SALDA

SOUTHERN AFRICAN LABORATORY DIAGNOSTICS ASSOCIATION

SUBMISSION BY SALDA ON THE OFFICE OF HEALTH STANDARDS COMPLIANCE (BILL B24-2011]

1. Who SALDA is

SALDA is a voluntary association of 41 companies involved in the laboratory and in vitro diagnostics ("IVD") environment.

The main objects of SALDA are to:

- Represent the interests of its members in the laboratory- and in vitro diagnostics ("IVD") environment and participate at all relevant forums, which shall include, but is not limited to representation at health sector industry bodies, government departments and health sector stakeholder- and industry collaborations.
- Respond to health sector and business environment changes affecting the interests of its members.
- Promote the field of IVD in the health sector and broader business community and to interact with other health sector- and business stakeholders as may be required from time to time.
- Make representations to legislative authorities where legislative and regulatory frameworks are proposed and bring all legislative and regulatory issues affecting its members to the attention of appropriate authorities.

SALDA in principle supports the objectives of the Office of Health Standards Compliance (OHSC) Bill B24-2011 which ultimately will focus on setting and enforcing norms and standards for quality and safety for the entire health system.

2. Background: current and envisaged frameworks applicable to the in vitro diagnostics sector

Medical device and IVD regulatory frameworks are often divided into -

- pre-market regulation (registration of products and/or licensing of manufacturers/importers),
- health technology management (HTM) and
- health technology assessment (HTA).

The above is in line with the Health Technology Strategy document of the Heath technology Unit in the National Department of Health, as approved by the National Health Council in 2011.

The larger pieces of equipment (such as electro-medical devices or radiation emitting devices) currently fall under the provisions of the Hazardous Substances Act No. 15 of 1973. Patient-operated diagnostic devices (e.g. glucometers and pregnancy tests) are not subject to any regulatory requirements at present but majority of these products are governed by international regulatory requirements and standards.

SALDA is concerned that with the pending medical device regulations as published by the Department of Health in draft format for comment in July 2011, the Consumer Protection Act and now the norms and standards that the OHSC will regulate there is potential for duplication in terms of carrying out policy- and legislative mandates.

SALDA also understands that a Ministerial Advisory Committee on Health technology has been tasked with looking at HTM and HTA and in addition that a Health Technology Policy has been approved by the National Health Council on amongst others, HTM.

As it is understood that the OHSC will also accredit facilities for HTM, and as the regulatory arena is therefore still quite uncertain, SALDA proposes that some clarity be provided in the Amendment Bill as to which institution will, in the end, take responsibility of specific aspects of medical device and IVD regulation.

In the absence of an understanding of the grand scheme under which IVDs would be comprehensively regulated, it is difficult to comment on the OHSC piece of the scheme. For example, daily and routine maintenance, depending on instrument type, would be the responsibility of the labs whilst the manufacturer / importer would be responsible for preventative maintenance. Servicing would also be the responsibility of the manufacturer / importer, but might also be subject to other contractual arrangements.

SALDA proposes closer interaction between the health technology unit in the national department of health and the OHSC as a matter of legal necessity (i.e. it should be written into the Amendment Bill), so as to prevent duplication of standards being set, and duplication in terms of carrying out policy- and legislative mandates.

An analysis would also be required as to potential overlaps between the duties imposed by the Hazardous Substances Act (and new medical device/IVD regulations) and the standards set by the OHSC.

3. Specific comments on specific clauses proposed by the Amendment Bill

Clause 77:

The independence of the OHSC, referred to in the explanatory memorandum to the Bill, is not included in this section.

SALDA proposes that the independence of the OHSC be written into the law, as is the case with the Ombud, where it is explicitly mentioned.

It is also not clear what type of independent body is being created under the Public Finance Management Act – something akin to the current Medicines Control Council, or a schedule 3-body (such as the Council for Medical Schemes or the National Health Laboratory Service).

SALDA proposes that clarity be provided as to the exact status of the OHSC under the PFMA.

Clause 78 – monitoring vs certification and enforcement:

The objectives of the OHSC do not include "accreditation", indicating its objective as merely "monitoring", although clause 79(1)(b) talks to "certification". However, when looking at the powers of inspectors to, amongst others, issue compliance orders and fines, the powers appear to exceed "monitoring".

SALDA proposes that the objectives be aligned to cater for the functions and powers awarded to the OHSC and its inspectors elsewhere in the Bill.

Clauses 78, 79(1)(a), 79(1)(f), 79(2)(e) – standards and systems prescribed by the Minister:

Although independent, the OHSC will only enforce standards as prescribed by the Minister of Health.

SALDA proposes that standards be published by the OHSC as binding after-

- being drafted by expert committees or as aligned to international standards,
- being published for public comment, and
- mandatory consultation with other bodies on whose domain such standards may also fall.

The Amendment Bill could provide for publication on, for example, the OHSC official website and in major newspapers, to ensure speedy adoption of new standards (i.e. the standards are not published as regulations, but as notices in terms of the applicable section of the National Health Act).

Clause 79(1)(f) – quality assurance ("QA") and quality management ("QM") systems:

QA and QM systems also exist in the IVD manufacturing, importation, distribution and local or international registration systems, as applicable. As clause 79(1)(f) is currently phrased as covering the "national health system" it brings the QM and QA systems that would form part of the future South African Health Products Regulatory Authority (which is to be formed in line with Medicines and Related substances Act,

Act 72 of 2008) within the ambit of the OHSC. Although SALDA recognizes that this is not the intent of the Bill, the wording creates this scope.

SALDA proposes that clause 79(1)(f) be amended to read "the Office must - publish quality assurance and management systems for the national health system as is applicable to health establishments."

Clause 79(2)(b) – publication of standards:

SALDA proposes that standards also be published before it is finalized, as a mechanism to ensure that expert input is obtained, and that information on possible previously unknown existing standards could be acquired.

Clause 79(2)(b) to be amended to read "publish any information relating to existing and invite for comment submission on proposed norms and standards …"

Clause 79A(2):

The coordination and harmonization might not solve the complexities of two or more overlapping legal frameworks and mandates. Other legislative frameworks may prohibit deviations that might be required by OHSC standards. Other legislative strategies to resolve such possible conflicts are, for example, to go for the specific legislation over the general legislation, or for the stricter legislation to apply.

SALDA proposes that the provision be changed to read: "The Office – (c) must negotiate … to coordinate and harmonise…"
SALDA proposes that an analysis be undertaken of all the possible laws that could necessitate such harmonization (e.g. the Standards Act, the National Regulator for Compulsory Specifications, the Medicines and Related Substances Act, Health Professions legislation, the Pharmacy Council Act, the Hazardous Substances Act, the Medical Schemes Act and regulations, etc.) and that resolution be sought in the texts of these laws and the Amendment Bill, rather than leaving it to ad hoc arrangements.

Clause 79D:

It is not clear why the Office would have no direct accountability to Parliament, which is normal for many independent bodies under the PFMA.

SALDA proposes that the OHSC be directly accountable to Parliament, and to the Minister of Health.

Clause 81A, clause 88A - Ombud:

It appears from this clause that the Ombud would investigate and make recommendations to the CEO of the OHSC. It would therefore, so it appears, have no powers to make any findings or decisions. Only where the CEO does not react, can the Ombud approach the Minister for "intervention".

The Ombud is therefore not a "true" Ombud, as s/he would not be able to resolve any matter, which is normally the function of an Ombud. S/he would not be able to make any rulings or decisions, and would rely on, firstly, the CEO, and then on the Minister to take action. This could weaken the independence of the Ombud.

If the Ombud is unable to resolve a matter or decision, the provisions in clause 88A that a recommendation by the Ombud could be subjected to an appeal does not seem appropriate. If the recommendation is merely a recommendation and the CEO or Minister has to act thereon, the appeal should be against the CEO or Minister, and not against the Ombud.

SALDA proposes that the powers of the Ombud be brought in line with examples of Ombud Offices in other fields in South Africa, and that his/her resolutions would be regarded as binding on the parties to a particular complaint. Such decision would then be subject to clause 88A (i.e. an appeal).

Clause 82A:

The imposition of a fine (of up to R10m) on either the "person who is in charge of a health establishment" or "a health establishment" is unclear – if standards bind establishments, under which circumstances would a person be held liable to pay a fine? What would the impact of this provision be on persons employed by the department of Health, i.e. would the Department pay a fine to the OHSC (which, in turn, is accountable to the cabinet head of the Department)? Or if the person acted within the scope of his/her employment, would the employer not be liable to pay the fine on behalf of the employee?

Non-compliance could lead to a health establishment's Certificate of Need being withdrawn. SALDA understands that this means that the Certificate of Need would be implemented at some stage. As this Certificate will affect its customers (including pathology laboratories, pharmacies, medical practices, etc), clarity would be required in terms of the timelines for implementation, and the criteria that will be used.

Clause 89 - Offences and penalties:

The rationale for the issuing of fines based on clause 82A, versus the penalties in this clause is not clear. Under clause 82A inspectors appear to have judicial powers, whereas clause 89 requires prosecution. However, the fines under clause 82A are quite stiff.

It is noteworthy that non-compliance with the aspects listed under the powers of- or functions exercised by the OHSC or its CEO does not attract the status of an offence under clause 89. This would defeat the objective of ensuring greater accountability for compliance, and the assurance of patient rights to quality care and safety.

4. International case studies

Accreditation standards set optimal achievable levels, providing a target to strive for, whereas licensing uses minimum standards that have to be passed to, designate the

organization fit to provide a service to the public.[1] It appears that the regulatory choice exercised by South Africa appears to be somewhat in the middle, as current documents used to accredit facilities are described as "core" (minimum) standards[2], whereas initiatives such as "BestCare Always"[3] appear to set aspirational standards.

The WHO[4] describes accreditation options as follows:

Table 4.1 Dimensions in the construction of accreditation systems

Dimension	*Original model adaptations*
1 Levels of standards	optimum ..... minimum
2 Geographical coverage	national ..... local
3 Focus of standards	organizational ..... process ..... outcome
4 Pressure to participate	internal ..... external
5 Number of agencies	one agency ..... many agencies
6 Purposes of accreditation	self-development ..... public reassurance
7 Participation	voluntary ..... compulsory
8 Information	confidential ..... public
9 Grading schema	pass/fail ..... comparative assessment
10 Content	whole hospital ..... single service
11 Surveyor employment status	part-time ..... full-time

Source: Scrivens (1996)

Internationally, there is solid experience on accreditation.[5] The three biggest and oldest organisations are the Joint Commission on Accreditation of Healthcare Organization (JCAHO), the Canadian Council on Health Services Accreditation (CCHSA), and the Australian Council on Healthcare (ACHS). Common elements in the organisations are standards, indicators, surveyors, surveys, accreditation report, and end-result. The establishment of the International Society for Quality in Health Care (ISQua) and The Agenda for Leadership in Programs in Healthcare Accreditation (ALPHA) programme has motivated increasing comparability[6].

In Japan,[7] before the on-site survey, several kinds of documents on the hospital characteristics, number of patients, hospital architecture and facilities, medical equipment, financial data, etc. are to be examined. A management system for medical equipment is one of the domains being 'surveyed'. On-site visiting survey is carried out 2 to 3 days by 4 or 7 surveyors according to the scale of the hospital. Inspections, interviews or hearings in each division or ward are performed in the arranged order. After the survey, the temporary results of scores and comments on each standard by surveyors are to be informed to the hospital in 4~6 weeks. The hospital could express its own opinion on the results and also improve problems pointed out within 2 months. Inspectors (called "surveyors") are persons experienced in hospital management, clinical and nursing and management. The standard score to be achieved is published and there is no penalty for non-accreditation.

[1] WHO 2002 *Regulating entrepreneurial behaviour in European health care systems*.
[2] Department of Health 2011 *National Core Standards for Health Establishments in South Africa (Abridged version)*
[3] www.bestcare.org.za/
[4] WHO 2002 *Regulating entrepreneurial behaviour in European health care systems*.
[5] Accreditation Why is it Important to You International Healthcare Standards.mht
[6] Ugeskr Laeger. 2002 Sep 16;164(38):4412-6 *Accreditation of hospitals. A review of international experiences.*
[7] http://jcqhc.or.jp/html/index.htm; http://heaj.org/index.html

In the UK, the Care Quality Commission (CQC) oversees the quality of the care provided and reports findings to the government[8]. Their job is to make sure that care provided by hospitals, dentists, ambulances, care homes and services in people's own homes and elsewhere meets government standards of quality and safety. The CQC began operating on 1 April 2009 as the independent regulator of health and adult social care in England. Their Essential Standards of quality and safety sets out the outcomes people should be able to expect when they receive care. It is designed to help registered persons comply with the regulated activities and registration regulations. These are the regulations that most directly relate to the health, safety and well-being of people who use services. Where the Essential standards are not being met they can take compliance action, or enforcement action if this is due to failure to meet the requirements of the law[9]. The CQC clearly set out enforcement options and principles ensuring that all that have contravened the law are aware of the outcomes. All results of their audits are made publicly available.

SALDA recommends that the processes to be used during inspections and of findings of non-compliance be specific in the legislation, i.e. publication of draft standards, publication of final standards, processes to be followed during and after inspections. Alternatively, the drafting of specific regulations on the procedural aspects should be mandated in the Amendment, to ensure a fair process that leads to the ultimate enhancement of quality. The imposition of fines on facilities, as is proposed in the amendment bill might not have the desired effect. Institutional heads should also be held to account for instances where prerequisite standards are not met.

In Canada, healthcare accreditation is done by the Canadian Council on Health Services Accreditation. (CCHSA). Their accreditation is voluntary, free from government intervention, national, bilingual and not-for-profit. The CCHSA participates in the ISQua's ALPHA program and it provides an external, independent assessment against a formally established set of international standards. The program puts emphasis on the development and monitoring of performance and outcome indicators. Most Canadian healthcare facilities will have a Continuous Quality Improvement program (CQI) and will have CQI teams to monitor and improve the delivery of their services. When managing physical resources the facility must be able to provide evidence that they ensure the safe, efficient and effective use of the facilities, equipment, supplies and medical devices. This covers areas such as preventative and routine maintenance, storage, utilities and energy conservation, upgrading of equipment and systems, waste creation and it's disposal, health and safety, meeting laws, regulations, standards and codes, proper use of space, proper training on equipment and providing a comfortable environment for staff and clients.

[8] http://www.cqc.org.uk/

[9] Care Quality Commission. Our Enforcement Policy. October 2011

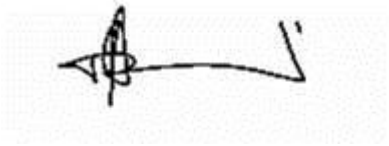
SALDA recommends consideration of measurement of health outcomes as part of the OHSC's mandate. This is currently not included in its scope. A good health outcome is the ultimate measurement of the achievement of quality in healthcare.

As all of the above examples show that the standards bodies are wholly independent from the respective Departments of Health, SALDA recommends that the same level of independence be built into the OHSC. This means that reports and findings, as well as the standards have to be published independent from the Department and should not be subject to the Department of Health prior to publication.

5. Conclusion

SALDA supports the OHSC as a key initiative to ensure that quality of care reaches all patients, irrespective of the facility they go to, or the specific care they require. The few concerns raised by SALDA can easily be addressed during the legislative process.
SALDA will gladly provide further information or assistance to the Honourable Portfolio Committee, as and when required.

Kind Regards



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