide access to relevant and quality medtech. Inclusivity likewise entails our commitment to women and youth inclusivity and the sector's transformation, diversity and sustainability.
- The way we embrace **innovation** and invest in technological advancement across the entire medtech value chain needs to ensure the relevance, quality, efficacy and efficiency of products and services required by our market.
- The **impact** ascribed to medtech should recognise individuals and organisations that make, supply, maintain and otherwise engage with settings that use and benefit from medtech products – devices, technologies, in vitro diagnostics and other related items.

As 164 individual SAMED member companies and many times that number in terms of the employment generated and products and services provided by the medtech value chain, we have directly enabled and strengthened the health systems we interact with. We acknowledge and celebrate our impact, these milestones and the opportunities to support healthcare and socio-economic progress for years to come!

HOW DO YOU SOLVE A BILLION-RAND GOVERNMENT DEBT PROBLEM?



Outstanding
Public Sector
Payments
Project

SAMED fully appreciates the severity of the public sector debt problem and the critical threat it poses to the survival of SAMED members and sustainability of the medtech sector. I wish to report to the members that in compliance within the sustainability of medtech aspect of its mandate, SAMED leadership and secretariat devoted extensive time and effort to addressing and resolving the issue on behalf of the

members. This work entails gathering and tracking the debt (through SAMED's Data with Integrity portal), reporting on the figures to members and key government officials, creating awareness through public channels, advocating with government through meetings and correspondence and proposing short- and longer-term solutions.

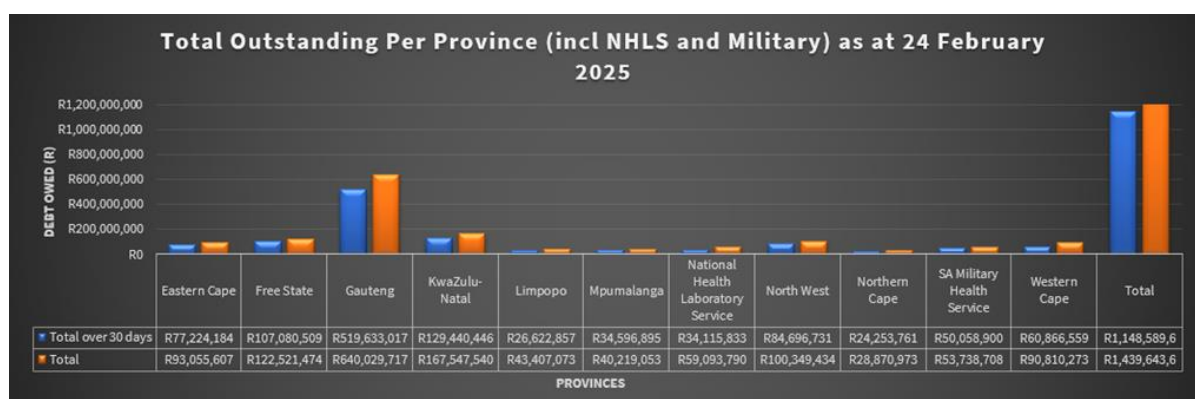
In this regard, SAMED hosted government debt forums, one of which included legal information and advice by a lawyer with whom SAMED has negotiated a reduced fee for member companies that wish to explore that route.

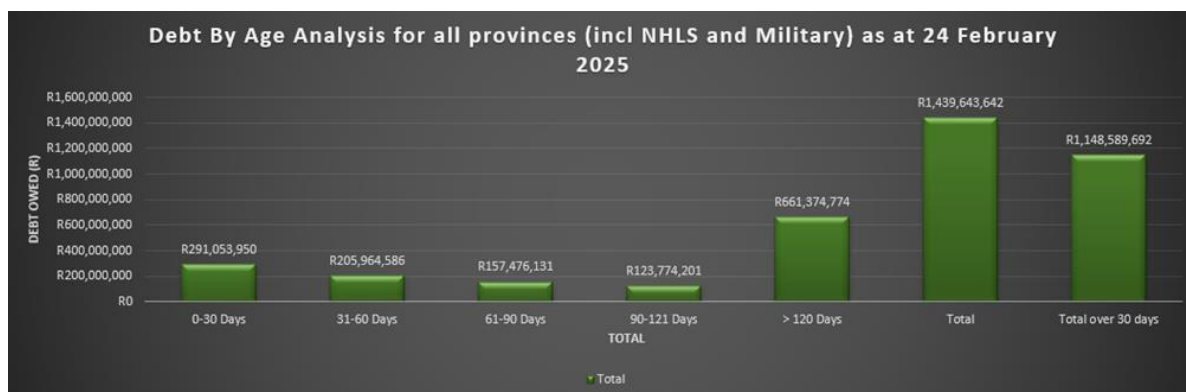
SAMED has also written to the Ministers of Health, Finance and *the dtic* and MECs for Health and Treasury in Gauteng and KwaZulu-Natal and engaged with the media to highlight systemic budgeting and transactional inefficiencies as the main reasons for financial mismanagement and late payments of suppliers by provincial health departments. We are leveraging our relationships with government leaders who are part of the MEDTECH Master Plan and building the business case for how to use the NHI process to facilitate holistic, sustainable and impactful procurement and reimbursement frameworks going forward.

The most recent update is that we are waiting for a formal response from the Health Sector Standard Chart of Accounts (SCoA) non-negotiable (NN) and key accounts workshop held 26 and 27 March. The session is a collaboration between the National Department of Health, National Treasury, Provincial Treasuries and Provincial Departments of Health. SAMED's presentations highlighted the following requests and recommendations:

- Improving/streamlining communication between suppliers and the responsible provincial officials.
- Hosting provincial member forums.
- Focusing on longstanding debt in addition to making payments for the more recent invoices.
- Strengthening provincial budgets to avoid provinces having to use next year's budget to settle current invoices.

I wish to emphasise that the best leverage we can use for these engagements is data. We need information on how much is owed to member companies so we can present accurate, current data to elevate the urgency and importance of this challenge. In the last quarter, we noticed a substantial increase in the number of member companies adding their information to the portal, which speaks to the relevance and seriousness of the problem. The data from the portal is pulled and analysed quarterly, and the most recent (February 2025) figures are represented below. So if your business has government debt, please participate in the next round of data collection.





ADDRESSING OTHER REIMBURSEMENT MATTERS

During the year, SAMED initiated dialogues with the private medical scheme sector and the regulator, **Council for Medical Schemes (CMS)** relating to gaps in the representation of medical technology expenditure and to lobby for clearer, more transparent, accurate and medtech-appropriate data/terminology use in reimbursement processes and reports.

This data serves as a basis for reimbursement guidelines, setting of fees and payment procedures. Without insight into this information, it is difficult to correctly apportion fees and payments for medtech to suppliers against allocations for hospital or HCP fees or to challenge insufficient, misinformed or inequitable allocations for medtech products. SAMED ensured our representatives were well prepared for these engagements and that we used them as strategic platforms to communicate other essential information about the medtech industry and how to ensure medtech and innovative solutions function well across the diverse conditions under which they are applied.

I am pleased to report that we have since signed a Memorandum of Understanding with CMS that will assist to realise this imperative objective. The MOU will provide a framework for collaboration between CMS and SAMED, with a view to sharing information, data and research on medtech and supporting each other on joint projects by consulting on experiences and challenges in our respective business environments.

The partnership has already facilitated SAMED's participation in CMS's policy roundtable where SAMED Executive Officer Tanya Vogt reiterated the message that the medtech sector lacks access to data which is vital for value-based procurement (VBP) and standardised health technology assessments (HTA) processes and requirements across multiple schemes.

SAMED had several productive engagements with **Discovery Health** during the year to put forward the members' voice on cost pressures our sector faces and manages every day. In the context of value-based outcomes and the sustainability of our industry as well as its contribution to essential health services, SAMED has requested that as the dominant funder, Discovery Health reviews its reimbursement models and consult with SAMED and industry when they create the models to ensure optimal health outcomes.

SAMED has also raised the matter of the high cost of commercialised published data and that it is in everyone's interest – most importantly the patients' – if those reports can be more easily accessed by the medtech industry to inform strategies.

Addressing these areas will provide valuable insights for our sector and contribute to a more comprehensive understanding of healthcare financing in South Africa. The achievements speak directly to the SAMED strategy in multiple ways, and we undertake to keep you posted on the future benefits and outcomes of this intervention.

Another key aspect of reimbursement – and cause of the frustrations felt by some members – that SAMED addressed relates to HTAs and health economics and outcomes research (HEOR). SAMED initiated a collaboration with a service provider, **Syenza**, that will empower SAMED members with the critical knowledge and skills needed to navigate HTAs and HEOR for market access and more effective reimbursement. The nine-month course is only accessible to SAMED ordinary members at this stage so make sure your company benefits from this offer!

COMPLIANCE AND REGULATORY REPORT

This SAMED pillar was exceptionally active during the year. I would like to recognise SAMED and the Code Committee for their insights, commitment and many hours that went into revamping and upgrading the central piece in SAMED's sector self-regulatory framework – the Medical Technology Code of Ethical Marketing and Business Practice.

The Code is now a user-friendly digital resource that is proving to be a valuable component in the broader SAMED compliance programme. The Code promotes and encourages ethical principles and practices during supplier-customer interactions such as training events. Despite its depth and breadth, the Code is nevertheless easy to navigate and contains valuable information about the laws, activities and procedures that govern the way medtech companies do business in South Africa and how they interact with HCPs.





The Code				
Part 1: Interactions with healthcare professionals				
General criteria for events	Third-party organized educational events	Company events	Virtual and hybrid events	Educational grants and support to HCP participation in events
Supporting independent third-party research	Promotional items, items of medical utility, gifts and competitions	Charitable donations	Consulting agreements	Demonstration, samples and evaluation products
Part 2: Dealing with transgressions of the code				
Addenda				
Management of indirect support and associated educational grants		Example template of consulting agreement		Registry principles and position paper

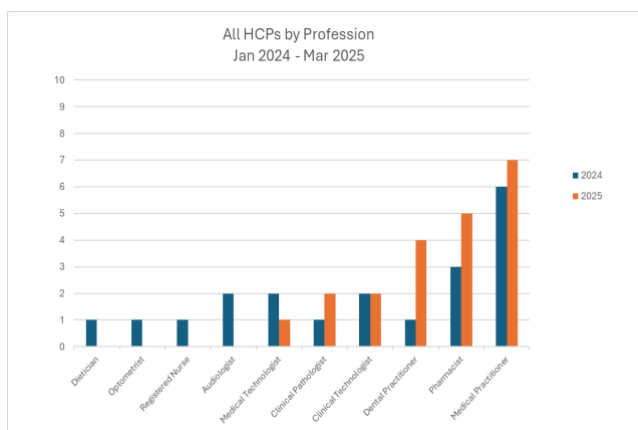
With leadership from SAMED's Compliance and Regulatory Manager, Alwi Spearpoint, SAMED has updated and aligned the Certification questions and criteria with the Code, as well as streamlined the certification processes and opened the Certification up to all stakeholders including healthcare professionals (HCPs) and professional conference organisers (PCOs) with the objective of deepening the Code's adoption and use. Furthermore, becoming a signatory of the Code – as a demonstration of ubuntu and accountability – has been extended to all medtech companies, regardless of their membership of SAMED and is open to SALDA and MDMSA members as well. The intention is to raise awareness of bribery and corruption risks and to build a movement dedicated to ethics and governance throughout the industry.

To publicise and mobilise interest and uptake of the Code and completing the Certification test among external stakeholders, SAMED published a CPD-accredited article in leading medical media and through organisations such as the Health Professions Council of South Africa (HPCSA) as part of a communication and marketing drive targeted at professional societies and conference organisers.

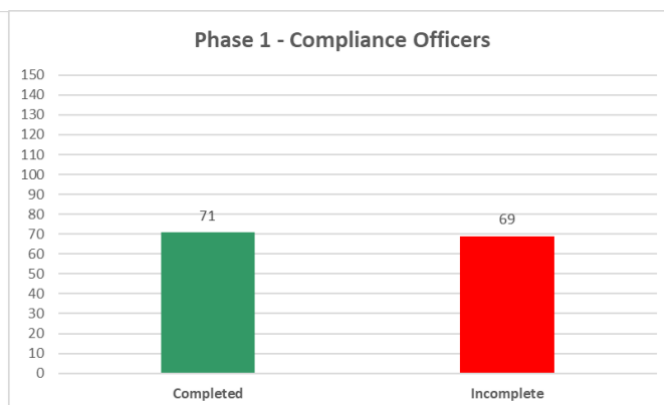
The graphs below illustrate the status of Code Certification:

- By HCPs from different health disciplines: 21 HCPs received certification since January and 42 have requested the Certification Voucher that allows them three free attempts (thereafter a nominal fee applies).
- The phased certification of member companies' staff, namely the Compliance Officers which needed to be completed by March and all customer-facing employees whose certification began in April.

Graph 2: The increasing number of Code Certification by HCPs status

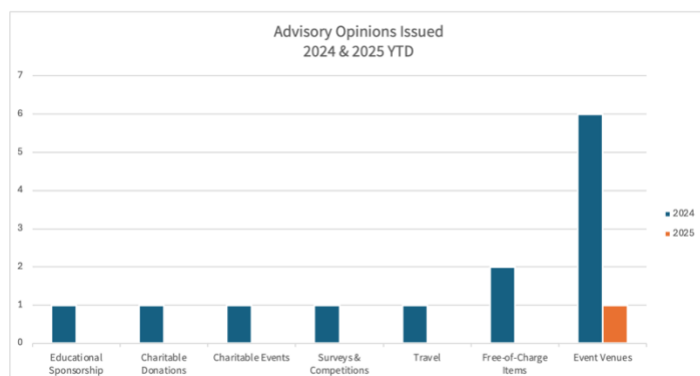


Graph 3: Member companies' Code Certification



SAMED diligently facilitated and monitored member company certifications, as well as managed three cases reported to the Code Hotline during the year and responded to 14 requests for advisory opinions.

Graph 4: The uptake of The Code advisory opinions



As the graph on advisory opinions illustrates, selection of compliant venues for HCP education is a complex and frequently raised topic that SAMED intends to address in collaboration with MedTech Europe and MECOMED so that SAMED gains access to the CVS platform used by these entities with the intention to simplify venue vetting for SAMED members.

This vital data is shared with partners, including the Health Sector Anti-Corruption Forum (HSACF) and SAHPRA.

Table 1: The Code Hotline use during the year

Month	Code Hotline Complaint	Outcome
Aug 2024	Sponsorship of entertainment	Case closed – dismissed. No contravention of the Code
Aug 2024	Sponsorship of a congress at a non-compliant venue (Sun City)	Case closed – sanctions issued
Feb 2025	Advertising of Class D medical devices on public platform	Case closed - referred to relevant authority (SAHPRA)

- SAMED has participated in meetings and workshops hosted by the Health Sector Anti-Corruption Forum (HSACF), which as a multistakeholder collaboration includes various entities such as the Special Investigating Unit (SIU), the National Department of Health, SAHPRA, Section 27, the South African Medical Association (SAMA) and the HPCSA.
- Further information and capacity building sessions are planned for the coming year, with priority being doctors in training and medical schools.
- SAMED and HSACF are collaborating on the identification and appropriate sanctions for bogus doctors.
- SAMED and SAHPRA have entered into a non-disclosure agreement (NDA) to support SAHPRA, patients and member companies on anticorruption and fraud education and prevention. This initiative is aligned to the World Health Organization action plan to address substandard and falsified medtech products throughout the supply chain.



These initiatives are strategically connected to Project 18C that seeks Ministerial recognition of industry self-regulation codes, including the Medical Technology Code and MCA (Marketing Code Authority) as well as the applicability of the codes to all relevant suppliers of health products.

Presenting and receiving validation of the Code by the HSACF is a significant step towards achieving this objective. The initiative is an added element in our regulatory engagements with SAHPRA which, it is envisaged, will be a responsible party in the enforcement of these codes.

In addition, SAMED has undertaken the following activities as part of compliance and regulatory affairs. I would like to note the stellar work by SAMED secretariat and committees which committedly apply their attention and time to source, analyse and prepare the submissions which benefit every SAMED member.

Table 2: SAMED participation in regulatory affairs

Initiative	Activities
Policy comment submissions and related member communication	<p>SAMED responded to 11 pieces of legislation during the year to strengthen regulations and help member companies prepare for compliance. While it is not always possible to influence policy once it has been passed, SAMED's ongoing member feedback assists member companies to formulate organisational strategies in response to the legislation.</p> <p>These submissions relate to: employment equity targets; low-cost benefit options; interim block exemption for tariffs determination in the healthcare sector; traceability of health products; local manufacture and B-BBEE; health technology coding systems; clinical evaluation; investigation and post-market surveillance of medical devices; HPCSA Booklet 20 Ethical Guidelines on the use of artificial intelligence; clinical investment in medtech; export of radioactive sources and Botswana Medical Regulatory Authority's proposed regulatory fees.</p>

SAHPRA engagements	The evolving regulations are a high priority for SAMED and the Association has collated and shared various updates with members. SAHPRA is currently undertaking a feasibility study that will inform timelines and approaches to the regulations on product registration. SAMED is expecting these to be published for comment. SAMED appreciates SAHPRA's assistance to jointly address challenges at Port Health and with consumables covered by regulations on radiation control.
Exemption of medtech from 18A and 18B	Three-year exemption extension until December 2027 has been granted.
ISO13485	SAMED has continually informed members of SAHPRA communications about the timelines for the implementation of ISO13485. To enable SAMED to meaningfully represent members in SAHPRA engagements, we initiated a member survey on preparedness for accreditation – which revealed various challenges that SAMED is helping to address. A significant focus was placed on expanding the member companies' understanding and access to Conformity Assessment Bodies which play a crucial role in certification.
International affiliations and collaborations	SAMED had a fulfilling year regarding international engagements which help to lift SAMED's profile within the global medtech community and unlock exposure to information, research and best practices we can bring to South Africa. Alwi represented SAMED at two relevant events: 4 th MedDevReg AfriSummit in December 2024 in Cairo, Egypt. The event is largely aimed at industry and the highlight is having exposure to African regulators and networking opportunities. SAMED's attendance was acknowledged. Global Harmonisation Working Party (GHWP) Annual Meeting in December in Kuala Lumpur, Malaysia. Aimed particularly at regulators, the event focused on assessing and regulating with excellence, agility, economic stimulation, convergence and harmonisation.

TRANSFORMATION AND DIVERSITY

In deliberately and vigorously driving transformation and diversity, SAMED has amplified the positive impact of the medtech industry beyond the straightforward contribution to healthcare and patient outcomes to address other social dynamics including youth and women empowerment.

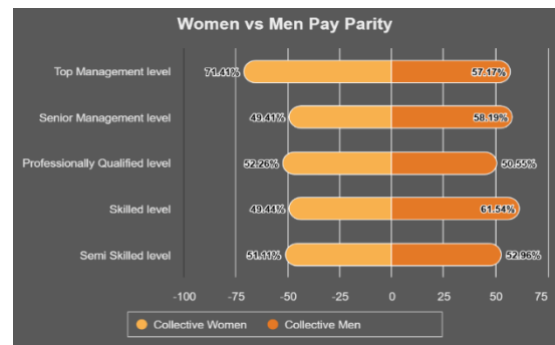
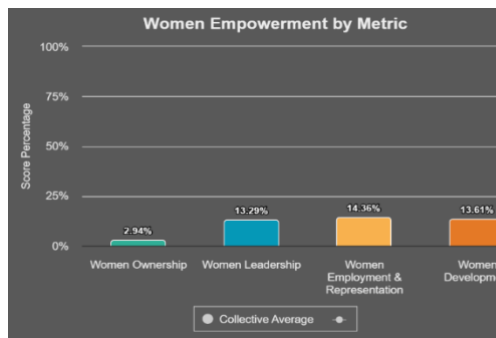
We are immensely grateful to all the SAMED members that have supported two critical medtech industry interventions where we got to show our mettle – SAMED Women Empowerment Index (WEI) and SAMED x YES youth employment programme. While these initiatives are an expression of good corporate citizenship by members, they also provide the member companies with tangible transformative business benefits.

By signing up to WEI – at no cost to your company, you can obtain a certificate that benchmarks your entity’s women empowerment status and progress against the industry average. This certificate can be included in business bids and tenders to improve the competitiveness of your organisation compared to suppliers that are not yet part of the initiative. So far 29 member companies have completed their WEI data inputs on our secure Data with Integrity platform. The average member index score currently stands at 44% (see the metrics summary in the table below).

SAMED continued to promote the WEI to members as well as significant stakeholders such as SAHPRA and private hospital groups. Tanya also attended the 2025 Women Economic Assembly (WECONA) and presented the WEI as a blueprint that WECONA plans to introduce to logistics and other key industry sectors to enable them to follow our lead and ensure that these organisations play an active role in gender equality and transformation. WECONA was launched by President Cyril Ramaphosa with the objective to unlock partnerships to improve inclusion for women-owned-businesses in the economy and specifically supply chains. There is great synergy between WECONA and SAMED and this relationship is of strategic significance as it propels us as a thought leader in high-level business and government networks.

- As the first published result of WEI, it serves as a critical baseline for members to benchmark their individual progress and for customers and other role players to track medtech industry’s impact
- The score is based on data from **4** key metrics. The 5th metric ie Women Remuneration is voluntary and not yet included in the overall score.

Key metric	Aggregate score	Weighting
1 Women ownership	2.9%	15%
2 Women leadership	13.3%	30%
3 Women employment & representation	14.4%	30%
4 Women development	13.6%	25%
Total	44%	100%
5 Women remuneration	Measured as a ratio of the average pay of women compared to male peers employed across different levels within the business	



The medtech sector's partnership with **YES 4 Youth** has been one of our most impactful transformation achievements in the last few years. SAMED applauds the change-maker companies that have opened up to the initiative to date.



YES 4 Youth and **45 medtech companies** have created
3 502 youth jobs (62 % female youth employees)
and injected **R197 512 800** into local economies
through YES Youth salaries.



More than half of the participating companies (20) have achieved a level up in their B-BBEE score by participating in the YES programme.

MEDTECH Master Plan goal is to generate 1 000 new jobs in the medtech sector over the next three years.

Whether your organisation is a medtech supplier or a hospital, or another healthcare service provider, you can support YES next time you are recruiting. All you need to do is go to the [SAMED X YES Alumni portal](#) [use password **samedmemberCVportal123**] to access profiles for hundreds of young, trained administrators, stock controllers, marketing and other professionals.

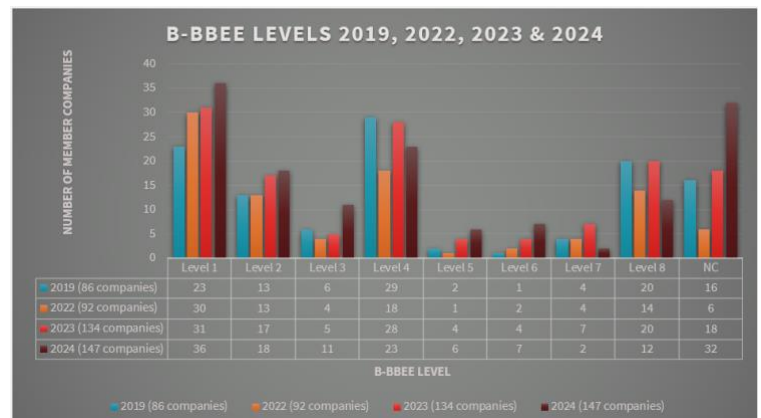
Speaking from personal experience both as the SAMED chairperson and the senior executive of a member company, I can vouch that YES 4 Youth is an invaluable resource and call on all SAMED members to sign up to help boost diversity, transformation, workplace energy and competitiveness across the medtech supply chain. Simply put, there is enormous benefit to opening up our companies and teams to young, educated and enthusiastic professionals who enrich our collectives and help us appreciate and embrace every individual's own personality and competencies.

SAMED is currently onboarding the second YES youth, Ntombikayise Mabuza who has already shared her talents for public relations and communication while working with SAMED's Nomthi Mnisi, Marketing, Communications and Events Manager, on SAMED's 40th anniversary branding and the upcoming annual conference. The first YES youth, Dikapo Magolego, completed his one-year tenure with SAMED having shown eagerness to get involved and learn, be helpful to the SAMED team and members and taking personal pride and ownership of his work and contributions. We wish Ntombikayise, Dikapo and all the YES youth much success in their professional and personal endeavours!

Transformation remains a key strategic pillar for SAMED and our members. In 2024, we gathered B-BBEE data to analyse the member transformation landscape and used some of this vital information in our submissions on SAHPRA's draft B-BBEE policy and Employment Equity regulations.

The findings show encouraging progress, with **many companies improving their B-BBEE levels** between 2019 and 2024. However, there is still **room for growth, particularly in addressing non-compliance**.

Graph 5: SAMED member companies' 2024 B-BBEE scores



PROGRESS ON LOCAL MANUFACTURE

SAMED has remained a driving force in the implementation of the MEDTECH Master Plan which was signed in May 2024. SAMED has established a Local Manufacturers Interest Group with the objective to identify synergies and activities to support the growth of the medtech manufacturing sector. The interest group is not limited to local manufacturers and welcomes engagements with all parties keen on exploring this objective, including distributors and multinationals.

SAMED coordinated the collaboration between the different industry associations with local manufacturing interests, namely MDMSA, SALDA and the Western Cape Cluster to present a unified approach by the sector towards the MEDTECH Master Plan. Together with these associations, SAMED has committed to a significant financial contribution to the Trade and Industrial Policy Strategies (TIPS) as the dtic-appointed provider of Master Plan Services. The funding is specifically for the Project Manager responsible for the execution of the MEDTECH Master Plan. Vic van Vuuren was appointed as the Project Manager with effect from 1 February 2025.

Two SAMED board members, Reiner Gabler and Ian Wakefield, have been appointed to the Steering Committee for the MEDTECH Master Plan with the brief to represent SAMED's members interests. SAMED also has a presence in the four sub-committees.

Pillar 1. Regulatory Framework | Avanthi Govender Bester and Madeleine Pearce

Pillar 2. Market Growth | Reiner Gabler and Ian Wakefield

Pillar 3. Skills | Tracy Moonsamy and Stuart Blackbeard

Pillar 4. R&D, Innovation, Data | Monica Lucas and Scott de Oliveira

ADVOCACY, NETWORKING, EVENTS AND PUBLIC RELATIONS

The Board strategy recognises and gives prominence to these functions within the Social pillar with some of the KPIs being to: (i) establish SAMED as the go-to authority on medtech in South Africa; (ii) develop strategic lobbying and policy influence efforts; (iii) strengthen member engagement and buy-in; and (iv) improve communication with patient groups and the public.

I hope that you have noticed and have engaged with SAMED's diverse member and stakeholder communication platforms which are among key benefits of the Association to us, members. SAMED News and the dedicated recently introduced SAMED Compliance & Regulatory News mailers are a treasure-trove of practical, relevant, curated information. The SAMED Annual Conference and last year's AGM along with 18 other top-notch events that were attended by 1 794 delegates is worthy of celebrating!

I wish to recognise the SAMED secretariat and Tanya, the Executive Officer for the active, quality, multichannel and interesting content they prepare and distribute, for growing our LinkedIn community, for ensuring members have resources they need on the website and for advocacy, PR and networking that elevates SAMED and helps us demonstrate leadership on topics that are material to members' businesses and the medtech value chain.

By highlighting just a few prestigious invitations and opportunities that were extended to Tanya and SAMED during the year helps to illustrate the credibility of the Association and the relevance of our work to the top-tier business, government and public sector partners and stakeholders: launch of B20 in February in Cape Town, WECONA in March in Gauteng and the shortlisting of candidates and their interviews in the Department of Health's appointment process for the Essential Equipment Specialist. This resource will serve under the Director: Medical Devices & HealthTech Procurement Management in the DOH's NHI Branch for Health Products Procurement.

Well done to the team for getting the SAMED Annual Conference and the Code Certification by HCPs CPD-accredited – this will further increase the established value of these SAMED initiatives, with plans to expand accreditation to other SAMED events.

The assistance of Board members and Committee leadership to engage with the media during interviews on diversity, local manufacture, NHI, the outstanding public debt and ethics and bring to life the voice of the medtech across public platforms is greatly valued and appreciated.

FINANCIAL AND GOVERNANCE REPORT

Thanks to the support of member companies, SAMED ended 2024 with healthy financial results. The board believes that SAMED has adequate financial resources to continue its operations for the foreseeable future. The financial statements were prepared on a going concern basis. The board members are satisfied that SAMED is in a sound financial position and has access to sufficient facilities to meet its foreseeable cash requirements.

The year was ended with a deficit of R1 058 424 driven by the closing out of the VAT matter referred to in the paragraph below. The interest charges raised by SARS was in the amount of R1 682 553. In fact, excluding the SARS interest charge raised, there was a trading surplus of R624 129 despite a budget deficit having been planned for 2024. This was due partly to judicious control of expenditure, some underspending by certain SAMED committees and significant interest earnings on SAMED's cash reserves. Equity, in the form of an accumulated surplus, dropped to R11 691 626 because of the deficit. SAMED has significant cash reserves of R11 966 731 at year end.

Previous financial reports explained how it came to be that SAMED was exposed to a substantial VAT liability, interest charges and possible penalties. SAMED is pleased to report that the VAT matter has now been closed once and for all. All VAT due to SARS, including interest charges, was paid over to SARS during 2024. SARS has waived all penalty charges raised so no further monies are due to SARS in respect of arrears VAT, penalties or interest.

A total of 91 members (54% of SAMED membership) took the option to settle membership fees early, thereby benefitting from a 3.5% fee reduction for 2024. Annual financial statements for the year ending December 2024 are in a separate attachment sent with this report.

The board members led by the chairperson oversaw SAMED's robust governance processes and procedures. For the first time in SAMED's 40-year history a new chairperson had to be elected during the year when the previous chairperson resigned from a member company, thereby making him ineligible to remain in the chair. The board acknowledges Scott de Oliveira and Ian Wakefield who respectively took up the vacated chairperson and vice-chairperson roles. They provided valuable expertise and dynamic, hands-on leadership and decision making, as well as ensured monthly engagement session with the SAMED Executive Officer and the Association's secretariat. The board has since instituted amendments to the Association's Constitution to include roles relating to the election of chair, vice chair and treasurer and specifying the process in case of a split vote/tie in the number of votes each nominee receives.

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