south african medical device industry association
advancing innovation responsibly

SAMED

December 5th, 2012

For attention:

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cc. Honourable Minister of Health: Dr Aaron Motsoaledi; Honourable Minister of Science and Technology: Mr Derek Hanekom

SAMED submission: Revised Broad-Based Black Economic Empowerment Codes of Good Practice – as published on 5 October 2012

Dear Madam / Sir

The South African Medical Device Industry Association (SAMED) represents the interests of 150+ Medical Devices, Medical Equipment and In Vitro Diagnostics companies in South Africa. Established in 1985, the association has grown significantly in recent years and is now recognized as a significant stakeholder in the South African healthcare industry. SAMED is committed to ensuring a sustainable medical device industry in South Africa, to encouraging ethical principles and practices and promoting innovation and better patient outcomes in a responsible manner.

SAMED and its members support the achievement of economic transformation by means of the principles espoused in the Broad-based Black Economic Empowerment Act of 2003 (BBBEE Act). SAMED has reviewed the revised Broad Black Economic Empowerment Codes of Good Practice as published on 5 October 2012 and hereby submits its comments thereon. SAMED respectfully requests an opportunity to meet face to face to provide a verbal submission on the matter.

We look forward to a response to our request.

Yours sincerely

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Chief Operating Officer

SAMED

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Executive summary

SAMED and its members support the achievement of economic transformation by means of the principles espoused in the Broad-based Black Economic Empowerment Act of 2003 (BBBEE Act). SAMED also supports the various policy instruments designed to address job creation and industrial development. In order to align with the principles of economic transformation and empowerment and to facilitate achievement of the goals, there needs to be a balance between creating an **attractive, and business-friendly investment** environment, and placing **societal requirements** on businesses that may hamper this imperative.

SAMED member companies are committed to South Africa, and both multinationals and local companies wish to expand their businesses, create jobs and grow the economy. This means serving more healthcare institutions and patients, meeting sales targets, and **integrating transformational objectives** within the main objective of bringing health to the nation. In addition, the industry is indispensable in South Africa, as its products are critical to the delivery of healthcare. Currently South African patients have access to innovative healthcare diagnosis and treatment – all of which may be compromised as a result of the proposed punitive approach drafted into the revised Codes.

A **survey** conducted amongst SAMED members (full results attached as Annexure "A") indicates that members regard some of the targets as unachievable, or difficult to achieve over the shorter term. SAMED also attaches a wider industry-survey undertaken on skills and training needs for both medical device and pharmaceutical companies (Annexure "B"), that indicates the current profile of staff, as well as the most important training types and skills shortages in the broader health products industry.

SAMED understands the rationale of employment creation and local procurement behind the changes proposed in the draft Codes. However, the **cumulative effect** of the changed points to be scored to maintain one's current B-BBEE status, the 2-level discount system and the increased and in some cases doubling of targets have a cumulative effect that measured entities drop from a level 3 or level 4 BEE entity, to level 8 or even non-compliant. This has a severely demoralizing effect on measured entities, most of whom have been working hard in order to assist the achievement of economic transformation.

The financial commitments and business changes required by the draft Codes are tremendous, and it is unlikely for any entity to effect such changes within the space of a year or two. In this regard **SAMED proposes** a delay in the implementation of the amendments, so that companies are able to, where possible, adjust budgets and change business policies accordingly. Incremental targets would also assist, as many SAMED members indicated they would only be able to achieve certain targets "over time".

Some of the scorecard elements are **outside of the control** of the measured entity. This includes the numbers of suppliers available to be "enterprise developed" and/or supported. The number of value-added suppliers, relevant to the medical device industry is also beyond the control of the measured entity.

For both multinational- and local companies the inclusion of **imported content** in the procurement-portion of the scorecard is extremely detrimental. This criteria makes it impossible for companies to comply with this part of the supplier development pillar. The likelihood of local manufacturing industries being created not only depends on the availability of a highly technical infrastructure and skilled resources, but also whether economies of scale can be achieved to make such endeavors viable. The achievability of this also differs from sector to sector, where factors such as the skills level and technological requirements need to be considered. Even if potentially viable, setting up local manufacturing sites in health products may simply not be possible, given the very expensive requisite international accreditation required for medical device manufacturing sites. And even in such cases the likelihood of having to import significant percentages of content /constituent materials /products are high.

For medical device companies **product training** is critical, and has become more so under the provisions of the Consumer Protection Act relating to product liability. This training, and the subsequent training to the users of medical devices (including healthcare professionals and in some cases, patients), forms the heart of any medical device business. Due to the specificity of each device (and device type), "generic" training courses are inappropriate and inadequate. However, the manner in which the skills development scorecard requires accreditation and recognition within a formal qualification framework leaves this form of skills development outside of the realm of recognition.

For the most part, in-company training is offered by overseas companies from which local measured entities procure, as well as by multinational principals, neither of which would be recognizable under the proposed draft skills development principles. Medical device companies also contribute significantly to **skills development of health sector providers and professionals**; however, such training will not fall within the definitions of apprenticeships or internships, but should merit recognition.

SAMED proposes that the skills development pillar be reassessed to include in-company training and the training of healthcare professionals that do not fall within the proposed skills matrix.

SAMED is of the view that the proposed amendments to the Codes may have the opposite effect, in that measured entities may see **the bar as being set too high** in too many of the pillars, bringing the targets out of reach of many companies. Although a simplification in bringing the pillars down from seven to five, performing, measuring and tracking the requirements to obtain points are **still complex**, if not more, in particular where the **supplier development** pillar is concerned.

Due to the specificity and unique nature of the medical device industry, and the requirements placed on it by the interest of access to healthcare as mandated in the South African Constitution, a one-size fits all approach to employment creation and supplier development (which depends on the nature of specific types of businesses) may not be the best route to achieve economic transformation.

SAMED proposes that the DTI considers the differing impacts on the very specific requirements placed on various industries, where opportunities to create employment and opportunities to create local manufacturing may vary.

1. Introduction

The South African Medical Device Industry Association (SAMED) represents the interests of 150+ Medical Devices, Medical Equipment and In Vitro Diagnostics companies in South Africa. Established in 1985, the association has grown significantly in recent years and is now recognized as a significant stakeholder in the South African healthcare industry. SAMED is committed to ensuring a sustainable medical device industry in South Africa, to encouraging ethical principles and practices and promoting innovation and better patient outcomes in a responsible manner.

The Medical Device Industry is a relatively young and very diverse industry made up of a few large companies and a large number (~80% of industry) of small- and medium-sized enterprises (SMEs) – over 10,000 worldwide. While often referred to as part of the pharmaceutical or medicines industry – the research, development, testing, marketing, training and use of medical devices, medical equipment and in vitro diagnostics are unique and different to that of the pharmaceutical Industry.

The following are key characteristics of the Medical Device Industry, all of which are very important when looking into the ability of medical device companies to change business models, and to fulfill B-BBEE criteria:

1.1 Products/Innovation

The medical device field encompasses a **very large number (tens of thousands)** and **broad variety of products** ranging from syringes, hospital beds and bandages to implantable pacemakers/defibrillators, prostheses and pumps and human tissue products.

- Products are traditionally based on mechanical, electrical and materials engineering and often designed in cooperation with Healthcare Professionals, including doctors and nurses.
- Continuous innovation and iterative improvements are based on new science, advances in diagnostic and therapeutic and related technologies and available materials.
- Very **short product life cycles and investment recovery** periods — approximately 18-24 months on the market.

1.2 Essential Support Services

- Sustainability in medical device businesses requires **high and ongoing distribution and training costs**, underpinned by a requirement to provide services and maintenance (especially for high tech devices) and to ensure that the legal requirement that sellers and users of devices are appropriately trained on the latest models, are adhered to.
- These services are often an integral part of medical & surgical procedures, so user support, training and education are essential for safe and effective use of products.
- Require a large investment in distribution, and training/education (and retraining) and a requirement to provide service and maintenance of equipment.

2. General comments on the proposed amendments to the Codes

SAMED supports the principles that underpin B-BBEE. The steps to be taken to achieve broader-based economic participation need to be achievable, albeit in an incremental fashion.

The principles described by the DTI include the requirement that B-BBEE aligns itself clearly with government's developmental policies, objectives and the tools/initiatives which have been designed by government to achieve these developmental objectives (such as the National Growth Plan, the Industrial Policy Action Plan and Preferential Procurement regulations). The developmental objectives include specific reference to Skills Development, Job Creation, Localization, Industrialization and Supplier Development.

These initiatives are supported by SAMED. SAMED in particular supports the **expansion of skills development** to include internships and apprenticeships and that these supported individuals do not need to be a measured entity's employee.

It must also be noted that the broader developmental policy objective documents referred to are in some cases much narrower in their objectives and scope than the application thereof in the B-BBEE Codes.

For example, IPAP does not identify the medical devices industry as a potential growth point for local manufacturing (for good reason), and only does so for the limited scope of gloves and syringes, for example. The B-BBEE Codes however now requires of all medical device suppliers to manufacture locally (through the inclusion of imports in the procurement-part of the Codes) and to support the localization of suppliers to it (where such localization has limited possibility and feasibility).

The proposed amendments create the impression that companies are penalized for non-compliance (as opposed to be encouraged to transform) through three different mechanisms, the cumulative effect of which is that companies that have been making steady progress over the past number of years, have to 'start over' with very low or even non-compliant B-BBEE status i.e.:

- For large enterprises a drop in two B-BBEE levels ("discounting") should a sub-minimum of 40% not be achieved in the three core pillars;
- A change in the scorecard points system, leading to another one to two level drop on any company's current B-BBEE status;
- Changes in targets per indicator in various pillars, some being doubled, and the removal of indicators where progress is most achievable in our sector (such as in junior management).

The **increased score required for each B-BBEE recognition level has been set at a required increase in points of between 10- and 25**. Achieving or maintaining *levels 5 or 6* compliance has been made increasingly difficult (20 and 25 *more points* are required), whereas maintaining levels 3, 4 or 7 (15 additional points are required) is easier with lower increases in points required. SAMED believes that companies who have made progress in achieving **level 5 or 6 should not have to achieve proportionally more than those at levels 3 or 4, or those at level 7**.

Limiting procurement to value-added supplier entities penalizes certain industries or sub-sectors over others. Where suppliers to our industry are not **labor-intensive** due to the nature of their businesses, compliance is left to factors totally outside of the control of the measured entity. SAMED strongly suggests that more research is needed in order to ensure that the Codes have a fair application across sectors, and are able to fit more than one type of business.

The amendments may also introduce inefficiencies in a health sector market where all role players are encouraged by the Honorable Minster of Health to ensure that the prices of products are fair and reasonable. SAMED fears that instead of ensuring efficient, productive and pro-competitive companies operating in the health sector, the amendments to the Codes may introduce increased **costly regulatory compliance** and **higher prices** as a result of business shifts in employment and procurement necessitated by the draft amendments.

Some of the challenges for B-BBEE compliance are as a result of **system limitations elsewhere**, such as the number of graduates produced within the fields of relevance to the devices industry and the number of matriculants graduating with appropriate subjects. It should be borne in mind that the medical device industry is highly technical, and it competes, for certain levels of staff, with health establishments[1] from an already acknowledged pool of scarce healthcare-, science- and technical (engineering) skills. For example, only a hand-full of Universities of Technology train **clinical engineers**.

With the latest population report (Census 2011) showing that only 28% of South Africans over the age of 20 are in possession of a grade 12 and only 12.3% have some post-matric higher qualification, the pool of available candidates for which healthcare manufacturers / distributors and healthcare facilities compete, is limited. Research from the Department of Higher Education[2] shows that, in 2010, the graduate output in the fields of Health Professions and Related Clinical Sciences was 2 893 African persons, 503 Coloured and 380 Indian persons. Companies therefore compete with health facilities and others suppliers and service providers in the health sector for this limited pool of scarce skills. When looking at Life- and Physical Sciences, the graduate output was 2 278, 268 and 246 respectively.

A subgroup of graduates in engineering would also be part of the pool of potential persons to skills develop and employ, adding an approximate 500 persons to the potential pool.

SAMED proposes that, in setting targets, the limitations of the existing realities are considered, as well as the limitation of SAMED members to make a difference at this level.

[1] The Department of Health's *Human Resource for Health 2012 – 2016* Policy indicates the severe shortages amongst various groups of healthcare professionals.

[2] University and university of technology awards by race and subject, 1991 and 2010a (actual numbers): degrees Department of Higher Education and Training, www.dhet.gov.za, 20 March 2012.

SAMED has also noted some instances where old Codes provisions are not proposed to be deleted by means of indicating the text in bold and square brackets. One example is the previous management control scorecard which SAMED believes is intended to be deleted. **SAMED proposes** that, once finalized, the new amended Codes be published in their totality, so that a clear and complete picture of requirements would be available.

SAMED also understands that Technical Assistance Guidelines (**TAG**) are to be released sometime soon, and that Codes on Qualifying Small Enterprises and a new Equity Equivalent Programme Statement is also to be released. SAMED urges the DTI to ensure that clarifications are made in the Codes itself and not in the TAG. SAMED members have in the past experienced differences in interpretation (and legal challenges and appeals) these being best avoided by ensuring clarity in the Code texts.

SAMED furthermore is concerned that it is **unable to evaluate the Codes in their entirety**, due to the outstanding elements and uncertainty to some members as to whether they would be QSE's or larger enterprises and what the implications thereof will be.

3. Comments on the amendments proposed to the ownership pillar (Code 100, Statements 100 (shareholding), 102 (sale of asset), 103 (equity equivalents))

3.1 Code 100, Statements 100

SAMED does not support the amendments to the Code in terms of the proposed weighting changes or the 40% sub-minimum, as such change do not facilitate or encourage broad based economic empowerment and will result in companies being down-graded on their scored levels.

SAMED's proposal is to align to the spirit of long-term sustainable development and increase the weighting for skills development. A survey amongst SAMED members shows that the **40% sub-minimum would be difficult to achieve for at least 52.6% of its membership that are not multinationals**. 21% of respondents said they would be able to achieve this, with another 21% of respondents saying they could achieve between 12% and 25.1%, with some commenting that they are already at the 25.1% level.

It would appear that the 40% threshold only applies to the net-value component of the scorecard in this Code. If companies are disincentivised (as the sub minimum in the net acquisition value does) to allow cash flow to go onto black shareholders, structures like charitable trusts that need the cash-flow to pay for projects and donations will not be able to function.

It is understood that the DTI wishes to ensure that black shareholders build value for the longer term at the expense of short term cash flow. This approach impacts on free cash flow for grass-roots development in the case of not-for-profit types of investors. The principle behind a trickle dividend traditionally in BEE deals is to ensure that real economic value flows through to the BEE shareholder in a graduated manner. The calculation of net value is based on the increase (decrease) in the equity interest held by the BEE parties and through the reduction or paying off of the Acquisition Debt. When a Measured Entity structures a transaction it is incentivized to maximize the Net Value created through a combination of offering:

- a BEE discount;
- having as low a funding rate as possible;
- paying out as high a dividend policy as possible, so the BEE party can settle the acquisition debt; and
- limiting any trickle dividends to the BEE party as these funds would have no impact on the Acquisition Debt.

The unintended consequence of this is that employee shareholding schemes will be unable to receive trickle dividends and employees will only get a capital gain, if any, at the end and community trusts will similarly not benefit from any cash flow or trickle.

SAMED proposes that, in the net value formulae the Acquisition Debt is reduced by all trickle dividends paid to the BEE shareholder (accumulated with the same interest as the Acquisition Debt) such that the company is not penalized for accelerating real cash flow to the BEE Shareholder. An added suggestion is that the Acquisition debt could be reduced by a factor of trickle dividends paid, to really encourage BEE shareholders.

3.2 Code 100, Statements 102 and 103

Amendments are only proposed to the shareholding option (Statement 100) in the ownership pillar and not to viz. equity equivalent programmes (EEPs) (current Code Statement 103) and sale of an asset (current Code Statement 102). It appears unfair to require of shareholding to only have to perform up to 40% to get points (i.e. graduation is permitted) and avoid downgrade, whereas in an EEP an entity must perform up to 100% of the target to get points.

Although the DTI has indicated a revision to Codes 100 on Equity Equivalents is imminent, it is difficult to comment on the impact of the ownership pillar on multinationals.

It is **recommended** by SAMED that it should be possible for multinationals to perform up to the level of 40% of the EEP and sale of an asset programme. For EEP's it would mean an annual contribution of 1.6% of turnover or a once-off equivalent to the value of 40% of 25.1% of the value of the local operation. This may also revive interest in sector-wide programmes, which could be impactful in the current health sector.

4. Comments on the management control pillar (new proposed Code 200, Statement 200)

4.1 Gender recognition at Board- and Top Management level [par 2.1 and 2.2 of the scorecard]

In relation to Board and Top Management, it is noted that the adjusted recognition for gender has been removed and replaced with a separate target for black women and black persons. In practical terms, this means that Measured Entities are likely to prefer black women for these two categories over black men, as black women will lead to scores in two of the measurement categories, whereas black men will only lead to a score in one category per measurement level. As this has been a bone of contention in the previous versions of the current Codes, where the unintended consequence is that Measured Entities are likely to prefer black women to the exclusion of black men, this matter may require re-consideration.

The points-split between board/top management (9 points) and senior/middle management (4 points) is large, and does not align with the principle of broad-based empowerment. Increasing the points in the latter category will incentivize companies to focus primarily on those categories.

4.2 Mirroring racial and gender demographics as per the Economically Active Population [par 2.3 and 2.4 of the scorecard and Annexe 200B]

The proportional split required in the Middle Management category (par 2.4) introduces significant calculation difficulties to employers who do not have **large contingents of middle managers**. To not lose any points, a Measured Entity must employ at least one Indian female. The ratios as per the Economically Active Population (EAP), as per the 2012 Commission for Employment Equity Report, is:

BM 40 : BF 34 : CM 6 : CF 5 : IM 2 : IF 1

This means that to achieve full points and a truly equitable representation, an employer must have at least 88 employees at senior and middle management.

The SAMED survey shows that most companies' (60% of respondents) middle management is between 0 and 10 employees, with 25% having middle-management of between 11 and 20 persons. A small minority of respondents (6%) have middle managements of from 31 to over 50 employees.

To calculate the senior management ratios under paragraph (2.3.1), the following ratio's will have to be achieved: 26 : 4 : 1, which means a senior management of at least 31 employees. The SAMED survey shows that most companies have senior management of between 1 and 10 employees.

Using this mechanism also means that the **current inequity in society** where males are more economically active than **females** is carried through into these calculations, whereas the previous adjusted recognition for gender set the target at equal representation (at least 50% to be females). The EAP has gender levels of below 50%. Regionally based companies may also be prejudiced if national EAP figures are used to determine racial and gender demographics.

It is inconsistent that for top management and board, special recognition is given to females, whereas for senior and middle management the effects of gender inequity in employment figures as per the economically active population is set as the standard, which, for example, for all racial groups means that a representation of more men than women is required. This could not have been the intention of the Codes.

SAMED recommends that Senior and Middle Management ratios be set that are realistic in relation to the size of a Measured Entity's management levels with no penalty in points should the requisite racial composition work out to less than a full person. It is also proposed that, as far as gender is concerned, a balance of 50 – 50 be set, rather than that of the EAP gender split of less than 50% for females.

The number of points to be scored for Senior- and Middle Management are relatively low, and the proposed amendments may have the opposite effect to that intended, i.e. Measured Entities may decide that the achievement of an exact split per racial group (for senior management) and per racial and gender group for Middle Management of 1, 1 and 2 points respectively, is a disincentive and not worth the effort required to achieve such exact splits. Furthermore the proposed configuration of 9 points for Black board and top management appointments and 4 points for senior and middle management downplays the importance of employment equity.

The SAMED survey shows that for 70% of respondents, the targets for board, executive and top management is not achievable within the next five years. 8.6% of respondents can achieve the targets immediately and 20% would only achieve them over a number of years. Reasons given for this includes the "relatively flat structure" of companies, "low employment numbers", "multinational limited options", etc.

In the end, the behavior encouraged and the objectives are not aligned.

SAMED proposes higher points to be allocated to the management control and employment equity measurement categories in order to ensure incentive and reward compliance.

SAMED also **proposes** that a statement be inserted in Annexure 200B relating to "Calculating Compliance" under the formula for the calculation that, "*should a Measured Entity have staff levels below those required by the EAP to ensure full compliance of all racial- and/or gender groups than, as the case may be, be required to achieve overall compliance with the target across all racial groups that constitute black persons (i.e. fewer than 40 senior managers and fewer than 88 middle managers), provided that all racial groups are represented*".

The removal of junior management from the scorecard may also have a negative impact on the achievement of targets in middle- and senior management and **SAMED proposes** that it be re-included in this pillar.

4.3 Linking the EEA with the B-BBEE Codes on employment equity [par 3.4 Code 000]

The proposed new par 3.4 in Code 000, Statement 000 states that employers with less than 50 staff are not required to submit EE Reports and such measured entities could apply the QSE scorecard on management control and employment equity. However, this statement is not in line with the provisions of the Employment Equity Act (EEA) that defines designated employers not only as those with more than 50 employees, but also those with less than 50 employees but with turnovers above those listed in Schedule 4 to the Act. Therefore, in certain cases where turnovers exceed those stipulated in the Act, an employer must still comply with the affirmative action provisions in the EEA and it would be improper for the draft B-BBEE Codes to suggest otherwise.

SAMED recommends that the provision be changed to read as follows [our proposed amendments in italics]:

"The requirement to submit data … is only applicable to designated employers who employ 50 or more employees*, or, when employing less employees, whose turnovers exceed those stipulated in schedule 4 to the Employment Equity Act*. Therefore, despite 3.2.3, Measured Entities employing fewer than 50 employees *and who fall below the threshold levels stipulated in the Employment Equity Act will have the option* …". This means that Measured Entities with employee numbers below 50 and within the EEA threshold cannot be exempted as is stipulated in the current draft 3.5 of Code 000, Statement 000.

5. Comments on the skills development pillar [New Draft Code 300, Statement 300]

SAMED supports the emphasis on skills development in the draft amendments. There are however some structural concerns which may have the opposite effect than actually leading to increased skills development, and which may divert from the necessity of growing competence in the medical device field, as the requirements are generic and not suited to the way in which medical device companies operate, and have to operate in relation to skills development. Consideration must be had for the fact that because of the highly technical nature of the field, matriculants, but mostly graduates, are at the least level of having the potential to work in the industry. Hence the success of skills development depends on graduate outputs from universities (see our comment above on the DHET data), once there is sufficient output, industry-specific skills developments could quite quickly grow a pool of technical skills in this field.

SAMED welcomes the broader definition of learnerships and introducing apprenticeships and internships. The draft amendments to the Codes extend skills development to include unemployed people. Although there are reportedly[3] some 600 000 unemployed graduates in South Africa, research on learnerships and skills development shows that SAMED members and pharmaceutical company's members require employees with degrees in science and healthcare backgrounds. It is reported that "professionals such as accountants, lawyers, medical doctors and **engineers** enjoy the **lowest unemployment rates, at 0.4%**. Holders of degrees including BCom (commerce), BSc (**science**) and BCompt (accounting science) also have a **very low unemployment rate, at 3.1%**". This means that the pool from which SAMED members would draw skills development beneficaries are reduced. Secondly, the possibility to undertake certain types of skills development and learnership / internship / apprenticeship programmes are limited by statutory criteria relating to where such persons can achieve the practical part of their qualifications, e.g. in a public health sector facility and not in a private sector medical device business.

5.1 The target for skills spend [par 2.1.1.1.]

The SAMED survey found that it would be **unlikely for the majority** of its members to achieve the target of **6% of payroll** being spent on skills development in the racial and gender demographic profiles as outlined above, in the near future. 43% of respondents stated that they would not even be able to make the sub-target of 2.4% of payroll on skills spend. The reasons for this include

- Significant and often compulsory training is completed at a global / international level;

[3] http://www.citypress.co.za/SouthAfrica/News/Young-jobless-and-desperate-Degrees-with-no-guarantees-20120616.

- Insufficient number of Black employees;
- High payroll costs to retain employees with scarce skills in this sector, and need to keep costs down to justify continued investment in SA and enough return on investment / profit.

SAMED recommends that, if the 6% target is to be kept, consideration should be had for skills development undertaken by companies in other workplaces that also enhance the health sector, such as training of Black nursing professionals in both the public and private sectors, training Black medical practitioners on the use of technologies, assisting the processing of imparting that knowledge and skills to others, etc., provided that recognition is given for the short-course nature of this type of training.

The deletion of categories F and G of the Learning Programme Matrix takes away recognition for critical types of training. As companies are obliged to make sure that training on products, the affected disease entities and aspects such as the health economics of a product is internationally standardized, companies will continue to have to do this, but with no recognition as to the contribution that this makes to skills development. Likewise mentoring and coaching now falls outside of the allowable skills development spend, even though these interventions are often an integral part of implantation of employment equity and skills development. **SAMED recommends** that categories F and G be reinstated in the Matrix and that salaries spent on the beneficiaries be allowed and recognized as part of the target spend.

In addition it is **proposed** that if the 6% target is to be kept, the 1% leviable amount paid is included into the calculation and that the achievement be graduated over time with sub-targets being set for the first three or five years.

5.2 Pivotal Report [par 3.1.1]

This requirement effectively means that employers have to embark on learnerships for unemployed persons. As pointed out above, the **relatively low unemployment figures in the fields** from which SAMED members draw its employees, and the legislative/regulatory limitations on the places where such programmes can take place (mostly in public health facilities) makes this a hard target to achieve.

Furthermore, the regulations that would govern this were published in draft format in Government Gazette No 34932 of 12 January 2012 and appear to have not been finalized. Commenting on this being made a criterion for skills development, in the absence of finalization, is difficult.

5.3 Informal training and workplace-based formalized, but unaccredited training [Annexe 300A]

The removal of the recognition of informal and internal or work-integrated learning or training is extremely detrimental to the medical devices industry (as previously found in parts F and G f the Learning Matrix in the Codes].

Due to the unique character of medical devices, even if they fall within a larger group of similar devices, training and familiarity with the devices, and ensuring appropriate use by healthcare professionals and patients (where applicable) is critical. This, together with the legal liability faced by medical devices companies under the Consumer Protection Act necessitates significant in-house training relating to product and procedures. This training cannot be provided by third party training institutions and constitutes more than half of all members' training activities for the vast majority (60%) of SAMED respondent members. A further 14% of respondents' stated that internal/informal training constitute between 26 and 50% of all training. Internal assessment almost always follows such events, but is not accredited by South African entities and are not independently assessed. International training courses cannot be accredited locally and to attempt to do so for the multitude of training events taking place overseas would be practically impossible.

For 60% of SAMED respondents, **the possibility to obtain recognition in BB BEE terms for its training are limited by at least 50%**!

In an industry-wide survey on skills requirements, medical device and pharmaceutical companies indicated that in-house training is by far the most important type of training for its staff.

SAMED therefore proposes that internal training be recognized on the Learning Matrix under category E, and that the requirement of formal assessment by an accredited body as a necessity, be removed. This is because there is no accredited body and no accredited providers, with companies being totally dependent on SETA's, and the SAQA system, before they can comply.

SAMED proposes that assessment records be available to verification agencies to show compliance with category E-type work-integrated learning events. Even if accreditation were possible, the current lack of SETA-accredited training and the fact that training is specialized and product-specific are highlighted in the SAMED survey.

5.4 Short courses [Annexe 300A]

The health sector has a system of well-developed continued professional development (CPD). **CPD events**, as well as other short course training does not fall within the scope of the learning matrix, but makes a significant difference to the skills development in the sector and, more importantly to patient outcomes, cost-savings, less stay in hospital, less rework, reduction in hospital acquired infections, reduction in adverse events and inappropriate use, etc. The rate of technological change in the device field also necessitates constant up-skilling in the use of medical devices. It would be impossible to accredit all such training events, other than CPD accreditation (which would only apply to healthcare professionals registered at the HPCSA) and which, in itself, does not lead to a qualification and therefore would in any event not be recognized under the Matrix.

SAMED proposes that such short courses be inserted into the skills development matrix, and that recognition be provided not only for own staff training, but also for training of others in the health- and medical device sector in order to ensure a broader-based recognition of skills in the field.

5.5 Following the EAP demographics [par 2.2]

As the exact race- and gender demographics have to be followed in this pillar as well, any negative performance under management control will have a knock-on effect into a company's skills development performance. This means that even if the Measured Entity achieves the overall target, but there is no EAP equity achieved in the employment figures, it is not possible to achieve full recognition and points.

5.6 Learnerships, apprenticeships and internships

SAMED welcomes the expansion of the learnership measurement category to also include internships and apprenticeships. It also understands the rationale of requiring half of those to be from previously unemployed persons. Apart from the availability of unemployed graduates, the definition of "unemployed" should be clarified.

In the medical device & diagnostics sector it is critical that medical practitioners and other users of devices (technologists, clinical engineers, perfusionists, etc.) develop the skills and experience to operate and use medical devices and equipment. In many instances a professional will gain such experience overseas by means of **short-course training**, and on his return positively impact the skills and knowledge in South Africa by training and coaching others.

Although this would typically be an apprenticeship, fellowship or an internship, this would not be recognized under the Codes as it does not from part of any formal qualification. It is, however, critical skills development activity upon which many healthcare professionals have extended their competence and expertise in the past, and therefore falls within the ambit of what the Codes aim to achieve.

SAMED recommends that such training be recognized as a form of apprenticeship.

There is a significant issue in relation to the **accreditation of training providers** and the existence of appropriate and **accredited learnerships** (and apprenticeships and internships) for the employees of our members. Most of the SAMED respondents (53%) currently do not have any learnership programmes. The main reason for this, as recorded by respondents is the absence of SETA accredited learnerships, followed by lack of headcount, lack of skills and the nature of the business (niche market).

In a different survey in which SAMED participated with various other companies (pharmaceuticals) the lack of appropriate learnerships was identified as a challenge for 60% of respondents, and the absence of accreditation by 45% of the respondents.

It is important to note that **general sales and marketing learnerships are not appropriate for the medical device sector**. The fast-moving consumer goods (FMCG) sector, to which most of the learnerships are tailored, differs vastly from the medical device sector, where the sale is not made directly to the consumer, and where intermediaries such as hospitals and various healthcare professionals as prescribers, procurers, operators and users are involved. The fact that patients' lives and health are at stake also means that marketing has to take place within frameworks of ethics, risk management/mitigation and responsibility. Promotional activities have to take place within internal frameworks for medical device post-marketing requirements. Promotional activities aim to achieve responsible risk management, and not to merely make a sale.

Although there are some more generic learnerships, the heart of a medical device business is not sales and marketing per se, but the sales and marketing of medical devices. Most importantly, this sales and marketing function is subject to global rules relating to the manner in which products may be marketed, claims that might be made in relation to it, strict provisions relating to post-marketing surveillance and various standards- and competency-based criteria relating to the product, its users and the sales force. This also makes the fit for the overarching statements as to the **general principles** applicable to this Code, viz. "value added manufacturing" and "labour intensive industries" **not easily aligned with the medical devices sector** and the manner in which it operates.

The definition of learnership as found in the amendments state that a learnership must lead to a **qualification**. Such a qualification would depend on all the hurdles outlined above being addressed and no qualifications exist for medical device staff (or are likely to exist in future, bearing in mind the large numbers- and ranges/types of products that make up the industry). This is unlikely to be achieved by the time the amended codes come into operation.

It is unlikely that medical device learnerships would be in place in the immediate future. The situation for medical device companies and possible learnerships that might be relevant at the various SETA's are even more dire.

This means that, unless the various SETA's where our members are registered ensure that there are relevant learnerships, internships and apprenticeships, our members are unable to comply with this requirement. The bureaucracy associated with the development of unit standards that have to be approved by SAQA, which includes a process of Quality Assurance by a recognized quality assurance body, and on which SETA's base their learnerships and the subsequent accreditation thereof is non-productive and a major obstacle.

SAMED proposes that learnerships where the academic contents are being managed by a locally or internationally accredited provider of training should suffice, irrespective of whether it leads to a qualification or not or irrespective of whether the course itself aligns with the SAQA system.

In general, there appear to be discrepancies between the definitions of "learnership", "internship" and "apprenticeship" and the descriptions in the new proposed Learning Programme Matrix. For example, a learnership on the Matrix has to be "formally assessed by a statutory occupational or professional body" leading to "registration or licensing". A qualification, as per the definition of a learnership does not in the devices field necessarily imply *registration or licensing*. An internship on the Matrix should result in a degree, diploma or certificate. However, in practice, many internships follow on (and not only precede) a degree, diploma or certificate and are regarded as a pre-condition for practicing a profession. However, as the bulk of staff in medical device companies do not have to be professionals and/or if they are professionals, they would have had to achieve their internship qualification at a public health facility, or an accredited engineering entity. This **limited interpretation of internship and learnership limits the potential of companies to contribute to this important category in the scorecard**.

As far as internships and apprenticeships are concerned, opportunities are limited due to the lack of accredited learnerships in this field; the difficulties relating to SETA accreditation where the needs of our industry are not understood, **skilled labour is needed instantly**, and a lack of suitable candidates with life sciences qualifications. It is also noteworthy that the majority of surveyed members (48.57%) felt that they would only be able to **absorb less than half of their learners, interns, etc**. 34.28% could not say, as that would depend on whether they would have headcount to do so. Only 14.28% felt they would be able to absorb all learners.

The reasons for this relates to limited value and volume growth in a sluggish market that makes it difficult to justify additional employees and additional costs. Investment into Sub-Saharan Africa, rather than South Africa is more attractive, where the commercial environment is conducive to growth and not punitive as proposed in the draft Codes.

SAMED proposes that its members not be penalized for the above-mentioned difficulties and that carefully designed and assessed learnerships, internships and apprenticeships undertaken by an accredited training provider (whether accredited by a professional body, a SETA or an entity recognized by the CHE or any other recognized quality assurance body, including bodies accredited overseas) be recognized for B-BBEE points. Short courses should be recognized and count, as these are a critical element of medical device training.

The matrix does not provide for learning that might be acquired outside of these programmes, and which would be recognized under a system of Recognition of Prior Learning.

6. Comments on the supplier development pillar [New Draft Code 400, Statement 400]

6.1. Inclusion of imported content [deletion of previous paragraph 6.6 of Code 400]

The majority of the South African Medical Device Industry, whether they are multinationals or importers, **procure the products required for an efficient healthcare sector, from overseas markets**. It is virtually impossible for South Africa, given the vast range and extent of medical devices (as outlined above under point 2), to ensure local production of even a significant number of items. There are literally thousands of medical devices ranging from large pieces of capital equipment, measurement equipment, implants, diagnostic tests, consumables, disposables, etc. In many cases volumes sold in South Africa are low, albeit that the device is necessary in the health sector. The SAMED survey shows that **more than 68% of respondents** (multinationals and local companies) **distribute exclusively international products**, and another 25.7% distribute both local and international products.

Both multinational and local importers have to adhere to strict global supply chain targets in order to ensure global consistent quality standards, and as a result of international trade agreements between countries. Coupled with the small size of the South African market, unrealistic labour market expectations, skills levels suitable for the device industry, productivity and the impact of the economic downturn (lower than expected growth) makes it unlikely that South Africa would become a manufacturing hub for medical devices. **SAMED believes** that what South Africa has in terms of a viable device industry should be enhanced, and lead to greater reward than an exclusive focus on local manufacturing of devices.

The inclusion of imported content in this part of the scorecard will be extremely detrimental to the more than 68% of SAMED respondent companies, with **over 30% of respondents importing more than 80% of its products, and another 42.85% importing between 61 and 80%**. It would be impossible to achieve the procurement targets at all if imports are to be included. Only 25.7% of companies have less than 25% of its procurement as “imports”.

Hence the criterion that products have to be locally manufactured have a detrimental impact on not only multinational companies, but **also on all local distributors of medical devices and on local companies who import finished goods or components of finished goods**. These goods are essential for the provision of healthcare services in South Africa, and the exclusion of product from the market by means of the operation of this Code is not only detrimental to local and foreign investment, but affects the rights of access to healthcare of patients. It also results in a reduction in choice and competition.

It must be noted that medical device companies must comply with **stringent regulatory processes globally**, which applies in the absence of local device regulations for all products (some products, such as electro-medical devices are subject to the control of the Radiation Control unit in the National Department of Health). Unless these frameworks are in existence, the future of an, albeit limited, local manufacturing sector for medical devices is not promising.

Most of these imported products are required in the health sector, and many appear on the Department of Health’s Essential Equipment List.

SAMED proposes that paragraph 6.6 remains as it was in the previous Codes, and proposes that a mechanism be introduced to incentivise increased local value add- and/or local production *where possible*. Requiring of measured entities the near-impossible will not lead to the achievement of industrial development or to economic growth. However, incentivizing compliance over time could achieve meaningful changes. It should also be noted that the B-BBEE system goes far beyond IPAP and other government programmes. If certain changes are not possible in such policy frameworks – how would it be achievable within the BEE framework?

6.2 Value-added suppliers [paragraphs 2.1.1, 2.1.2 and 2.1.3 of the new Draft Code]

SAMED's survey shows that **only 28% of respondents have 11 to 20 Value Added Suppliers (VAS)** from which BEE points can currently be scored. This is because of the fact that the suppliers to device companies are often knowledge-based, and not employment-rich workplaces. The definition of VAS's and the limitation that only procurement from such entities will count, severely limits the benefits of B-BBEE compliance, and may produce the opposite effect – why would an entity aim to achieve a good B-BBEE score if it is impossible for such an entity to become a VAS?

SAMED proposes a rethink on the definition of a VAS for non-labour intensive sectors or types of suppliers, and that not only VAS-procurement count towards a Measured Entity's B-BBEE score.

An unintended consequence of the proposed amendment is that a B-BBEE contributor at a level 3, but who is not a VAS, will not get preference or any recognition over a VAS that is a level 5, or a level 6. Hence this single criterion, i.e. VAS, overrides the B-BBEE Codes in its totality. It could also have grave repercussions if health facilities do not procure from entities due to such entity not being a VAS, which could lead to a lessening in competition or even the unavailability of certain medical devices in the health sector.

SAMED recommends that rather than dropping non-value adding enterprises altogether out of the BEE system, that **the spend with value adding enterprises be marked up 1.5 times as an incentive**. This will encourage the move to value adding in a positive way and the targets could be adjusted accordingly so that the momentum in this process is retained.

6.3 Supplier development [definitions and paragraphs 2.2.1 and 2.2.2 of the new Code]

SAMED is of the view that **limiting qualifying transactions** to the above types of businesses will unduly limit potential progress that could be made in enterprises not 50% empowered, but which could make a difference to industrial development and employment.

Thus instituting a narrow-based criterion of ownership only, could limit potential contributions to broad-based BEE.

SAMED proposes that supplier development be measured against the entity's overall B-BBEE status, and not be limited to ownership only and a combination of B-BEE compliance and turnover of the beneficiary entity could for example be used.

The objective of enterprise development is to drive job creation as SMMEs are strong catalysts in this regard. Restrictions on black ownership would reduce the pool of SMMEs that could be developed. SAMED members in the survey stated that it found **supplier development impossible (38%)**, not possible due to not enough qualifying suppliers (14.7%) and that most of the suppliers supply services, and not goods (excluding imports) (29%). Only 14.7% of respondents felt it was possible, but with serious effort. In terms of the suppliers that would qualify for enterprise development, **most companies only have 1 to 5 suppliers that are 50% black-owned**.

Furthermore, developing suppliers in rural and under-developed areas would not assist the nature of the business of the medical devices industry. In addition, no definition of "youth" is provided. An unintended consequence of the draft amendments may be that entities currently being supported by Measured Entities may lose such support. It is proposed that a study be undertaken as to the nature and extent of enterprise development contributions, so as to avoid or limit the impact of withdrawn contributions.

Exactly how an entity is to be supported, in particular the suppliers that are important to the device industry in South Africa and which are mostly-knowledge, and not product-based, **to become more "local" is unclear**.

SAMED members are of the view that the specific requirements relating to supplier development are unnecessarily onerous. It can also be disempowering as the measured entity may be "taking over" from the beneficiary entity, instead of providing empowering assistance.

7. Comments on the socio-economic development pillar [New Draft Code 500, Statement 500]

SAMED supports the withdrawal of the proposed amendments and that this Code will revert to its previous (current) version.

8. Comments on compliance required from QSE's

Many of SAMED's members are QSE's, as they distribute medical devices on behalf of principals in various other countries in the South African market. Such QSE's have to now comply with not only four of the seven pillars as was the case previously, but to all 5 pillars. This is a significant increase in the required levels of performance. However, for QSE entities (R35m to R50m) who previously had to comply with the generic scorecard, the lower targets of all new, still unknown 5 QSE pillars would be advantageous as compliance would now be easier, whereas for smaller QSE's would face an increased burden. Although an unintended consequence, consideration may need to be given to the creation of two levels of QSE's to prevent smaller, and more vulnerable QSE's from being penalized due to their size, and facing unfair competition from a number of businesses who previously faced more onerous compliance criteria.

The SAMED survey shows that amongst its QSE respondents, 57% found it difficult to comply with B-BBEE. 43% finds it easy, but they are uncertain as to how it will be in future, due to the lack of details as to how the new QSE Codes would look.

SAMED urges the speedy release of the envisaged system for QSE's as it is difficult to formulate a view on the impact on QSE's if the nature of the amendments are not known. This release will also affect existing companies required to comply with the complete scorecard – comments for such companies would entail an assessment of both systems, which at this point in time is impossible.

9. Conclusion

SAMED supports the overall economic transformational objectives of B-BBEE. Compliance requires a balance between push and pull criteria. The amendments combine a number of push criteria, with very few pull criteria that recognize existing contributions that can be increased and enhanced. The risk is that the Codes may achieve the opposite, i.e. lead to companies "not even trying" due to the unachievable targets in the short- to medium term. In the Codes there must be a sufficient number of categories where achievement is at least, in part, achievable.

Unfortunately for SAMED members the bulk of the targets and criteria makes achievement in ownership, skills development and supplier development near impossible. This means that instead of achieving transformation, the targets and criteria are such that no progress would be possible within the foreseeable future.

Other African countries are increasingly competing with South Africa for foreign direct investment. Any investments directed away from South Africa will also be detrimental to the health sector, where the scale is not necessarily of such an extent that it would merit local manufacturing, but the products might be needed as much as mass-produced products.

In this regard, The 2012 UNCTAD World Investment Report (page 9 - Overview) notes that –

"Comparing the FDI Attraction Index with another UNCTAD index, the FDI Potential Index, shows that a number of developing and transition economies have managed to attract more FDI than expected, including Albania, Cambodia, Madagascar and Mongolia. Others have received less FDI than could be expected based on economic determinants, including Argentina, the Philippines, Slovenia and South Africa."

SAMED will gladly engage the DTI's BEE Unit on any of the issues raised in this submission. Its Health Policy Committee, under the leadership of one of its Board members, and with the participation of others, is eager to contribute to the development of conditions that facilitate economic transformation, that rewards progress made towards the achievement of this objective, whilst ensuring that access to medical devices, as a prerequisite of healthcare delivery, is sustained and enhanced.

- End -