



11/4/11

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

DRAFT MINUTES OF PROCEEDINGS

STANDING COMMITTEE ON COMMUNITY DEVELOPMENT (Health)

Wednesday, 18 September 2015, (at 09:00) Committee Room 2

PRESENT

Members

Democratic Alliance

Kivedo, BD (Alternate)
Wenger, MM (Acting Chairperson)
Wiley, MGE (Alternate)

African National Congress

Gopie, D

Apology

Botha, LJ
Gillion, MN

Officials in attendance

Western Cape Provincial Parliament

Adv. A le Roux: Legal Advisor

Department of the Premier

Mr V/D Schyff: State Law Adviser: Provincial Department of Premier

1. Election of Chairperson

The Committee proceeded to the election of an Acting Chairperson in terms of Standing Rule 77(2) of the Western Cape Provincial Parliament Standing Rules.

On the motion of Mr Wiley:

That Ms Wenger be the Acting Chairperson.

Agreed to.

2. Consideration of the Negotiating Mandate on the *Medicines and Related Substances Amendment Bill* [B6B -2014] (NCOP)

- 2.1. The Chairperson requested the Committee Coordinator to brief the Committee on the process followed in publicising the Bill.

Ms Jamce indicated that during the meeting of 1 September 2015, the Committee agreed to hold two public hearings on the Bill, one in Vredendal in the West Coast, on Monday, 14 September 2015 and the second hearing in the Western Cape Provincial Parliament in Cape Town on Wednesday, 16 September 2015. The reasons for the identifying the areas were based on the fact that both venues were central for people who want to attend the hearings from the surrounding areas, that all other areas can attend any of the two public hearings and committee can pay for transport for people to attend if requested to do so.

The public hearings were advertised in the following newspapers.

- a) Cape Argus – Mainstream English newspaper
- b) De Son – Afrikaans Community newspaper
- c) City Vision – Xhosa Community newspaper
- d) Ons Kontrei – Afrikaans newspaper in Vredendal

She also informed the Committee that all Municipalities in the Western Cape were informed and invited to the public hearings. The committee also agreed that the WCPP Communications Section sent out a press release to all media houses in the Province and WCPP Public Education and Outreached Unit invited relevant stakeholders to the hearings.

- 2.2. The Chairperson requested Adv. le Roux to give input on the Bill. He proposed the following technical amendments:

- 2.2.1. 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;

- 2.2.2. On page 5, in line 25, after “or”, to insert “,”.

Mr V/D Schyff, pointed out that subclause (2) is duplicated on page 15 in lines 12 and 21 and suggested that the numbering of the subclauses be corrected throughout the clause.

- 2.3. The Committee raised the following concerns:

- 2.3.1. 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.

- 2.3.2. 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.
- 2.3.3. 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.
- 2.3.4. 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).

The committee agreed that the above proposed amendments and concerns should be part of the Committee's Negotiating Mandate.

On the motion of Ms Wenger:

That the Committee supports the Bill with amendments and concerns.

Agreed to.

The Chairperson submitted the Draft Committee Report which was considered and adopted.

3. The Chairperson submitted the draft minutes of 1 September 2015 which were considered, amended and adopted.
4. The Chairperson informed the Committee that the minutes of the public hearings of 14 and 16 September 2015 were ready for adoption, but the adoption of these minutes was not included in the notice of 18 September 2015. Members agreed to adopt the minutes.
5. The Chairperson submitted the draft minutes of the 14 September 2015 which were considered, amended and adopted.
6. The Chairperson submitted the draft minutes of the 16 September 2015 which were considered, amended and adopted.

The meeting adjourned at 10:30.

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MS MM WENGER, MPP

ACTING CHAIRPERSON: STANDING COMMITTEE ON COMMUNITY DEVELOPMENT