PIASA
Pharmaceutical Industry
Association of South Africa

**Submission by the Pharmaceutical Industry Association of South Africa to the Portfolio Committee on Health**

# AMENDMENTS TO THE NATIONAL HEALTH ACT BILL [B 24—2011] AS INTRODUCED IN PARLIAMENT

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*Improving lives with quality medicines*

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## 1 Introduction

PIASA represents 18 pharmaceutical companies operating in South Africa. Our members are made up of both multinational and local companies. PIASA is the longest established pharmaceutical association with our membership providing more than 25% of medicines consumed in the private and public sectors.

PIASA fully supports the institution of a structure and standards aimed at ensuring quality of care. However, PIASA believes that this very important objective of creating a system of standard-setting, accreditation and accountability are not optimally worded in the Bill, and could lead to legal- and political issues.

## 2 Background to the National Health Act ('NHA')

The NHA was passed by Parliament in 2003, and came into operation in May 2005. The Act sought to overhaul the total healthcare system, and, amongst others, make it clear that the Act aims to –

"establish a national health system which—
(i) encompasses public and private providers of health services; and
(ii) provides in an equitable manner the population of the Republic with the best possible health services that available resources can afford"

PIASA also notes that many sections in the Act that had not been operative, have recently been brought into operation by promulgation, and applauds the progress being made in the implementation of a more coherent health system.

## 3 Establishment of the OHSC (Clause 77)

The Amendment Bill aims to establish the Office of Health Standards Compliance as a "juristic person", which means that it would be sued, and could sue, in its own name. As there is no Council or Board that would set policy or strategy direction, the full responsibility for this falls on the shoulders of the CEO.

However, as the CEO is accountable to the Minister of Health, and as all standards will be prescribed by the Minister of Health, there is some doubt as to whether the OHSC would be truly independent in its own decision-making as a juristic person. The principle of independence is only written into the Bill as it pertains to the Ombud.

This state of affairs could cause legal and procedural issues for this very important structure in the future.

## 4 Objects of the OHSC (Clause 78)

The OHSC would "monitor" compliance to norms and standards. However, the functions of the OHSC (clause 79) are much more forceful than just "monitoring" in that non-certification and fines could result from non-compliance.

It is not clear what is meant by the complaints process having to be "economical". It is proposed that this concept be clarified as it appears to be one of the key principles on which the Ombud will operate, the other being procedural fairness and expeditiousness (both being well-known concepts within such contexts). The word "economical" could mean "cost-effective" (i.e. not in an expensive manner) or it could mean "by considering the financial constraints of (e.g. a facility)". Clarity in this clause, and the clause 81A is important.

## 5 Functions of the Office of Health Standards Compliance (Clause 79)

The OHSC can only *advise* the Minister on which norms and standards should be adopted (clause 79(1)(a)). This, in PIASA's view, erodes the independence of the Office. A system could be created whereby standards are developed by experts in the applicable fields, published for public and stakeholder comment and where the Minister are, in the law, compelled to consider such work and comments. The clause can be re-worded to give effect to this.

Although the powers of inspections are outlined, the process and frequency of required certification (clause 79(1)(b)), is not clear in the Bill, also not what the repercussions are of non-certification. Also no provision is made for regulations to set this out, which PIASA proposes as a solution. Quality systems depend on repeated certification of compliance with standards from time to time. Entities subject to such certification however require certainty as to what would be expected of them, and when that would be expected.

The OHSC has a wide mandate to "investigate complaints relating to the health system" (clause 79(1)(c)). This means that literally *any complaint* can be lodged at the OHSC, whereas the complaints system created under the Ombud-clauses relates *only to norms and standards*.

Clause 79(1)(f) refers to "quality management and quality assurance" systems. It should be noted that for medicines (which includes pharmacies in all hospitals, as well as distribution systems), these systems are set, enforced and inspected in terms of the provisions of Medicines and Related Substances Act and the Pharmacy Act. PIASA therefore proposes that the phrase "insofar as such systems are not regulated and enforced elsewhere by recognized statutory

bodies and/or organs of state" be added to this provision. In PIASA's view the "harmonization" requirement in clause 79 is not sufficient to avoid unintended overlaps and conflicting jurisdiction.

As both entities that regulate a similar standards matter could charge fees for its services, there could be an intended financial impact on the cost of care if conflicting and overlapping jurisdictions are not addressed in the Bill itself.

## 6 Delegation (Clause 79B)

It is proposed that the clause be amended to read: "Unless the OHSC possess the required technical skills and expertise on a particular matter, the CEO must appoint an expert and technical committee". It is inconceivable that the OHSC would be able to possess, for example, the clinical skills in all medical fields to evaluate adherence to treatment guidelines (clinical governance is one of the areas found in the Department of Health's current guide to quality called "Core Standards for Health Facilities").

The fact that the Minister of Health must approve the organizational structure of the OHSC also goes against the principle of independence which has been highlighted in the Memorandum to the Bill and in the media.

## 7 Accountability (Clause 79D)

As the OHSC is not directly accountable to Parliament, it raises questions as to whether the legislative intent is to create an independent body, or rather just to create a division within the National Department of Health that is financially separate from the health budget. If that is the case, it has to be clear in the law. There should be no confusion and no future conflict in terms of who has what powers in terms of the principles of reporting, accountability and standard-setting.

## 8 The Ombud (Clauses 81, 81A – B)

The Ombudsperson would be able to investigate complaints, but have no powers to make rulings or to ensure that findings are enforced. This is to be done via the office of the CEO or failing that, the Minister. No guidance is given in the Bill as to how the CEO or Minister must deal with such a matter. This could lead to the Ombud losing face in the public eye if matters are not definitively resolved. This limitation on the powers of the Ombud is contradictory to the stated independence of this office.

## 9 Inspectors and Inspections

There is the potential for overlap between inspectors and inspections under the Medicines- and Pharmacy Acts. For example, OHSC inspectors can "take samples of any substance". Provisions are required to ensure that this not be exercised without the actual presence of inspectors who are experienced in medicine matters. It is suggested that provision be made for this specific type of cooperation in the inspection clauses.

Many procedural issues are covered in these clauses, ranging from powers to enter, warrants and powers to seize goods. It is in this respect that pharmaceuticals might be affected.

## 10 Fines, Offences and Penalties (Clause 82A AND 89)

The fines-section in clause 82A appears to relate to fines that could only be imposed by Inspectors following non-compliance with standards. This means that inspectors become executive and judicial officers, and the only remedy for an aggrieved entity would be an Appeal to the Tribunal to be set up by the Minister. There are no other health establishment accountability provisions in the Bill, which means that the whole quality system would depend on an inspector being dispatched and issuing a fine.

PIASA is of the view that there is likely to be other types of accountability mechanisms which could be included in the Bill.

The penalties and criminal prosecution is limited only to offences relating to prevent inspectors and others from executing their duties under the Bill. The only substantive provision on which a prosecution could take place is for non-compliance with a compliance order.

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