SAMED position paper
Pandemic preparedness: lessons from COVID-19
September 2021

Introduction

As existing health risks surge and new ones emerge, humanity's past successes in overcoming health challenges are no guarantee of future results. People's health may be undermined not only by crises caused by infections or pandemics but also by natural or man-made catastrophes. Such events would require similar planned, timeous and effective responses from governments and health experts – including the medtech industry.

The COVID-19 pandemic exposed new vulnerabilities resulting from changing social, environmental, demographic and technological conditions. These threaten gains in health, wellness and prosperity that have been enabled by medical advances and health systems over the last century. Now, health systems around the world are under immense pressure and risk, being seen as unfit for purpose. Health nationalism – manifested in competition for health resources – is on the rise, as leaders prioritise the interests of their own nations rather than measures that recognise global interconnectivity with one nation's health having the potential to affect the entire world.

The significant role of socio-political factors in overcoming threats caused by infectious agents has become evident. A lack of information, the circulation of misinformation and hesitancy in relation to behavioural and biomedical responses (including vaccines) have been features of the COVID-19 pandemic.

The COVID-19 experience has also highlighted the fact that medical technology, along with health practitioners and pharmaceuticals, constitutes the foundation of quality healthcare, both in normal and emergency circumstances. The medtech industry was therefore at the forefront as the pandemic propelled healthcare systems, governments, researchers and societies into crisis mode with a combination of protocols aimed at reducing transmission rates while preparing for a surge of cases. Hard lockdowns ground economies to a halt and the unknown nature of the virus escalated fear, anxiety, misinformation and uncertainty.

While other pandemics have occurred over the last two decades going back to the smallpox epidemic, none was comparable to COVID-19 in terms of scale and concentrated impact. Within the medical technology space, suppliers struggled to meet the demand for personal protective equipment (PPE), ventilators and other breathing aids, while many companies battled for survival as elective surgeries were cancelled, health facilities were off-limits to their representatives and supply chains became uncertain.

SAMED played a critical role in supporting its members during the first year of the pandemic. The association recognises the importance of continuing to work with relevant stakeholders to ensure the supply of essential medical technologies until the end of this pandemic and assisting the economic recovery of its members. It also seeks to play a role in preparing the health sector to respond more

effectively to equivalent challenges in the future. This will entail crafting solutions to long-standing shortcomings in the health system, many of which were exacerbated by the pandemic.

This position paper is intended to:

- Inform strategies to address continuity in the medtech industry and healthcare beyond the crisis.
- Contribute to planning for future pandemics and other public health crises.
- Enable a shift from short to long-term planning in the medtech industry and the health system more broadly.

Pandemics demand a comprehensive medtech strategy

The South African government, healthcare sector and business community, including the medical technology industry, were forced into urgent action once the coronavirus reached the country. Many measures instituted under the National State of Disaster led to positive results, slowing down transmission, delaying the peak of the first wave and allowing the health sector to prepare an appropriate response.

However, the speed of the response also had negative consequences. It led to corruption in the procurement and supply of essentials including PPE and other medtech; opened the doors to inexperienced and sometimes fraudulent suppliers; allowed the use of unchecked, poor-quality products; complicated and delayed approvals for COVID-19 tests, ventilators and other critical medtech; and hindered efforts to ramp up local production of these products.

Specifically, the pandemic highlighted the following:

- The need for reliable data about the South African medtech sector.
- The crucial role of an organised industry association like SAMED.
- The vital role of medtech and, in particular:
    - The significance of ethical practices in the industry.
    - The value of quality medical technology.
    - The need for value-based procurement of quality products.
- The linkages, interdependencies and need for collaboration across the health system.
- Challenges to supply chain integrity, in terms of:
    - Dealing with increased demand.
    - Overcoming constraints on supply and restrictions on import/export.
    - Efficient administration of import tax rebates and export licences.
    - Logistics for the movement of medical supplies.
    - Availability of raw materials.
    - Effective procurement processes.
    - Capacity to expand local manufacture.
- Shortcomings in relation to medtech policy and regulations.
- Factors threatening business sustainability, resilience, and the customer interface.
- The challenges of maintaining patient-centricity in times of crisis.

SAMED has documented members' experiences in all these areas, drawing lessons that may enable the medtech industry and a range of other stakeholders to prepare better for future pandemics or other public health threats.

Enhancing data quality on the South African medtech sector

SAMED's position

Up-to-date data on the medical technology industry is integral to influencing policy and practices, engaging with internal and external stakeholders, and achieving SAMED's strategic objectives. SAMED recognises the inadequacy of current data and is committed to the development of a credible and relevant body of data. Such data needs to be accurate, statistically valid, and of value to SAMED, its members and external stakeholders. The data collection mechanism needs to be trusted and the collection process ongoing and consistent, to ensure periodic updates. The collection, storing and reporting of data must comply with the Protection of Personal Information Act (POPIA), competition law and other applicable legislation.

As early as January 2020, local and international organisations contacted SAMED for information on local suppliers of essential COVID medical products. As the pandemic deepened, the queries increased in urgency, pressing for information on available quantities and sources of PPE and other COVID-related products.

SAMED initially provided rolling data collated through daily collection from its members but soon recognised the need to scale-up and digitise the process. This was done in partnership with Business for South Africa (B4SA) through a digital platform that helped track the availability and supply of various essential COVID products in South Africa.

SAMED advised on questions and criteria to consider when tracking supplies on the platform. While this system was only deployed during the initial wave of the pandemic, it could be expanded to provide a tool to track medical technologies in a future emergency.

The scramble for data on the medtech sector underscored the necessity for accessible, current information and led to SAMED's data integrity initiative which aims to collect credible data about its members (and the medtech sector more broadly) on an ongoing basis.

This data will assist members to navigate local and international market dynamics and make business decisions. It will also strengthen stakeholder relationships and deepen their appreciation of the value of medtech. SAMED will use the data to identify gaps in policy or policy implementation, substantiate industry positions, guide its responses to a variety of stakeholders, and help strengthen the healthcare system more broadly.

Validation of SAMED's role in the health system

SAMED's position

Established associations like SAMED (with its association members, SALDA and MDMSA) are crucial in times of crisis. These organisations must be strengthened and afforded recognition in advance of health emergencies. SAMED's ability to represent members and communicate to them enable companies to respond with agility to extraordinary circumstances than they would do if operating in isolation. This substantiates the need for a strong, active and connected industry, championed by an engaged envoy.

During the COVID-19 pandemic, SAMED acted as the voice of medtech and facilitated numerous engagements. It assisted the national PPE response through B4SA and circulated calls from the

Department of Trade Industry and Competition (the dtic) to upscale supply. It held numerous information sessions about and with the South African Health Products Regulatory Authority (SAHPRA) to help the medtech sector understand the significance of regulatory measures with respect to ensuring safe, quality products enter the market. SAMED communicated daily with members during the first wave of the pandemic to provide the latest news on legislation and policy and the state of the pandemic.

As a representative of the medtech sector, SAMED acts as a conduit for information, facilitating consultations and partnership requests and serving as a repository and disseminator of knowledge. This is particularly valuable in a rapidly changing pandemic environment.

During 2020, SAMED strengthened relationships with government, the private sector, including Business Unity South Africa (BUSA), funders, and international/continental agencies. In 2021, SAMED provided expert guidance on ancillary technologies, such as needles and syringes, for the national vaccination rollout plan. It supports the industry by clarifying regulatory requirements.

SAMED will build on the recognition it achieved and the relationships it forged in a national effort to meet the enormous demand for COVID-related medtech, taking this momentum forward into its daily work and its preparation for future health crises.

Significance of ethical practices

SAMED's position

SAMED's commitment to an ethical medtech industry is underscored by its adoption of the Medical Device Code of Ethical Marketing and Business Practice which is binding on all members. The association will continue to strengthen the Code and advocate for its wider applicability. In addition, SAMED:

- Actively supports anti-corruption initiatives by government, the private sector and civil society.
- Advances value-based procurement and the supply of quality medical products.
- Recognises and supports the role of SAHPRA in building a trustworthy, regulated medtech industry.

SAMED members adhere to the Medical Device Code of Ethical Marketing and Business Practice. This promotes best practice by medtech companies when dealing with healthcare establishments and professionals and fosters an ethical and compliant medtech sector. Its provisions contrast sharply with the exploitative and fraudulent conduct of some medtech companies – both established and newly founded – that favoured massive profits over ethics as the country wrestled with COVID-19.

SAMED publicly condemned all inappropriate and unethical business and marketing practices relating to medtech and will continue to do so. It holds the view that inflated prices and the unlawful procurement of essential products must be prevented or punished as these have a negative impact on patient care and quality outcomes of the health system in general.

The Code is a powerful instrument and SAMED takes the view that it should be formally recognised by the authorities so that all medtech suppliers would be obliged to comply with it. The association is lobbying for this.

SAMED participates in the Health Sector Anti-Corruption Forum (HSACF) to curb fraud, waste, abuse and unethical conduct in the healthcare space. It recognises the value of the sector regulator, SAHPRA, in combatting opportunistic participation in the medtech market. SAMED has recommended to National Treasury that only medtech companies registered with SAHPRA should be eligible to bid for open tenders.

COVID-19 exposed members of the public to medical devices and lifesaving technologies in an unprecedented way and many people began to purchase items. SAMED used this interest to educate the public on how to establish the quality and efficacy of various products.

This educational role extended to those making medtech procurement decisions within the health system. This was particularly helpful in an environment where many new suppliers had entered the market and some were ignoring regulatory requirements, either intentionally or due to a lack of experience, putting the safety of health workers and patients at risk and wasting limited resources.

SAMED encourages suppliers to ensure that the products they sell meet local regulatory requirements, follow good manufacturing practice and are quality tested against local or international standards. Suppliers also need to implement monitoring and vigilance protocols to assure themselves that their products do not fail or, in event of failure, to initiate product recall and other measures. Such monitoring may also inform product innovation which plays a crucial role in the context of responding to a novel infection. If not for this type of post market surveillance, it would not come to the fore that the AstraZeneca vaccination was unsuitable for the dominant variant in South Africa and government would not have been able to respond accordingly.

SAMED promotes a value-based model of procurement which means procuring medical devices to achieve the best possible healthcare outcomes. Value is not just about cost but is primarily about the benefits a medical device delivers in terms of patient health, health system performance and social returns. To achieve value, procuring authorities should focus on spending well, rather than spending less. Factors such as patient quality of life, the servicing and maintenance of medtech, and the training and support offered to health professionals need to be considered by decision makers to ensure that they make the best possible procurement choices.

Collaboration for a comprehensive response

SAMED's position

SAMED believes that collaboration among a wide range of role-players is fundamental to strengthening the South African health system, which is the country's best defence against future pandemics and health crises. The association will sustain and deepen the relationships forged in the heat of the COVID-19 response, contributing to common initiatives to "build back better" in an authentic and, when necessary, constructively critical manner.

The South African COVID-19 response spanned multiple sectors and was implemented under the authority of an array of government agencies, led by the President, Cabinet and the National Coronavirus Command Council.

The healthcare sector alone is a complex ecosystem. This and the interdependence of its elements have the potential to reduce the speed of its response. The scale of the pandemic required a concerted reaction across the entire system and the building of inter-agency relationships and communication channels.

Various departments and agencies sought SAMED's collaboration as they realised the vital role that medtech would play in the pandemic response. The dtic engaged SAMED on the challenges faced by the sector in order to help resolve them. Through SAMED, the department arranged information sessions and worked with other agencies to overcome bottlenecks and assist medtech companies.

SAMED worked particularly with the following agencies:

- SAHPRA, which was responsible for licensing suppliers of COVID-19 products and ensuring that unlicensed suppliers were regulated.
- The National Health Laboratory Services (NHLS) which had to upscale its own COVID-19 testing output, outsource additional testing capacity, and perform quality testing of COVID-19 tests and test kits.
- The National Regulator for Compulsory Specifications (NRCS) which checked the quality standards for PPE and hand sanitisers.
- Port Health authorities which helped to prevent unlicensed companies importing PPE and ensured that licensed companies had PPE on their licence listings.
- National Treasury which found ways and means to fund the national pandemic, including measures to mitigate the pandemic's destructive impact on the economy and society.
- South African Medical Research Council (SAMRC) and Department of Science and Innovation (DSI) identified local innovators for manufacturing of COVID-19 related products such as point of care diagnostic test kits. The dtic which provided funding mechanisms for upscaling local manufacture of COVID-19 products.
- The International Trade Administration Commission of South Africa (ITAC) which administered rebates on imports of essential goods and granted export licenses for these.

SAMED will continue to strengthen its relationships with most of these agencies with the aim of ensuring a more agile response for future national health emergencies and improving general functioning of the healthcare system.

Strengthening supply chain integrity

SAMED's position

The experiences of SAMED and its members during the COVID-19 pandemic have led us to propose that governments should collaborate to avoid future disruptions by agreeing in advance on specific steps to be taken during a global health crisis to improve supply chains and reduce costs. Such measures should include:

- Prohibiting export restrictions.
- Designating medical device facilities to be "essential" so that they are not threatened with closure.
- Expediting trade in medical supplies through a "fast track" process in customs.
- Immediately suspending all import tariffs on designated medical technologies.
- Harmonising specific regulatory procedures.
- Providing designated cargo space for medical supplies.

In addition, governments should commit to maintaining minimum stockpiles of essential medical technologies to meet immediate demand surges.

The global pandemic caused unprecedented shortages of COVID-related medtech products. Demand far exceeded any need previously recorded and exposed the vulnerability of the South African

healthcare system. Many countries, including South Africa, imposed a ban on the export of these items. Overall, South Africa was adversely affected because its medtech market is largely driven by imports.

Increased demand and limited supply

SAMED recommends maintaining strategic stocks of critical medical products, including in vitro diagnostic (IVD) tests and testing supplies, PPE and ventilators, in preparation for future waves of COVID-19 as well as future pandemics. These stockpiles might reduce the tendency of governments to impose export restrictions on essential products.

Responsible stockpiling requires effective monitoring of supplies and the platform created by SAMED in partnership with B4SA could be repurposed for this. It was handed over to the NDOH at the end of the first wave in 2020.

Maintaining minimum stock levels would require financing – and the public healthcare budget is already overstretched. Alternative funding mechanisms should be investigated. For example, the Solidarity Fund could act as a rolling funding mechanism for future crises, if contributions were adequately managed and protected.

Capacity to upscale the production of medtech supplies would impact on maintenance of minimum stocks and would involve both domestic manufacturing companies as well as firms in other countries.

Import rebates and export permit delays

SAMED recommends that tax breaks and rebates on the import of essential goods form part of standard health disaster protocols and that the infrastructure of agencies administering such measures should be improved to overcome bottlenecks, which weaken the positive impact of the concessions, and improve efficiencies.

In response to the COVID-19 crisis, the South African Revenue Service (SARS) instituted a rebate on the import tax on essential goods. SAMED commends this measure, which not only reduced the cashflow burdens of medtech (and other) companies but potentially lowered prices and increased access to medtech products.

However, rebate applications were made through ITAC in advance of the goods arriving in South Africa and ITAC was also responsible for granting special export permits to South African companies supplying medtech to other African countries.

ITAC was understaffed and under-resourced to handle the unprecedented volume of applications during the first wave of the pandemic. This delayed both the import and export of life-preserving technologies. Preparedness for future pandemics should include electronic systems to manage these processes.

Logistical challenges to importing

During the pandemic, when passenger traffic ground to a near-halt, cargo bays of planes were no longer available to move medical supplies. Many medtech suppliers had difficulty finding flights. Those available were chartered flights, which were more costly and less frequent than commercial flights. This

not only impacted medtech suppliers' cash-flow and the cost of imported goods but also prolonged lead times on acquiring imported medtech.

In future pandemic events where air traffic is limited, government needs to help resolve these logistical bottlenecks to ensure that medtech reaches its destination in a timely and cost-effective manner. Possible actions include:

- Negotiating better rates on freight flights for essential medical technologies.
- Using military aircraft to assist in getting supplies to where they are needed.
- Allowing essential cargo in passenger compartments of planes. Ethiopian airlines, for example, pivoted to meet surging air freight demands by repurposing passenger jets into cargo carriers.
- Providing incentives to airlines – such as making their receipt of recovery funds conditional on them prioritising the transport of medical supplies.

Escalating exchange rates

The rand depreciated in relation to international currencies during the pandemic. Importers of medical technologies were forced to add this cost increase to those arising from increased freight charges and demand on stock. While there is little that can be done to influence the exchange rate, it should be considered by procurement officials when setting budgets for tenders and quotes. Measures to stimulate the economy should also be executed as early as possible in a pandemic to mitigate major currency fluctuations. Unspent Treasury loans could be earmarked for this purpose.

Availability of raw materials

During the first wave of the pandemic, there were challenges in sourcing raw materials for production of PPE and sanitiser. Some export restrictions included inputs for production of masks. For example, in March 2020 the Taiwan government began requisitioning melt-blown fabric (used in mask manufacture), resulting in a de-facto export ban and causing global supply chain disruptions. Likewise, India restricted the export of cloth used in masks.

Early action should be taken to protect supply chains for raw materials in preparation for additional waves of COVID-19 and the mass immunisation programme. In future, governments should develop a strategic plan, in advance, with specific steps to improve supply chains and reduce costs.

Medtech procurement

In all situations and scenarios certain principles should underpin the procurement of MedTech and other health products. An efficient and transparent procurement environment is indispensable to a well-functioning health system and enhances access to the best available technologies.

SAMED will continue its initiatives to strengthen supply chain capacity across the health system in collaboration with the industry and other relevant stakeholders.

Both the public and private healthcare sectors need to build processes for mass procurement before the next pandemic or major health crisis.

These processes should adopt a value-based approach and must consider the potential risks within the value chain. In addition:

- Medtech procurement should incorporate open contracting principles that ensure a fair and transparent selection of suppliers and guard against corruption.

- Tenders should be developed in conjunction with stakeholders to ensure that they specify the correct international and/or SABS product standards.
- Supplier diversity should be encouraged. The award of multi-supplier contracts encourages participation in the market, strengthens competition and promotes sustainability of supply.

Boosting local manufacture

SAMED's position

A stronger South African medtech manufacturing sector would benefit South Africa's economic recovery, enhance trade into Africa, strengthen national and continental healthcare systems, and improve access to health services. SAMED, therefore, views itself as an active partner in efforts to expand local manufacturing. It believes government has a major role to play in providing well-informed strategic guidance, developing a more enabling policy and regulatory environment and resolving cross-cutting economic challenges including securing the power supply at reasonable cost which is essential for all manufacture. The complementary roles of international and domestic supply chains should be maintained so that access to a full range of medtech is always guaranteed.

Although the pandemic highlighted low-middle income countries' dependence on imported medical devices and pharmaceutical products, in South Africa this has not yet resulted in major upscaling of local manufacture of healthcare products. The process takes time and needs to be viewed as a longer-term project that requires sustained resources. However, some innovative solutions developed locally during the pandemic have strengthened local expertise and capacity, as well as benefitted patients. These hint at the potential for a more vibrant medtech manufacturing industry in South Africa.

The government recognises the healthcare sector as a priority sector for economic stimulus projects. The DTIC has approach SAMED and MDMSA to collaborate in programmes with the Industrial Development Corporation (IDC), Council for Scientific and Industrial Research (CSIR), Department of Science and Innovation, the SA Medical Research Council (SAMRC) and the Technology Innovation Agency (TIA).

Going forward, it is important for government to scope the requirements for increasing local manufacture while ensuring the sustainability of medical technology industry. This exercise would include establishing the extent of current local capacity, exploring what types of local manufacturing are feasible, and weighing the relative benefits of working with established and reputable companies with the necessary expertise vs promoting newcomers to the sector. The Health Sector Masterplan should be used as a strategic document to grow the local Medtech industry.

The complexity, resilience and variety of medical technology supply chains need to be appreciated by policy makers.

- About 90% of medical technology used in South Africa is manufactured overseas, as are components for some locally manufactured products. Local manufacturers need to plan not only for fluctuations in demand but also possible disruptions to the import of components or raw materials.
- Multinational medical device/IVD companies that invest in local production often select a regional manufacturing centre to supply multiple countries in the area.
- Where localisation involves trade restrictions, this may increase the risk of irregular supply of medtech. Furthermore, reciprocal trade restrictions by other countries can limit export

opportunities. This is a major consideration for South African medtech companies that already export about 50% of their products to other African countries.

SAMED believes that a strong drive towards local manufacture should be combined with restoring confidence in international supply chains in order to achieve reliable and sustainable supplies of medtech at all times, including health emergencies. Medical technologies currently manufactured in South Africa include masks, face shields and hand sanitiser.

The manufacture of syringes and needles presents a possible area for local manufacturing expansion. There may not be enough capacity in the global industry to manufacture the number of syringes and needles required within a short period of time for the COVID-19 global mass immunisation effort. It is also crucial that routine childhood vaccination capacity be sustained. Clear advance estimates by the NDoH of national demand for ancillary devices for vaccination are a vital input for decisions on the import and/or local production of these items.

Any localisation plan must deal with factors that currently deter local manufacturing, including:

- Regulatory hurdles, related bottlenecks and resulting delays in approvals.
- Limited resources for implementing quality management systems.
- A lack of testing and sterilisation services.
- The sustainability of small, medium, and micro enterprises (SMMEs).
- A need for policies to back National Treasury's appeal to "buy local" even if prices are higher than those of imports.
- Power supply challenges which cause load-shedding, disrupt manufacture, and increase electricity/generator costs.

Targeted incentives, such as offtake agreements, should be introduced to support sustained local manufacture. The dtic should consider a subsidy or tax breaks to encourage international manufacturers to localise production and facilitate technology transfer. In terms of technology transfer, commitment from the industry is as significant as the support of governments.

Regulatory convergence across countries is a strategic measure that would greatly facilitate localisation of medtech manufacturing.

Other countries, such as Malaysia, Ireland and Israel, have succeeded in increasing local manufacturing capacity for medtech and dealt with similar challenges to those faced in South Africa. We would be wise to draw lessons from their experiences.

Medtech policy and regulations

SAMED's position

SAMED acknowledges the critically important role that regulation of healthcare (including the medtech industry) plays in all circumstances and certainly during health emergencies. The association argues, however, for the need to review and reform regulatory processes and overhaul related administrative systems to attain the agility required in times of crises.

The South African regulatory framework does not yet call for individual product registration of medical technologies. It does, however, require medtech suppliers to apply for a Medical Device Establishment Licence on which they list the products that they manufacture, import and/or export. Companies are

prohibited from trading in medical devices if they do not have an establishment licence and may only trade in products mentioned in their licence listing.

Company licences and associated product listings issued by SAHPRA presented a major hurdle for medtech suppliers during the pandemic. SAHPRA effectively used these to regulate the import, export and approved supply of COVID-related products in South Africa.

Outstanding licences and licence amendments disrupted companies' ability to trade in essential items. At the same time, many unlicensed suppliers entered the market and were profiting excessively off the pandemic without the necessary regulatory oversight.

SAHPRA was inundated with applications for establishment licences and amendments to existing licences and lacked the infrastructure and human resources to respond at a pace demanded by the crisis. The regulator indicated that incomplete applications exacerbated the backlog. Clearly an online application system that could immediately flag gaps in applications would have increased the efficiency of the system.

Due to concerns of substandard COVID-19 products flooding the market, additional regulatory and administrative processes were put in place. While SAMED recognises the intention behind this, the result was further delays in delivering essential products.

Test kits not only had to be approved by SAHPRA but also by the National Health Laboratory Service (NHLS), which was swamped with requests for testing patient samples for COVID infection. Despite international emergency use authorisation, SAHPRA required additional testing on serological tests, which impacted the availability of test assays and test kits.

In terms of medical grade PPE, the National Regulator for Compulsory Specifications (NRCS) had to validate the specifications, including testing requirements. This was intended to prevent substandard medical technology entering the market. However, the requirement resulted in lengthy delays, as suppliers were sent from one regulator to the next before PPE could be listed on their licences.

Robust problem-solving, agility in introducing new policies and regulations, and capacity to fast-track licensing are critical to ensure supply in times of crisis and should be considered in crisis planning.

The pandemic has highlighted an urgent need to review, align and improve regulatory processes across government agencies before another health crisis occurs. SAMED recommends that policy makers formulate a joint response to future health emergencies and include input from all key stakeholders. Scenario planning and pressure-testing, with the participation of stakeholders, would identify gaps and help build solutions that can be efficiently implemented.

SAMED is able to contribute information on global best practice in the application of standards to ensure quality, safety and performance, the improvement of systems for inspection and post-market surveillance across the medtech value chain. We will work to build coordinating mechanisms to address fragmentation and duplication in regulations and policy, to assist with harmonisation (medical device regulatory convergence) with global agencies and to create mechanisms for congruence/cohesion to ease compliance and prevent disruptions to doing business.

SAMED will also continue to work within the medtech sector to identify challenges and address propose solutions regarding policy implementation.

Business sustainability and resilience

SAMED's position

In representing the medtech industry, SAMED notes the destructive impact of the COVID-19 pandemic on the majority of companies in the sector and will strives for changes within medtech companies, among other healthcare role-players, within business and on the part of government to prevent a recurrence of this experience. With a view to future pandemics and health emergencies, SAMED will make the case for:

- Rapid implementation of measures to support the cash flow of companies in times of extraordinary demand (and limited supply).
- Regulations and policies that will balance the urgent pandemic health response with the need for continuity of providing services to the remaining elements of the health system.
- Immediate recognition of the medtech sector as an essential industry and its representatives as an intrinsic part of personal health services.
- Better planning for business continuity by medtech companies.

The pandemic has had a negative effect on the financial performance and viability of medtech companies, even those that were primarily involved in supplying high volumes of COVID-19 essentials.

Cash flow concerns and lack of resources

Medtech companies that supplied or manufactured COVID-19 products were inundated with requests for supplies. This led to cashflow concerns as they upscaled their supplies to meet the demand. Another source of stress was insufficient human resources as companies tried to ensure social distancing within their manufacturing and supply chain operations.

Importers faced particularly severe cashflow constraints as international suppliers implemented "pay first" policies instead of their usual 30-day terms. B4SA and the Solidarity Fund encouraged payment upon receipt of essential goods to mitigate these cashflow constraints. Ideally, where existing product partnerships exist, international suppliers should not introduce immediate payment policies. But if they do, in future, the approach of payment-on-receipt of essential goods should once again be invoked.

Elective and non-urgent surgical procedures

A serious concern about the viability of medtech companies was largely due to regulations and hospital policies that permitted emergency medical treatment only and deferred all elective and non-emergency surgeries.

These restrictions resulted in a huge drop in demand for medtech products and meant many suppliers had little to no income. Affected companies were forced to take drastic action in terms of salary reductions, retrenchments (both temporary and permanent) and downsizing.

Access to healthcare facilities by company representatives was also restricted, possibly limiting healthcare professionals' access to valuable innovative medtech. Digital solutions have since allowed company representatives to interact remotely with healthcare professionals. Healthcare providers should invest in these digital platforms to retain the profound benefit of company support for the use of novel technology to improve patient outcomes.

As the restrictions eased, elective procedures resumed. Healthcare facilities required medical technology representatives to be tested at least weekly for COVID-19 and provide a negative test result in order to enter facilities to service medical equipment, provide in-theatre support to healthcare professionals or make operational calls.

In negotiations with health facilities, SAMED argued that facility screening procedures applicable to facility staff should also apply to medical device representatives, provided they were fully compliant with the disaster management regulations. SAMED also argued that the repeated testing of asymptomatic company representatives unnecessarily diverted resources required for testing of symptomatic patients.

SAMED consulted with members, healthcare providers, patient associations and international medtech associations to understand their concerns and solutions and developed a SAMED position on the re-entry of medical device representatives to healthcare facilities.

The position paper took account of the need for patient care; the limited availability of PPE; the availability of diagnostic testing; the current understanding of COVID-19 disease and immunity; the lack of an approved vaccine (at the time); and the application of local regulations and official guidelines, which would prevail in the event of any inconsistency with the principles of the position paper.

The policy paper recommends that clinicians and medical representatives should be protected in a way that conserves and prioritises the use of limited PPE; avoids duplication, inefficiency, or other waste; and meets the obligations of both providers and suppliers.

The SAMED-endorsed Company Representatives in a Clinical Environment (CRICE) course was adopted as an accreditation requirement by many private healthcare groups to reduce risk within the sterile field and clinical environments. SAMED recommends that an educational approach to safety should be prioritised over blanket restrictions in any future healthcare crises, as the latter impacts on both suppliers and patients.

Restrictions on elective and non-emergency procedures resulted in an unprecedented global backlog of essential health services. Locally tuberculosis, cancer and diabetes screening and testing declined significantly. Delayed or lack of treatment of these co-morbidities further exacerbates the impact of COVID on the health system.

In 2020, Discovery, a leading healthcare funder and medical scheme administrator, noted significant year-on-year reductions in hospital admissions. Surgical admissions were down 23%, general medical admissions down 32 %, and obstetric admission down 12%. It also recorded reduced uptake of screening for diabetes (-74%) and breast cancer (-27%). During level 5 lockdown, when restrictions were at their highest, there were 69% fewer orthopaedic surgery claims, 40% fewer pathology claims, 46% fewer general practitioner claims and 52% fewer radiology claims[2].

It is imperative that future health pandemics consider the impact of restrictive measures on other areas of health and ensure that the response to one overwhelming health condition is not at the cost of several others. SAMED recommends a holistic approach to managing the pandemic in which healthcare facilities consider how to isolate sections in order to continue providing routine and non-emergency care.

SAMED recommends a holistic approach to managing the pandemic in which healthcare facilities consider how to isolate sections in order to continue providing routine and non-emergency care.

Human resources

Many medtech companies acquired additional infrastructure to enable employees to work from home, compounding expenses when operations were severely reduced. The new working environment presented challenges, including a need for closer management of productivity.

Initially, when declaring lockdowns, government did not identify "essential" sectors. This lack of planning caused disruptions of medical device manufacturing and distribution facilities which should be avoided in the future.

Once identified as essential, those medtech employers with staff who could not perform their duties from home faced shortages of PPE to protect their staff. The supply of PPE increased operational costs to mitigate the risks to their staff.

Business should plan now for business continuity in the face of future pandemics and include stockpiles of PPE for the early stages of future crises and investment in remote infrastructure. Information and communication technology has major potential to contribute to business continuity through the provision of data for decision-making, digitalisation, tele-therapeutics and innovative provision of support to professionals and patients using medtech.

SAMED and other stakeholders could advise members on preparations to withstand prolonged disruptions. Workshops could feature scenario-planning to identify the biggest risks and opportunities and stress-test operating models in terms of supply-chain management, cash preservation, go-to-market models, customer support, and clinical trials.

Patient-centricity

SAMED's position

The patient should be at the centre of all efforts to ensure preparedness for future national and global health emergencies. A concerted effort should be made to listen to patients' experiences as we reshape health services for the future and redefine medtech's contribution. The potential to continue and expand helpful and efficient digital models for service delivery must be explored.

A patient-centric model needs to raise a voice of reason in advocating for the continuity of health services that are not linked to the crisis. Ongoing and long-term patient care cannot be sacrificed, and therefore policy makers must consider models and mechanisms for patients to receive the care and consultation they require even during a pandemic.

Digital and therapeutic innovation have a key role to play in driving patient-centricity and self-treatment. Telemedicine grew significantly during the COVID-19 period, sustaining a degree of access to care. Discovery reported a thirty-fold increase in virtual GP consultations from 2019 to 2020[3]. It is however important to note that this is only possible where there is a pre-established patient-practice relationship. Digital technologies also enable home healthcare through remote monitoring and analysis of key indicators of patient health. Self-administration and novel dosing regimens free patients from visiting healthcare facilities where they may feel or be at risk of viral exposure.

As patients are empowered by these digital and therapeutic innovations, they are more likely to adhere to treatment. Healthcare systems are likely to improve acuity levels which in turn creates space to handle the demands of a major disease outbreak. Funders benefit by the reduced costs of consultations and healthcare has the potential to become more affordable without sacrificing patient outcomes.

In conclusion

It is essential that we prepare now for the next phase of this pandemic and future serious outbreaks of disease. There are many learnings to be taken from the historic COVID pandemic response. SAMED and its members are committed to working with government and its respective agencies to ensure the continued provision of healthcare in emergencies through the supply of essential medical technologies.

As we look to the next phase of the pandemic and the vaccine rollout, SAMED is keen to examine infrastructure and supply chain solutions that will support this effort.

As policymakers evaluate laws, regulations and policies and introduce changes, SAMED encourages the preservation of vibrant, robust, and resilient supply chains in order to ensure that medtech is always available to support and protect frontline healthcare workers and the public. We support the funding and implementation of health innovation as a tool to meet diverse and challenging health needs within all communities. We stand ready to engage with government and its agencies on measures aimed at accomplishing an improved and agile pandemic response.