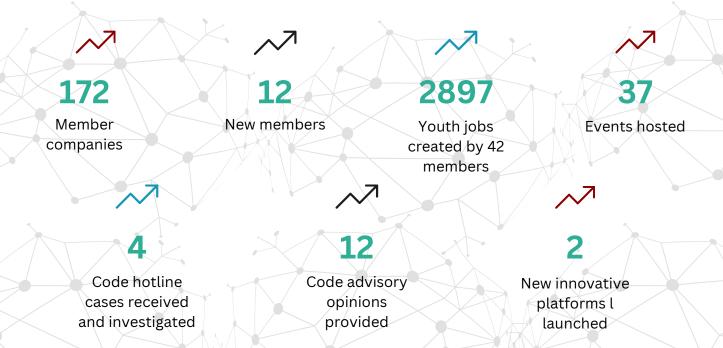


## SAMED ANNUAL REPORT MAY 2023 - MAY 2024

Elevating the agenda of medtech in South Africa



## **METRICS THAT MATTER**





## **Chairperson's Report**

The biggest thing the SAMED board wanted to achieve this year was inclusion and diversity within the SAMED member collective, our sector and the board where the deliberate appointment of diverse new members has enabled us to shift transformation and governance to the next level.

This emphasis on diversity, inclusion, equality and transformation has showcased our industry as one that is socially in touch which has visibly furthered SAMED's pursuit of the 2022/23 organisational strategy.

We continued to elevate medtech, partner with key stakeholders, provide value to members and ensure our association and its influence are continually transforming and growing to ensure sustainability of member companies and of the medtech value chain.

The sector's and SAMED's contributions to the healthcare sector and health reform were justly recognised by this year's launch of the MEDTECH Master Plan by the Minister of Trade Industry and Competition, Mr Ebrahim Patel, the medtech industry, agencies of government, representatives from the private sector hospital groups, organised labour, regulatory bodies, pharma, media and private procurers.

The MEDTECH Master Plan seeks to provide guidance for the public and private sectors to dedicate resources and time to strengthen the sector and place it on a growth trajectory. The milestone embodies the devotion and effort invested by SAMED in research, stakeholder engagement and crafting of the plan, in the belief that it can unite the South African health system to spur medtech towards greater economic prominence and to benefit South African and African patients.

Guided by patient-centricity and commitment to serving healthcare professionals (HCPs) and other customers, we remained involved in policy development, giving special focus to medtech regulations and national health insurance. This discourse reached a crescendo when President Cyril Ramaphosa signed the NHI Act in mid-May and continued to occupy a prominent place in public discourse in the run up to elections.

With the massive outstanding payments owed by government to SAMED members conspicuously at the top of SAMED's agenda, we used this time to advocate in the media that the newly promulgated NHI Act does not have adequate policies to facilitate the establishment of fundamental administrative functions that can resolve public debt challenges. This influenced SAMED's position on NHI which is that it cannot support the implementation of the Act until key administrative functions including human resources and information and communication infrastructure necessary for processing millions of claims, invoices and payments are enabled. These elements are absolutely necessary for the efficient procurement, reimbursement and independent assessment of quality/ efficacy/pricing of health technologies.



Peter Mehlape SAMED Chairperson

# Supporting growth for sustainability

When we look at macro-economic and geopolitical forces, medtech localisation, regulatory convergence and harmonisation and other factors that influence medtech industry sustainability and future growth, it becomes clear what a dynamic year is behind us.

I believe that as SAMED, we acted resolutely and quickly when the economic and political complexities threatened to disrupt relations with South Africa's main trading partners, namely the United States. These could easily have interrupted medtech supply and patient services. However, we were bold in putting our best foot forward and even succeeded in turning certain opportunities to our advantage to further elevate medtech among key stakeholders.

With the intention to point out the challenges as well as suggest solutions, SAMED leadership attended important meetings, two of them facilitated by AMCHAM, to advocate for policies that are pro-South Africa and pro-sustainable medtech industry.



We were able to state our case to the President Cyril Ramaphosa, the Minister of International Relations and Cooperation Dr Naledi Pandor, and on two different occasions to the Deputy President Paul Mashatile. I am eager to share that these high-ranking officials gave us their full attention. They had keen interest and genuine appreciation for the role of medtech in healthcare, society and economy and invited SAMED to stay engaged.

During these productive meetings, we spoke about pain points such as the impact of the energy crisis on the healthcare value chain including hospitals, suppliers and local manufacture, crime and corruption, transport, logistics and the red-taperelated obstacles to business productivity. These national leaders assured us about government's commitment to a continued relationship with the US and to safeguarding business sustainability and appraised the SAMED representatives of plans to renew AGOA in light of its expiry in 2025.



## Appreciation and tributes to colleague and friend



Rob Millar Honorary Member

Rob Millar built an illustrious career in our industry and within the health sector holistically. He has served as the SAMED Chair, Treasurer and chair and vice-chair of SAMED's Code and other committees. Rob's depth of knowledge on ethics and good governance will be hard to surpass – but it was his straight-as-the-arrow manner and deep humanity that gave him the awareness and aptitude to know wrong from right, what drives them and how to resolve the negatives and encourage the positives. SAMED will miss Rob and his inspirational and generous contributions. Thank you, Rob – all of us wish you much joy in your retirement.

Rob was awarded SAMED honorary membership in 2023, the only one thus far in SAMED's history.

On behalf of the board, I wish to thank the SAMED secretariat and its small but growing and always exceptionally committed staff for their efforts and support provided to me, our committees and most importantly, the members.

Peter Mehlape Chairperson

## **Executive Officer's Report**

During 2023-24, it became clear that SAMED's position and recognition have been elevated. This past year has opened a number of doors. We received more invitations to attend and represent the industry on many more forums than ever before, showing that we were determined and successful in pursuing the strategic imperative to elevate medtech and elevate SAMED.

This provided energy and impetus to address challenging topics and areas of concern for our members such as outstanding government payments. SAMED also achieved much on matters of compliance and regulatory alliance, regulatory harmonisation and convergence.

Looking ahead we are soon going to experience major regulatory changes, starting with a pilot programme for medical device product registration that SAHPRA will initiate towards the end of 2024. This is a whole new era for our sector and SAMED will make sure that we are involved, that we are guiding SAHPRA, that we are listening to them and that we are sharing the latest information so that our members can plan for the future.





Tanya Vogt SAMED Executive Officer

## To the next level on localisation

SAMED is supportive of the momentum that is building among policy makers, partners, funders, medtech industry and other stakeholders in taking the localisation of medtech to the next level. We all share in the key learning from the COVID-19 pandemic and the country's trade deficit underscores the urgent need to meaningfully elevate local medtech in terms of supply chain integrity, policy, resources, empowerment, job creation. skills creation. technology transfer, research and more. I am pleased to report on several positive developments in this area that SAMED has undertaken or been part of during this last year.

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.

The key here will be to work together and to work smart rather than to duplicate efforts or start demarcating territories. In this spirit, we held an introductory meeting and on 10 April 2024, a longer follow-up session with fellow interest-group partners, namely SALDA, MDMSA, Western Cape Device Cluster and the Medical Device Professionals Group. We discussed each entity's current activities related to local manufacturing and opportunities for joint action. The agreed next step is to regroup with the goal of identifying areas for collaboration.

Closely linked to the localisation mission is the MEDTECH MasterPlan.

SAMED appreciates the dtic and other involved roleplayers who have given invaluable support to this national initiative that is poised to benefit the healthcare sector, our customers and patients and more broadly, South Africa and the continent.

Realising the vision and objectives of the Master Plan requires institutional coordination, as well as a range of policy, regulatory and programmatic interventions. Before it was finalised, SAMED held a CEO pulse meeting where the plan was presented and thereafter shared with member companies to obtain your opinions and suggested changes.



Masterplan pillars to be actioned by 2030	Priority Masterplan deliverables	
<ul> <li>Grow a proficient, competitive and digitally savvy medtech industry prioritising small business capable of supplying domestic and international markets</li> <li>Reduce trade deficit by 5% over the next five years</li> <li>Create employment and productive and technical skills. The Masterplan aims for 1 000 new jobs over the next three years</li> </ul>	<ul> <li>Create an enabling regulatory environment</li> <li>Introduce preferential procurement agreements in public and private sectors</li> <li>Identify medtech to be locally produced</li> <li>Develop the African Market Access Strategy</li> <li>Establish the innovation-commercialisation- manufacturing pathway</li> </ul>	

### **Shaping regulations together**

SAMED contributed to two exceptionally valuable and well-planned workshops focused on African crossborder medical technology regulatory convergence and good practice. Implementation of best practices will reduce cost, inefficiencies, poor quality and the deployment of unsafe products, services and infrastructure.

Convergence is another area that is reaping the benefits of partnership efforts that envisage greater localisation of medtech, greater ease of trade across the AfCFTA and other positive socioeconomic outcomes. SAMED played a major role in planning a medical device regulatory workshop which was held under the Medical Device Regulatory Convergence (MDRC) project in November, with joint organisation by SAHPRA and regulators from Australia, Brazil, Singapore and the United States. The programme included capacity building sessions and presentations by subject matter experts including global and local manufacturers.

A score of topics was addressed, such as IMDRF, international standards including ISO 13485, conformity assessments and Good Reliance Practices. SAMED participated in the US Trade and Development Agency regulatory convergence workshop that covered medical device and medicines regulatory frameworks, reliance models, impact assessments and industry perspectives.

We supported the organisers in terms of the programme and moderated a session on the implementation of reliance models in which the participants unpacked the critical role of regulatory convergence and strengthening collaborative efforts to close the gaps between concept and implementation. I urge members to consider the implications of Project 18C not only for the health sector but all its stakeholders and health system users. The project will further spotlight ethical marketing and business practices and compliance with the Medical Device Code across our sector and magnify what is at stake. We can best respond by standing together and aligning principles, positions and actions on ethics, governance, and accountability

### **Elevating our values and sectoral interests**

I'm delighted to highlight that although this year brought multiple developments and important rewards through our efforts to elevate medtech and SAMED among stakeholders, the secretariat ensured this was matched by energetic, considered, and productive internal management.

As part of ongoing work to safeguard and strengthen governance, SAMED's task team in consultation with experts reviewed and revised the SAMED Constitution, which was adopted at the 2023 AGM and is now in effect.

A notable change is the introduction of an elected board nomination and selection process designed to encourage equity, diversity and inclusion in the representation of and participation by SMME member companies. As you might have gleaned from various regular updates that we share with member companies, including SAMED News, From the Desk of the EO and In the SAMED Chair, the association is being sought after as a thought leader on medtech and more broadly on other topics such as good governance, anti-corruption, ethics, industry selfregulation, diversity and transformation, regulatory convergence and patient access.

To help SAMED leaders who are selected to represent SAMED at various stakeholder platforms and meetings be aligned on message and approach, the coming year we will be developing SOPs for the executive officer, committee chairs and the chairperson and other members of the board. SAMED organised 30 member events during the year. Most events strive to equip members with information and practical resources they can use to strengthen and improve their businesses. The total attendance of members and external stakeholders at our events was 1 533 delegates. Strong attendance speaks to the strategic approach SAMED brings to its events so that they provide value to all speakers and participants. Two events that accounted for 250 attendees were the annual conference (144) and a Market Access Forum that was devoted to the public sector debt (106).

Working strategically, SAMED used its own activities – such as the launch of four new platforms – as well as opportunities provided by national developments to elevate our public presence. If you have not done so already, you can catch up on the positive media reports on SAMED in <u>timeslive</u>, <u>African Business</u> <u>Quarterly</u>, <u>newzroom afrika</u> and <u>Business Day</u>.

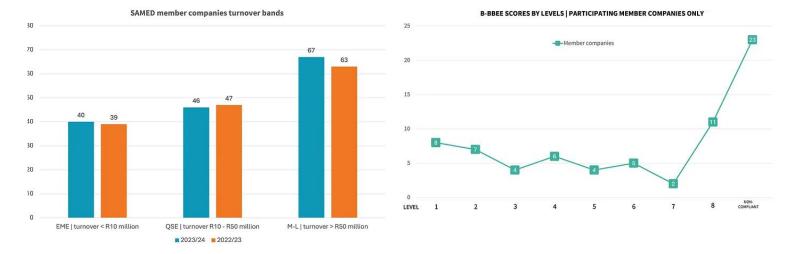
This year SAMED piloted having a promotional presence at Africa Health with a conference booth and joining other speakers in a session on transforming medtech through youth and women development. That we are on the right track to elevate medtech in South Africa and much further is evidenced by frequent approaches and invitations from foreign trade missions to meet SAMED and to learn about our industry and opportunities it presents. During this year, we had the pleasure to engage with delegations from France, Japan, Korea, Switzerland and Vietnam.

An exciting initiative that we spent more time on during the reporting period is the Rare Diseases Access Initiative which also involves funders, pharmaceutical industry and patient advocacy groups.We have convened a number of meetings to discuss how we can support and possibly co-create policy for patients with rare diseases as their needs are often overlooked both in the public and private sector due to insufficient funding or treatment options. We have convened a number of meetings to discuss how we can support and possibly co-create policy for patients with rare diseases as their needs are often overlooked both in the public and private sector due to insufficient funding or treatment options.

Our public sector debt initiative is based on the Data with Integrity platform which we began to develop in 2022. In order to help members adopt and become comfortable with the system, we are using it for invoicing, and we now channel the collection of any data we require from members through the platform. The outstanding payments data is being generated by facility, province and age, allowing us to compare amounts owing and use that data to meaningfully engage with provincial departments of health, provincial treasury, the national department of health and as needed, the presidency.

The Women Empowerment Index is another section added to the data platform. I wish to acknowledge the chair of the Diversity in Medtech Committee, Scott de Oliviera, for his leadership and for bringing his passion and energy to fuel progress in transformation. Under his leadership. the committee was renamed from 'Transformation' to Diversity in Medtech, to symbolise SAMED's integrated approach to making and realising real opportunities to pioneer sectoral economic empowerment of women, youth and people with disabilities.

Under the guidance from the Code Committee, SAMED provided 12 non-binding advisory opinions to members and external stakeholders regarding the Code. Opinions are circulated to company compliance officers and these resources are available for you to access in the <u>SAMED library</u>.



### SAMED secretariat growth and capacity building

To ensure that the association's strategies are successful, that members' needs are adequately met, to efficiently manage the volume of work, and achieve greater reach and impact, the SAMED office has also seen transition and capacity building. During the year, the secretariat welcomed four new staff members.

- Ntokozo Dlamini is the projects coordinator responsible for Data with Integrity, the Medical Device Code certification and outstanding public sector payments.
- Linda Crystal joined SAMED in October as the Executive Secretary and Membership Relations.
- In March, Nomthi Mnisi was appointed as the new Marketing, Communications and Events Manager.
- In April, SAMED itself said YES and the new intern, Dikapo Magolego, is already showing passion to work hard and learn fast.

We wish the newcomers much professional and personal success and fulfilment during their tenure at SAMED and look forward to harnessing your interest and energy to jointly elevate medtech. A special thank you to Amanda Wilde who stepped in to assist with secretariat support and administration, particularly in getting membership invoices and VAT debit notes paid.

In the atmosphere of growing, building and strengthening, Ntokozo Dlamini and Emily Mehtlape have attended different practical skills-building courses which they are busy putting to great use.

Sadly, towards the end of the reporting period, we said goodbye to Caroline Scott who handed over the baton for marketing, communication and events to Nomthi Mnisi. We appreciate the many innovations and improvements Caroline realised within her portfolio during the four-year tenure at SAMED and wish her many successes and adventures along the professional journey.

In closing, I would like to express my heartfelt appreciation to the Chairperson, Vice-chair, the Treasurer, members of the Board and its committees, SAMED staff and members of SAMED for helping to advance patient care through medtech.

Tanya Vogt Executive Officer

## **CAUSES WE CHAMPIONED THIS YEAR**

Elevating Diversity in Medtech Data With Integrity

The Code: upping the ante on formalised self-regulation Building a robust fit-forpurpose regulatory system

Medtech reimbursement

# Diversity in Medtech

## **Elevating Diversity in Medtech**

This year SAMED pulled out all the stops to elevate diversity and inclusivity not only internally – meaning within the secretariat, the board and among our members – but also externally.

## New seminal initiatives catalysing change

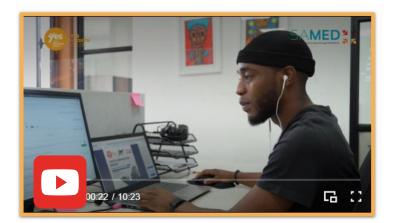
**SAMED Women Empowerment Index** was unveiled to members, partners, influential industry voices, government and captains of industry during the SAMED Catalysts of Change forum on 11 April 2024. The in-person event launched two ground-breaking initiatives: the SAMED Women Empowerment Index (WEI) and the SAMED x YES Youth Alumni Portal.

The WEI is a benchmarking tool developed in collaboration with Deloitte and SAMED members to monitor and encourage progress made towards greater economic inclusion and empowerment of women in the medtech industry.

The **WEI** will establish baseline scores and track these metrics that matter over time: women's employment rates and remuneration levels, female representation in leadership positions, women's ownership in medtech companies and opportunities for women's development. Industry executives and influencers among whom were Adv Mikateko Joyce Maluleke, Director General, Department of Women, Youth and People with Disabilities, and Futhi Mtoba, Co-Chairperson, Women Economic Assembly (WECONA), Dr Rolene Wagner, HOD, Eastern Cape DOH, Dr Viola Morolo, Specialist Urologist, African Synergy Health (ASH) and powerful panels underscored the urgency of addressing gender disparities.







## <u>SAMED x YES Youth Alumni</u> <u>Portal</u>

The <u>SAMED x YES Youth Alumni Portal</u> is an online platform that puts medtech companies in touch with talented young professionals who already have valuable industry experience.

This resource hosts the profiles of 166 talented youth who have already gained experience in our industry. We encourage members to give it a go and see how you can skip recruitment fees and fill your vacant positions with young people who have the passion to succeed and understand our field.

"Simply put, we have to hire more women and open equal access for our female peers to educational and professional opportunities within our companies and workplaces."

Scott de Oliviera, Chairperson, Diversity in Medtech committee

SAMED's other main transformational interventions include a commitment to WECONA since it was inaugurated in 2022, the creation of more than 2 897 youth jobs (64% female youth employees) by 42 SAMED members through the partnership with YES Youth Employment Service and participation in the Skills Village capacity building hubs that lead to income-generating activity for youth, women and persons with disabilities. Considering the unemployment crisis in South Africa, these positive outcomes and their impact are worth celebrating.

Visit portal >



## **Data With Integrity**

Data With Integrity (DWI) is SAMED's custom-made member company information collection and storage system which went live in 2022, with ongoing system checks, management, maintenance and development to improve user experience and ensure ease of use.



#### Ntokozo Dlamini SAMED Projects Coordinator

As part of member education and change management, SAMED provided numerous briefs, practical mailers, training sessions and reminders to support members' participation, engagement and registration on the portal. The slow-to-start first phase provided invaluable learnings that were used to inform when and how we send data collection requests for data and the development of system pathways.

We heard and acted on the feedback from member companies that they would find participation more manageable if the phases and methods for data collection were more flexible. The portal was updated for easier navigation and to enable the submission of topic-specific smaller batches of data, for example company details, company invoicing, employment, finance and so on, at different times and by different registered users. Since the platform went live, two new layers of data collection have been integrated, namely the public sector debt and the Women Empowerment Index. This approach is working well for concentrated campaigns and quick polls which deliver real data with integrity to inform vital submissions, such as those on the SAHPRA fees payable and SAHPRA's draft B-BBEE policy.

We are indeed witnessing the power of data at play as we use our "numerical treasure" to improve SAMED representation and submissions, understand and manage our own businesses more effectively and further elevate medtech among stakeholders.

#### Table: Latest DWI participation statistics

QUESTIONNAIRE	# ASS	IGNED USERS # COMPLE	TE # NOT PARTICIPATED
Company Details	164	100	64
Company invoicing	172	109	63
Employment	38	15	23
Finance	42	8	34
Import & Export	39	7	32
Regulatory Affairs	82	37	45
Local Manufacturing	26	3	23
Research & Development	30	6	24
Outstanding payments	68	41	27
Regulatory fees submission	152	26	126
Total	813	352 (43%)	461 (57%)



#### Read More

## The Code: upping the ante on formalised self-regulation

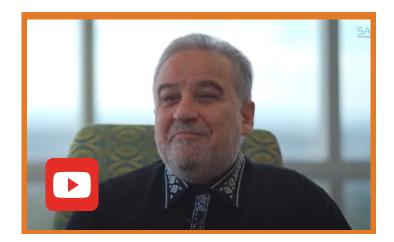
SAMED's Code Committee has had an extremely busy and productive year during which it tackled several sizable endeavours. SAMED's Code Committee completed the eight version of the Medical Device Code of Ethical Marketing and Business Practice. This was a lengthy labour of love that now suitably displays SAMED's respect and dedication to the strongest ethics and business and marketing practices in all transactions between medtech suppliers and HCPs and other customers. The committee members individually and as a group reviewed our Code letter-by-letter and page-by-page multiple times. They compared the Code against international benchmarks like the codes enforced by Mecomed in the Middle East, MedTech Europe and Advamed in the United States.

Old sections were updated, and new sections added. The 90+ questions-answers were examined and strengthened by including new responses to the most frequent topics of enquiry from members and other SAMED stakeholders. Nine documents and templates will be downloadable from the digital Code. The launch of the attractive and user-friendly new-andimproved Code is among SAMED's top priorities for the coming year.

Additionally, the script and the complaint form used by the third-party independently managed Medical Device Hotline were assessed with some of the elements and messages strengthened to support efficient collection of information and evidence to enable successful investigations and rulings on reported cases.

Frequent questions on conference vetting and criteria that influence whether an event falls under the jurisdiction of the European CVS prompted SAMED to host a spirited Medical Device Forum to clarify uncertainties and misunderstandings. Following this event, we have provided a simplified one-page resource to member companies' compliance officers, marketing, public affairs and other departments, professional societies, conference organisers, academic institutions and other entities involved in educational events.

The dynamic Project 18C has gained encouraging impetus, with the signing of a memorandum of understanding by SAMED and the Marketing Code Authority (MCA) in January 2024. We followed that up with two constructive engagements with the National Department of Health. The focus has now shifted to ensuring the industry and government collaborate on a rigorous policy formulation and adoption process – which will greatly benefit, in time, from member support and involvement.



### Dr Vitor Ferrão Chair: SAMED Code Committee



ENFORCING ETHICAL MARKETING OF HEALTH PRODUCTS

The scope of Project 18C covers advertising and promotion of medical devices, IVDs and medicines – collectively health products. It aims to successfully motivate for the publication of regulations that recognise and support the enforcement of industry self-regulation codes. Such regulations are set to level the playing field by making it compulsory for all licenced health products suppliers to commit to a recognised industry code.

The <u>MOU</u> between SAMED and the Marketing Code Authority covers other matters including: (i) funding; (ii) member associations' roles such as the development of policy, regulations and codes; (iii) enforcing and monitoring these Codes; and (iv) collaborations to raise awareness and educate stakeholders on ethical marketing and business practices health products.

## Building a robust and fit-for-purpose regulatory system

The year 2023/24 presented numerous occasions for SAMED's continued engagements on legislation and policy developments related to the medtech sector and the healthcare environment more broadly.

SAMED supports the overarching objectives of sections **18A** and **18B** of the Medicines and Related Substances Act and the intent of related draft regulations which is to prevent perverse activities and ensuring affordable medical devices and IVDs. However, the potential prohibition of certain practices that are applicable and beneficial in the medtech sector but not the pharmaceutical industry could cause downstream impact that needs to be properly understood so that the unfavourable consequences can be avoided.

In response to SAMED's previous request, the Minister of Health had granted medical devices and IVDs a three-year exclusion from these regulations. As the exclusion ends on 10 December 2024, SAMED engaged with SAHPRA and the Pricing Committee during this year regarding timelines for the finalisation of relevant regulations and to explore options for a further exemption. It is pleasing to report that in March 2024, SAHPRA responded positively to SAMED's reminder of the upcoming expiry of the exclusion, indicating that the Medical Device Unit will submit a request for the extension of the exemption and that SAMED can follow-up with the unit in September for any updates.

In consultation with members, the various SAMED Committees with assistance from legal counsel, made comprehensive submissions on eight policy drafts, namely: the draft Medical Device Regulations, the Public Procurement and NHI bills, SAHPRA's fees payable and its B-BBEE policy, the updated Employment Equity Act Sector Targets, Western Cape Health Department's proposed pricing labels and Private Nurse Practitioners Regulations.

A clear priority for the upcoming year will be the draft Medical Device Product Registration road map which SAHPRA officially communicated in April 2024. The roadmap incorporates a feasibility pilot for product registration. As we travel this journey together, we truly appreciate the regulator's ongoing willingness to engage with SAMED – demonstrated by SAHPRA's recent removal of medical device and IVD product registration fees from the revised Fees regulations until after the draft medical device regulations had been finalised and the pilot conducted.

Regarding **National Health Insurance**, SAMED participated in the Business Unity South Africa (BUSA) NHI discussions and strategies to further elevate medtech considerations within the broader business community and strengthen partnerships to achieve mutual goals.



#### Avanthi Govender Bester Chair: SAMED NHI Committee

Closely connected to this is the future procurement model under NHI and we used multiple platforms to communicate SAMED's view on the risks of the proposed centralised "all eggs in one basket" approach and to argue for the establishment of an independent health technology assessment (HTA) agency. However, we still face another hurdle along this path which is the absence of empowering legislation for the formal establishment of an HTA agency without which any recommendations will lack legitimacy and therefore enforceability.

## **Medtech reimbursement**

During the year, SAMED leadership continued with intensive work to motivate for appropriate reimbursement of medtech technology by customers in both the public and the private sectors.



Donata Kubheka Chair: SAMED Market Access Committee

Unfortunately the old problem of massive **debt by public sector customers** to our members persists. Some 15 years ago, SAMED resorted to raising the matter through the media while the previous year, we mobilised action and short-term relief by involving the Presidency. As the consolidated member company invoices that are due over 30 days surpassed the R1 billion mark in February 2024, once again we formulated a plan in case we have to escalate matters beyond the regular monthly communications and provision of detailed analyses of outstanding amounts to the national and provincial health departments. Please note that in addition to emailing the health department key officials, SAMED has held meetings with some of them, namely at national level as well as with Gauteng, Limpopo and the Western Cape teams who have all expressed a commitment to look into the matter.



This table with the outstanding payment summary from February	y 2024 illustrates the severity of the problem.
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Province	0-30 Days	31-60 Days	61-90 Days	90-121 Days	> 120 Days	Total	Total over 30 days
Eastern Cape	R16 554 401,00	R4 776 932,00	R5 424 337,00	R4 732 434,00	R26 694 063,00	R58 182 167,00	R41 627 766,00
Free State	R10 491 936,00	R2 969 935,00	R2 910 306,00	R1 082 732,00	R58 317 496,00	R75 772 405,00	R65 280 469,00
Gauteng	R80 467 097,00	R49 923 902,00	R43 646 960,00	R46 607 934,00	R272 965 400,00	R493 611 293,00	R413 144 196,00
KwaZulu-Natal	R28 712 685,00	R7 194 441,00	R5 154 934,00	R6 030 941,00	R101 960 237,00	R149 053 238,00	R120 340 553,00
Limpopo	R7 272 290,00	R3 957 599,00	R1 531 062,00	R665 543,00	R21 375 167,00	R34 801 661,00	R27 529 371,00
Mpumalanga	R5 590 937,00	R2 868 490,00	R620 461,00	R1 276 922,00	R33 066 228,00	R43 423 038,00	R37 832 101,00
North West	R16 403 711,00	R6 874 268,00	R10 707 027,00	R6 171 010,00	R57 164 495,00	R97 320 511,00	R80 916 800,00
Northern Cape	R4 128 458,00	R2 005 782,00	R2 712 949,00	R1 592 136,00	R12 398 190,00	R22 837 515,00	R18 709 057,00
SA Military Health Service	R1 829 573,00	R730 409,00	R671 876,00	R787 359,00	R36 741 463,00	R40 760 680,00	R38 931 107,00
Western Cape	R31 525 492,00	R3 544 688,00	R4 000 648,00	R3 017 069,00	R51 398 952,00	R93 486 849,00	R61 961 357,00
Total	R202 976 580,00	R84 846 446,00	R77 380 560,00	R71 964 080,00	R672 081 691,00	R1 109 249 357,00	R906 272 777,00

What is additionally concerning is that these figures are likely to be higher because not all the member companies that have public sector invoices outstanding provide information on the debt owed to them. We urge all affected members to participate and thereby enable SAMED to address the issue in its entirety and to put the matter to government more convincingly. South Africa has the necessary government instruments in place for this issue to become a concern of the past. They just have to be properly implemented. So if your business is being negatively impacted, if you're struggling with cashflow and stressing at month-end how to pay salaries or suppliers, by participating in providing your data, you will be doing good for your own organisation as well as helping SAMED act on your behalf by ensuring we have more complete and more credible information to put forward a convincing argument to our government counterparts. In the meantime, we have significantly improved the collection and quality of the outstanding payments data by integrating the submission process with the Data with Integrity portal. Please use the system and provide your data timeously to reap its benefits for your own organisation and strengthen SAMED's case with the relevant authorities. Please reach out to **projects@samed.org.za** for help with registering.

On the private sector front, SAMED held crucial conversations with Discovery and the Council for Medical Schemes to educate them about our sector, its essential role in health service provision and the urgent need to recognise the reimbursement pressures and cost of doing business. All of these have impacted on the industry since the tail end of the COVID-19 pandemic. The multiple factors that have hit the medtech industry include the state of South Africa's economy, exchange rate fluctuations, the increased costs of logistics and fuel and power disruptions. These all erode the already slim margins. The message we shared with Discovery, the Council and other relevant roleplayers is that these factors must be considered when engaging member companies on annual price negotiations.

## **Financial report**

Thanks to the support of members, SAMED ended 2023 with healthy financial results.

The year was closed out with a small surplus of R219582 – despite a budget deficit having been planned for 2023 – due partly to judicious oversight of expenditure. The Audited Financial Statements for the year ended 31st December 2023 were ratified by the SAMED Board on 19 April 2024.

To match SAMED's elevated level of activity that was sustained throughout the year, there was increased spending on advertising, marketing and events and critical committee activities that are underway, with some continuing into the year ahead.

Equity, in the form of an accumulated surplus, grew to R12,750,055 with significant cash reserves of R12,436,766 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. Substantial progress has been made in resolving the VAT issue: the arrears VAT has been paid to SARS; SAMED has recovered a significant percentage of this VAT from members which, as input tax, had no cashflow impact for VAT registered SAMED members; and SAMED is engaging with SARS on curtailing the interest and penalty charges amounts.

#### Reiner Gabler SAMED: Treasurer



## Summary of income and financial position

#### Statement of income for year ended 31 December 2023

Revenue	7 876 567	7 635 671
Other income	32 514	33 516
Operating expenses	(8 851 928)	(6 778 730)
Operating (deficit) / surplus	(942 847)	890 457
Investment revenue	1 162 429	700 689
Finance costs	-	(34)
Surplus for the year	219 582	1 591 112

#### Statement of Financial Position as at 31 December 2023

	R 2023	R 2022
Assets	39 892	6 196
Non-Current Assets		
Property, plant and equipment		
Current Assets	1 422 348	3 266 952
Trade and other receivables		
Cash and cash equivalents	12 436 766	9 962 852
Total Assets	13 899 006	13 236 000
Equity and Liabilities	12 750 055	12 530 473
Equity		
Retained income		
Liabilities	1 148 951	705 527
Current Liabilities		
Trade and other payables		
Total Equity and Liabilities	13 899 006	13 236 000

## **SAMED Board Members**

18 May 2023 – 27 May 2024



#### Peter Mehlape SAMED Chairperson

Managing Director Southern Africa Medtronic



Neil Venter SAMED Vice Chairperson

Managing Director SA Biomedical



#### Avanthi Govender Bester

Associate Director – Regulatory Affairs & Quality Alcon Laboratories



#### Bulelwa Maponya

Head Government Affairs, Policy & Market Development Middle East, India and Africa Siemens Healthineers



Dave Roberts | Resigned 31/08/2023

General Manager Southern Africa Johnson & Johnson Medtech



#### Donata Kubheka

Head: Market Access Africa Medtronic



#### Ian Wakefield

General Manager: Africa BD



#### Madeleine Pearce

Director of Regulatory Affairs: International Region, Middle East, Türkiye, Africa Philips Healthcare



Marlon Burgess | Resigned 5/10/2023

Country Manager GE Healthcare



#### **Monica Lucas**

General Manager Werkomed



#### Merilynn Steenkamp | Resigned 29/11/2023

General Manager Southern Africa Roche Diagnostics



#### Reiner Gabler SAMED Treasurer

Managing Director Gabler Medical



Sabashini Naicker | Resigned 30/11/2023

Senior Director Smith & Nephew



Rob Millar | Resigned 28/02/2024

Independent Consultant Zomelele

## **SAMED Committees**

Committee	Chairperson
Code	Vitor Ferrão
Diversity in Medtech	Scott de Oliviera
Market Access	Donata Kubheka
NHI	Avanthi Govender Bester
Regulatory	Athene Saul

## **SAMED Members**

#### **ORDINARY MEMBERS**

Abbott Rapid Diagnostics (Pty) Ltd Abex Pharmaceutical (Pty) Ltd Absolute Orthopedics (Pty) Ltd Acino Forensics (Pty) Ltd Advanced Orthopaedic Solutions (Pty) Ltd Africoncur Medical (Pty) Ltd AHG Health Solutions (Pty) Ltd Akacia Medical (Pty) Ltd Alcon Laboratories (Pty) Ltd Allenco Medical and Dental Supplies Alltech Healthcare (Pty) Ltd Ample Resources (Pty) Ltd Anstem Medical (Pty) Ltd Ariste Health (Pty) Ltd Arjohuntleigh South Africa (Pty) Ltd Arterial Medical (Pty) Ltd Ashanti Medical cc B.Braun Medical (Pty) Ltd Bausch + Lomb Bcc Pharmaceuticals (Pty) Ltd Becton Dickinson (Pty) Ltd Beier Drawtex Healthcare (Pty) Ltd BioTech Africa (Pty) Ltd Bloemed Medical Supplies and Services cc BMG Orthopaedic Solutions (Pty) Ltd Bone SA Boston Scientific South Africa (Pty) Ltd BSN Medical (Pty) Ltd Carl Zeiss (Pty) Ltd Casmed Logistics (Pty) Ltd Centre for Tissue Engineering Chairman Industries (Pty) Ltd Cherrymed Enterprises (Pty) Ltd Coloplast A/S Continuous Oxygen Suppliers (Pty) Ltd Trading as Medics (Pty) Ltd VitalAire

**Convatec South Africa** Corin SA (Pty) Ltd Cossni Medical (Pty) Ltd Creatori Health (Pty) Ltd Dahlhausen (Pty) Ltd Demant South Africa (Pty) Ltd (previously Oticon) Dimela Health (Pty) Ltd Dr Temp (Pty) Ltd Dräger South Africa (Pty) Ltd Duzane-Africa Medical (previously Future Med Co) Edwards Life Sciences South Africa (Pty) Ltd Elegant Line Trading 64 cc Elekta (Pty) Ltd Endosurgical (Pty) Ltd Ethitech (Pty) Ltd Fluorovizion Holdings Fresenius Medical Care South Africa (Pty) Ltd Gabler Medical (Pty) Ltd GE Medical Systems South Africa (Pty) Ltd Grobir Medical Suppliers (Pty) Ltd Guerbet South Africa (Pty) Ltd H.A.S.S Southern Africa (Pty) Ltd Hartmann Vitamed (Pty) Ltd HemoCue South Africa (Pty) Ltd Hi Care Surgicial (Pty) Ltd Imperial Market Access Healthcare SA (Pty) Ltd Implantcast South Africa (Pty) Ltd Imvula Health care Logistics (Pty) Ltd JaLo Enterprise (Pty) Ltd Johnson & Johnson Medical (Pty) Ltd K2 Medical (Pty) Ltd Karl Storz Endoscopy SA (Pty) Ltd Kiara MedTech (Pty) Ltd Langamedics (Pty) LtdLatroglo

LDK Intertrade (Pty) Ltd Lechoba Medical Technologies (Pty) Ltd Ligamed (Pty) LtdLorumir D (Pty) Ltd Lukatit Investments 14 (Pty) Ltd ta Unitron SAMaars Medical (Pty) Ltd Maisha Med (Pty) Ltd Maquet Southern Africa (Pty) Ltd Marcus Medical (Pty) Ltd MED-EL Distribution (Pty) Ltd Med-EL Impant Systems South Africa (Pty) Ltd Medhealth Supplies (Pty) Ltd Medical International Orthopaedic cc Medical Plant Africa (Pty) Ltd Medtronic Africa Meducat Medical (Pty) Ltd Melemo Medical Mental Link International (Pty) Ltd Merck Life Science Meril SA (Pty) Ltd Merit Medical South Africa (Pty) Ltd Mezotrix (Pty) Ltd Modiro Medical (Pty) Ltd Morgan Joshua Innovation Mossmed (Pty) Ltd MyOrtho Solutions (Pty) Ltd National Bioproducts Institue NPC Neurophysics (Pty) Ltd NGL Logistics Solutions Nipro Medical South Africa (Pty) Ltd NuAngle Solutions (Pty) Ltd O&M Halyard South Africa Obsidian Health (Pty) Ltd OMS Medical (Pty) Ltd Optimum Orthopaedics (Pty) Ltd Ortho-Design (Pty) Ltd Orthomedics Ortho-Xact (Pty) Ltd Osteologix SA (Pty) Ltd

Paragon 28 Medical Devices Trading Limited Patient Medical Care T/A Zebra MedicalPerryhill International Trading (Pty) Ltd Philips South Africa (Pty) Ltd **Phoenix Neomed** Pinnacle Innovations (Pty) Ltd Pointer Medical (Pty) Ltd Population Services International SA (Pty) Ltd PrimeSafe (Pty) Ltd T/A SteriTech PrionGuard Priontex SAPrism Inter Africa cc Procter & Gamble South African Trading Professional Orthopaedics (Pty) Ltd **Progress Medical Supplies Progressus Digital Q-Surgical** Responsive Orthopaedics (Pty) Ltd Roche Diagnostics (Pty) Ltd SA Biomedical Holdings (Pty) Ltd Safarmex (Pty) Ltd Safmed (Pty) Ltd Sea4 Medical Logistics (Pty) Ltd Selective Surgical (Pty) Ltd Siemens Healthcare (Pty) Ltd Smith & Nephew (Pty) Ltd

Soflens Southern Ear Nose and Throat (Pty) Ltd Southern Implants (Pty) ltd Staar Surgical (Pty) Ltd Stiegelmeyer Africa (Pty) Ltd Stryker South Africa (Pty) Ltd Supra Healthcare (Pty) Ltd Sure Medical (Pty) Ltd Surgical and Ophthalmic Supplies (Pty) Ltd Surgical Innovations (Pty) Ltd SXS Surgical Solutions (Pty) Ltd Synthecon Sutures Manufacturing SA cc Systagenix T/A Solventum Tara Healthcare **Teekay Link Medical Solution** Teleflex Medical (Pty) Ltd The Scientific Group Thogwa Medicals and Pharmaceuticals (Pty) Ltd Umsebe Healthcare Vertec Scientific SA (Pty) Ltd Vertice Healthcare (Pty) Ltd Viking BCT (Pty) Ltd Viking Cardiovascular (Pty) Ltd Werkomed (Pty) Ltd WS Audiology South Africa (Pty) Ltd Zimmer Biomed South Africa (Pty) Ltd

#### ASSOCIATE MEMBERS

AfriPharm SA (Pty) Ltd BRANDTECH Health Technology Consulting CEASA (The Clinical Engineering in South Africa) CSIR **DI Medicine Regulatory Consultants Diverse Conversations** Dr Vitor MLdeA Ferrao Executive Consultant DSV Solutions (Pty) Ltd **Enterprise Ireland** Institute of Bio Research Auditing and Training in Southern Africa (IBRATSA) IQuad Integrated Management Systems (Pty) Ltd JC Auditors JPJ Medical KOTRA Mark Banfield & Associates Masoom Training Solutions Mawele Investments cc MC Pharma Consulting (Pty) Ltd MEDInc SA **Regulatory For Africa** 

### Exciting times in the coming year

- SAMED's 40th anniversary
- Implementation of the MEDTECH Masterplan and medical device and IVD product registration
- Continuing to strengthen our stakeholder relationships
- Finding lasting solutions to public health debt
- Growing our Data With Integrity
- Reporting on the Women Empowerment Index
- SA hosting G20 Summit and taking over its Presidency



## **Connect with us**





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