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HON. W.G. MITTLEM
CHAIRPERSON OF COMMITTEES

DATE
21/09/2015

Provincial NCOP Permanent Delegates to
Negotiate in favor of the Bill, taking into
Consideration the inputs mentioned therein.

Vote of the Legislature:

Date of Deliberation : 18 September 2015

Number of the Bill : [B6B - 2014]

Name of the Bill : Medicines and Related Substances Amendment Bill

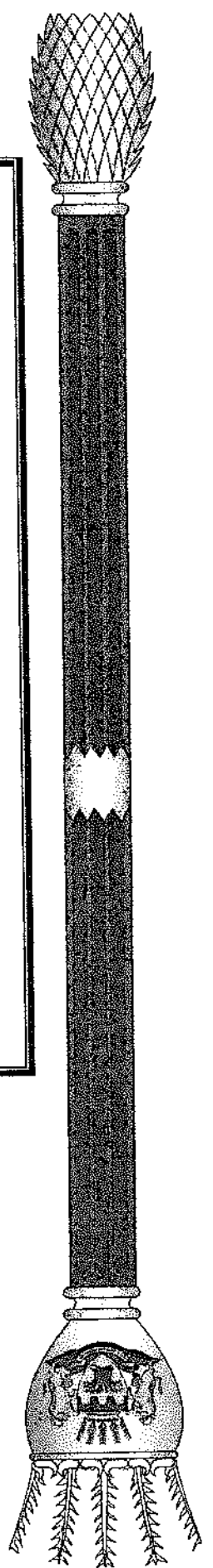
To : The Chairperson: SC on Social Services

NEGOTIATING MANDATE

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PORTFOLIO COMMITTEE ON HEALTH

NEGOTIATING MANDATE ON THE MEDICINES AND RELATED SUBSTANCES AMENDMENT BILL [B6B-2014]

1. INTRODUCTION

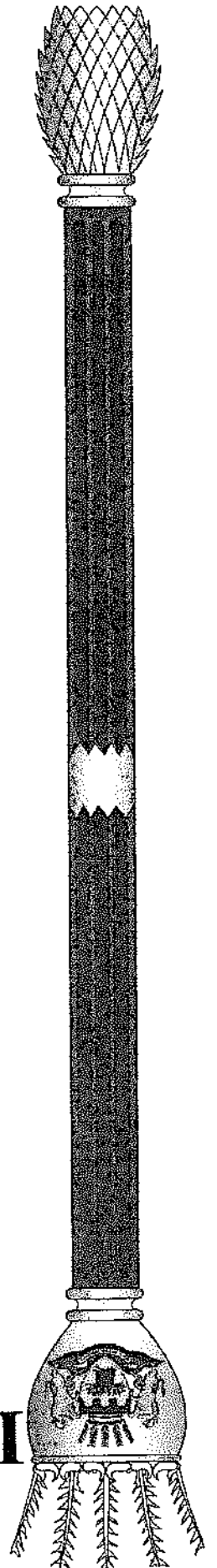
The Medicines and Related Substances Amendment Bill [B6B-2015] was referred to the Limpopo Provincial legislature by the National Council of Provinces (NCOP). Subsequently, the Bill was referred to the Portfolio Committee on Health for considerations. A Public Hearing was conducted in Polokwane.

The following stakeholders were represented in the hearing: Provincial Department of Health; Hospital boards; Clinics board; Traditional Health Practitioners; Pharmacists from private sector; Pharmacists working at public institutions and Members of the General Public. The Committee noted all the views and inputs made during the public hearing, however this report will only reflect views and inputs relevant to the Bill under discussion.

2. BACKGROUND OF THE BILL

The Medicines and Related Substances Amendment Bill [B6B-2015] seeks to amend the Medicines and Related Substance Act, 1965 (Act No. 101 of 1965), that has been recently amended by Medicines and Related Substances Amendment Act, 2008 (Act 72 of 2008) so as to define certain expressions and to delete or amend certain definition; to provide for the composition, appointment of chairperson, vice-chairperson and members, disqualification of members, meeting and committees of the Board of the Authority; to replace the word "Products" with the word "medicines" and expression "Schedule substance" in order to correctly reflect the subject matter of the said ACT; and to effect certain technical corrections; and to provide for matters connected therewith.

The amendment Act (Act 72 of 2008) established a new regulatory authority for all medicines, medical devices and food stuff called the South African Health Product



Regulatory Authority (SAHARA). It also provides for the appointment of the Chief Executive Officer to carry out, amongst others things, the function assigned to SAHARA under the principal ACT as amended by the amendment act.

3. INPUTS TO THE BILL BY THE PUBLIC

The attendees of the public hearing agreed with all the objects of the Bill and further more made the following inputs to the Medicines and Related Substance Amendment Bill [B6B-2015]:

- The Bill should be consistent with the use of the words "Humans and animals";
- The Bill should be consistent with the definition of [product], wherein "Schedule substances" is omitted;

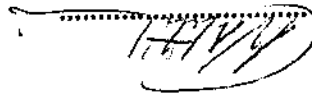
• Composition of Board

- 2C. (2)(a) not more than 10 persons who have expertise in the fields of medicine, medical devices, IVD, vigilance, clinical trials, good manufacturing practice, public health, epidemiology, pharmacology and pharmaceuticals;
- (g) one person on account of his or her knowledge of traditional health practice.

4. CONCLUSIONS

The Public Hearing unanimously support the Bill with the inputs made above. The representatives of all districts thanked the Portfolio Committee for involving them in the law making process. In turn the Chairperson of the Portfolio Committee also thanked the Public for the contribution and positive responses made during the entire hearing.

The Committee, therefore recommends to the NCOP Delegates to negotiate in favor of the Bill, taking into consideration the comments and inputs stated in therein.



HON. W.G. MITILENI

Chairperson of Portfolio Committee on Health