



Data with Integrity: Rationale and data security

Background

A key objective of SAMED is to provide our members with a collective, objective and credible platform to engage with all stakeholders on matters of significant importance to the industry. To this end, SAMED is embarking on a comprehensive data management project to collect, consolidate, store and report relevant information on the medical technology industry in South Africa.

This information is vital for SAMED to facilitate a sustainable, ethical and transformed medical technology (MedTech) industry and to influence appropriate policy and decision-making by public and private bodies pertaining to the MedTech sector. SAMED recognizes that certain information might be of a sensitive and/or commercially relevant nature and the bidder, processes, systems, reporting mechanism and platform(s) used will ensure absolute confidentiality thereof.

Entities that might be provided aggregated information or reports include but are not limited to: private and public bodies such as the Competition Commission, the Department of Trade, Industry and Competition, the National Department of Health, Provincial Departments of Health, the South African Health Products Regulatory Authority [SAHPRA]), private and public hospital groups, Business Unity SA [BUSA], the World Health Organisation [WHO], universities, the African Union, the Industrial Development Corporation [IDC] and the World Trade Organisation [WTO] etc, for purposes related to procurement, money owed to members by government departments, submissions on legislation, economic policy, research and development, transformation of the Medtech sector and any other purpose related to the furthering of the interests of the MedTech sector or as otherwise permitted by law.

Company information will be de-identified unless relevant to the request, for example information on which companies supply which products might be provided in an identifiable format. No commercially- sensitive information of members or information in respect of which we owe a lawful duty of confidence will be disclosed to any party. Participants will be given the opportunity to agree to terms and conditions and/or sign a non-disclosure agreement with SAMED.

The purpose of this project is to ensure that SAMED has credible, statistically valid data that will be of value to both our members and stakeholders, and it aims to answer questions relating to:

- Market size of the South African medical technology sector (financial terms) and the range of different types of medical technologies on the market
- Types and proportion of medical technology which are imported (with main countries of origin), exported (with main countries supplied), manufactured locally, and new/ innovative products entering the market
- Percentage of local manufacturers/distributors/wholesalers in the medical technology sector and who the biggest industry players are
- Anticipated impact of National Health Insurance on provision of medical technology in South Africa

- B-BBEE status of the medical technology sector
- Any new legislation, threats and opportunities, and the main challenges faced by the sector for i) local manufacturers, ii) distributors, iii) multinationals, iv) wholesalers and v) SMMEs

NOTE: these are subject to change, and it is anticipated that this survey process will be run at least bi annually with some minor modification relevant to the environment at the time. It is intended that SAMED staff will draw data out of the system in order to develop insights, but they will not be able to have full access to the data (which will remain proprietary to SAMED). High level dashboard and progress reporting will be available for all participating SAMED members, but they will not be able to access any of the data besides that of their own company / data they have entered.

Terms and Conditions

When signing on the platform for the first time, you will be required to read and accept the terms and conditions including the Protection of Personal Information (POPI) disclaimer. Acceptance will constitute that you understand and agree that all information provided, whether personal or otherwise, may be used and processed by SAMED as the "owner" of the platform.

Further by continuing to access the platform you specifically agree that SAMED will use such information provided by you, irrespective of the nature of such information. No individual company data will be shared with a competitor and all data usage will consider competition law compliance and other relevant regulations.

SAMED will, of course, take all reasonable measures to protect the personal information of users as defined in the Promotion of Access to Information Act, Act 2 of 2000 ("PAIA") and the Protection of Personal Information Act, Act 4 of 2013 ("POPI"). Personal information of users is processed by SAMED as set out in our <u>Privacy Policy</u>. Please familiarise yourself with the contents of this Policy before accepting these terms and conditions.

Queries

Should you encounter any challenges in accessing functionality or should you require an non-disclosure agreement with SAMED. Please contact 011 704 2445 or communication@samed.org.za.

^{*}Note: the term 'medical technology' includes in vitro diagnostics (IVDs)