

REPUBLIC OF SOUTH AFRICA

**SELECT COMMITTEE
AMENDMENTS TO**

**MEDICINES AND RELATED
SUBSTANCES AMENDMENT
BILL**

[B 6B—2014]

*(As agreed to by the Select Committee on Social Services
(National Council of Provinces))*

[B 6C—2014]

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AMENDMENTS AGREED TO

MEDICINES AND RELATED SUBSTANCES AMENDMENT BILL [B 6B—2014]

CLAUSE 3

1. On page 5, in line 25, to omit “or” and to substitute “or,”.

CLAUSE 18

1. On page 11, from line 19, to omit paragraph (f) and to substitute:
 - (f) by the substitution for subsections (3) and (4) of the following subsections, respectively:

“(3) The analyst, pharmacologist, **[or]** engineer, scientist, pathologist or expert designated by the Authority to whom a sample has been transmitted in terms of the provisions of subsection (2) shall with all convenient speed test, examine or analyse the sample delivered to him or her, and the result of the test, examination or analysis shall be stated in a certificate in the prescribed form.

(4) The owner of the **[product]** medicine, Scheduled substance, medical device or IVD from which the sample was taken may claim from **[the]** the Authority an amount equal to the market value thereof”.

CLAUSE 22

1. On page 13, in line 57, to omit “, Scheduled substance”.
2. On page 13, in line 60, to omit “, Scheduled substance”.
3. On page 14, in line 15, to omit “medical devices” and to substitute “Scheduled substances, medical devices”.
4. On page 14, in line 27, to omit “subsection (6) of the following subsection” and to substitute:
 - subsections (5) and (6) of the following subsections, respectively
5. On page 14, after line 27, to insert:

“(5) Regulations made under subsection (1)(xi) may prescribe that any **[product]** medicines, Scheduled substances, medical device or IVD or any component thereof shall comply with the requirements set out in any publication which in the opinion of the Authority is generally recognised as authoritative.

6. On page 14, in line 28, to omit ““(6)” and to substitute “(6)”.

CLAUSE 26

1. On page 15, in line 21, to omit “(2)” and to substitute “(3)”.
2. On page 15, in line 24, to omit “(3)” and to substitute “(4)”.

3. On page 15, in line 26, to omit “and food control”.
4. On page 15, in line 44, to omit “(4)” and to substitute “(5)”.
5. On page 15, in line 53, to omit “(5)” and to substitute “(6)”.
6. on page 16, in line 3, to omit “(3)” and to substitute “(4)”.
7. On page 16, in line 9, to omit “(3)” and to substitute “(4)”.
8. On page 16, in line 21, to omit “(6)” and to substitute “(7)”.
9. On page 16, in line 27, to omit “(7)” and to substitute “(8)”.