



Wes-Kaapse Provinsiale Parlement
Western Cape Provincial Parliament
IPalamente yePhondo leNtshona Koloni

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Datum
Date Umhla 18 September 2015

Verwysing
Reference Isalathiso 11/3/1

NEGOTIATING MANDATE

To: Hon LC Dlamini
Chairperson: Select Committee on Social Services

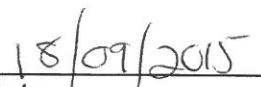
Name of Bill: Medicines and Related Substances Amendment Bill

Number of Bill: [B 6B -2014]

Date of deliberation: 18 September 2015

Vote of Legislature: The Standing Committee on Community Development reports that it confers on the Western Cape Permanent Delegate in the NCOP the authority to support the Bill with the attached amendments.


Signature


Date

Hon. MM Wenger
Acting Chairperson: Standing Committee on Community Development



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COMMITTEE REPORT

(Negotiating mandate stage) Report of the Standing Committee on Community Development on the *Medicines and Related Substances Amendment Bill* [B 6B–2014] (NCOP) dated 18 September 2015 as follows:

The Standing Committee on Committee Development, having considered the *Medicines and Related Substances Amendment Bill* [B 6B–2014] (NCOP), referred to the Committee in terms of Standing Rule 220, confers on the Western Cape’s delegation in the National Council of Provinces the authority to support the Bill with the following amendments:

1. On page 2, in the seventh line of the long title, to omit:

to 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 to substitute:

to replace the words “product” and “products” wherever they occur with the words “medicine” and “medicines” respectively, or to replace the word “product” with the expression “medicine, Scheduled substance”, as the case may be, in order to correctly reflect the subject matter of the said Act;

2. On page 5, in line 25, after “or”, to insert “,”.
3. To correct the numbering of the subclauses throughout the clause in that subclause (2) is duplicated on page 15 in lines 12 and 21.
4. The Committee wishes to raise the following concerns:
 - 4.1. The Bill was initially published in 2012, whereupon comments were submitted and substantial changes were made to the Bill. The substantially changed Bill was not published for comment, and the Committee is concerned that there may have been inadequate opportunity for the public to comment on that version of the Bill.
 - 4.2. Medical devices and *in vitro* diagnostics are not registered in South Africa. The Committee is of the view that registration of these devices is of great importance to patient safety and that registration and control of these items are necessary. The Committee is concerned that the Medicines Control Council may not have the capacity to review these items for registration.

The draft MRSA 101 General Regulations of 1965, relating to medical devices and *in vitro* diagnostic medical devices, makes provision for transitional arrangements with a phased-in approach to registration.

It is imperative that adequate time and resources be allocated to implementation. Careful consideration must be given to the implications of these provisions, and cognisance must be given to existing medical devices that cannot be readily replaced in the event that they are not registered within the required time frames.

- 4.3. The Committee is concerned about the budgeting and staffing of the new entity (SAHPRA) and about the potential financial impact on the Provincial Budget Allocation. The Province recommends thorough consultation with provincial governments on the budget and resources of the South African Health Products Regulatory Authority (SAHPRA).



MS MM WENGER, MPP

18/09/2015

DATE

ACTING CHAIRPERSON: STANDING COMMITTEE ON COMMUNITY DEVELOPMENT