



NATIONAL HEALTH AMENDMENT BILL
ASPECTS RELATED TO THE
INTRODUCTION OF THE OFFICE OF
HEALTH STDS COMPLIANCE

PRESENTATION TO PC HEALTH BY
INNOVATIVE MEDICINES SA
(IMSA)

IMSA MEMBERS



Bristol-Myers Squibb
(Pty) Ltd



Boehringer
Ingelheim



MSD



SANOFI



FRESENIUS
KABI

GE Healthcare



Nycomed: a Takeda Company



COMMENDABLE OBJECTIVE OF THE OHSC

Quality objective of the DoH:

- Office of **Health Standards** Compliance
 - Accredit all facilities
 - Standards and clinical governance
 - Proper process on dispensing, etc
 - Ombudsperson

S.79 recognises existing legislation & regulatory authorities

- National Health Act
- Medicines and Related Substances Control Act 101
- Medical Schemes Act
- Childrens Act
- Counterfeit Goods Act
- For Health Professionals dispensing medicines – Health Professions Act, Pharmacy Act, Allied Health Professions Act, Nurses Act...
- Etc...

Departments of Health & T&I



Councils:
National Office of Standards
Compliance
Medicines Control Council
Council for Medical Schemes
Companies & IP Commission
Nursing Council, Pharmacy Council,
HPCSA




innovative


Phrasing of S.79? 2 laws of = standing...could lead to entities facing 2 different & conflicting sets of requirements & enforcement

Examples of overlaps that may impact medicines

Example 1: Core Std – Domain 3: Clinical Support Services

- Licence required for facilities that store and dispense medicines from Pharmacy Council/MCC or DoH as the case may be 

then

Supervised by a qualified pharmacist 

- Legislation prohibits pharmacists & doctors from working together
 - Many public health facilities do not have a post for a qualified pharmacist

Implication: Amendments to existing law to enable multi-disciplinary practices required (application HCPs with Councils enforcing single-disciplinary practices).

Alternate? Establish exemption application process

Examples of overlaps that may impact medicines

Example 2: Core standards re: stock controls

- Medicines must be in stock and delivered
- Stock levels are prescribed

*CONFLICT - the Pharmacy Council also set and enforce detailed “medicines control” criteria through inspections and through making the pharmacist responsible for specific functions into the Good Pharmacy Practice Rules published into Pharmacy Act

SOLUTION: OHSC to refer to Pharmacy Practice Rules and in general all other applicable Rules and Guidelines setting standards

Examples of overlaps that may impact medicines

Example 3: Core standards re: medicines to be prescribed in accordance with “treatment guidelines”

- Which treatment guidelines?

This must be explicitly stated

- NOTE: We have EDL based booklets with guidelines in the public sector but NO NATIONAL CONSENSUS treatment guidelines in SA to date
- What access to treatment does a patient have when an adverse reaction to a medicine is suffered and there must be deviation from the “guideline”, how will this be managed? Medical schemes legislation may help to define who and how to evaluate etc
- Reference to National Co-ordinating Centre for Clinical Excellence as contained in HRH Strategy 2012-2017 – More information required on how this will be linked and how this will work to ensure efficiency, transparency and continuity

PROPOSED SOLUTIONS

- ENSURE TRANSPARENCY: PUBLISH FOR PUBLIC COMMENT/INPUT ALL STANDARDS BEFORE FINALISED
- ENFORCEMENT EFFORTS BY THE OHSC AND PROFESSIONAL COUNCILS MUST ALL SUPPORT EACH OTHER – CONSULTATION MUST OCCUR TO ENSURE PROPER ALIGNMENT
- ESTABLISHMENT OF EXPERT COMMITTEES THAT THE OHSC MAY REFER TO FOR GUIDANCE AND ASSISTANCE