AMPLIFYING THE VOICE OF THE MEDICAL DEVICE INDUSTRY
STRENGTHENING THE VOICE OF INDUSTRY

SAMED is the voice of the medical device industry in South Africa with member companies that develop, manufacture and sell innovative medical device and diagnostic products. Established in 1985, the association supports the needs of members of all sizes. These include innovative, entrepreneurial small companies, emerging growth and mid-size organisations as well as the largest innovators and manufacturers. The association has grown significantly in recent years and is now recognised as an important stakeholder in the South African healthcare sector.

SAMED is uniquely positioned to advocate for policies that support patient access to innovative and life-saving medical devices. It is able to offer knowledgeable guidance in areas critical to industry’s success: regulatory affairs, payment and healthcare delivery, legal and compliance matters, global strategy and analysis as well as government and public affairs.

The activities of our association are guided by our strategic plan 2014-2018.

In September 2014, the SAMED Board reviewed its strategic focus and decided on the following key STRATEGIC OBJECTIVES for the next four years:

**SO1**
Increase the awareness of being the authentic voice of the medical devices industry to all stakeholders, thereby aiding in the protection of the rights of patients and consumers of our products.

**SO2**
Continually demonstrate value to members and communicate that by means of representation, communication and development.

**SO3**
To proactively influence and drive, appropriate regulations by engaging and educating stakeholders and consumers of our products.

**SO4**
Actively promote the transformation of our industry in particular, and health services in general.

These objectives are encapsulated in our vision:

**TO DEVELOP A SUSTAINABLE MEDICAL DEVICE INDUSTRY BY RESPONSIBLY IMPROVING PATIENT ACCESS TO INNOVATIVE HEALTH TECHNOLOGY.**
OUR MEMBERS ARE AT THE FOREFRONT OF EVERYTHING WE DO

ASSOCIATE MEMBERS:

ASSOCIATION MEMBERS:
As an organisation, SAMED is in a better position today than at any time in its history to continue taking forward our goal of “advancing innovation responsibly.” Creating a policy and regulatory environment that nurture the power of innovation has never before been more critical. The needs of patients are expanding faster than ever and the future holds boundless opportunities to continue improving the environment in which we work. However, without an efficient regulatory process, adequate coverage and payment, many patients will not receive the much needed life-changing technologies that our companies provide.

SAMED will continue its unwavering battle for acknowledgment of the uniqueness of the medical device industry. Through our engagement with key partners, we are seeing a changing attitude in how they engage with the industry. SAMED regularly meets with national and provincial government, regulatory bodies, doctor societies, private hospital groups, procurement departments, other health product industry associations, the Portfolio Committee of Health and others like the South African Bureau of Standards (SABS), to pro-actively influence decisions that impact the medical device industry.

As SAMED continues to amplify the voice of the medical device industry, our expanding membership (with 40 new members in this past year alone) stands as a testament to the extraordinary value we provide to our member companies.

When the association looks back on this past year, we can highlight some key milestones that yielded important benefits to SAMED members and the patients they serve. One of these was providing extensive input into previous drafts of the regulations pertaining to medical devices and in vitro diagnostic devices (IVDs). Therefore, when these final regulations were released and the Medicines Control Council (Pfizer) announced subsequent requirements to licence medical devices and IVD establishments, there were no surprises for our members. In addition, SAMED established a unique medical device working group with the MCC.

Aside from increasing our membership, SAMED also offers more benefits to our members and stakeholders. During the year under review, SAMED held a total of 30 workshops, training events, general member meetings as well as our flagship annual conference. SAMED also held a special procurement workshop with the Kwa-Zulu Natal Department of Health and is planning to host another for supply chain managers of the Gauteng Department of Health this year.

A major focus in 2016 involved the issue of outstanding payments to our members by provincial health departments. This report mentions several of SAMED’s interventions aimed at trying to resolve the issue. We shall continue to engage and advocate on our members’ behalf.

The rapid advance and evolution of medical technology impacts on the relationship between SAMED members and their customers. The complexity of many products creates interdependence between suppliers and customers, which necessitates working together to serve the best interests of patients. While these unique features of our industry are highly beneficial, the required relationships can also be open to manipulation. It was decided that a dedicated, purpose-built code for our industry would allow SAMED to steer a prudent course and enable us to fulfil our vision to develop a sustainable medical device industry by responsibly improving patient access to innovative health technology.

The process towards self-regulation inevitably required that SAMED withdraw from the Marketing Code Authority, a regulatory forum that jointly governed both the pharmaceutical and medical devices industries for seven years. We are delighted to report that our members strongly endorsed the new Medical Device Code of Ethical and Marketing Practice at a well-attended meeting held in Johannesburg on 23 February 2017. This upcoming year, we shall continue to implement processes that will help garner support from our members and other significant role-players. In so doing, we shall be able to facilitate the Code’s application so that it becomes a valuable facet of our industry.

FINANCIALS

As a financially responsible association with good fiduciary practices, SAMED values its responsibility in dealing with members’ money. As such, we are audited to ensure transparency and clarity around the association’s finances.

COMMITTEES

SAMED operates several committees whose updates and successes are documented in this report. We would like to personally thank all committee chairpersons and their committee members for their contributions, robust debate, tireless hard work and the real change they are generating within our industry. In many ways, our members perceive SAMED’s value through these committees, so we urge all to actively participate and be part of the change they would like to see in their industry association.

A WORD OF THANKS

We would like to thank the SAMED team for the unswerving work it does to ensure that the association runs smoothly and effectively. We would also like to thank all the board members for their time and expertise, as well as the committee chairpersons for all their hard work.

Finally, we would like to thank the members for their contributions and their questions in order to ensure we are a more needs-oriented association.

We look forward to a prosperous 2017!
SAMED once again has returned a sound set of financial results for the year ended 31st December 2016. The Audited Financial Statements for the year were approved by the Board on 14th April 2017 and reflect a surplus of R962,383 for the year comprising operating surplus R621,414 and investment income of R340,983. For the eagle-eyed – the R14 differential is attributed to a small finance cost! Whilst subscription fees showed a 13% growth over 2015, the income attributed to seminars was substantially down for the reported period due to the Regulatory congress held late in 2015. Overall income was up 7% year on year. On the expenditure line, expenses showed a 16% growth year on year mainly due to higher spend on committee activities and legal and accounting fees. The Statement of Financial Position shows cash and cash equivalents up by about R1 million and a concomitant increase in our equity now at R4,021,265 against R3,058,882 the previous year. The sound financial status of the association allows for SAMED to provide seed capital for an educational project that is intended to benefit all members in future. Thank you again to all our members for your continued support.

### SAMED EXECUTIVE COMMITTEE

- **Jeff Hampton**
  - SAMED Chairperson
  - (Chief Operating Officer, Baroque Medical)

- **Leanne Cook**
  - SAMED Vice-Chair
  - (General Manager – Medical Devices, Johnson & Johnson Medical)

- **Rob Millar**
  - SAMED Treasurer
  - (Chief Executive Officer, Condor Medical)

- **Marlon Burgess**
  - Chief Executive Officer
  - MDG Health Solutions

- **Ruwaida Shaikh**
  - Country Director
  - Boston Scientific SA

### SAMED BOARD OF DIRECTORS

- **Albert Denoon**
  - Chief Executive Officer
  - Baroque Medical

- **Reiner Gabler**
  - Chief Executive Officer
  - Gabler Medical

- **Robyn Howes**
  - SALDA Board Representative

- **Sophie le Cordeur**
  - MISA Board Representative

- **Anthony Lowther**
  - Managing Director
  - Ascenda Medical

- **Madeleine Pearce**
  - Senior Quality & Regulatory Systems Manager
  - Philips Healthcare

- **Che Potter**
  - SA Biomedical

- **Malan de Villiers**
  - MDOMA Board Representative

- **Ruwaida Shaikh**
  - Country Director, Boston Scientific SA

- **Leanne Cook**
  - SAMED Vice-Chair
  - (General Manager – Medical Devices, Johnson & Johnson Medical)

- **Jeff Hampton**
  - SAMED Chairperson
  - (Chief Operating Officer, Baroque Medical)

- **Rob Millar**
  - SAMED Treasurer
  - (Chief Executive Officer, Condor Medical)

- **Marlon Burgess**
  - Chief Executive Officer
  - MDG Health Solutions

### STATEMENT OF COMPREHENSIVE INCOME

<table>
<thead>
<tr>
<th></th>
<th>2016</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Conference fees</td>
<td>408,871</td>
<td>394,254</td>
</tr>
<tr>
<td>Meeting and workshop fees</td>
<td>60,486</td>
<td>44,211</td>
</tr>
<tr>
<td>Subscription fees</td>
<td>4,809,730</td>
<td>4,268,679</td>
</tr>
<tr>
<td>Regulatory income</td>
<td>23,751</td>
<td>421,367</td>
</tr>
<tr>
<td></td>
<td>5,302,838</td>
<td>5,128,511</td>
</tr>
<tr>
<td>Other operating income</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other income</td>
<td>49,250</td>
<td>4,211</td>
</tr>
<tr>
<td>Expenses</td>
<td>(6,730,674)</td>
<td>(6,094,908)</td>
</tr>
<tr>
<td>Operating profit</td>
<td>621,414</td>
<td>1,037,814</td>
</tr>
<tr>
<td>Investment revenue</td>
<td>345,983</td>
<td>197,812</td>
</tr>
<tr>
<td>Finance costs</td>
<td>(14)</td>
<td>-</td>
</tr>
<tr>
<td>Profit for the year</td>
<td>962,383</td>
<td>1,235,626</td>
</tr>
</tbody>
</table>

### STATEMENT OF FINANCIAL POSITION AS AT 31 DECEMBER 2016

<table>
<thead>
<tr>
<th></th>
<th>2016</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assets</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-Current Assets</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Property plant and equipment</td>
<td>24,866</td>
<td>37,576</td>
</tr>
<tr>
<td>Current Assets</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trade and other receivables</td>
<td>44,979</td>
<td>178,812</td>
</tr>
<tr>
<td>Other financial assets</td>
<td>100,662</td>
<td>-</td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>4,059,385</td>
<td>3,039,668</td>
</tr>
<tr>
<td></td>
<td>4,205,026</td>
<td>3,218,138</td>
</tr>
<tr>
<td>Total Assets</td>
<td>4,231,892</td>
<td>3,255,714</td>
</tr>
<tr>
<td>Equity and Liabilities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Equity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Retained income</td>
<td>4,021,265</td>
<td>3,058,882</td>
</tr>
<tr>
<td>Liabilities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current Liabilities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trade and other payables</td>
<td>218,627</td>
<td>196,832</td>
</tr>
<tr>
<td>Total Equity and Liabilities</td>
<td>4,231,892</td>
<td>3,255,714</td>
</tr>
</tbody>
</table>

### RESIGNED BOARD MEMBER

- **Vassie Ponsamy**
  - Managing Director – Sub Saharan Africa Region, Smith & Nephew
Bard has spent the last 100 years partnering with patients and physicians to develop, manufacture and supply advanced healthcare products and services in the areas of urology, oncology, vascular disease and surgical specialty areas.

Year after year Bard commits its people and resources to create better outcomes for you and your patient. Bard has pursued new ideas, inventive solutions and imaginative approaches, for improving healthcare system efficiencies, lowering the costs of care, achieving quality outcomes and delivering value to patients.

At Bard, our core values of Quality, Integrity, Service and innovation drive every aspect of how we operate - helping our company to become a global leader in health care. More than mere words, these values represent our commitment, our compassion and caring to make a meaningful, lasting difference for the health and healing of people around the world.

Rapid advances in the development of medical technology influence the relationship between SAMED members and their customers. The complexity of many products has created an interdependence between suppliers and customers and the need to work together to serve the best interests of patients. However, the pharmaceutical industry’s relationship with its clients does not have these features in common. While these unique features of our industry are highly beneficial, the required relationships can also be open to perversity. The SAMED Board decided that implementing a dedicated, purpose-built code for our industry would allow us to steer a judicious course. With this in mind, the SAMED Board decided to resign from the MCA on 29 September 2016 to reinforce and apply its dedicated Medical Device Code of Ethical Business and Marketing Practice.

The SAMED Code of Business Practice Committee was re-established with the objective of updating the Medical Device Code of Ethical Marketing and Business Practice.

During a well-attended member meeting on 23 February 2017, at a SAMED presented its new Medical Device Code of Ethical Business and Marketing Practice. The SAMED Code of Business Practice Committee was re-established with the objective of updating the Medical Device Code of Ethical Marketing and Business Practice.

There’s a special beauty to lasting relationships

Bard has spent the last 100 years partnering with patients and physicians to develop, manufacture and supply advanced healthcare products and services in the areas of urology, oncology, vascular disease and surgical specialty areas.

Year after year Bard commits its people and resources to create better outcomes for you and your patient. Bard has pursued new ideas, inventive solutions and imaginative approaches, for improving healthcare system efficiencies, lowering the costs of care, achieving quality outcomes and delivering value to patients.

At Bard, our core values of Quality, Integrity, Service and innovation drive every aspect of how we operate - helping our company to become a global leader in health care. More than mere words, these values represent our commitment, our compassion and caring to make a meaningful, lasting difference for the health and healing of people around the world.

Rapid advances in the development of medical technology influence the relationship between SAMED members and their customers. The complexity of many products has created an interdependence between suppliers and customers and the need to work together to serve the best interests of patients. However, the pharmaceutical industry’s relationship with its clients does not have these features in common. While these unique features of our industry are highly beneficial, the required relationships can also be open to perversity. The SAMED Board decided that implementing a dedicated, purpose-built code for our industry would allow us to steer a judicious course. With this in mind, the SAMED Board decided to resign from the MCA on 29 September 2016 to reinforce and apply its dedicated Medical Device Code of Ethical Business and Marketing Practice.

The SAMED Code of Business Practice Committee was re-established with the objective of updating the Medical Device Code of Ethical Marketing and Business Practice.

During a well-attended member meeting on 23 February 2017, at a SAMED presented its new Medical Device Code of Ethical Business and Marketing Practice.

SAMED developed its code of business practice about 12 years ago. This code provides clear guidelines in the marketing of health products and how its members should conduct themselves in their interactions with healthcare professionals and procurers of their products.

Six years ago, SAMED entered into an agreement with the pharmaceutical industry to create a joint South African Code of Marketing Practice under the Marketing Code Authority (MCA). However, it soon became apparent that the two industries - medical devices/technologies and pharmaceuticals - are very different.
The committee is currently working tirelessly to plan its national launch of the code to key stakeholders. In this regard, it has proactively sought meetings with key government officials, including the Minister of Health, the Deputy Director General, Health Regulation and Compliance Management, the Chief Director: Sector-Wide Procurement and the Registrar of Medicines to discuss the changes.

The sub-task team on certification and training is developing a strong and exciting certification programme on the code for members and healthcare professionals. This programme, in conjunction with training workshops for both members and stakeholders on the code, is set to be implemented in the latter part of 2017.

SAMED recognises that one of Government’s objectives is to regulate the healthcare industry effectively and efficiently. We are confident that our fortified code will enable our industry to contribute to attaining this goal.

1. SAMED Code Committee members present the new Medical Device Code of Ethical and Marketing Practice to SAMED members on 23 February 2017

MAKING AN IMPACT ON THE WORLD OF HEALTH. Across the healthcare continuum, BD is known for medical technology, devices and laboratory equipment—from medication management and parenteral drug delivery to diagnostics and solutions for clinical research. What may be less known about us is the difference BD has made in untold millions of lives in ways as diverse as helping enable inoculation of children for the final eradication of polio, identifying infectious organisms and providing the research tools to help advance the discovery of a vaccine for AIDS. Today our associates serve every corner of the world, united by one purpose: advancing the world of health. And through our extensive experience with partnerships, our depth of insights and exceptionally broad portfolio of solutions from discovery to delivery, we aim to make an even greater difference in human health across generations. Discover the difference one company can make. Discover the new BD.

Learn more about the Difference of One at bd.com/One-Company

© 2016 BD. BD and the BD Logo are trademarks of Becton, Dickinson and Company. MC6419
SAMED GOES GLOBAL

Through its international partnerships with key associations, SAMED advocates on behalf its members for increased harmony in trade, regulatory and reimbursement practices, thereby ensuring greater access and eliminating trade barriers and length of time to reach the market.

This year, SAMED participated in international events in order to highlight key developments, issues and possible solutions in the South African medical device market:

The Global Medical Technology Alliance (GMTA) 69th World Health Assembly (WHA) met from 23 to 28 May 2016. SAMED’s Executive Officer, Tanya Vogt participated in a panel at a WHA side-event discussing ‘Access to innovation for all: Is it possible?’ The panel explored the current challenges in motivating the development of innovative technologies that addresses the burden of disease globally; specifically those that are poverty-related and neglected to ensure that technology is more accessible.

SAMED’s Executive Officer, Tanya Vogt, was part of a panel that discussed the key topic; Procurement in Emerging Markets: New Compliance Challenges. Third party distributors and compliance remain big issues in emerging markets. Associations were therefore urged to screen and provide training to distributors in our market.

SAMED’s participation in international events in order to support better procurement of medical devices; good regulatory practices and global convergence. As the representative from the South African medical device industry, SAMED presented on the subject: Industry view on effective Medical Device regulations at a pre-ICDRA meeting.

International organisations often contact SAMED to obtain information and insight into the South African market. This year, SAMED met various trade commissioners from the Canadian, Israeli and German high commissions as well as Enterprise Ireland. AdvaMed and MedTech to discuss various topics. These encompassed the recent developments in the South African regulatory environment, understanding the dynamics of the South African medical device market and opportunities to develop partnerships between our organisations.

SAMED sits on the international GMTA Board, whose members are national or regional medical technology associations. They represent innovative companies that currently develop and manufacture 85% percent of the world’s medical devices, diagnostics and equipment. This board provides a forum for the development and advocacy of policies that support innovation in medical technology to address patient’s healthcare needs. GMTA is also officially recognised by the Organization WHO and engages with it on matters relating to medical devices. During a meeting of the GMTA Board on 23 May 2016, SAMED agreed to collaborate with GMTA on supporting better procurement of medical devices. It also gave input into the World Health Organization regulatory framework, which has been supported worldwide.

SAMED ENGAGES WITH KEY PARTNERS

Through significant presentations at stakeholders’ conferences, SAMED is continuously drawing in key partners. In 2016/2017, SAMED represented industry’s views and developments within our sector at several local conferences. These events were held by the South African Pharmaceutical Regulatory Authorities Association (SAPRAA); Southern African Health Technology Assessment Society (SAHTAS); SANAS; South African Federation of Hospital Engineering (SAFHE) and the Clinical Engineering Association of South Africa (CEASA).

The Global Medical Technology Alliance (GMTA) 69th World Health Assembly (WHA) met from 23 to 28 May 2016. SAMED’s Executive Officer, Tanya Vogt participated in a panel at a WHA side-event discussing ‘Access to innovation for all: Is it possible?’ The panel explored the current challenges in motivating the development of innovative technologies that addresses the burden of disease globally; specifically those that are poverty-related and neglected to ensure that technology is more accessible.

The MCC hosted the International Conference of Drug Regulatory Authorities (ICDRA), which was held in Africa for the first time from 27 November to 02 December 2016. The meeting, which welcomed delegates from the World Health Organization (WHO) member states facilitated focused discussions on several key issues. These included regulating harmonious African medicine practices; strengthening global regulatory systems; regulatory preparedness around public health emergencies; collaborating and harmonising the regulation of medical devices; good regulatory practices and global convergence. As the representative from the South African medical device industry, SAMED presented on the subject: Industry view on effective Medical Device regulations at a pre-ICDRA meeting.

International organisations often contact SAMED to obtain information and insight into the South African market. This year, SAMED met various trade commissioners from the Canadian, Israeli and German high commissions as well as Enterprise Ireland. AdvaMed and MedTech to discuss various topics. These encompassed the recent developments in the South African regulatory environment, understanding the dynamics of the South African medical device market and opportunities to develop partnerships between our organisations.

SAMED sits on the international GMTA Board, whose members are national or regional medical technology associations. They represent innovative companies that currently develop and manufacture 85% percent of the world’s medical devices, diagnostics and equipment. This board provides a forum for the development and advocacy of policies that support innovation in medical technology to address patient’s healthcare needs. GMTA is also officially recognised by the Organization WHO and engages with it on matters relating to medical devices. During a meeting of the GMTA Board on 23 May 2016, SAMED agreed to collaborate with GMTA on supporting better procurement of medical devices. It also gave input into the World Health Organization regulatory framework, which has been supported worldwide.

SAMED ENGAGES WITH KEY PARTNERS

Through significant presentations at stakeholders’ conferences, SAMED is continuously drawing in key partners. In 2016/2017, SAMED represented industry’s views and developments within our sector at several local conferences. These events were held by the South African Pharmaceutical Regulatory Authorities Association (SAPRAA); Southern African Health Technology Assessment Society (SAHTAS); SANAS; South African Federation of Hospital Engineering (SAFHE) and the Clinical Engineering Association of South Africa (CEASA).

The Global Medical Technology Alliance (GMTA) 69th World Health Assembly (WHA) met from 23 to 28 May 2016. SAMED’s Executive Officer, Tanya Vogt participated in a panel at a WHA side-event discussing ‘Access to innovation for all: Is it possible?’ The panel explored the current challenges in motivating the development of innovative technologies that addresses the burden of disease globally; specifically those that are poverty-related and neglected to ensure that technology is more accessible.

The MCC hosted the International Conference of Drug Regulatory Authorities (ICDRA), which was held in Africa for the first time from 27 November to 02 December 2016. The meeting, which welcomed delegates from the World Health Organization (WHO) member states facilitated focused discussions on several key issues. These included regulating harmonious African medicine practices; strengthening global regulatory systems; regulatory preparedness around public health emergencies; collaborating and harmonising the regulation of medical devices; good regulatory practices and global convergence. As the representative from the South African medical device industry, SAMED presented on the subject: Industry view on effective Medical Device regulations at a pre-ICDRA meeting.

International organisations often contact SAMED to obtain information and insight into the South African market. This year, SAMED met various trade commissioners from the Canadian, Israeli and German high commissions as well as Enterprise Ireland. AdvaMed and MedTech to discuss various topics. These encompassed the recent developments in the South African regulatory environment, understanding the dynamics of the South African medical device market and opportunities to develop partnerships between our organisations.

SAMED sits on the international GMTA Board, whose members are national or regional medical technology associations. They represent innovative companies that currently develop and manufacture 85% percent of the world’s medical devices, diagnostics and equipment. This board provides a forum for the development and advocacy of policies that support innovation in medical technology to address patient’s healthcare needs. GMTA is also officially recognised by the Organization WHO and engages with it on matters relating to medical devices. During a meeting of the GMTA Board on 23 May 2016, SAMED agreed to collaborate with GMTA on supporting better procurement of medical devices. It also gave input into the World Health Organization regulatory framework, which has been supported worldwide.

SAMED ENGAGES WITH KEY PARTNERS

Through significant presentations at stakeholders’ conferences, SAMED is continuously drawing in key partners. In 2016/2017, SAMED represented industry’s views and developments within our sector at several local conferences. These events were held by the South African Pharmaceutical Regulatory Authorities Association (SAPRAA); Southern African Health Technology Assessment Society (SAHTAS); SANAS; South African Federation of Hospital Engineering (SAFHE) and the Clinical Engineering Association of South Africa (CEASA).
In addition, SAMED pointed out that since there has been no call-up of these devices in terms of medical device regulations, companies are not legally required to register such products with the MCC. SAMED fiercely contested this a few years ago, which resulted in the current NAB policy allowing for combination medical devices to be given NAPPI codes without medicines or section 21 registrations. SAMED has continued to fight for recognition of these products by engaging in meetings with private hospital groups and the outcome of these discussions looks promising.

One of SAMED’s key strategic objectives is to work more closely with all doctor societies to understand their needs. SAMED also needs to be actively engaged in relevant issues that will enable the medical devices industry to meet the growing healthcare needs and expectations of its stakeholders. During the year in review, SAMED worked with several doctor societies such as:

South African Orthotics and Prosthetics Association (SAOPA): SAMED met with SAOPA’s executive committee on the Health Market Inquiry to discuss the cost of private healthcare and medical device regulations.

SAMED sits on the Strategic Health Innovation Partnerships (SHIP) steering committee. The Department of Science and Technology nominated our Executive Director, Ms Tanya Vogt to represent it on the SHIP steering committee.

SAMED pushed for industry representation on the Council for Medical Schemes’ Task Team, which is reviewing the Prescribed Minimum Benefits (PMB) Code of Conduct. SAMED succeeded in its action, which resulted in a member of SAMED’s Health Economics and Reimbursement Committee, Ms Bulelwa Maponya being appointed to be part of this task team and provide key inputs from the industry’s perspective.

SAMED sits on the Global Health Innovation Accelerator (GHIA) innovation stakeholder forum with the Department of Trade and Industry, the Department of Science and Technology, Medical Research Council, National Department of Health, PATH and the Industrial Development Corporation. This forum explores ways to accelerate access to the most promising technology innovations to better serve the health needs of resource-limited communities.

South African Society of Anaesthesiologists (SASA): SASA has educated SAMED’s members on how to engage with medical device users and how to avoid perversity and conflicts of interest. During SAMED’s annual conference, SASA outlined how important clinician advisory boards are in informing equipment-purchasing decisions.

A World Class Service for Medical Device Manufacturers

Our mission is to ensure patient safety while supporting timely access to global medical device technology. We strive to set the global standard in thorough, responsive, predictable conformity assessments, evaluations, and certifications.
A major focus this past year is the ongoing issue of outstanding payments to our members by provincial health departments. After SAMED received several member complaints, it conducted a survey among members to establish the extent of this problem. A total of 63 members responded to the survey. It emerged that various departments owe them R1.2 billion for invoices exceeding 30 days. The Gauteng Department of Health is responsible for R695 million of this amount.

SAMED is concerned that this level of non-payment will make it impossible for its members to maintain the status quo. Small companies, in particular, may have to close their doors and/or stop selling to the public sector. This may potentially affect service delivery and patient access to products and care, resulting in fewer players and less competition. This would not only be a blow to the industry but also to overall healthcare delivery in South Africa.

The procurement committee also met with the task team on non-payment of suppliers’ invoices within the Department of Planning, Monitoring and Evaluation (DPME) that sits within the Presidency. This department provided all our members with contact details of each MEC and Heads of Finances within the various provincial departments of health. The DPME also shared the latest statistics with the Deputy Minister within the Presidency. SAMED assisted some of its smaller members in contacting the DPME, which resulted in the payment of their outstanding invoices.

The committee also met with the MEC of Gauteng Department of Health, Ms Barbara Creecy, to explore ways of collaborating with the department through the implementation of its open tender system. This system encourages transparency as all tenders are conducted in an open forum. A positive outcome of this meeting was that the department gave SAMED a commitment to consider all our members’ invoices in their April payment run with the aim of paying outstanding ones by Mid-April 2017.

The committee and the Gauteng Department of Health and Treasury will be working closer in future to investigate the consignment stock process in the Gauteng region.

Through our partnerships with key health departments, SAMED is trying to transform these systems to avoid a recurrence of outstanding payments.

The National Treasury has implemented a centralised procurement mechanism whereby it will procure all essential devices for government hospitals. This centralised procurement system has already resulted in a number of successful transversal tenders. A couple of years ago, the National Treasury approached SAMED to assist in drawing up an essential equipment list for government hospitals. SAMED is now looking at new ways to support the National Treasury in its programmes to prevent any obstacles in the medical device value chain.

The KZN Department of Health in collaboration with SAMED found it necessary to bring all stakeholders together for an enlightening information sharing workshop to assist the Department of Health in understanding the dynamics involved in medical devices procurement. This is seen as a step in ensuring that the Department of Health improves its medical equipment and devices procurement process. With a positive response to the workshop, SAMED intends to develop a similar event with the Gauteng Department of Health and the Gauteng Provincial Treasury.

1. The MEC of Gauteng Department of Health, Dr Gwendoline Malegwale Ramokgopa addressing medical device companies at a supplier consultation meeting

2. SAMED and the KZN Department of Health hosted a successful procurement workshop on 9 December 2016
In 2015, SAMED became aware of a proposed guideline by the South African Bureau of Standards (SABS) on the re-use and re-sterilisation of single-use devices (SUD). Certain devices, which are deemed ‘single use’, are being reused on patients. In many instances, this occurs without their knowledge or express consent. In the absence of rigorous regulatory, safety and monitoring requirements for the re-use of single-use medical devices, SAMED therefore strongly advocated that users of SUDs adhere to the manufacturer’s instructions and intended number of uses. This is to safeguard the healthcare facility, patient and healthcare practitioner during the use of these products.

Since its inception in 1985, SAMED has advocated against the reuse of single use devices through presentations at key conferences. These include events by the South African Federation of Hospital Engineering (SAFHE), the Clinical Engineering Association of South Africa (CEASA) as well as our own annual conferences and workshops by the Central Sterile Services Department (CSSD).

On hearing about the proposed SABS guidelines, SAMED developed written opposing submissions and engaged with the organisation. SAMED succeeded in its vigorous efforts in reaching out to its network of stakeholders to raise its concern about the reuse of SUDS in many hospitals nationwide. Regulations pertaining to medical devices and IVDs were released on 9 December 2016. They clearly state that ‘single use’ in terms of a medical device means: “one use of a medical device on an individual or IVD on a sample during a single procedure and then the medical device or IVD is disposed of and is not reprocessed and not used again.” This now makes it illegal for any users of medical devices to re-use single-use devices.

WINNING THE FIGHT AGAINST THE RE-USE OF SINGLE-USE DEVICES

SAMED often advocates for its members through written and oral submissions to the South African government. We actively sought the views of our members on various key issues. These include the government’s procurement regulations, the National Health Insurance (NHI) White Paper, the Prescribed Minimum Benefit (PMB) Review, Health Market Inquiry into the cost of private healthcare in SA; the Davis Tax Committee’s funding proposals for the National Health Insurance and the Integrated National Strategy for Health Research. Through these submissions, SAMED ensures that the views of our industry are heard.

SUBMISSIONS, SUBMISSIONS SUBMISSIONS...

Contact us now to discuss how you can optimise your commercial model across Africa and how to approach promotion and communication in the increasingly digitised environment.

Market Research: Fill the data gap in Africa through ad-hoc surveys to make informed decisions.
Distributor Search: Expand your African footprint through our low-risk structured screening process.
Multichannel Campaigns: Complement your field force effort through cost-effective digital engagement.
App Development: Improve cost-effectiveness and control over your operations and CSI/CSR initiatives.

Tel: 010 500 7000 Skype: clientelis Email: info@clientelis.com www.clientelis.com
Address: Block A Edenburg Terraces 348 Rivonia Boulevard 2128 Johannesburg South Africa
and Economic Policies for MedTech Europe), as well as local reimbursement experts such as Professor Marie de Klerk, who is Head of Clinical Policies at MPh Health. SASA’s CEO Natalie Zimmerman also explained how companies should engage with users of their medical devices and how to prevent conflicts of interests and perversion.

A key objective of this committee is to find ways to influence and intervene in managed care policies. With the Council for Medical Schemes (CMS) embarking on a process to review the Prescribed Minimum Benefits (PMBs), this will affect the way in which schemes are required to fund PMBs. Another adverse effect of this review process is that people within the population who are currently being treated for a specific PMB condition may not be funded and will, therefore, go untreated. SAMED’s HE & R Committee developed a submission to the CMS highlighting some of the key issues and possible solutions as follows:

- The current PMB list (i.e. what is contained therein and the descriptions of treatment) is extremely outdated.

- It was also recommended that descriptors as well as procedural and professional codes should be updated and further defined by developing a national coding system. This could be prioritised through a public–private partnership, where the Council for Medical Schemes, the National Department of Health, industry and associations are consulted to ensure updated and appropriate coding in place in light of the NHI’s e-Health initiative.

- The PMB review seeks to address PMBs in terms of the belief that they drive costs. However, SAMED emphasised that the CMS should factor in any findings from the Health Market Inquiry, including an exclusive report that will deal with whether or not PMBs are indeed a cost driver.

- SAMED proposed introducing clear PMB treatment guidelines, based on clinical studies or the best available evidence (as defined in the regulations). CMS should consider such guidelines as the minimum standard of meaningful care.

- SAMED indicated that one way of treating PMB conditions is to consider various centres of excellence for the more prevalent and high-cost medical conditions. These centres would act as a vehicle to reduce costs due to the specific set of skills and experience they provide, thereby resulting in improved outcomes.

- SAMED’s suggestion to avoid fragmentation and movement of members between funders and thus increase costs entailed transferring e-files between funders in future, while giving due consideration to consumer protection and confidentiality.

This year the committee is looking at compiling a document that maps health technology assessment processes in both public (provincial and national) and private hospitals and medical schemes in South Africa.

---

**SAMED 2016 SALARY SURVEY: KEY HIGHLIGHTS**

The annual SAMED salary survey is a major value-add feature for SAMED members.

With significant subsidisation from SAMED, the survey assists members in making key decisions around remuneration and employee benefits. With 31 members participating this year, this is the 15th year that the remuneration survey has been conducted on SAMED’s behalf.

**Key survey findings included:**

**Actual salary increases granted**

SAMED members and survey participants’ average salary increases were about 1.0% above the average inflation rate of 6.1% for September 2016. The weighted salary increases awarded for 2016 was an average of 7.1%, which aligns with current national trends in salary movements.

---

**PERCENTAGE OF ORGANISATIONS THAT AWARDED SALARY INCREASES WITHIN CERTAIN RANGES FOR THE PERIOD UNDER REVIEW**

<table>
<thead>
<tr>
<th>SALARY INCREASE RANGE</th>
<th>General Management</th>
<th>Top Management</th>
<th>Middle Management</th>
<th>Professionals</th>
<th>Technicians, Clerical &amp; Administrative</th>
<th>Lower Level Staff</th>
<th>All Staff</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under 4%</td>
<td>7</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>4.1% to 6%</td>
<td>20</td>
<td>27</td>
<td>33</td>
<td>31</td>
<td>38</td>
<td>21</td>
<td>27</td>
</tr>
<tr>
<td>6.1% to 7%</td>
<td>27</td>
<td>13</td>
<td>21</td>
<td>32</td>
<td>25</td>
<td>22</td>
<td>28</td>
</tr>
<tr>
<td>7.1% to 8%</td>
<td>26</td>
<td>46</td>
<td>20</td>
<td>19</td>
<td>13</td>
<td>22</td>
<td>27</td>
</tr>
<tr>
<td>8.1% to 9%</td>
<td>7</td>
<td>7</td>
<td>13</td>
<td>6</td>
<td>6</td>
<td>21</td>
<td>-</td>
</tr>
<tr>
<td>9.1% to 10%</td>
<td>13</td>
<td>7</td>
<td>13</td>
<td>6</td>
<td>7</td>
<td>9</td>
<td>-</td>
</tr>
<tr>
<td>10.1% to 11%</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>7</td>
<td>-</td>
</tr>
<tr>
<td>11.1% to 12%</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>12.1% to 14%</td>
<td>-</td>
<td>-</td>
<td>6</td>
<td>6</td>
<td>-</td>
<td>9</td>
<td>-</td>
</tr>
<tr>
<td>Over 14%</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>
When you’re healthy and strong, you can grow up to do anything.
Upon membership, medical device companies automatically become part of a larger association that has the expertise and commitment to advocate for and protect the rights of its members.

NETWORKING AND WORKSHOPS
Members have access to regular member meetings and workshops on a range of industry issues. This enables them to benefit from opportunities and also connect with other individuals and businesses.

ADVOCACY AND RELATIONSHIPS WITH KEY STAKEHOLDERS
SAMED engages with policymakers, regulators, politicians, doctor societies, funders and international organisations in developing and proposing patient-centered policies that enable people to live healthy and productive lives. It also provides solutions that significantly drive the productivity and efficiency of healthcare systems.

In addition, SAMED subscribes to the Government Gazette and Tender Bulletins. The parliamentary monitoring group collects and provides privileged and reliable data to members on a wide variety of issues, which enables them to make informed business decisions.

SAMED synchronises standards and regulatory requirements within the field of medical devices manufacture and supply. In this regard, it has links with other stakeholders and international agencies. These include the Code Technical Advisory Committee for the Marketing Code (CTAC), the Internal Task Group (ITG), the Strategic Health Innovation Partnership (SHIP), the Non-Communicable Disease (NCD) alliance, the Pan-African Harmonisation Working Party (PAHWP), the Asian Harmonisation Working Party (AHWP), the Global Medical Technology Alliance (GMTA), MedTech, World Health Organization (WHO) and AdvaMed.

INDUSTRY-RELATED INFORMATION UPDATES
In the news — Members enjoy regular, industry-related information gathered from numerous sources, including government (PMLG legislation) and the private sector.
News Roundup — The SAMED News Roundup supplies our members with the latest local and international news best practices in procurement, the risks of re-using single-use devices, global fee tenders as well as the unintended consequences and the impact that outstanding payments have on the medical device industry.

TRADE DELEGATIONS
SAMED hosts both incoming and outgoing trade delegations upon request.

COMPANY REPRESENTATIVES IN THE CLINICAL ENVIRONMENT (CRICE)
CRICE, a SAMED initiative, is the industry standard for professionals representing medical device companies in the clinical environment. Masoom Training Solutions administers the CRICE system.

SAMED’s Offerings

Get certified to ISO 13485:2016 in 7 steps

1. Apply online
Send us an email or submit an enquiry form on our website, and we will be in touch about your best options based on information about your organisation’s products and services.

2. Find out if you are ready
Identify areas where your existing OMS differs from the new standard’s requirements with a Gap Analysis. LRQA will work with you on the scope to accommodate your business objectives.

3. Engage your stakeholders
Upgrade the knowledge of your quality management, regulatory affairs teams and internal auditors. Always engage top management, LRQA’s range of public and in-house training delivers against a wide range of needs, from introductory briefings to specialised role-based course.

4. Develop a plan
With the help of a credible third party assurance provider like LRQA, you should be able to sketch out a suitable plan for your organisation. LRQA will help you develop a plan to efficiently and effectively transition to ISO 13485:2016, and implement it for the first time.

5. Get certified
Once you have all the requirements in place, an LRQA assessor will certify your organisation against ISO 13485:2016, following a successful assessment visit.

6. Communicate the outcome
Let your stakeholders know the assessment was a success. Take a moment to celebrate, and remember to always uphold what certification ultimately represents—a stamp of approval against the credibility, quality, and integrity of your organisation.

7. Maintain and optimise
Following certification, your system will require regular reviews to ensure ongoing effectiveness and continuous improvement. LRQA can conduct regular reviews of your system, as well as check its compliance with ISO 13485:2016 and other applicable regulatory requirements.

The CRICE programme continues to expand, with 403 companies participating to date and 8087 enrolments nationally.
2016 was a pivotal year, not only for South Africa’s regulatory environment but also for SAMED’s Regulatory Committee. In the year under review, the South African National Department of Health’s mandate — given to the Medicines Control Council (MCC) to regulate medical devices — resulted in the gazetted release of the medical device and IVD regulations on 9 December 2016.

The MCC instructed medical device companies to start the process of listing their activities and products. This licensing initiative commenced on 24 February 2017 and is due by 24 August 2017. Responding to this instruction, the committee partnered with an associate member, the Southern Africa Laboratory Diagnostics Industry Association (SALDA) in presenting a series of monthly regulatory forums. During these events, which often attracted more than 100 SAMED members, participants gained knowledge about the imminent regulation of the industry. The need for regulatory guidance within our industry is evident, so SAMED has extended the forums to the Western Cape and Kwa-Zulu Natal to reach as many members as possible.

A recent development was the formation of the medical device-working group. This specialist sub-committee of the ITG (Industry Task Group) had its first meeting in October 2016. The working group focuses on involving representatives from the regulator and industry to look at issues that arise in the medical device industry. With regulations directing companies to implement quality management systems, members of the committee and other stakeholders met with SANAS (the South Africa National Accreditation System) at a forum in September. The aim of this meeting was to understand the steps required to allow companies to become certified locally to the ISO13485 standard for quality management systems for medical devices.

SAMED is currently participating in the SANAS working group for ISO13485.

SAMED advocated strongly against the requirement that companies need to submit a site master file with their application. The guidelines for the site master file were for pharmaceutical companies and not in line with how our businesses operate. We motivated to the MCC for the development of quality manual guidelines. This was needed and a guideline recently been released for comment. On the international front, the SAMED Regulatory Committee continues to be involved in a variety of forums that promote internationally harmonised medical device regulation. Harmonisation ensures that best practice for safety and quality is implemented in South Africa. This will reduce special requirements demanded of the industry by the Regulator, which could add unnecessary costs and regulatory burden companies that provide much needed medical technology to South African healthcare institutions and patients. In our quest to promote such harmonisation in South Africa, we participated in the Asian Harmonisation Working Party, and the Global Medical Technology Alliance (GMTA). The latter gives input to the International Medical Device Regulators’ Forum (IMDRF), standards of practice for regulation are decided. The committee also interacts with other groupings such as Medtech and WHO, among others, to ensure we are up to date on latest developments in medical device regulation.

Navigating the Complexities of Combination Medical Devices

SAMED has always maintained that the Medicines Control Council does not have jurisdiction over the registration of combination medical devices (i.e. where the primary mode of action resides with the device component) if the product meets the definition of a device. This issue has been ongoing for a number of years but came to a head this year with the release of medical device and IVD regulations. In terms of provisions of the regulations, it is readily apparent that any unregistered medical device that might have been sold in the Republic at the time of the commencement of the Regulations is considered to be sold legally until a call-up notice referred to in sub-regulation 28(2) for that medical device has expired. This includes combination medical devices, which currently are legally being sold until the MCC calls them up to be registered.

SAMED and the regulatory committee have taken several steps to resolve this issue on behalf of its members. Firstly, the committee approached the Regulator to determine the way forward for combination medical devices, which are currently registered as medicines. SAMED has indicated to the MCC that in accordance with the aforementioned Regulations and Guidelines, combination medical devices should be regulated as devices. Thus, they should not be regulated in terms of the regulatory pathway applicable to medicines that the MCC has historically applied to such products. SAMED indicated that the section 21-approval and registration requirements that have been applied to combination devices — and specifically to the products referred to herein should no longer apply to such products already in the market. Secondly, SAMED has continued to engage with all hospital groups and stakeholders to allow them to procure and use these products in their hospitals without MCC registration. The MCC has also just released a guideline on ‘borderline products’ for comment. This guideline is intended to provide recommendations to applicants wishing to submit applications to register a borderline medicine, medical device or a combination of a medicine and medical device. SAMED will obtain input from its members to comment on the guidelines.
In scientific research labs, your procedures, protocols, and personnel are changing all the time. You have to be nimble and flexible, doing more with less—and your liquid handling has to work right along with you. So we deliver true walkaway automation, freeing you up for more data analysis, more experimentation, more science. We’ve even automated your setup process, making it easy to learn and use.

Best of all, we can automate your science because we get your science—from first assay to final analysis. PerkinElmer automated liquid handling solutions. We’ve automated the most important application of all: Yours.

For Research Use Only. Not for use in diagnostic procedures.

www.perkinelmer.com/AutomatedLiquidHandling
The Medical Device Manufacturers of South Africa (MDMSA) is currently a SAMED member. In 2014, this association decided to utilise SAMED’s infrastructure but focus on promoting the local medical device manufacturing industry. This affiliation has resulted in MDMSA participating in many of SAMED’s initiatives and committees, inter alia Regulatory Procurement, and HE and R. The association’s ethical business standards are aligned through MDMSA’s pledge to abide by the Medical Device Code of Ethical Business and Marketing Practice. SAMED has not only supported MDMSA with secretariat services but will also fund a dedicated resource for the organisation this year; which will take MDMSA to new heights.

This past year the MDMSA Board developed key objectives to grow its organisation:

- **Objective 1:** Market the Association and grow the membership.
- **Objective 2:** Promote the availability of funding and incentive programmes offered by the DTI to support Development. Give input into DTI specific medical device local and export strategy.
- **Objective 3:** Interaction with relevant parties to promote development of and adherence to national and international regulatory standards and to promote and encourage among its member’s ethical principles and practices.
- **Objective 4:** Promote procurement of products developed and manufactured in South Africa both within SADC and for export markets.
- **Objective 5:** Interact with the various stakeholders in the networks of innovation in South Africa to optimise development and local manufacture of innovative, appropriate and sustainable medical devices for both local and export markets.
- **Objective 6:** Encourage and grow participation of POIs in the medical device industry.

Once MDMSA realised that the objectives of its board would only be realised through better funding, it approached the Department of Trade and Industry (DTI). This government body uses its various schemes to assist South African associations with support funding. After preparing and submitting a strategic plan based on its objectives, the DTI approved sector-specific assistance scheme funding for MDMSA. This funding will greatly assist the association in meeting its objectives in the coming year.

MDMSA has welcomed the release and subsequent implementation of medical device regulations, which enable local companies to compete in the global market. MDMSA is concerned that the cost of these regulations is higher for local manufacturers. It has, therefore, written to the MCC requesting a review of the fees. MDMSA has also examined ways in which it can lower costs with respect to ISO 13485 accreditation for its members. Having a local auditing capability would be very helpful in this regard. In addition, MDMSA has raised its concerns with the MCC regarding disinfectants being classified as medicines and not as combination medical devices. If a company has products that are classified as both medical devices and medicines, it becomes onerous on the company as it needs to have two quality management systems.

In January this year, MDMSA members also participated in and promoted their products to the Arab market during a very successful Arab Health Trade Mission, which the DTI funded for the second year running. Another opportunity for MDMSA to increase awareness of the organisation occurred in March, when it ran an information booth and was granted a speaking slot at a conference of the South African Federation of Hospital Engineering (SAFHE) and the Clinical Engineering Association of South Africa (CEASA). MDMSA is also hosting an exciting local manufacturers’ conference at Africa Health in June. It has negotiated with 12 companies to join MDMSA in having exhibit stands at the event.

Both SAMED and MDMSA sit alongside other organisations on the Global Health Innovation Accelerator (GHIA) stakeholder forum. This forum investigates ways to accelerate access to the most promising technology innovations to better serve the health needs of resource-limited communities. Other organisations represented on the forum include the Department of Trade and Industry, the Department of Science and Technology, the Medical Research Council, The National Department of Health, PATH and the Industrial Development Corporation (IDC). MDMSA is acutely aware that it needs to persuade as many local manufacturers as possible to become members. Increased membership will strengthen its standing when lobbying for a greater share of the devices’ business in South Africa. All MDMSA members therefore have an obligation to recruit more local manufacturers into the fold to ensure it has a more powerful, sustainable voice in the industry.
ACCELERATING SMALL BUSINESS

By leveraging the resources of the entire association, SAMED’s Small Business Forum focuses specifically on the unique needs and challenges of its early emerging growth enterprises. The forum’s main objective is to create an opportunity for small business members of SAMED to raise and discuss issues they are facing in the industry. In addition, the forum focuses on ensuring that the medical device industry is aligned with national strategic goals in transforming the economy.

SAMED has hosted three highly informative forums that have featured several speakers who are not only experts in their fields but also policymakers who could help small companies prosper. They include Colin Leshou, Gauteng Provincial Manager, Small Enterprise Development Agency (SEDA); Pierre Delaney, Director, KPMG; Vuyisile Mshudulu, Deputy Director: Creative Industries, Department of Small Business; Ben Berman, Managing Director, Business Partners and Ts’episo Makgothi, Chief Director: Strategic Partnerships and Customer Care, DTI.

SAMED will continue these forums to expose its smaller members to key customer groups and companies that could help their businesses expand.

The South African government will be implementing the new Draft Preferential Procurement Regulations 2016, which includes a 30% qualifying small enterprise requirement for all tenders. Simultaneously, SAMED aims to create a database of small-owned companies (especially level 1-3 B-BBEE companies) that will be advertised to other members and key stakeholders.

For a full life-cycle solution, from clinical development to commercialisation, allow us to become your lifetime partner. We cover everything from phase I to III trials, product registration, market access, reimbursement, sales and marketing. Create a portfolio of Real World Evidence with a partner that offers an adaptable, hungry, focused approach to robust scientific research solutions. We put you first, always treating you as our biggest client. Get your product to the market faster!

CONTACT US TODAY FOR A FREE CONSULTATION TO DEVELOP YOUR PORTFOLIO OF EVIDENCE

T: +27 12 664-1622 | E: outcomes@tcd-global.com | ortcd-global.com
THE PLACE TO BE

SAMED EVENTS
SAMED had its busiest event year yet in 2016. With 30 workshops, general member meetings, breakfast briefings and annual conference, SAMED has aimed to assist members with pertinent developments within the industry. Our successful regulatory forums with SALDA evoked a positive response from members, with over 100 attendees at most of the monthly meetings.

SAMED’s flagship event, the annual conference, took place at the end of August. With its theme ‘Partnering for Patients’ and attended by more than 200 delegates from government, the industry and the private sector, this was our most successful conference to date. Presentations by both local and international experts highlighted the need for proper health technology assessment, regulation and procurement systems to promote patients’ access to affordable, high quality and appropriate products to improve the country’s health outcomes. Value-based procurement of medical devices and ethical interactions with health care professionals was high on the agenda, particularly around ensuring that patients are the ultimate beneficiaries in a changing health system.

“The effectiveness of technology should be measured by patient outcomes and its total value to the healthcare system and not cost, irrespective of patients’ financial circumstances.” — Jeff Hampton, SAMED Chairperson at the 2016 SAMED Annual Conference.
HOW TO MEND A BROKEN HEART

When a valve in Katja Jensen’s heart stopped working properly, doctors said surgery would be too risky. However, doing nothing was not an option, either.

After Katja started experiencing chest pain, shortness of breath and dizziness, she found out that her aortic valve had narrowed to one-third of its normal diameter. The symptoms were the result of a restricted blood flow from her heart into her body and it was clear that something had to be done. Normally, repairing the aortic valve of a 25-year-old would require heart surgery, but Katja’s case was unique.

“I was born with a heart defect and had a transplant when I was 11,” she remarks. “As I’d already been opened up a few times and will probably need a transplant again in 10-15 years, the doctors wanted to avoid another operation.” The surgical team decided that the safest option was to replace Katja’s aortic valve with an artificial one, using a procedure called transcatheter aortic valve implantation (TAVI), which would not require open-heart surgery. “I was very relieved that I could get the TAVI instead of open-heart surgery. I trusted my doctors’ decision and even though the risk was low, I was still very nervous,” Katja recalls.

Aside from being the youngest person to ever have TAVI, Katja is the only person with a heart transplant to have undergone the procedure. It involved inserting a narrow tube (catheter) into an artery in her groin until it reached her aortic valve and then temporarily placing and inflating a balloon in the tight valve to stretch it open. Thereafter, using another balloon catheter, the new valve was placed in her heart before the balloon was deflated and removed. Within 30 minutes, the surgery was completed and Katja had a new, functioning aortic valve. She recovered fully and returned to the gym just six weeks later.

LIFE CHANGING INNOVATION

When a valve in Katja Jensen’s heart stopped working properly, doctors said surgery would be too risky. However, doing nothing was not an option, either.

After Katja started experiencing chest pain, shortness of breath and dizziness, she found out that her aortic valve had narrowed to one-third of its normal diameter. The symptoms were the result of a restricted blood flow from her heart into her body and it was clear that something had to be done. Normally, repairing the aortic valve of a 25-year-old would require heart surgery, but Katja’s case was unique.

“I was born with a heart defect and had a transplant when I was 11,” she remarks. “As I’d already been opened up a few times and will probably need a transplant again in 10-15 years, the doctors wanted to avoid another operation.” The surgical team decided that the safest option was to replace Katja’s aortic valve with an artificial one, using a procedure called transcatheter aortic valve implantation (TAVI), which would not require open-heart surgery. “I was very relieved that I could get the TAVI instead of open-heart surgery. I trusted my doctors’ decision and even though the risk was low, I was still very nervous,” Katja recalls.

Aside from being the youngest person to ever have TAVI, Katja is the only person with a heart transplant to have undergone the procedure. It involved inserting a narrow tube (catheter) into an artery in her groin until it reached her aortic valve and then temporarily placing and inflating a balloon in the tight valve to stretch it open. Thereafter, using another balloon catheter, the new valve was placed in her heart before the balloon was deflated and removed. Within 30 minutes, the surgery was completed and Katja had a new, functioning aortic valve. She recovered fully and returned to the gym just six weeks later.

CHANGING LIVES FOR THE BETTER IN WORCESTER, SOUTH AFRICA

The lives of 67 residents in Worcester, South Africa, will soon be changing for the better – following DePuy Synthes Companies of Johnson & Johnson generously pledging to donate 67 arthroplasty implant sets to the patients of Worcester Hospital, in commemoration of Mandela Day, celebrated globally on 18 July 2015.

Speaking at the official donation handover, Elbie Vosloo, CEO of Worcester Hospital, acknowledged that although the facility has a state-of-the-art and well-functioning orthopaedic department – with a specific interest in arthroplasty – it has a waiting list of over 350 patients who require arthroplasty-related surgery. “Worcester Hospital is able to assist approximately 100 patients per year with joint replacement surgeries, consequently leaving a waiting time of four years, which is ever-increasing,” comments Vosloo. “With De Puy Synthes’ donation, Worcester Hospital will be able to assist an additional 67 recipients at no cost to them, reducing the waiting time by approximately 3 months.”

Vosloo adds that due to a number of socio-economic factors, such as increased levels of unemployment and poverty in the Worcester region, many of the individuals who require arthroplasty surgery to improve the quality of their life are not able to afford the cost of the procedure and are therefore reliant on the public health system.

Dr Theodore Franken, head of the Orthopaedics Clinical Unit at Worcester Hospital, will drive the project and says that the recipients of the joint replacement surgery will benefit in many ways.

He highlights that pain relief is the key benefit for any individual who undergoes joint replacement surgery, because the diseased cartilage and bone are removed. “Other benefits include gains in functional activity, particularly mobility as well as an overall improvement to the individual’s life,” he says. “The 67 recipients will be selected from the current orthopaedic surgery list and their selection will be based on international criteria.

This is the first time that De Puy Synthes has embarked on a donation of this scale in South Africa. Westley Turnbull, Sales Director for the company, says that the donation serves the sole purpose of improving the lives of 67 patients in need. “This donation is made in celebration of the late Nelson Mandela’s birthday, known around the world as Mandela Day, and serves to emulate his character by serving those in need. This resonates with our company Credo, which guides us to care for the communities in which we live and work,” adds Turnbull.