



health

Department:
Health
REPUBLIC OF SOUTH AFRICA

MEDICINES CONTROL COUNCIL

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Dear Mr Gavin Steel

EXEMPTION OF MEDICAL DEVICES AND IVD'S FROM THE PROVISIONS OF SECTIONS 18A, 18B AND 22G OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965) AS AMENDED

Your letter dated 15 November 2017 refers.

Kindly note that your request for exemption from the requirements of sections 18A, 18B and 22G of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), was tabled at the Medicines Control Council meeting of the 23 November 2017.

Resolution 12.06

In terms of section 36 of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) Council resolved to **recommend** to the Minister of Health that:

MEDICAL DEVICES AND IVD'S

Be exempted from sections 18A and 18B of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) as amended, for a period of one (1) year effective from the date of Council resolution publication through the Government gazette.

Council further resolved that section 22G of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) as amended, is not within the mandate of Council but of the Pricing Committee.

Yours faithfully

A handwritten signature in dark ink, appearing to read 'Dr J Gouws', is written over the printed name.

Dr J GOUWS

REGISTRAR OF MEDICINES

DATE: 05/12/2017