

An exploratory, qualitative study was conducted to establish the reasons why local medical device manufacturing firms are not starting up in South Africa. The South African medical device industry is growing at Compound Annual Growth Rate of 7.74%, while the number of medical device importers are increasing at a higher rate than the number of medical device manufacturers.

Semi-structured interviews were conducted with local medical device manufacturers to understand the market environment(s) companies operate in, the competitive environment(s) companies operate in as well as elements of strategy implemented within these companies. A deductive content analysis, comparative analysis and participant observation was conducted to achieve the objectives of this study.

A trend of stable company growth was identified across all medical device manufacturers. Local manufacturers were faced with highest competition from importers and distributors, including multinational companies. The most severe problems experienced by local manufacturers included irregularities and inconsistencies in the regulatory framework governing medical devices; the unreliability of raw material suppliers locally; importers and import duty structures; private sector penetration and the unavailability of funding and incentives.

The competitive forces with the highest impact on medical device manufacturers in South Africa were the barriers to entry and competitive rivalry in the market. Formalized strategies, however, were not key to the success of medical device companies. Success factors of local medical device manufacturers included brand representation, quality of products, reduced product costs through import substitutions, product innovation, being first to market and the level of after sales technical support.

Recommendations were made for medical device manufacturers to mitigate any potential problems that may be faced immediately by the company as well as for medical device regulations and future policy development in the industry. Included in this, is suggestion for regulations to be aligned to other successfully implemented regulatory frameworks across the world.

The study concluded with scope for future research which included developing marketing strategies to enhance brand representation; investigating problems with the medical device regulatory framework; as well as investigating the relationship between local manufacturers and the private healthcare sector in South Africa.