REPUBLIC OF SOUTH AFRICA

PORTFOLIO COMMITTEE AMENDMENTS TO

MEDICINES AND RELATED SUBSTANCES AMENDMENT BILL

[B 44B—2008]

(As agreed to by the Portfolio Committee on Health (National Assembly))

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AMENDMENTS AGREED TO

MEDICINES AND RELATED SUBSTANCES AMENDMENT BILL [B 44—2008]

CLAUSE 1

1. On page 2, after line 21, to insert the following definition:

"advisory committee" means the advisory committee established in terms of section 4.

CLAUSE 2

- 1. On page 4, in line 7, after "<u>established</u>", to insert "<u>as an organ of state but outside the public service.</u>".
- 2. On page 4, after line 14, to add the following subsection:
 - (4) In performing its functions, the Authority shall act without fear, favour or prejudice.

NEW CLAUSE

1. That the following be a new clause:

Substitution of section 4 of Act 101 of 1965

4. The following section is hereby substituted for section 4 of the principal Act:

Advisory committee

- **4.** (1) The Minister shall establish an advisory committee to advise or act as a consultative body for the Minister and the Authority on matters concerning corporate governance of the Authority.
- (2) The advisory committee contemplated in subsection (1) shall consist of not more than 5 persons who shall be appointed from persons outside the Authority.
- (3) The Minister shall appoint a chairperson for the advisory committee from among the members after having consulted the members.
 - (4) Members of the advisory committee shall—
- (a) be appointed for a term not exceeding five years, which is renewable;
- (b) be fit and proper persons; and
- (c) have appropriate expertise, skills, knowledge or experience and the ability to perform effectively as a member.
- (5) The advisory committee shall determine procedures for its meetings.
- (6) An advisory committee member who has a personal or financial interest in any matter on which the advisory committee gives advice shall disclose that interest and where the advisory committee deems it necessary withdraw from the discussions.
- (7) The Authority shall remunerate a member mentioned above and compensate the member for expenses, as determined

by the Minister after consultation with the Minister of Finance. (8) The advisory committee or its members shall not interfere with the powers assigned to the Chief Executive Officer or the Authority in terms of this Act in so far as those powers relate to the safety, efficacy and quality of products, medical devices or IVDs.

CLAUSE 4

- 1. On page 5, in line 11, to omit "**4**,".
- 2. On page 5, in line 12, to omit the second "4".

CLAUSE 30

1. On page 15, from line 33, to omit "<u>Chief Executive Officer</u>" and to substitute "<u>Minister</u>".