

INPUT BY
THE INNOVATIVE PHARMACEUTICAL ASSOCIATION OF SOUTH AFRICA (IPASA)
ON
THE PROPOSED AMENDMENTS TO THE BROAD-BASED BLACK-ECONOMIC EMPOWERMENT
CODES (BBBEE CODES),

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1. Introduction

The Innovative Pharmaceutical association South Africa (IPASA) was established in April 2013. IPASA was formed from a desire for a credible, respected association to engage with stakeholders in both the private and public sectors. IPASA comprises of 26 research-based pharmaceutical companies and aims to be an association that focuses on building an environment for sustainable access to innovative research-based healthcare.

IPASA thanks the Department of Trade and Industry (the DTI) for this opportunity. It has noted that the DTI has been responsive to the contributions of many stakeholders, and the fact that these are incorporated into the proposals. IPASA applauds the responsiveness of the DTI to the business sector.

IPASA understands and supports the constitutional imperatives of ensuring the achievement of equality, and the importance of doing so within the context of realizing access to healthcare rights for all.

2. General comments

Request for meeting

IPASA would welcome the opportunity to meet with the DTI on the implementation of the BBBEE Codes within the multinational, innovative pharmaceutical industry. Issues such as the recognition of transformational initiatives, the possibility of equity equivalents and industry-wide projects, as well as the specific areas within which the industry believes it has the strengths to participate in the building of a knowledge-based economy.

The innovative pharmaceutical value-chain

As a background to the inputs made in this comment, IPASA wishes to highlight the importance of its value chain, which is different from the value-chain of other industries, and different from the generics industry. In terms of the value chain of the innovative pharmaceutical industry, a large portion of its contribution to the South African economy lies in the fields of skills development and research & development, which is different to the value chain of the generics industry.

Most importantly, the overarching principles that should guide all interventions and policies affecting the health sector, is the right of access to healthcare. The focus of BBBEE should therefore support and enhance access to healthcare. Innovative pharmaceuticals are developing into a sector where specialized, and in some cases, personalised-, pharmaceutical care will be rendered. Unmet medical needs, including cases where conventional- or other therapies have failed, or caused adverse events, are, and will increasingly, be addressed through such specialized medicines.

Regulatory impact assessment and the cost of compliance

The cost of compliance with the BBBEE Codes, NIPP and the likes amounts to opportunity cost surrendered. There lies a need for a proficient and systematic assessment of the proposed Youth Employment Scheme (“YES”) – most importantly in light of the impact this may have on multinationals and the consequences thereof. A RIA would be the best mechanism in order to evaluate the impact of implementing the scheme – most significantly towards meeting the states aim of NDP objectives, broad industrial policy as well as an alignment with international practices immersed in human rights.

The RIA should be used as a testing mechanism so as to evaluate projected outcomes and consequences of the proposed Policy, thus showcasing a more realistic and transparent picture in how the overall aims of the state will be met.

We respectfully submit that the RIA process will enable a transparent view on:

- The full impact of proposals;
- Alternative options to meeting overarching objectives;
- A clearer assessment of options (regulatory and non-regulatory);
- Meaningful consultation meeting broad range of stakeholders;
- The achievement of benefits and whether this surpasses costs incurred;
- Determination of whether there are certain sectors disproportionately affected;
- If proposed measures will meet objectives of the government.

Further, a key concern remains the **impact of the cost compliance with the Codes** over and above compliance with other regulatory and policy criteria. For example, compliance with the National Industrial Participation Programme (NIPP), as well as the costs of ensuring a good BBBEE score (i.e. additional contributions to skills development, the cost of a local value-add programme, etc.) and the cost of sub-contracting and developing EME and QSE sub-contractors (in addition to the supplier development programme), is significant. It is therefore recommended that the BBBEE system be subjected to a regulatory- and cost impact assessment, seen in the context of other regulatory and compliance costs.

Ownership and its alternatives

For multinational entities, whose inability to sell shares locally, has been recognized in Statements 102 and 103, as issued under the previous versions of the Codes (2007), being able to effect maximum compliance with the Code, and thereby the BBBEE Act, is important, not only from a legislative point of view, but also in showing its commitment to transformation.

IPASA therefore proposes that these two codes also be reviewed, and that alternatives be explored, in order to leverage the strengths of the innovative pharmaceutical industry, and the contributions it can make through its current value chain.

Alignment: with other regulatory frameworks and by rating agencies

There are two forms of alignment which should occur within the context of the BBBEE Codes, namely alignment with existing regulatory framework, as was done with the proposed amendment to recognize compliance with the EE Act; and, secondly, consistency and therefore internal alignment of roleplayers (such as rating agencies) within the BBBEE system.

In terms of the first, IPASA wishes to stress that there are health-sector specific initiatives and critical skills development initiatives, such as the PHEF and the continued professional development systems as developed and accredited under the auspices of the Health Professions Council of South Africa (HPCSA), or the South African Pharmacy Council (SAPC). If these bodies recognise training and accredit it, rating agencies should also recognize such under the category E of the skills matrix. A key challenge faced by all in the health sector, is the absence of a category E – type framework from the SA Nursing Council (SANC). Nurse training, and skills development, and in particular specialized skills, such as in theatre, ICU, and areas such as wound care, stomatherapy, etc. are not formally recognized, due to the absence of such a system of recognition by the SANC.

There should be adequate flexibility in the recognition of skills development contributions which should recognise contributions that are compliant in substance, even if not formalised, due to the absence of a regulatory framework or regulatory action. Another example of this is the various global and overseas training events, which are recognized within such systems, but not locally.

A further example of the lack of regulatory alignment is where the Preferential Procurement regulations, 2017, require sub-contracting to EMR's and QSE's, whereas such subcontracting is prohibited by section 22H of the Medicines and Related Substances Act. The amended Codes proposes streamlining and simplifications for these beneficiaries of BBBEE, however, non-alignment with the Medicines Act pose a challenge to successfully implement such sub-contracting to entities that will be better recognized under the proposed amended Codes.

The way in which rating agencies interpret and apply the Codes differ, in some cases even within a specific rating agency. Pertaining to the above, for example, in the field of skills development, some rating agencies have recognized the contribution of pharmaceutical companies (with other health-sector roleplayers) to the Public Health Enhancement Fund (PHEF), but others have not. IPASA believes that in giving effect to the constitutional principle of equal benefit and protection of the law, rating agencies should apply the codes similarly in similarly situations, but also show flexibility and adherence to substance over form, in assessing whether an aspect or project indeed assist in achieving transformational aims, or not.

3. Input on the Codes up for comment

3.1. General Code (Statement 000)

Ownership

As the new Codes did not include an updated version of Statement 102 or 103, the way in which the concept of priority pillars would manifest in the application of these codes are not clear. As at least 40% compliance is required in order to prevent the one-level drop, a compliance target of at least 1.4% of the target of 4% of turnover for an Equity Equivalents programme would be required.

It is understandable that all entities with a black ownership received added recognition. However, IPASA believes that there should be transparency in such entities' performance in the other BBBEE pillars, and that this goes against the broad-based nature of BEE, as is required by the BBBEE Act.

The Youth Employment Service (YES)

The members of IPASA looked forward to participate in the YES. The exclusion of IPASA members from participation in the programme on the basis of the criteria listed in par 11.2.1.1. Although it might be possible to participate under the alternative "50% across the three priority elements" – the weighting and exact calculation is not clear. The second condition is a 100% performance on the bursary-allocation under the Skills Development Statement (par 2.1.1.2 therein).

IPASA proposes that, in view of the impact of the YES programme on youth unemployment, no entity be excluded from participation, and that the recognition system be refined in order to categorise participations. For example, an entity that is unable to sell shares, could off-set that with the YES programme, i.e. not face a level downgrade, but also not face a level upgrade.

The targets for the YES is also steep, and IPASA members fear that instead of contributing, entities may have to decide, due to the cost of the programme, to not participate. IPASA proposes that an incremental programme, with corresponding incremental stages of recognition, be considered, so as to prevent an "all or nothing" approach to the YES.

It is common cause that multinational innovative pharmaceutical companies are not set to grown employment numbers ('head count") and that there is increasing pressure, to all affiliates, to not increase head count. This however does not mean that the YES, or skills development contributions do not yield results. Skills and experience, over and above the basic qualification required, is an important component of entering the industry, or on starting a new business. These could be in the fields of regulatory services, research and development (CROs), out-sourced sales and marketing, opportunities for sub-contractors in the state tender system under the new Preferential Procurement Regulations, and so forth.

In IPASA's view the opportunities created for individuals through YES, or the skills development pillar, even if where the company is unable to absorb such staff, should be recognized. The creation and supporting of skills development in itself addresses the deficit effect that concerns the industry and the health sector at large. The impact of a skilled, experienced workforce in the larger healthcare sector in the end benefits patients, and has an impact on care, and access to healthcare.

IPASA proposes that, instead of setting the target for the YES as the highest of the three options set out in par 11.3.2, it be set at the lowest of the three options (or at the choice of the measured entity), with a possible variation in recognition under the BBBEE system per chosen target.

IPASA also proposes that its members would, in certain fields, be able to impart the necessary skills for certain types of work, e.g. a Quality Assurance position, within 6 months, and could potentially assist two persons over a 12-month period, and that this should be an option. This would, of course, be in line with the principle that there is no compromise in the actual content and learning outcomes to be achieved.

IPASA welcomes the increased level of recognition of contributions under categories F and G on the skills matrix. IPASA wishes to emphasize that in many respects, the skills and experience gained, and to be gained, may not yet, or may never, be recognized under the South African qualifications framework, although such skills may be necessary and/or advantageous in order to fulfil a particular function successfully and/or may provide a participant with a market advantage.

3.2. Skills Development (Statement 300)

IPASA welcomes the split of general skills development into general, and bursaries, and the increased point allocation for that part of the skills development scorecard. It also welcomes and supports the increase in recognition of spend in categories F and G, and wishes to also here note the limitations faced by the industry in terms of the absence of recognition of skills development obtained overseas, or in sub-fields not included in any of the current SAQA frameworks, such as, for example, that set out above in the research field, and the absence of a continued professional development system under the SANC and the Nursing Act, 2005.

The measurement of skills development per race group (as it is under the employment equity part of management control – Statement 200) remains a challenge, mathematically:

- Unless the workplace is at least 93 to a 100 strong, a company would never be able to score full marks, even if it has filled, and accordingly train – all staff within the correct proportions. To get to at least 1.2 Indian females (the smallest group to be represented) being recipients of skills development, there must be exactly 35.7 African females also receiving skills development, and 5.4 (or 5.5, or 6, depending on rounding off) Coloured females, etc. For smaller workplaces, which includes the majority of IPASA members, it becomes impossible to, even if the best efforts are undertaken, to score full marks under skills development.
- Rounding off, i.e. to get to 2 Indian male persons, instead of 1.9, means that a position is taken in its totality from another BBBEE category, or that points will be lost due to the downward rounding off in the case of coloured males or females.

Because portions of staff have to work in various provinces, and as the provincial EAP influence staff components in those provinces, coupled with sales potential per province, full compliance is never mathematically possible, even if maximum mathematical representation is achieved.

4. Other areas

IPASA wishes to raise the following other issues in relation to the BBBEE Codes, which is an opportunity posed by this amendment opportunity:

- The review of the Equity Equivalent and Sale of Asset Statements, which have not been updated since the 2007 version of the BBBEE Codes.
- The recognition of training undertaken overseas, if such training is, in such other jurisdiction, recognised, and proof thereof can be provided in order to set such training as equivalent to a category of training on the skills development matrix locally.
- Ensuring that where there are blockages at SETA to SETA level, companies who have embarked on learnerships and other skills development projects, are not disadvantaged due to the lack of progress in one SETA recognising the activities of the other on, for example, learnerships.
- Ensuring that recognition is provided for continued professional development belonging in category E, but for which a regulatory framework have not yet been implemented by the relevant statutory body, providing that such training are indeed bona fide and materially, continued professional development.
- Ensuring recognition of industry- or sector-wide contributions for all companies participating, such as to the PHEF (as skills development corporate social investment and/or enterprise development) and future initiatives on, for example, Equity Equivalent programmes.
- Clarity in the meaning and extent of “value-added production” as a condition for the exclusion of components (i.e. API, etc.) and products not being locally produced is required. Also when such procurement falls within paragraph 6.5.1 and when it falls under 6.5.2. IPASA requests a meeting with the DTI as is envisaged in par 6.5.4 to address the contribution of the industry and opportunities it can offer”.

The exclusion of imports are made subject to not only the goods being unique, but ALSO that those goods or components must promote value-added production. Value-added production in par 6.5.2.1.2 is NOT the same as being a value-added supplier. So in both 6.5.1 and 6.5.2 it is expected of companies to do something to ensure there is some local component in their products being imported BEFORE they can exclude imports from their procurement calculations. It means that unless a company complies with the “and” in clause 6.5.1, it falls under 6.5.2 and therefore needs to comply with 6.5.2.3. IPASA would welcome engagement with the DTI as referenced in clause 6.5.4

5. Conclusion

IPASA thanks the DTI for this opportunity and reiterates its willingness to engage with the DTI on the fruitful implementation of the BB BEE Codes, to the benefit of South Africa. IPASA can be contacted at the office of its CEO.

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