REPORT OF THE PORTFOLIO COMMITTEE ON HEALTH AND SOCIAL DEVELOPMENT ON MEDICINES AND RELATED SUBSTANCES AMENDMENT BILL, [B6B-2014]

1. INTRODUCTION

The Speaker referred the Medicines and Related Substances Amendment Bill, [B6B-2014] (the Bill) to the Portfolio Committee on Health and Social Development (the Committee) for consideration and report back to the House in accordance with the legal prescripts and the Rules and Orders of the Mpumalanga Provincial Legislature.

In terms of section 118(1) of the Constitution of the Republic of South Africa, Act 108 of 1996, the Legislature has a mandate to facilitate public involvement in the legislative and other processes of the legislature and its committees. It is against this background that the Committee conducted public hearings to solicit inputs and views from members of the public on the above-mentioned Bill.

2. OBJECTIVES OF THE BILL

The purpose of the Bill is to;

- amend the Medicines and Related Substances Act, 2008;
- define certain expressions and to delete or amend certain definitions;
- provide for the objects and functions of the Authority;
- provide for the composition, appointment of chairperson, vice-chairperson and members, disqualification of members, meetings and committees of the Board of the Authority;
- require the Minister to consult with the Pricing Committee when prescribing acceptable and prohibited acts in relation to bonusing;

- replace the word "products" with the word "medicines" and expression "Scheduled substances" in order to correctly reflect the subject matter of the said Act and;
- effect certain technical corrections and to provide for matters connected therewith

3. METHOD OF WORK

The Committee was addressed by the National Council of Provinces (NCOP) permanent delegate, Hon LC Dlamini, the Deputy Director General from the National Department of Health, Dr. Anban Pillay, as well as the Mpumalanga Department of Health on 01 September 2015 for a briefing on the Bill. The Committee then conducted public hearings in order to solicit inputs/comments from members of the public.

The Public hearings were conducted on Friday, 04 September 2015, from 09h00 – 13h00 in the following Districts.

DISTRICT	VENUE	No. of Attendees
Ehlanzeni	Leroro Community Hall – Thaba Chweu Local Municipality	139
Nkangala	Nokaneng Community Hall (Moretele) – Dr JS Moroka Local Municipality	138
Gert Sibande	Kgotso Tsotetsi Community Hall (Mbalenhle) – Govan Local Municipality	89

The Committee thereafter met on 15 September 2015 to consider the draft report and the negotiating mandate on the Bill and such mandate was duly submitted to the NCOP.

4. INTERACTION BY THE COMMITTEE WITH NCOP PERMANENT DELEGATE AND DEPARTMENT OF HEALTH ON THE BILL

The permanent delegate gave a political overview on the Bill and the Deputy Director General made a presentation on the Bill. The Committee thereafter made comments and asked clarity seeking questions.

The permanent delegate highlighted the background on the Bill as follows;

- Health services are a functional area listed in Schedule 4A of the Constitution. This implies that the national legislative authority has concurrent competence with the provincial legislative authority;

- In all Bills referred to the Provincial Legislature, it is a legislative requisite that public participation is complied with.

- She emphasised on the need to understand the Bill by the public for relevant input and knowledge;

- The Bill will strengthen the current medicines regulatory authority – the Medicines Control Council (MCC) through the establishment of a new authority (replacing the MCC) – the South African Health Products Regulatory Authority (SAHPRA). The new entity will not be regulated by the Public Administration Management Act, but will be classified under the private sector.

- She also indicated that there is a structure that consults the traditional healers in terms of the Traditional Health Practitioners Act 22 of 2007.

The Permanent Delegate, Hon Dlamini also reported that the National Assembly Portfolio Committee (NA PC) on Health considered and supported the Bill after agreeing to some amendments to the Bill set out below: The NA PC agreed that;

- The Medicines Control Council (MCC) be replaced by the South African Health Products Regulatory Authority (SAHPRA). SAHPRA will be responsible for monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, clinical trials and medical devices and related matters in the public interest.
- Clause 1 should include the definition of medical devices;
- A new clause on bonusing be introduced - Substitution of section 18A in Act 101 of 1965, as substituted by section 15 of Act 72 of 2008

Organisational Structure of the South African Health Products Regulatory Authority (SAHPRA)

Currently, there is a backlog on the regulation, testing and approval of medicines because the Medical Control Council (MCC) does not have its own permanent personnel; the National Department of health provides support to the MCC to execute its functions through the Registrar and there are scientists and qualified personnel (academics) from universities that are serving on the MCC on a part-time basis.

The establishment of SAHPRA provides that it has its own appointed personnel reporting to the Chief Executive Officer (CEO). The staff will consist of skilled Inspectors, Technical and Administrative staff. It is also reported that the technical board will be replaced by a Board that will have governance and fiduciary functions, the Board will be appointed by the Minister of Health. The Board may appoint one or more committee from amongst its members to assist with the performance of its functions. The Board will then appoint a CEO, the CEO will report to the Board.

Financial Implications

It was reported that the transition from MCC to SAHPRA might result in some savings or cost neutral if done accordingly. The budget utilised for the supporting

personnel from the National Department of Health will be allocated to the Authority for internal processing (for its own personnel).

Impact of SAHPRA

- The Authority will address the challenges of access to quality, safe and affordable medicines and medical devices/IVDs; this avoiding the circulation of untested and unregistered medicines to the public for use that might result in more illnesses or even fatalities. The Authority will improve the efficiency of the current system, fast-track the registration of priority public products.
- The Authority is also envisaged to make essential medicines and products more readily available, with the potential to reduce prices through increased competition and licensing of generic products.
- Regulation and registering of proposals for medicines will enable the development of cures for currently incurable illnesses.
- The Committee requested that the Authority must periodically run awareness campaigns on medicines and to discourage treatment defaulters.

SAHPRA Offices

It was reported that SAHPRA will have its national office and provincial office upon its establishment. Skilled candidates per province will be considered for placement in their respective provinces, however if there are no skilled candidates identified; appointment and placement of personnel will be done accordingly, the National Department of Health has a programme to train unemployed graduates on evaluating medicines. Mpumalanga Province is neighbouring other bordering countries – Swaziland and Mozambique. The regulating and monitoring of medicines movement internationally will be vital. Aware that some medicines from outside the country are harmful and in some cases contain illegal substances, the National Department of Health has employed and deployed 300 people at South Africa's ports of entry to evaluate medicines coming into the county.

Medical Depot

The Committee cited that Africa is known to be a disease borne continent, the Committee then suggested that the National Health Department must research on and consider establishing a sufficient and effective number of provincial medical depot to ensure timeous distribution of medicines throughout the country.

Implementation on the Bill

Once the Bill is passed into law, the Department of Health will have sessions to engage with provinces on the substance of the Amendment Act. Circulars will also be distributed to provinces and stakeholders.

Constitutional Implications

The Constitution is the supreme law of the country. It is central to developing and implementing health law and policy which it regulates. It regulates the content of all laws and policies, primarily through its Bill of rights. It further regulates the role of government and non-state actors "such as private companies" in realising the right of access to health care services.

Section 27 of the Constitution provides that: every person has the right to have access to health care services. Section 27 further provides that all reasonable steps must be present to ensure that the right is protected, promoted and fulfilled and over time universal access to quality and comprehensive health care is achieved. This can include the passing of laws.

In the *Government of the Republic of South Africa v Grootboom 2001 (1) SA 46 (cc)*

"In this case a principle was established that the Constitution imposes an obligation on the state to develop and implement reasonable plans to ensure that rights are realised. The courts stated that:

- Sufficient flexibility to deal with emergency, short, medium and long-term needs.
- Making appropriate financial and human resources available for the implementation plan.
- Legislatures assuming responsibility for ensuring the adequacy of laws, policies and programmes, including the clear allocation of responsibilities and tasks, as well as monitoring programmes implemented at provincial and local government level.

The Grootboom case notes that the needs of the people must be given special attention by the government. The government's duty is to ensure access to *healthcare services* (my emphasis), create legislative framework to have access to health care services.

Section 114 of the constitution provides that the provincial legislature may consider, pass, amend or reject any Bill before the legislature. Section 116 further provides that a provincial legislature must facilitate the public involvement in the legislative and other processes of the legislature and its committees. The legislature through its Rules and Orders has created an enabling environment for community consultation and improvement of the lives of the people in the province.

5. INTERACTION BY THE COMMITTEE WITH STAKEHOLDERS ON THE BILL

The following stakeholders were invited by the Committee to attend the public hearings held on 04 September 2015;

- ❖ Community Members
- ❖ Department of Health
- ❖ Department of Social Development

- South African National Council on Alcoholism & Drug Dependence (SANCA)
- Mpumalanga House of Traditional Leaders (HTL)
- South African Local Government Association (SALGA)
- Executive Mayors of Districts
- Ward Committees
- Community Development Workers
- Other stakeholders (organized labour formations, Health Systems Trust, Aids Council, Corridor Empowerment Project, Broad Reach, South African Medical Association, Right to Care, Love Life)

During the public hearings, members of the Committee explained the Bill thoroughly. The stakeholders who were present at the public hearings generally supported the Bill and raised the following concerns:

- The Bill must have good regulations that will ensure that the Board and the SAHPRA work effectively;

- There should be professionals from Mpumalanga who will sit on the Board of SAHPRA;

- SAHPRA must assist to close gaps in high pricing of medicines in the private sector and generally high cost of private medical care, such as private doctors and hospitals. The price of medicines through Medical Aid schemes should be revised for the affordability of the public.

- The Bill must strengthen the testing and approval of traditional medicines.

- The Bill should clarify the roles or functions of the structure when the offices are established at National and Provincial level

- SAHPRA must continually run programmes to educate the public on medicines and also conduct awareness campaigns on the side effects or after effects of medicines and the dangers of taking medicines not prescribed by a Doctor (including the dangers of the use of illegal/unregistered on the street medicines – creams, herbs, etc.)

- SAHPRA must also have measures/plans to counteract the practice that people have of seeking conventional medicine and medical help after they have consulted traditional healers without success;

- The package insert and information on the medicines should be in all the eleven (11) official languages in the country, considerate of the patients' native/home language.

- The Bill should assist in terms of coming up with a plan to address the criminal activities identified on medicines and related substances.

6. OBSERVATIONS AND FINDINGS BY THE COMMITTEE

Generally, members of the public were in support of the Bill.

7. RECOMMENDATIONS

The Portfolio Committee on Health and Social Development after considering the Bill confers on the permanent delegate representing the Province of Mpumalanga in the NCOP, the mandate to negotiate in considering the proposed Amendments of the Bill.

8. CONCLUSION

The Chairperson wishes to thank all members of the public for their worthwhile participation in the public hearings and for the inputs or comments they have made. A word of gratitude to the NCOP Permanent Delegate, Hon Dlamini, the Deputy Director General from the National Department of Health, Mpumalanga Department of Health, Members of the Portfolio Committee on Health and Social Development for their efforts in ensuring that the committee meets its obligation and the support staff who contributed to the success of the public hearings and the production of this report.

HON P NGOBENI
CHAIRPERSON: PORTFOLIO COMMITTEE
ON HEALTH AND SOCIAL DEVELOPMENT

15/09/2015
DATE