OMBUDSMAN
SINT MAARTEN

FINAL REPORT
(Article 21 sub 1 National Ordinance Ombudsman)

Systemic Investigation into procurement procedure of SZV for the selection of medical aid equipment (glucometers)
Date investigation initiated: 5 August 2020
Complaint no.: 2020/00112

Uitvoeringsorgaan Sociale en Ziektekosten Verzekeringen (SZV)

History
On 26 May 2020, a complaint was filed with the Ombudsman against *'Sociale Ziektenkosten Verzekering'* SZV regarding alleged faulty glucose testers being provided as the sole option under the insurance of SZV. Complainant made reference to ongoing communication regarding this matter with SZV, that began in March 2020. According to Complainant several other persons living with diabetes have received inaccurate readings after using the Perfect 3 glucose meter (Perfect 3) provided by SZV. Complainant emphasized the importance of the accuracy of meters being provided by SZV, as faulty results could have detrimental effects on the health of persons living with diabetes, in particular pensioners. On 19 May 2020 SZV informed Complainant that a response including a solution would be made available by 22 May 2020, however no response or interim solution was provided to Complainant, including up until the Ombudsman closed Complainant's individual case to proceed with a systemic investigation into the procurement of the Perfect 3 (Perfect 3).

In response to the investigation of the Ombudsman, SZV informed the Bureau Ombudsman by letter dated 10 June 2020 that prior to receiving complaints from persons insured by SZV, there was initially no specific procedure in place to ensure the quality of the Perfect 3. In said letter SZV stated that the glucose meters currently being insured by SZV are not faulty and persons insured by SZV were informed to visit their general practitioner if they suspected a faulty reading had occurred. SZV further stated that a pilot study would be carried out to ensure the quality of the newly proposed glucose meters and once the results are available persons insured by SZV and health care providers would be notified accordingly.

During a radio talk show on 17 June 2020, five individuals including a district nurse called in indicating that they had similar experiences as complainant with the new glucose meters (Perfect 3) being provided by SZV.

Upon further investigation the Ombudsman was informed, by the Operations Manager of the White and Yellow Cross Care Foundation (WYCCF), the Sint Maarten Medical Association (SMA) and Windward Islands Medical Association (WIMA), on separate occasions that the test results of the Perfect 3 were not reliable and many persons living with diabetes under their direct care reverted to the Freestyle Precision glucose meter (Freestyle Precision), previously insured by SZV. To guarantee the safety and well-being of their clients, the WYCCF decided to immediately stop using the Perfect 3 and were forced to pay for the test strips for their clients as SZV does not refund the cost. According to WYCCF and WIMA the price of the strips of the Freestyle Precision are fairly expensive, especially for pensioners that receive *'algemene oudersdomsverzekering'* (AOV) pension as their only source of income. These pensioners have no alternative but to use the Perfect 3 as it is the only glucometer covered by SZV medical coverage. The WYCCF notified SZV on 9 January 2020 of complaints regarding inaccurate readings being produced by the newly introduced Perfect 3. By email that same day, the Unit Operations Manager at SZV informed the WYCCF that a response would be forthcoming. Approximately five (5) months later SZV provided WYCCF with a general letter dated 7 May 2020 addressed to the Sint Maarten Medical Center (SMMC), WYCCF, General Practitioners (GPs) and persons insured under SZV.[1] In said letter the Director of SZV (Director) stated that an assessment was done by a third party to test the quality of the Perfect 3 meter against international standards and that the Perfect 3 meter was found to be of good quality and fulfilled the relevant criteria for international standards set for glucose meters. The Director further acknowledged that the new meters were not properly introduced to the stakeholders and that human error could influence the glucose readings. Lastly the Director stated that despite the positive assessment SZV has decided to look into the introduction of a new meter by the supplier, Medicosmetics N.V. (MC). The WYCCF, SMA and WIMA have all requested the results of the test carried out by SZV via the laboratory, however to date of this final report this has not been provided to them by SZV.

The WYCCF further claims that MC lacks the infrastructure and logistics to supply the needs of all their clients. Previously, there would be a procedural document with clear instructions on which medical aid requires approval from a GP, specialist and/or SZV, this document has been promised but not delivered, which is not transparent. Secondly, the location of MC has also presented various bottlenecks, as most seniors/persons living with disabilities may not

[1] Although addressed to SZV insured clients, it is unclear how this letter was distributed to them. This letter was not distributed through the media.

have access to a vehicle nor is there direct public transportation available to the location. Persons living with diabetes and insured under SZV are provided with one (1) box of strips (containing 30 strips) per month; thus, are required to find their way to MC once a month to pick up their strips. In addition, according to the WYCCF, the duty of care towards clients imposed on pharmacies is lacking. MC is not bound by the same requirement applicable to pharmacies with regard to the duty of care to clients.

On 2 July 2020 SZV provided the Ombudsman with a digital copy of a presentation SZV received from Sint Maarten Laboratory Services NV (SLS), that conducted the research on the glucose meter as well as a digital copy of the report on this issue.

Considering mentioned history, including the non-conclusive response from SZV to the queries from the Ombudsman, an in-depth systemic investigation was initiated.

Summary of concerns:

1. Various concerns and complaints reaching the Ombudsman that SZV has not addressed complaints of its clients and stakeholders regarding the accuracy and effectiveness of the Perfect 3. These include complaints regarding the inaccessibility of the location and affordability of the strips for the Freestyle Precision meters for seniors who are highly reliant on pension as a main source of income and individuals earning minimum wage;
2. SZV had not provided its stakeholders and clients with an interim solution;
3. Good governance requires openness and accountability regarding procurement policies and procedures used to assess whether the medical supplier is qualified to provide quality medical aid products. To date SZV has not responded to requests from GPs and WYCCF for an overview of the test results that indicate the Perfect 3 is not faulty;
4. Alleged lack of transparency and or clarity in the procedure to request medical aid products from the current medical aid supplier; according to the WYCCF there is no written protocol for same.

Considerations

Considering that:

- the core of the complaint filed is a matter of good governance and in the interest of the general public;

- government entrusted SZV with several tasks and authorities that fall under the (functional) responsibility of the Ministry of Public Health, Social Development and Labor (VSA);
- according to SZV increasing medical costs was the reason for deciding to centralize medical aid distribution;
- according to WYCCF approximately 60% of their clients are persons living with diabetes;
- based on complaints and their own analysis the WYCCF immediately stopped using the Perfect 3 to ensure the safety of their patients;
- persons living with diabetes have been recognized as one of the most vulnerable groups during the ongoing COVID 19 pandemic;
- inaccurate readings could have detrimental effects on the health and well-being of persons living with diabetes and in some cases can even result in mortality;
- despite the proclaimed positive assessment of Perfect 3, SZV sees the need to look into the introduction of a new meter by the supplier without providing a justifiable reason for the decision to switch;
- SZV indicated that new testers would be provided once a pilot study has been completed. However, no timeline for this procedure and as to when the new testers would become available was given;
- SZV was made aware of complaints since January 2020 regarding the alleged inaccurate results and to date has not provided an interim solution considering the potential detrimental consequences of a faulty glucose reading whether caused by Perfect 3 or human error;
- complaints have been brought forward by GPs, WYCCF and SZV clients and these complaints did not exist in this capacity with the previous glucose meter which had been used for decades on Sint Maarten;
- SZV stated that there was initially no specific procedure in place to ensure the quality of the Perfect 3 glucose testers;
- SZV clients (who complained (thru their GP) to SZV) are not being reimbursed in the interim for purchasing the old strips, neither has SZV sought another concrete interim solution with its clients;
- Government and government administrative bodies including SZV are expected to be open and clear, involved and result oriented;
- An administrative body is obliged to weigh interests in reaching a decision and to observe the principle of proportionality;

- This requires that the negative consequences of an action to achieve a certain goal may not be disproportionate to the interest of the person(s) involved;
- A public body is required to conduct a thorough and adequate investigation into the relevant facts and circumstances; adequate information should be gathered. Subsequently, the acquired facts have to be weighed against the interests of the citizen; the outcome may not be unreasonable;
- Generosity should be applied in situations of probable, but not proven mistakes of government, when citizens incurred expenses or made investments in time, without it having been established that government indeed made a mistake. Compensation is based on the reasonable assumption that it would be fair to compensate the citizen for the expenses made and the time invested.

Resolution

The Ombudsman resolves to conduct a systemic investigation regarding:

1. The procurement procedure of SZV as it relates to the selection of the supplier for medical aid equipment, in particular the process of selecting the Perfect 3 glucometer, including the strips, and service level to SZV clients in need of such;
2. The procedures used by SZV to select and acquire medical aid products and the role of the Inspectorate of Public Health (Inspectorate) in the process;
3. The role of the Inspectorate in the chain of procurement and approval of medical aid suppliers, medical aid products for public consumption, complaints levied concerning medical aid products and SZV;
4. Transparency to stakeholders (SZV clients, WYCCF, GPs and others) with regard to complaints levied to SZV and the test results carried out by SZV.

Investigative process

Findings:

By letter dated 7 May 2020 addressed to healthcare providers including WYCCF, SZV expressed having received complaints of discrepancies concerning the glucometers that are covered by SZV, as a result thereof a third party entity was hired to conduct an assessment to evaluate the quality of the Perfect 3 meter against international standards. According to the letter, the conclusion of the assessment was that the Perfect 3 glucometer is of good quality and that it fulfilled the relevant criteria for international standards set for glucose meters. SZV goes on to acknowledge that, nonetheless the glucometers were not properly introduced and that stakeholders were not fully equipped with the knowledge of possible challenges they

may encounter when switching from one machine to another. One of those challenges being the increased chance of human error, which could influence the glucose readings. The letter goes on to list those possibilities for human errors: a suboptimal storage of the strips by leaving the leaving the strips container open for prolonged period or by using alcohol swabs on finger before taking sample for glucose measurement while not letting the skin dry first. SZV concluded the letter by stating that despite the assessment that the Perfect 3 meter is of good quality, they have decided to look into the introduction of a new meter by the supplier, which would allow for a better user experience. Further information on its introduction would be provided throughout the process of its implementation.

White and Yellow Cross Care Foundation

The care services of the WYCCF were established in 1970 on Sint Maarten. In 1991 hospital care was transferred to the Sint Maarten Medical Center and the WYCCF continued to focus on chronic care, elderly services and the intellectually disabled.
In 2003 the WYCCF was established and in 2006 an organizational change was initiated with the switch from departmental descriptions to care product definitions. Since the inception of the foundation the organization has grown from a charity focused entity to a professional healthcare organization.
The foundation is presently one of the major healthcare providers on Sint Maarten, providing tailor-made care to a growing, diverse, group of persons including persons living with diabetes. Prevention and cure have become a growing part of the foundation's services.

According to the WYCCF, 60% of its 225 clients are persons living with diabetes. Information derived from the WYCCF indicates that approximately 14% of the entire population of Sint Maarten are persons living with diabetes and there remains a large segment of the population that are susceptible to diabetes. During the initial stages of the investigation the Ombudsman was informed by the Operations Manager of the WYCCF that contact was made via email on 9 January 2020 with the Unit Operations Manager of SZV regarding faulty readings received by the Perfect 3. At the time no comprehensive response was provided. Complaints regarding the faulty readings continued leading up until June 2020. During this period a number of requests for assistance were made by the WYCCF regarding the inaccurate results received.
After having received instructions from the General Manager of MC on how to properly program the Perfect 3 and ensure that the strips were not contaminated, the District Nurses continued to see discrepancies in the results. The GM of MC was made aware of the situation as early as February 2020.

Subsequently, the Operations Manager of WYCCF requested confirmation from the Unit Operations Manager of SZV as to whether a laboratory test was done and that the readings provided by the Perfect 3 were accurate. The Operations Manager of the WYCCF also informed the Unit Operations Manager of SZV that the WYCCF cannot proceed with using the Perfect 3, as the application of medication based on inaccurate readings can be fatal for persons living with diabetes.

Email correspondence between the Operations Manager of WYCCF and the Local Manager of MC indicates that a separate request was made by the WYCCF to have the perfect 3 glucometers replaced. As no response was received, in a follow up email the Operations Manager of the WYCCF requested clarification from the Local Manager of MC as to whether MC would replace all the Perfect 3 meters on Sint Maarten and whether a copy of the test results from SLS laboratory could be provided.
In said email the Operations manager of WYCCF again requested whether MC or SZV would compensate the WYCCF for the extra cost incurred due to having to replace the Perfect 3 with the Freestyle based on the inconsistent readings received by the Perfect 3 glucometer. To date of this FR no response has been provided, according to WYCCF. SZV did however indicate in its response to the Ombudsman that SZV insured would be compensated with the prevailing SZV tariff, it is unclear if this also had been the case with the WYCCF.

The letter from SZV dated 7 May 2020 did not comprehensively address the concerns raised and the requests of the WYCCF.

On 26 June 2020, a meeting was held with the Operations Manager of WYCCF who had informed the Ombudsman that the preferred supplier of medical aids and artificial devices (MC) lacks the infrastructure and logistics to supply the needs of all their clients. The Operations Manager of the WYCCF further informed the Ombudsman that when the foundation confronted SZV about the faulty readings received from the Perfect 3 glucometer, there was no viable solution presented by SZV at the time. Subsequently, the foundation decided to resume use of the Freestyle glucometer in order to ensure the safety of their clients living with diabetes.

When asked about the differences between the previous supplier and the current supplier, WYCCF stated that there is no transparency regarding the sourcing of products compared to the old contracting company which had an entire written protocol. The WYCCF further informed the Ombudsman that the foundation did request copies from SZV of the study

carried out by SLS and the written protocols/procedures used to source products (medical aids and artificial aids) from the preferred supplier. Upon further investigation and based on the responses received by SZV and MC, the introduction of a sole supplier of medical and artificial aids has resulted in the discontinuation of providing healthcare providers with written procedures and protocols to source products, as there is only one provider of medical and artificial aids. The new procedures applied by SZV requires that GPs write out a prescription (medical and artificial aids) then the prescription is sent to MC. MC in turn would send the requested prescription to SZV for authorization.
The WYCCF concluded by informing the Ombudsman that SZV remains of the opinion that the glucometers are not faulty and the errors in the readings are due to human error, regardless of the experiences of the district nurses and complaints submitted by the WYCCF. According to the WYCCF, the foundation was informed by SZV that a new pilot study would be conducted. The WYCCF requested to participate in the study, however their request was denied by SZV.

General Practitioners

Subsequent to the letter dated 7 May 2020 from SZV to the GPs, WYCCF and SMMC, a number of GPs made follow up queries and expressed concerns which took place via email correspondence.[2] Upon request for an update by the representative of the SMA on the progress of the investigation into the Perfect 3, SZV stated on 12 May 2020 that the meters were investigated (referring to the letter of 7 May 2020), however due to the continued complaints and discrepancies, SZV will be looking into having an alternative meter provided by Medicosmetics. According to SZV the plan is to have quality testing done and properly introduce a new glucometer before its implementation.
In response to the reaction provided to the GP, another GP from the SMA expressed concern regarding the level of testing capabilities in Sint Maarten to determine if a certain medical device is reliable or not for safe clinical or patient use. SMA continued to explain that the types of tests needed are usually done by highly specialized frequently audited labs contracted by (multi) national health quality authorities like the USA's Food and Drug Administration (FDA) or the EU's European Medicines Agency (EMA) and if approved such a device is listed on a publicly accessible web page from the health authority's database with any relevant particulars and a seal of approval sticker or imprint. SMA further elaborated on the possibility that a faulty batch could have led to the inconsistent results received. SMA

[2] Many GP's were cc'ed in this correspondence.

concluded by requesting that SZV provide the name of the health authority that approved the Perfect 3 glucometer for use.

In response to the requests received, SZV informed the GPs that the local laboratories are capable of testing if the results of at-home/self-use meters comply with international standards known for these types of meters. SZV referred to different standards such as ISO, FDA and ADA, which were used in the quality testing earlier this year. The Perfect 3 meter was stated to ensure its quality and that international standards mentioned were used to compare the meter to that of the venous blood glucose test from the lab. According to SZV, this was done knowing that the lab always has the most reliable glucose readings. SZV further stated that the Perfect 3 performed well in this test, resulting in the letter sent on 7 May 2020. *However, SZV did not confirm whether the Perfect 3 was authorized by a health authority.* SZV further informed SMA the possibility was being looked into by SZV that 'a faulty batch' may have led to discrepancies in the results received by SZV insured and healthcare providers. *It remains unclear what the results were regarding the test conducted to conclude whether a faulty batch of strips could have resulted in discrepancies in results.*

Simultaneously to the ongoing discussion, SMA conducted research on the Perfect 3 and also inquired with the Health Care Laboratory Sint Maarten (HCLS) regarding the perceived inaccuracy of the new glucometers and the diabetic diagnostic health care in general. SMA concluded that it could not identify the qualifying authority (CE, FDA, ADA) for the Perfect 3 glucometer.
The inquiry with HCLS further concluded that there were three (3) areas in general where testing could go wrong, which are as follows:
"(…)

a. *Sampling. Not deep enough puncture followed by milking blood dilutes capillary blood with other fluids from your body leading to an incorrect result. Having had orange or other sugar containing fruit on your finger can lead to an incorrect result. Bottom line is patient needs proper instruction at start how to avoid these pitfalls.*
b. *Glucometer. Damaged from fall or other exterior forces. What is the quality of the glucometer. Not from a trusted brand like Abott or Roche etc. Precision is from Abbot Precision Xtra Blood Glucose & Ketone Monitoring System / 9881465*
c. *Strips. Are the strips expired. Are they stored properly? Here the same as in sub a applies, patient needs initial proper instruction to recognize potential problems leading to inaccurate readings (…)"*

On 26 June 2020, the SMA informed the Ombudsman that although a number of requests were made to SZV regarding the authorizing authority (ISO, FDA, EMA, ADA), accuracy and reliability of the newly acquired Perfect 3 glucometer and strips, their inquiries were not adequately answered.

By email dated 26 June 2020, a GP of the Windward Islands Medical Association (WIMA) informed the Ombudsman that the newly introduced Perfect 3 glucometer has been a contentious topic for a while and the inaccuracy has been discussed by many GPs of the WIMA.

WIMA further informed the Ombudsman that the test results of the glucometer are not reliable and that SZV had been aware of the situation, however no action had been taken. WIMA concluded by stating that many of their diabetic patients that have reverted to using the Precision Freestyle glucometer are now forced to pay for test strips out of their own pocket, as SZV does not refund the cost incurred.

Sint Maarten Laboratory Services (SLS)

On 21 September 2020 a meeting was held with the Ombudsman and the Interim Director and Clinical Chemist of SLS regarding the results of the study on the comparison of the glucose measured on the laboratory analyzer from SLS versus the two glucose meters. SZV also provided the Ombudsman with documentation including a report of the study conducted by SLS. During the meeting the Ombudsman was informed that the test conducted on behalf of SZV involved 20 participants consisting of persons living with diabetes and non-diabetics in a controlled laboratory environment. According to the report all samples were measured on the same day. All patients were first measured on the two glucose meters (finger stick), followed by a venous puncture for glucose measurement on reference analyzer. The data was analyzed according to current ADA, FDA and ISO guidelines. The importance of accurate readings was emphasized; blood glucose test results are used by people with diabetes to make critical decisions about their treatment; therefore, it is important that the results are accurate so that nutritional and drug dosing errors are better avoided.
The laboratory results from SLS indicated that the Freestyle Precision failed all current and "new" accepted international criteria and that the Perfect 3 passed all the internationally accepted criteria, with the exception of the ADA standard.

The report as well as the Clinical Chemist pointed out the limitations of the study conducted. The small sample size (20); normally such a study would usually be conducted with a larger sample size and over a longer term to verify the conclusions reached.

The Clinical Chemist acknowledged that the study carried out on behalf of SZV was primarily focused on the accuracy of the glucometer and not whether the strips used may have been faulty or exposed. Only one lot number strip was used for comparison. Studies showed that the measurement of accuracy can vary remarkably within one system; lot-to-lot variations can occur. And hematocrit was not taken into consideration.
The Clinical Chemist further informed the Ombudsman that based on the (small) sample size used to measure blood glucose, the margin of error could be much higher than found through the test conducted.

According to the Clinical Chemist factors such as physiology and environmental conditions can affect results from at home testing when compared to a controlled laboratory setting. It was also established that in the interest of providing quality care for persons living with diabetes, healthcare suppliers can 'criteria shop' for ISO certified products, however the criteria must be set beforehand. The Clinical Chemist continued to explain that an ADA certification has much higher criteria than that of ISO and FDA certified products as it pertains to diabetic medical aid devices. When asked about the certification surrounding the Perfect 3 glucometer, the Clinical Chemist informed the Ombudsman that the information surrounding the Perfect 3 certification could not be found online.
The recommendations provided in the report of the Clinical Chemist further emphasized that glucometers should be evaluated before use and the specific meter model should be based on the technical and clinical performance in the intended patient population.

Medicosmetics (MC)

Established in 2001, MC are wholesalers and distributors of pharmaceuticals, medical health supplements and professional hair and skin products. MC has been operating and established in Sint Maarten for more than 15 years and provides similar services in Aruba. MC was contracted by SZV in 2020 to provide medical- and artificial aid devices to SZV insured on Sint Maarten. To date, 2000 glucometers have been distributed to SZV insured persons. According to information derived from MC, 50% of persons living with diabetes are between the ages of 60 to 85 years of age and the other 50% are under the age of 60. During a meeting on 2 March 2021, the General Manager (GM) informed the Ombudsman that the Perfect 3 has been used in Aruba for more than 20 years by the private sector and that throughout its use of more than 20 years (in Aruba) not many complaints were received compared to Sint Maarten. According to the GM, MC has received 30-50 official complaints regarding the Perfect 3. The GM further elaborated that the majority of complaints received are based on the lack of knowledge of how to use the Perfect 3 glucometer.

During the meeting the GM acknowledged that factors such as the lack of properly programing the glucometer by the user (incorrectly setting date and time), not being properly informed on how to use the machine, external environmental factors and the sensitivity of the strips to the touch could lead to false results. The GM further informed the Ombudsman that the glucometers are programmed in advance and each SZV insured person receives an explanation on how to use the Perfect 3 glucometer upon pick up. According to the GM it is not guaranteed that persons picking up the Perfect 3 glucometer on another person's behalf will provide accurate information.

When asked whether a campaign was launched to properly introduce the new glucometer to SZV insured living with diabetes and healthcare providers before making the switch, the GM stated that MC did not carry out a media campaign and that the question should be directed towards SZV. The GM informed the Ombudsman that upon receiving complaints from the WYCCF an information session was held whereby district nurses and staff were informed on how to properly use the Perfect 3 glucometer. However, after complaints persisted the WYCCF stopped using the Perfect 3 glucometer. The GM concluded by stating that he was not sure what was done by SZV to ensure that the information reached the relevant stakeholders (SZV insured, Healthcare providers).

As it pertained to the quality of the newly introduced glucometer, the GM stated that pricing may determine the quality of the product, as quality may differ per brand and per meter. Each glucometer produces different results and may vary in class. The GM continued to explain that glucometers are not comparable and in order to compare they must be of the same brand as the quality of the meter may vary.

During the meeting it was established that the Perfect 3 glucometer is an American product and is FDA cleared and not FDA approved.[3] The meeting concluded by the GM informing the Ombudsman that the remainder of the questions posed would be answered via email correspondence, however to date no response has been provided, despite several follow ups by the Ombudsman.

[3] "FDA approved" means that the agency has determined that the "benefits of the product outweigh the known risks for the intended use." Manufacturers must submit a premarket approval (PMA) application and the results of clinical testing in order to get approval. "FDA cleared" means the manufacturer can demonstrate that their product is "substantially equivalent to another (similar) legally marketed device" that already has FDA clearance or approval. (definition based on web searches)

Based on further research carried out by the Ombudsman, derived from the official website of the United States (US) FDA, it was established that the FDA is responsible for protecting public health by regulating human drugs and biologics, animal drugs, medical devices, tobacco products, food (including animal food), cosmetics, and electronic products that emit radiation. However, not all products undergo a review of safety and effectiveness by FDA experts and agency approval before a product can be marketed. In some cases, FDA's enforcement efforts focus on products after they are already for sale. Even when FDA approval is not required before a product is sold, the agency has a regulatory authority to act when safety issues arise. [4]
It was further established that the FDA classifies[5] devices according to risk.
For Class II and Class I, the FDA doesn't give 'approval', it just gives clearance.
The FDA establishes moderate-risk medical devices, such as self-monitoring blood glucose systems (SMBG),(i.e. glucometers), as Class II devices. These devices are cleared for marketing once it has been demonstrated that the device is substantially equivalent to a legally marketed predicate device that does not require premarket approval.[6]

SZV

The executing agency, SZV, is an independent administrative body with legal personality established by *Lvo SZV*.[7] As such SZV exercises public authority and can therefore make binding decisions. SZV is largely charged with executing the administration and management of the social and sick insurances schemes of Sint Maarten. The organization is independent with regard to its internal organization, the management of its resources and the promotion of its interests.[8] SZV is managed by a Director who represents SZV legally and otherwise.[9] The Supervisory Council (SC) supervises the management of the funds, assets of SZV and

[4] Is it really FDA approved, U.S. Food and Drug Administration, 01/17/2017, https://www.fda.gov/consumers/consumer-updates/it-really-fda-approved.

[5] The Food and Drug Administration (FDA) has established three regulatory classes based on the level of control necessary to assure the safety and effectiveness of a device: Class I General Controls (with and without exemptions); Class II General Controls and Special Controls (with and without exemptions); Class III General Controls and Premarket Approval

[6] Is it really FDA approved, U.S. Food and Drug Administration, 01/17/2017, https://www.fda.gov/consumers/consumer-updates/it-really-fda-approved.
[7] Article 2 Landsverordening uitvoeringsorgaan sociaal ziektekostenverzekering (Lvo USZV)
[8] Article 2, sub 3, Lvo USZV.
[9] Article 3 and 6, para. 3, Lvo USZV.

general affairs of SZV. The SC are upon recommendation of the SC appointed/ dismissed by national decree of the Minister.

In accordance with article 3 of its national ordinance the tasks of the SZV include, but not limited to, the following:

- the execution of social or health insurances or insurances of a predominantly social nature, insofar it is entrusted to it by or pursuant to national ordinance;
- advising the minister (and upon request the council of ministers) on legislation and policy frameworks regarding social and health insurances;
- implementing and executing policy established by the minister regarding social and health insurance;
- to perform executive activities in the field of social and health insurance as instructed by or pursuant to national ordinance.

According to article 4 in regards to the execution of its tasks and authority SZV has to ensure:

- timely preparation and execution;
- the quality of the procedures used;
- the proper handling of persons and entities that comes into contact with SZV;
- the proper handling of objections and complaints that are received.

As a *'Zelfstandige Bestuursorgaan'* (ZBO), SZV is a non-departmental agency, meaning is not in a hierarchical position to the minister, however the minister is still responsible for how SZV executes its policy and for the supervision thereof. The minister is also accountable to Parliament. The checks and balances mechanism for the minister is outlined throughout the Lvo USZV. The Director is (financially) accountable to the Minister.[10] The minister signs a yearly performance contract with the Director, in which quantative, qualitative and financial norms and objectives are taken up.[11] The Director sends the budget, via the Supervisory board to the minister for approval.[12] The Director provides the minister with an established balance sheet, profit and loss, and the annual report within 6 months of the end of the fiscal year.[13]

[10] Article 18, Lvo USZV.
[11] Article 19, Lvo USZV.
[12] Article 20, para. 2, Lvo USZV.
[13] Article 21, para. 5, Lvo USZV.

The minister provides the balance sheet, profit and loss, the annual report and the accountant's declaration to Parliament. The minister reports every 5 years to Parliament for the purpose of evaluating the effective and efficient functioning of SZV.[14] The SC is accountable to the minister in regards to the execution of its tasks; a yearly report concerning their activities is sent via the minister to Parliament.[15]

Based on the response provided by the Inspectorate regarding the non-compliance with the yearly performance contract, it is not clear whether the existing checks and balances are being applied appropriately. Considering that no clear guidelines or objectives have been set by the Minister since 2016, brings to question what are the current objectives of the institution, considering that the current needs in the healthcare system have changed dramatically since 2016.

Tender procedure

The impetus of the systemic investigation are complaints regarding glucometers that are provided to medically insured clients of SZV. The glucometers are provided by a third party that was selected through a bidding procedure initiated by SZV. The scope of the investigation of the Ombudsman regarding SZV is their observance of propriety as an administrative organ as it relates to their procedures to enlist a third party to supply medical aid devices, the quality of the glucometers and the complaint handling process in regards to complaints concerning the glucometers.

Medicosmetics won the bid initiated by SZV to provide i.a. glucometers to its insured clientele. Considering that SZV is an administrative body executing a government/public task which is in the interest of the public, article 4 paragraph 1, sub b, of the Lvo USZV requires SZV to ensure that quality of its procedures used. The Ombudsman requested information regarding the tender process, in particular to gain insight into the driving factors of the process and requirements. General principles of good governance apply to SZV as well as contracted parties it enlists to supply medical/artificial aid devices. This includes the transparency and duty of care in regards to the procedures and the product/services rendered. Considering the aforementioned, the process leading up to the selection of the provider of glucometers has been deemed equally important by the Ombudsman. However, questions in regards to the tender process remain unanswered throughout the process, with SZV holding the position that the tender process is not relevant to the issue at hand. In accordance with article 19 of the Lvo Ombudsman, the Ombudsman is authorized to request the information

[14] Article 22.
[15] Article 15, para 6, Lvo USZV.

relevant to the investigation and the administrative organ is obligated to comply with the request. SZV did not comply with the request of the Ombudsman in clear contravention to the national ordinance Lvo Ombudsman. Notwithstanding the above, during a session of Parliament (PY 20-21) the Director of SZV stated that it was a public tender sent out to all known suppliers of medical aid devices.
According to SZV the main reason for the change to the Perfect 3 from the Freestyle glucometer was to contain rising cost associated with having multiple suppliers of medical and artificial aid devices. The other reasons mentioned were, the reduction of the number of suppliers who could supply most or all certified artificial/medical aid devices, improve the management of the supply of the mentioned devices and synchronization of the benefits throughout the different medical expense insurances that SZV manages.

SZV further explained that the previous glucometer had been introduced in the year 2000 by *'Sociale Verzekeringsbank'*[16] (SVB) and had not been changed up until 2020. Considering that since 2010 SZV has been the executing body charged with the administration and management of the national health and social insurance on Sint Maarten, and there has not been a review or independent studies carried out by SZV to assess the quality of the Freestyle Precision over the years, displays a lack in the duty of care towards its clients. The response provided further demonstrates that SZV failed to review the quality of products that have been provided to SZV insured. This is further established by the results produced by the pilot study conducted by SLS in which it appears that the Perfect 3 glucometer performed better than the Free Style Precision. In response to the Ombudsman, SZV further indicated that they are currently developing a policy including procedures to ensure the safety and quality of not only glucometers but all medical aid devices, as one did not exist previously. The aforementioned statement further illustrates that SZV allowed its previous and current suppliers to supply the territory of Sint Maarten (for years) with medical/artificial aids and devices without existing procedures to ensure the quality and safety of products being introduced to SZV insured.

When asked about the role of the Inspectorate in relation to the tendering process, for the approval of the glucometers, SZV stated that the Inspectorate had no role in the tender process and they were not aware that the Inspectorate had a role in the approval of any artificial and medical aid devices. SZV confirmed that the Inspectorate also plays no role in the complaint handling process against SZV insured products.

[16] SVB was prior to October 10, 2010, the predecessor of SZV.

According to SZV, in order to maintain the legitimacy of the complaint handling procedure there is a separate Internal Audit and Control Department that handles internal investigations besides the investigation done by a department within SZV. Noteworthy is that according to SZV, less than 10 (of the 1500 devices distributed) complaints were received regarding the glucometers, while Medicosmetics informed the Ombudsman that the complaints were between 30 – 50 complaints. The Inspectorate were not aware of any complaints, whilst being tasked with crucial supervisory tasks with regards to public health and compliance with legislation in regards to public health and complaint handling. The Inspectorate is also tasked with providing advice and information upon its own initiative or upon request. Based on the responses provided by SZV regarding the Inspectorate, it appears that SZV does not recognize the important role that the Inspectorate bares on public health, and more specifically national public health. As one of the key institutions in advising and providing advice on all matters pertaining to the public health, the Inspectorate must be made aware of instances that can have a profound effect on public health, especially when it concerns specific vulnerable groups or possible faulty devices distributed to an estimated 1500 individuals living with diabetes.

In accordance with article 4, paragraph 1,sub d of the '*Landsverordening Uitvoeringsorgaan Sociale en Ziektekostenverzekering* (Lvo SZV)', SZV has to duly handle all incoming complaints received. Considering that the number of complaints/signals of concern received throughout the investigation from different parties has increased since the initial response provided by SZV, it remains unclear how these complaints were addressed. The information gathered throughout the investigation and the initial figures provided by SZV, are inconsistent with the number of accounts received from individuals and healthcare providers (GP's, MC, WYCF). The figures mentioned by SZV do not indicate whether the complaints were reported directly to SZV or generated by healthcare providers or institutions. This signals a serious fault in the complaint handling process and the lack of awareness amongst the public.

Despite SZV's assertion that the inaccurate readings are based on human error, this does not coincide with the findings of the pilot study carried out by SLS, nor the decision of SZV to replace the Perfect 3 with a new glucometer, considering that the results of the pilot study did not conclusively rule out whether the strips could were contaminated. In addition, the financial implications of replacing an approximate 2000 glucometers does not attest to the reliability of the glucometer. According to SLS the strips are not individually packaged like the previous glucometer and once opened, they are exposed to the elements which can also

have an effect on the readings provided. Therefore, the possibility of a faulty batch of strips or exposure to the touch or external environment could not be ruled out. While SLS did conclude that the Perfect 3 performed better in their laboratory testing than the Freestyle Precision glucometer, the results were limited due to the sample size. SLS did not conclude that the inaccurate readings were based primarily on human error. SLS acknowledged that factors such as environmental exposure, a patient's physiological condition and medication, can affect the readings of the Perfect 3 glucose meter.

According to SZV it is the sole responsibility of the healthcare providers and the supplier of medical aids to ensure that their clients were properly informed on how to use the glucometer (Perfect 3). However, it should be noted that SZV also has a duty of care (as well as to uphold the mentioned general principles of good governance) towards its clients/insured in accordance with article 4, paragraph 1, sub c of the *"Lvo SZV"*, which states that SZV ensures the careful handling of institutions and individuals that come into contact with the institution. The entire procurement process and terms of reference should be of a standard incumbent on a government administrative body. Furthermore, the insured clients of SZV are dependent on the products from the chosen supplier of SZV. Thus, the role of SZV should not be minimized in this context. SZV refused to provide information on what requirements the procurement process contained to ensure a certain quality of the glucometer, stakeholders were not involved in the process (such as stakeholders that frequently use glucometers). SZV also acknowledged that there was insufficient information provided regarding the role out and proper use of the new Perfect 3.

Furthermore, it is required for SZV to make provisions to enable persons and institutions that come into contact with it to make proposals for improvements to SZV's working methods and procedures[17]. It is uncertain whether the concerns raised and advices provided by the various stakeholders were considered by SZV. Although SZV stated that in the event SZV insured insist on using the Freestyle glucometer and strips, the insured would have to purchase the meters at their own expense and SZV would reimburse them according to the prevailing SZV tariff[18], this was not communicated to the general public. During the course of the investigation SZV had informed the Ombudsman that the organization was in the process of completing a policy to ensure the quality of all medical aid devices, however to

[17] Article 4, *Lvo USZV*.
[18] The SZV tariff can be lower than what an SZV insured would pay at the pharmacy

date of this Final Report, the policy has not been provided, despite SZV having stated that a new meter will be introduced to replace the Perfect 3.

In response to the findings and recommendations issued in the Preliminary Findings Report dated 9 August 2021, SZV informed the Ombudsman that questions posed regarding the procurement procedures used could not be provided without breaching confidentiality. However pursuant to article 19 of the National Ordinance Ombudsman, the Ombudsman is authorized to request from government bodies, civil servants, the complainant, civil servants as experts or witnesses, all information and or documents pertaining to the investigation[19]. The persons mentioned in the aforementioned article are obliged to respond to the request within the time indicated by the Ombudsman, except in cases where the persons can appeal to legal grounds ("*verschoningsrecht*" - see article 19 sub-4). This is further expounded in the explanatory memorandum ('*Memorie van Toelichting bij de Landsverordening Ombudsman')*[20],which states that the Ombudsman has a right to information ('*informatierecht'*) respectively an obligation to provide information is imposed on the government body/agency in question ('*informatieplicht'*). If, in a given case, such a ground for exception applies, then the government body/agency can conditionally state that the information in question can be disclosed in confidentiality ('*geheimhouding'*) to the Ombudsman. SZV did make mention of an existing confidentiality agreement between MC and USZV, however the response provided did not indicate which sensitive areas of the agreement/process could not be provided, thus raising additional questions regarding transparency and accountability. To date of this Final Report (FR) SZV has not properly motivated why the information on the procurement procedures could not be provided.
In SZV's response to the preliminary findings and recommendations of the Ombudsman, SZV also indicated that the institution was not agreement with a number of recommendations posed which were namely; to provide the Ombudsman with a response to the questions posed regarding the procurement procedures used, to engage with the Inspectorate and the DPH to establish legislation regulating minimum requirements for the provision of medical devices and establish a reporting obligation between SZV and the Inspectorate. SZV motivated its stance by stating that it is not within the jurisdiction of SZV to establish minimum requirements for medical devices and the responsibility to do so lies on the Inspectorate and the DPH. SZV did however agree that it will incorporate a requirement to have contracted parties thoroughly review the quality and certification of medical aids being introduced to

[19] Article 19, *Landsverordening Ombudsman*
[20] *Memorie van toelichting bij de landsverordening Ombudsman*

SZV insured in line with its non-exclusive approach that will be implemented in 2022. SZV further stated that when necessary and or if requested USZV will provide its input to the Inspectorate and DPH. Although the Ombudsman does recognize that it is not the sole responsibility of SZV to ensure that products introduced to SZV insured meets a minimum requirement, it does not negate the current need for cooperation between the three bodies. The statement also contradicts SZV's previous responses in which the institution recognized that a policy is needed and being developed to ensure the quality of all medical aids devices being introduced to SZV insured. Considering that SZV determines almost unilaterally which quality and brand of medical devices are made available to its clients and that the decisions made by SZV directly impact public health and the access and quality of care received by a large part of the population of Sint Maarten, cooperation and the development of legislation between the DPH, the Inspectorate and SZV is essential to promoting quality healthcare.

Inspectorate of Public Health

The tasks of the Inspectorate for Public Health are outlined in article 2, paragraph 2 of the National ordinance Inspectorate for public health (Lvo IV). These include the following tasks related to the subject matter. The supervision of public health, is a crucial task as it relates to the public health of the people of Sint Maarten.

The supervision of compliance with existing legislation pertaining to public health, including healthcare the provision of medicines, psychotropic substances and narcotics, pesticides, environmental matters, and goods). To this effect inspectors are given a wide range of authority to be able to fulfill this role. The Inspectorate can request all information, request insight into all documents and access to property.

The Inspectorate is tasked with the supervision of those authorized to execute supervisory tasks pertaining to public health.[21]

The Inspectorate also has an advisory role where advice can be rendered upon request and upon its own initiative and the task to provide of information.

Another significant task of the Inspectorate is complaint handling[22], however none of the institutions have a reporting obligation to the Inspectorate nor is the public (being made) aware of this task of the Inspectorate as no complaints were lodged at the Inspectorate.

According to article 2 of the Organizational decree of the Ministry of VSA, the supervision of the execution and the quality of public health, healthcare, the monitoring, control, advisory

[21] Article 2, paragragh 2 sub c Landsverordening Inspectie voor de Volksgezondheid.
[22] Article 2, paragraph, 2 sub f, Landverordening Inspectie voor de Volksgezondheid.

and evaluation of public health and healthcare policy including the preparation of legislation all fall within the task of the Ministry and thus the ministerial responsibility of the Minister. The legal tasks and competences of the Inspectorate must be seen as a means to assist the Minister with his ministerial responsibility for public health. The Inspectorate is therefore a pivotal stakeholder within this field and as such should see itself and be seen as an unmistakable link in quality of public health and healthcare on Sint Maarten. The tasks and competences should not be seen as unrelated/disconnected from the overall task of supervision of public health and healthcare and the operation of the Inspectorate should also not be in silo to the operation healthcare providers and institutions. Additionally, the public should at all times be made aware of the presence and competence of such an important institution.

Despite the supervisory and complaint handling role of the Inspectorate, they were not (made) aware of the complaints regarding the glucometers by individuals or healthcare providers that had been complaining for quite some time and had been in discussions with SZV. Additionally, based on the response received from the Inspectorate they were not made aware of the complaints and concerns of the community until the investigation of the Ombudsman. This strongly alludes to a lack of awareness of the community about the tasks and competences of the Inspectorate.
Additionally, there is no reporting obligation/policy to the Inspectorate by any of the general practitioners, SZV and Medicosmetics (as a provider of medical aid devices). Therefore, complaints received by SZV and MC were left solely up to the internal complaint mechanism of these institutions to process.

It is not within the competency and expertise of the Ombudsman nor the scope of the investigation to conduct technical investigation of the quality of the glucometers offered on the island or to make a qualified assessment of the glucometers. However, in investigating the conduct of the administrative bodies that should be involved in the process of providing medical coverage (read: medical devices), it is clear that these administrative bodies roles are not executed in such a way that would support the Minister in his responsibility for supervision of public health. While the infrastructure to support the Minister is outlined in the different legislations of the stakeholders and the Minister has tools to ensure these tasks are being executed, if there were indeed defective products in circulation the Minister would not have been alerted (in time) for preventative or mitigating actions to take place. Based on the information provided no independent investigation was launched by the Inspectorate, rather the narrative from SZV was echoed by the Inspectorate.

The Inspectorate concluded by informing the Ombudsman that its investigation had determined that the deviant readings were most likely a result of human error. No report regarding said investigation was provided. However, the Inspectorates conclusion seem to be in contradiction with the presentation of SLS lab whereby a number of factors can influence the outcome of results provided by the Perfect 3 glucometers.

Based on the information received, the Inspectorate plays no role as a significant stakeholder in public health regarding the quality of medical aid supplies provided through SZV medical coverage via the bidding process. The Inspectorate wasn't consulted by SZV to offer input on certification requirements for the medical aid devices. With regard to the progress of the investigation carried out by the Inspectorate, as it relates to the procurement procedures used, the Inspectorate informed the Ombudsman that to date the Inspectorate had only received some information on the procurement procedures and is currently monitoring the process. The Inspectorate did not further elaborate how it is monitoring the process. The Inspectorate did not motivate a reason or provide a legal basis for not receiving all required information on the procurement procedure. Pursuant to article 11, paragraph 5 of the *Lvo Inspectie voor de Volksgezondheid*, everyone is obliged to cooperate with the inspectorate when information is requested.

Through the responses provided by the Inspectorate the Ombudsman was able to establish that the contract with MC did not contain specific requirements for glucometers in regard to the selection and quality of assurance of said meters. The Inspectorate was assured by SZV that this would rectified.
Upon the Inspectorate's request for a complaint report with the information regarding the complaints, investigative steps, solutions and communication the clients, SZV indicated that this report was not drafted. SZV however referred the Inspectorate to the SLS lab 'pilot study' report from January 2020:
"According to the Inspectorate SZV concluded that the discrepancies in readings are most likely the result of human error and finds that it is up to the GP's and Medicosmetics to properly inform the users on how to use the meters.(…)"

After being informed that the complaints with the Perfect 3 were not rectified the Inspectorate again requested information on how the complaints were being handled, qualitative requirements agreed upon with Medicosmetics and/or information in the Terms of Reference pertaining to the provision of blood glucose meters. In response, SZV informed the Inspectorate that even though it was not aware of any remaining complaints, it had requested

that MC replace the Perfect 3 meters with ISO certified meters with individually packaged strips, as it expects that will reduce the deviations in measurements and the reliability of the meter readings.

Based on the reaction provided by the Inspectorate, it can be concluded that SZV has based its claim on one source, namely the results of the study carried out by SLS. Thus, the question arises whether a more thorough investigation should have been conducted by SZV in collaboration with stakeholders (Healthcare providers and persons living with diabetes) in order to come to a conclusion based on individual user experience.

Role of the Inspectorate of Public Health in relation to SZV

According to the Inspectorate, in the absence of specific legislation regulating minimum requirements for the provision and use of medical aid devices, the Inspectorate has authority to investigate based on its legal mandate as laid down in the *'Landsverordening Inspectie voor de Volksgezondheid'*, including but not limited to the supervision on compliance with the legal regulations pertaining to public health, including (but not limited to) healthcare and the provision of pharmaceuticals[23]. SZV is charged with the execution of several health insurances and – in that capacity- determines almost unilaterally which quality and brand of medical devices are made available to its clients. Decisions made by SZV directly impact public health and the access and quality of care received by a large part of the population of Sint Maarten. According to the Inspectorate, these decisions/actions fall under the supervision of the Inspectorate. Despite of this supervisory role of the decisions/actions of SZV and the general mandate provided to the Inspectorate, there is no reporting obligation to the Inspectorate, no role in the bidding process and no role in establishing criteria regarding quality of medical devices.

It is unclear based on the responses of the Inspectorate how the Inspectorate ensures in practice its supervisory role in regards to (in this case) SZV and more specifically medical aid suppliers on Sint Maarten, when there is a complete lack of checks and balances in this regard.

In response to the PFR, the Inspectorate indicated that the Inspectorate bares little influence when it comes to the development of policies with regard to the quality of medical aids being provided to SZV insured.

[23] Article 2, paragraph 2 c, *Landsverordening Inspectie voor de Volksgezondheid*.

According to the Inspectorate the sole responsibility for such lies with the Minister and the Supervisory Council of SZV. The Inspectorate in its response also questioned the efficacy of the current arrangement as the Supervisory Council's formation is incomplete and its advice bares no formal weight. The Inspectorate further expressed its concerns regarding the 'performance contract' between the Minister and SZV's director as prescribed by the National Ordinance SZV[24] which has not been completed since 2016.

The Inspectorate went on to explain that as long as there is no vision being set by the Ministry, the quality of care available to the population of Sint Maarten is to a large extent determined by care providers and SZV as the largest care procurer.

With regard to the investigation of the Inspectorate, the Inspectorate indicated that the SZV ordinance does not designate a supervisory role for the Inspectorate, resulting in the Inspectorates authority not being recognized by SZV. According to the Inspectorate the Ministry has lost its independent directing role as it relates to policy and legislation, as SZV heavily influences the process. The Inspectorate concluded by stating that the Inspectorate receives little support from the Ministry when it comes to addressing SZV.

The Inspectorate did however acknowledge and expressed the need for the Inspectorate to increase awareness amongst the general population regarding the role of the inspectorate. The Inspectorate further recognized the need for Sint Maarten to implement a registry for medical diagnostic devices much like the rest of the former Netherlands Antilles.

The Inspectorate maintains that its independent investigation had determined that USZV had ultimately investigated all the complaints received regarding the faulty readings, however to date the Inspectorate has not provided a report indicating how SZV had completed its investigation into the complaint to substantiate its (inspectorate) claims, nor does the reaction of the Inspectorate correspond with its previous statement indicating that no independent investigation had been carried out by SZV into the complaints levied against the institution.

[24] Article 19, *Landsverordening Uitvoeringsorgaan Sociale Ziektenkosten Verzekering*

Department of Public Health

The Department of Public Health[25] (DPH) is charged with advising the Minister on policies and legislation related to public health. The tasks of the DPH can be summarized as follows:

- *ensuring and evaluating policy, legislation regarding public health and healthcare*;
- *ensuring and evaluating policy, legislation and regulations regarding health care funding frameworks*;
- *promoting, conducting and directing epidemiological research and surveillance, including keeping track of mortality and morbidity (of infectious diseases, NCDs (Non-Communicable diseases and risk factors) statistics and monitoring the health status of the population, as well as policy support and evaluative research and planning activities related to public health and healthcare;*
- promoting the interests in the field of public health and health care in the Kingdom, international and regional context;
- supporting the coordination and implementation of public health aspects, medical assistance and population care in the event of disasters;
- *developing policy, legislation and regulations for specific target groups*;
- promoting the health status of the population in general and specific target groups in particular;
- preparing and advising on health care policy and sub-policy for specific target groups;
- promoting the development and maintenance of the distribution, quantity and quality of health care facilities and supporting the administrative bodies in this regard.

The organizational decree of the Ministry of VROMI assigns the DPH with general and specific authority to ensure the quality of public health and healthcare on the island. The DPH is another entity tasked with special authority to assist the minister in his responsibility of ensuring a standard of healthcare incumbent on the Sint Maarten population, this includes setting legislation and/or policy regarding the quality of medical aid devices. This makes DPH another relevant and significant stakeholder in this case.

The DPH acknowledges that SZV is an independent administrative body, whose director is accountable to the Minister. DPH also acknowledges the performance contract that is signed between the Minister and the director, which includes quantitative, qualitative and financial standards and targets. However, there is no legislation or policy in place setting quality standards for medical aid devices.

[25] Organisatiebesluit Volksgezondheid, Sociale Ontwikkeling en Arbeid.

Sint Maarten does not form part of or aligned with any supervisory body in this context. Such a body would e.g. have international/European standards in public health including medical aid devices. The DPH also recognizes their role in advising the Minister on legislation and policy as laid down in the organizational decree of the Ministry, including the role the department has in the development of policies and legislation for specific target groups. The DPH plays no role in setting requirements/criteria/standards for medical aid devices. According to the responses provided by DPH, it is apparent that the department has not developed any specific policies or legislation to meet the needs of persons living with diabetes on Sint Maarten and/or influence the actions of health care providers and medical aid suppliers catering to persons living with diabetes.

Advising the Minister on quality standards, policy and legislation for public health, healthcare and in this case medical aid advices is not equivalent to interfering with the legal and/or operational tasks of SZV, insofar as the DPH would have want to assert this position. As another major stakeholder there is no reporting policy in place from SZV or the Inspectorate to the DPH. How can the department charged with advising the Minister execute its function if executing agencies and the Inspectorate do not report information relevant for adapting important policy changes? Therefore, it is important that the DPH is more actively involved in developments taking place within public health sector to ensure and promote public health.

According to DPH health care providers are ultimately responsible for providing adequate care of good quality and prescribing pharmaceuticals/medical aid devices in line with applicable legislation and according to their client's needs.

When asked whether the department was consulted by SZV in their decision to switch medical aid suppliers, the DPH stated that all operational decisions are at SZV's discretion, however the department can influence the actions of SZV by developing and updating legislation which regulates the responsibility of the institution. Based on this response and in accordance with article 11 of the *Organisatie besluit Volksgezondheid, Sociale Ontwikkeling en Arbeid*, the DPH has considerable influence on legislation, policy and regulations regarding public health and healthcare. Although the institution does not actively interfere with the decisions made by SZV it has the responsibility to ensure that the policies being executed promote and ensure the general public health.
DPH further informed the Bureau that the director of SZV can decide to invite physicians and other persons or entities to participate in the execution of the social health insurances

('*Regeling medewerking aan de sociale verzekeringen*'). The director can set criteria for this participation in the contract between the SZV and the participating person or entity. Considering that the DPH is charged with promoting and ensuring the public health of specific groups of the population of Sint Maarten, it is unclear why the DPH was not involved in or informed of the decision to introduce a new glucometer.

When queried whether the department was aware of the situation regarding the complaints of faulty readings and the decision of SZV to switch to a single provider, the DPH stated that it was not aware of the complaints received nor had it been consulted by SZV in its decision to switch medical aid suppliers. Based on the responses received from the Ministry of VSA and more specifically the Inspectorate and the DPH, there seems to be little or no cohesion between the different institutions charged with promoting and ensuring the quality of health care on Sint Maarten. The Ombudsman notes that this can only be achieved by systematically reporting and addressing inadequacies in the public health system.

Conclusion:

The core task of the Ombudsman is the investigation of *Propriety* applied by government bodies and government agencies in their relationship and dealings with the public. The scope of *Propriety* goes beyond the law; it reflects the norms expected from government in executing the laws, policies and established procedures. Government is expected to be open and clear, respectful, involved and result oriented, honest and trustworthy.

The main question for consideration is: Did SZV observe propriety in contracting a preferred medical/artificial aids supplier and handling complaints received by healthcare providers and SZV insured regarding inaccurate results received by the Perfect 3?

On 26 May 2020, a complaint was filed by a member of the general public regarding alleged faulty glucose testers being allowed as the sole option under the insurance of SZV. During an investigation into the complaint, the Ombudsman became aware of a number of concerns that were raised by healthcare providers and SZV insured regarding the accuracy of the newly introduced Perfect 3. Subsequently, a systemic investigation was launched by the Ombudsman regarding the procurement procedures used by SZV and the process leading up to the decision to switch from the Freestyle to the Perfect 3 and the complaint handling process. As well as a structural review of the procedures, legislation and polices.

The Ombudsman observed that the standard of *active and adequate information provision* requires that administrative bodies actively and upon request provide adequate information to the public. In response to the questions posed by the Ombudsman, SZV acknowledged that the new glucometer had not been properly introduced to its insured clientele (persons living with diabetes). There was no information provided to properly facilitate the transition from the Precision Freestyle to the Perfect 3. SZV also affirmed that an interim solution was possible whereby SZV clientele that decided to switch back to the previous glucometer would be reimbursed according to the prevailing SZV tariff, however SZV later acknowledged that the interim solution had not been communicated to its clientele nor to the public. This means the public and in particular clients of SZV were not aware of the possibility of (partial) reimbursements by SZV. Additionally, according to SZV's own interpretation of the results of SLS report on the pilot study conducted in January 2020, human error was the (likely) cause of the many complaints of irregular reading on the glucometer. Despite the aforementioned, the Ombudsman has not observed any uptick in information provision on the usage of the Perfect 3 that until present date remains in distribution.
Information provision can assist persons in making informed decisions. Providing adequate information can clear up the air between public bodies and the citizens. In general, an individual is more willing to accept a situation when there is an explanation.

The investigation revealed that communication with healthcare providers (several GPs and WYCCF) had taken place months before the investigation of the Ombudsman regarding the complaints with the glucometers. The correspondence consisted of queries and suggestions (including certification of the glucometer, SLS test results and the authorizing health authority) about the causes of the complaints. SZV took very long to respond to healthcare providers and the responses were often inconclusive and/or unsubstantiated.
To ensure a high level of credibility in public bodies, transparency is essential. Being open and clear in providing adequate information regarding plans and actions of a public body, that affect the interest of the citizen is a requirement for enhancing the credibility of public bodies.
In a follow up response to the questions posed by the Ombudsman, SZV indicated that management was of the opinion that it was not necessary to disclose the results of the pilot study conducted by SLS, in an effort to prevent possible reputational issues by either provider or cause further consternation amongst the insured population that had no complaints and are satisfied. The non and/or lack of response coupled with the lack of attention for the concerns raised by GP's is very concerning, considering that upon SZV lies a legal duty of care in dealing with persons it comes into contact with and how complaints are handled.

The Ombudsman notes that administrative bodies are required to actively and upon request provide adequate information to the public, this entails the duty to provide citizens with information upon request, as well as the duty to inform the citizen on its own initiative about proceedings that have a direct effect on them. Proper information provision creates certainty for all. Considering the above, **the standard of active and adequate information provision is violated.**

The Ombudsman further observes that the standard of *active and adequate information gathering* requires that governmental bodies and semi-governmental bodies acquire the necessary relevant information in preparation of their decisions, or actions.
The investigation revealed that SZV did not set a standard (quality) for the glucometers during the procurement procedure for the winning contractor to adhere to. SZV also did not consult with relevant stakeholders in regards to medical aid devices, such as, the DPH, Inspectorate, healthcare providers and/or its target group. Neither was a (laboratory) evaluation done on the Precision Freestyle (with stakeholders) to gather information on what may need to be improved. The decision to procure according to SZV was largely financial, and while the Ombudsman can understand financial motivation, these reasons need not be at the detrimental expense of its clientele's health. SZV acknowledged that the chance of human error increased after introducing the new glucometer. Subsequently, a study was carried out by SLS after a number of complaints were received, this study should have been done before introducing the new glucometer. The recommendations provided in the report of the Clinical Chemist also emphasized that glucometers should be evaluated before use and the specific meter model should be based on the technical and clinical performance in the intended patient population. It is important to note that the Clinical Chemist also indicated that the study which was conducted by SLS was in a controlled environment allowing for little or no variation and that in order to measure the effectiveness of the glucometer on Sint Maarten a study would have to be conducted with a larger sample size over an extended period of time. The aforementioned recommendations made by the Clinical Chemist are further supported by research carried out by Slingerland *et al*, which pointed out that the selection of a suitable glucometer should be customized and not left up to the discretion of an insurance company to decide. According to research carried out by Slingerland *et al* on why the selection of a suitable glucometer should be customized and not left up to the discretion of an insurance company to decide, found that a number of variations in physiology, environmental

conditions, sensitivity of strips, storage of strips and human error can lead to misleading results which can be detrimental to persons living with diabetes[26].
The international standard ISO 15197 which was also used in the test conducted by SLS to assess the quality of the newly introduced glucometer, requires that glucometers need to meet the system accuracy standards of 2003 (ISO: 15197:2003) and 2015 updated standards which state that an accurate meter does not deviate more than 15% of laboratory results.
However, according to Slingerland et al, ISO 15167 remains a purely administrative exercise as manufacturers can indicate on their own whether their glucometer meets the standards of ISO15197[27].

As previously mentioned, SZV has a duty of care towards its insured population in accordance with the law, thus SZV is required to ensure that each medical aid and artificial aid device being provided to SZV insured has been thoroughly reviewed before being introduced. The Ombudsman understands that in order to keep healthcare affordable cost must be contained, however the quality of care must be maintained. A short-term saving on diabetes aids can result in an increase in costs in the longer term due to an increase in diabetes-related complications. Considering the aforementioned, **the standard of Active and adequate information gathering is applicable.**

The Ombudsman further observes that the standard of *Reasons* requires that actions taken by government should be carried by facts and logic communicated to the citizen. Proper reasons motives and grounds should be provided and explained to the citizen with all decisions made by government.
The Director of SZV has the authority to appoint a third party to execute tasks on the institution's behalf, however as a semi-governmental agency entrusted to execute tasks on behalf of the Minister, SZV must also ensure that the procurement process complies with the general principles of good governance, in this case the fundamental principles of public procurement. The assertion by SZV that this information was not relevant for the scope of the investigation is incomprehensible and incorrect. The procurement documents contain pivotal information regarding the requirements and guidelines set by SZV during the process and is thus an integral part of this investigation. Furthermore, the inquiry by the Inspectorate also included a request on the procurement documents to which it appears SZV did not comply.

[26] *Ophef over de kwaliteit van bloed glucosemeters, R. Slingerland en D. Telting, Nederland Tijdschrift Klin. Chem. Labgeneesk*. 2015, pg. 243.
[27] *Ophef over de kwaliteit van bloed glucosemeters, R. Slingerland en D. Telting, Nederland Tijdschrift Klin. Chem. Labgeneesk*. 2015, pg. 244.

While SZV is independent in its functioning, it is an administrative public entity governed by the laws applicable to it. This includes the laws governing the Inspectorate whose supervisory mandate is born out of the Minister's responsibility to public health of the people of Sint Maarten and SZV's legal task to manage public health insurance and premiums.
Considering that no information was provided to substantiate the procurement procedures to select the provider of the glucometers, the Ombudsman was hindered in making this assessment. As an (independent) administrative organ falling within the jurisdiction of the Ombudsman, this is a clear violation of article 19 of the Ombudsman. Therefore, no proper motivation was given to justify withholding the requested information.

Public procurement must also adhere to fundamental principles, such as transparency, integrity, economy, openness, fairness, competition and accountability. Based on the aforementioned, the **standard of Reason is violated.**

The Ombudsman further observes that an administrative body is obliged to weigh interests in reaching a decision and to observe the principle of *proportionality*.
This requires that the negative consequences of an action to achieve a certain goal may not be disproportionate to the interest of the citizen. SZV informed the Ombudsman that considering that there were only 10 complaints out of the 1500 insured persons with diabetes, it was not enough reason to reverse the decision to provide the new glucometer. The WYCCF also informed SZV that the Perfect 3 glucometer could no longer be used in order to safeguard the safety of its clients, however SZV remained of the opinion that the glucometers are not faulty and the errors in the readings are due to human error, regardless of the experiences of the district nurses and complaints submitted by healthcare providers.
In accordance with article 4 '*lvo uitvoeringsorgaan SZV', SZV* is required to carefully handle all incoming complaints. It remains unclear what further steps were taken by SZV to address the concerns of stakeholders and SZV insured. Based on the information provided by the Inspectorate there was no complaint report drafted by SZV. The Ombudsman further established that SZV did not consult with stakeholders (Healthcare providers, SZV insured) after the complaints were received in order to address their concerns raised. Subsequently, the acquired facts have to be weighed against the interests of the citizen; the outcome may not be unreasonable.
In SZV's response to healthcare providers, SZV stated that they would provide the previous glucometers to the SZV insured under the prevailing SZV tariff. The standard of proportionality provides that the consequences of a decision made, or action taken by a public body have to be proportional to the goal it is meant to serve.

A public body is to employ the measure that interferes the least with the interest of the citizen (subsidiarity principle). Considering that 50% of SZV insured diabetic population consist of seniors who have been recognized as one of the most vulnerable groups during the COVID 19 pandemic, coupled with declining income levels and the cost of living in Sint Maarten, SZV's decision to provide the previous glucometer at the current tariff is not considered a proportional response. The goal has to justify the means used (proportionality). When coming to a decision the public body has to be well aware of its impact.
The standard of proportionality furthermore entails that when taking a decision, a public body has to prevent a group of citizens being more heavily affected than others who are in the same position. Therefore, the standard of proportionality has not been observed.

As a result of the investigation the Ombudsman also identified a number of serious concerns regarding how the complaint procedure had been addressed not only by SZV but the functionally responsible departments within the Ministry of VSA. During the course of the investigation the Ombudsman was informed by both the Inspectorate and the DPH that SZV has the sole responsibility to ensure that products being introduced to the SZV insured meet safety requirements. However, SZV informed the Ombudsman that it is the responsibility of the medical aid's supplier to ensure that the safety requirements are met. The DPH also informed the Ombudsman that the Pharmaceutical Inspectorate is specifically tasked with handling and investigating complaints from the community or the pharmaceutical industry, ensuring the quality and safety of pharmaceutical products and issuing advice on request or its own initiative.
According to the existing ordinance[28] governing the working method of the Ministry, the Ombudsman notes that the Ministry has a responsibility to ensure that SZV works within guidelines that ensure the quality and safety of the types of medical aids that are introduced to SZV insured on Sint Maarten.
Based on the responses received from DPH, the Division Pharmaceuticals has the authority to ensure that medical aid devices are safe based on its supervisory role. However, the investigation of the Ombudsman has recognized that the division is only contacted when safety issues arise. As such, it is incumbent that the Ministry as a whole detect shortcomings in policy and legislation and develop the necessary policies to maintain and enhance the quality of healthcare on Sint Maarten.

[28] *Organisatiebesluit Volksgezondheid, Sociale Ontwikkeling en Arbeid artikel 1 t/m11.*

The lack of a performance contract since 2016 brings to question what policy and financial goals have been set by SZV. Considering that this requirement has not been met for approximately 5 years, indicates that the Ministry as a whole has not evaluated the performance of SZV nor has the Ministry sought to improve on existing processes that are currently being executed by SZV on behalf of Country Sint Maarten. The investigation also revealed that there is a lack of data on the side of the Ministry regarding SZV's policy goals and objectives. In addition, the lack of a reporting obligation to the Inspectorate, may allow serious offences to go unaddressed. In order to improve in the area of public health it is essential that the Inspectorate is made aware of complaints and incidences that can have a considerable impact on public health. Proper service includes organizing the administration in a manner that is lawful, effective, transparent, accessible, equipped to provide prompt service and information. Continuity should be guaranteed; proper registration and archiving are essential in achieving and guarantee continuity in the administration.

The responses provided by DPH and the Inspectorate further illustrates the need for closer coordination between the two key institutions responsible for monitoring and developing policies to promote and develop public health. Although the scope of the two departments may differ, in terms of deliverables, both departments do however have a shared responsibility as it pertains to the field of public healthcare. A government body may not hide behind its limited task and competence but take the initiative to work with other entities to provide the citizen the best service. **The standard of adequate organization of services has not been observed.**

The ministerial responsibility with regards to public health falls under the Minister. In order to fulfill this role different institutions are charged with different tasks. To this effect SZV, an administrative body, is tasked with providing social medical coverage. In this specific case, the medical coverage is supplied through the provision of glucometers through a SZV sanctioned medical supplier. Therefore, general principles of good governance and standards of propriety apply in the same way to the provision of medical aids to the clientele of SZV. The same applies for the Inspectorate that is tasked with the supervision of public health. The tasks of the Inspectorate are specific to directly giving content to the ministerial responsibility of the Minister. The investigation filed by a single person at the Ombudsman, as well as concerns from within the community and stakeholders, was sufficient to trigger a systemic investigation that revealed significant gaps in the system designed to support the Minister in his role. The lack of visibility of the Inspectorate as a significant stakeholder in the quality of public health, complaint handling and the lack of reporting obligation will

indeed make it difficult for the Inspectorate and therefore the Minister to be aware of public health matters, including severe concerns regarding possible faulty glucometers being provided to persons living with diabetes. The remarks of the Inspectorate also indicate that SZV does not recognize the authority of the Inspectorate. This is also compounded by the fact that a performance contract between the Minister and SZV's director has not been completed since 2016, which is vital for evaluating goals and objectives in healthcare and addressing issues in the healthcare sector. The findings of the investigation all indicate that SZV is allowed to operate independently from Government with little to no recourse.

Through the investigation of the Ombudsman, it was established that SZV insured, and health care providers had not been properly informed about the Perfect 3 glucometer. Although, the glucometers were found to be of adequate quality, based on the pilot study conducted by SLS, the individual circumstances had not been taken into consideration. The results of the investigation highlight the importance of having affordable alternative testing options available for persons living with diabetes, which should not be at the expense of the insured.

The findings of the investigation further indicate that SZV should have conducted a thorough investigation into the individual complaints regarding the faulty readings received and compiled a comprehensive report to address the individual concerns raised. As the national supervisory body of public health, the Inspectorate has an important role to play in ensuring that medical and artificial aids are safe. Therefore, it is important that the Inspectorate and more specifically the Ministry of VSA, coordinate efforts to ensure that complaints received are dealt with immediately and create legislation and policies to address (future) shortcomings in legislation. Although the Inspectorate initiated desk research and engaged with the relevant parties once it was notified about the complaint, no report indicating that an in depth investigation had been carried out by the inspectorate was provided.
Considering the evasive answers provided by SZV regarding SZV's procurement policy, the Ombudsman was unable to make a determination of the adherence of SZV's procurement policy to the fundamental principles of good governance and more specifically the principles of public procurement. Hence the Ombudsman concludes that the procurement procedure of SZV is not transparent.

Considering the facts and findings the Ombudsman concludes that the standards of proper conduct not being observed regarding this investigation, are: *Active and adequate information provision, active and adequate information gathering, adequate organization of services and reasons and proportionality.*

OMBUDSMAN
SINT MAARTEN

Judgment:

- The complaint is founded the standards of *Active and adequate information provision, active and adequate information gathering, reasons and proportionality* have been violated.
- SZV acted improper with regard to the complaint.

Considering the investigation and findings as stated hereinafter, the Ombudsman recommends as follows:

Recommendation(s):

- Comply with article 19 National Ordinance Ombudsman by providing the Ombudsman with answers to the unanswered questions regarding the procurement procedure;
- SZV should improve the legal framework for public procurement by enacting legislation or established standardized procurement guidelines that require civil or social mechanism (for example tender boards) to monitor the processes of public contracting;
- Create a contractual agreement between contracted parties to thoroughly review the quality and certification of medical aids and artificial aids before introducing to SZV insured;
- Create a policy that ensures that SZV insured and healthcare providers are properly informed before replacing existing medical aid devices with new medical aids devices;
- Engage with relevant stakeholders once complaints have been levied against SZV;
- Engage with the Inspectorate and the Department of Public Health in order to establish legislation regulating minimum requirements for the provision and use of medical devices;
- Establish a policy that ensures that SZV and healthcare providers report incoming complaints to the Inspectorate of Public Health for further review; (i.e. there should be a reporting obligation to the Inspectorate);
- Complete the formation of the Supervisory Council of SZV;
- Complete the required performance contract between the Minister and the Director of SZV;

OMBUDSMAN
SINT MAARTEN

The Ombudsman requests a status report on the recommendation(s) within three (3) months from the date of this letter.

Legal Basis:

Pursuant to article 19 sub 1 of the National Ordinance Ombudsman, the Ombudsman is authorized to request from government bodies, civil servants, the complainant, civil servants as experts or witnesses, all information and or documents pertaining to the investigation. The persons mentioned in the aforementioned article are obliged to respond to the request within the time indicated by the Ombudsman, except in cases where the persons can appeal to legal grounds ("*verschoningsrecht*" - see article 19 sub-4).

- ***Landsverordening uitvoeringsorgaan sociaal ziektekostenverzekeringen;***
- ***Organisatiebesluit Volksgezondheid, Sociale Ontwikkeling en Arbeid;***
- ***Landsverordening Inspectie voor de Volksgezondheid;***
- ***Landsverordening op de geneesmiddelenvoorziening;***

Standard(s) of Proper Conduct:

The Ombudsman investigates whether the behavior of public bodies towards citizens is correct. The applicable standards of proper conduct in this case are *Active and adequate information provision, Active and adequate information gathering, adequate organization of services, reasons and proportionality.*

Philipsburg, 30 December 2021

Ms. G. Mossel LL.M
Ombudsman