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innovative medicines South Africa

8 March 2012

The Portfolio Committee on Health
Submission on the National Health Amendment Bill
Attention: Secretary: Ms Vuyokazi Majalamba
E-mail: vmajalamba@parliament.gov.za

Per Email

Standards set, used for accreditation and enforced under the Office of Health Standards Compliance (OHSC)

1. Introduction and scope of submission

Innovative Medicines SA (IMSA) are trade association representing the following research-based pharmaceutical manufacturers: Boehringer-Ingelheim, Bristol-Myers Squibb, Fresenius Kabi, GE Healthcare, Genzyme, Lilly, Merck, MSD, Norgine, Novartis, Nycomed: a Takeda company, Pfizer, Roche and Sanofi.

IMSA supports the institutionalization of quality through the establishment of the OHSC. IMSA also welcomes the fact that the OHSC is envisaged to be independent.

In this submission IMSA limits its comments to the possible extent that the activities of the OHSC could affect medicines and medicines supply in health establishments. It bases its views on the existing standards that are being used by the Department of Health to accredit health establishments.

2. The promulgation of standards and harmonization

IMSA is pleased that recognition has been given to the need to harmonise (clause new section 79) potentially conflicting legislation dealing with standards in the health sector. This specific phrasing could create legal interpretation and application issues, as two laws of equal standing, with

overlapping jurisdictions, could lead to entities facing two different, and possibly conflicting sets of requirements.

And as the OHSC structure does not create any oversight-, policy- or advisory structure or any authority to which staff members could look for interpretative guidance, it is imperative that the Act itself is clear on what should be done in cases of overlaps or conflicts.

Although this may be the case for other types of products and for professionals, IMSA limits its comments below to where such overlaps could arise in relation to medicine.

This matter also relates to the independence of the OHSC – although stated in the Bill that the OHSC would be independent, the legislative provisions do not contain sufficient protection of this independence. This independence is eroded by the proposals that the Minister of Health will set the standards, and that the OHSC will report via the Minister to Parliament.

Transparency is integrally linked to independence, and in this regard (and also to assist in the early detection of possible conflicting standards or conflicting enforcement), IMSA proposes that all standards be published for public comment prior to being finally published, and that this process of compulsory publication (e.g. on a website and advertised in newspapers) be written into the amendment law.

3. Medicines-matters

Below IMSA illustrates with medicine-specific examples on one of the quality domains (reported to parliament in February), how the standards set by the OHSC could lead to overlapping and conflicting jurisdictional- and other disputes in the absence of either an exclusion provision for aspects already subject to standards and quality control, or in the absence of a provision in the Bill that clearly spells out which laws will get preference, or what will happen during conflicts or overlaps.

The "Core Standards" ("CS")[1] document issued by the Department of Health (and referred to in the Parliamentary briefings on the OHSC that took place in February) shows how the overlaps or possible conflicts referred to above, could occur.

[1] National Department of Health. National Core Standards for Health Establishments in South Africa. 2011

In domain 3 of the CS, "Clinical support services", facilities will be accredited on, amongst others compliance with certain standards in "pharmaceutical services".

Example 1:
All facilities where medicines are stored and dispensed have to have a licence for such activities from the Pharmacy Council and either the Medicines Control Council or the Department of Health. The current quality standard states that the facility must be licenced (i.e. the OHSC would check for that the correct licence exists). But the second part of standard 3.1.1 says "and are supervised by a qualified pharmacist". This creates an untenable situation, as in, for example a large oncology practice, this cannot be implemented, as legislation prohibits pharmacists and doctors from working together in one practice. Although individuals at this practice will have a DoH dispensing licence,[2] they will not be able to comply with the second part of the standard. The same scenario will occur in public health facilities that do not have a post for a qualified pharmacist to be present. In IMSA's understanding there are many, in particular in clinics servicing rural and under-serviced areas.

If this standard was published for comment prior to being issued, these discrepancies could have been pointed out. But under the current system, as drafted, the inspector would not be able to accredit the facility on standard 3.1.1 which would mean some kind of appeals or review process with the inspector returning to the OHSC, requiring some exemption or some decision to be made by, it is assumed, the CEO or a designated person. This creates unnecessary burdens on both the OHSC and the entity being accredited.

Example 2:
Standards 3.1.2 (medicines are *in stock* and delivered) and 3.1.3 (*stock levels*) overlaps with the criteria set and enforced through inspections, by the Pharmacy Council. The Rules relating to Good Pharmacy Practice (Government Gazette No 27112) of 2004 (published under the Pharmacy Act 53 of 1974), contains the following provisions that relates to stock management:

2.4.2 PROCUREMENT AND STORAGE:
(c) Procurement and stock control of medicinal products and all other items dealt with by the pharmacy must be the responsibility of a pharmacist. There must be written procedures, which must be updated regularly, covering all activities
...
(iv) *stock levels are adequate* to ensure the continuous supply and accessibility of medicine at all times, including the availability of essential drugs as per the latest edition of the EDL/Formulary (as applicable);

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[2] Regulations 18 of the Medicines and Related Substances Control Act, Act 101 of 1965 – "Licence to compound and / or dispense medicines"

...
(h) The responsible pharmacist must ensure that all medicine storage areas are inspected regularly (at least monthly) to at least ensure that:
(i) medicines and scheduled substances are stored and handled in accordance with the pharmaceutical manufacturer's requirements;
(ii) no expired or obsolete medicines are stocked;
...
Adequate inventory control systems for pharmaceutical stock held in the pharmacy and or pharmacy store as well as for ward and clinic pharmaceutical stock must be maintained by:
(i) establishing minimum and maximum *stock*/re-order *levels*;
(ii) stock control accounting for pharmaceutical products, received into and removed from stock;

In the above case – what will happen in Pharmacy Council finds compliance with its (similar) standards, whereas the OHSC finds non-compliance? Or if compliance is found with the simplified standards set by the OHSC for stock management, but the facility pharmacy does not comply with the Pharmacy Council's standards on stock management and procurement?
It is not clear in any guidance or legislation yet that, for example, the most stringent requirements would be set as the standard.

Example 3:
Core Standard 3.1.4 states that medicines must be prescribed 'according to treatment guidelines'. It is not clear what these treatment guidelines are, and/or how those guidelines are to be set. There is, apart from the EDL-based booklets and the treatment guidelines contained therein, no set of consensus Treatment Guidelines in South Africa. Furthermore, the updates and input into these EDL-booklets are not regularized or formalized.

It is also not clear how, for example, deviations from such guidelines (e.g. in cases of adverse reactions or treatment failure) will be evaluated, and how issues of scope of practice (i.e. where only trained and experiences healthcare professionals are authorised by their respective professional laws to pronounce on certain disease conditions and its treatment) will be evaluated and how that could affect processes of accreditation.
The medical schemes legislative framework in this regard provides a good illustration, as it considers all interventions (through a legislative mandate) on the basis of evidence-based medicine, considerations for where formulary-listed medicines are inappropriate etc. [3]

There also appears to be some potential conflict or overlap with a structure proposed in terms of the Human Resource for Health Strategy 2012-2017,[4]

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[3] Council For Medical Schemes. Medical Schemes Act of 1998 – Regulations Chapter 5: Provision of Managed Healthcare.
[4] National Department of Health. Human Resources for Health – HRH Strategy for the Health Sector: 2012/13 – 2016/17. 2011

where a National Co-ordinating Centre for Clinical Excellence in Health and Health Care is proposed. IMSA believes that these possible overlaps have to be explicitly addressed in legislation for the future, when those who are currently au fait with the system might not be involved anymore, and uncertainty could reign in relation to the actual intent behind the OHSC and its mandate.

Example 4:
According to standard 3.1.5 "reactions to drugs or severe adverse side effects" have to be reported. This is also a standard that is legally enforced by the MCC against manufacturers/importers. In terms of regulations 34 and 37 of the Medicines and Related Substances Control Act, Act 101 of 1965, the holder of a certificate of registration is required to report any unexpected event to the MCC, not only the "severe" reactions. Hence, in this case, the standard set as part of the 'Core Standards' are below that expected under medicines legislation.

4. Proposed solutions

IMSA therefore proposes to the Portfolio Committee that the following solutions be added to the Bill, in order to prevent the practical challenges we outline above:

1. All standards should be published for public comment prior to its finalization, in any media or form deemed appropriate to reach the intended audiences and stakeholders.

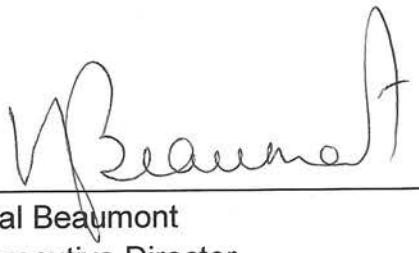
2. The proposed section 79 be amended to add the following text where "harmonization" is addressed:

   "In the case where a standards is set and reinforced by another regulatory body, and the health establishment has been found to be compliant with such standards according to a certificate or other proof and in line with the duration of the validity of such compliance as set by another regulatory body, the OHSC shall recognize, on receipt of proof of such compliance and shall a facility should not be required to undergo an additional inspection in relation to that specific standard or standards."

3. The OHSC should have to establish expert committees on the matters for which it does not have the necessary in-house capacity. This will also prevent issues arising as to the scopes of practice and whether

professional legislation allow pronouncements or guidance on certain matters or not.

We will gladly provide the Honourable members of the Portfolio Committee with more information, should they so require. IMSA Executive Director, Val Beaumont can be contacted at the IMSA Offices on (011) 8804644 or per email at val@imsa.org.za/ imsacom@imsa.org.za.



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