



21 December 2018

**STATEMENT REGARDING THE EXTENSION OF THE [SECTION 36 EXEMPTION](#):  
SECTIONS 18A AND 18B (MEDICAL DEVICES) OF THE MEDICINES AND RELATED  
SUBSTANCES ACT, 1965 (ACT 101 OF 1965)**

**To all Stakeholders**

On the 18<sup>th</sup> December 2018 the Minister of Health, in terms of section 36(1) of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), and upon recommendation of the South African Health Products Regulatory Authority (SAHPRA), approved the exclusion of all medical devices and *in vitro* diagnostics (IVDs) from the provisions contemplated under Sections 18A and 18B of Act No. 101 of 1965.

This exemption relates to the supply of medical devices and IVDs according to a bonus system, rebate system or any other incentive scheme and sampling of medical devices and IVDs.

This exemption shall be effective immediately for a period not exceeding three (3) years from the date signed herein by the Minister.

Please note that while the Section 36 exemption has been approved by the Minister of Health, the signed Government Notice awaits publication in the Government Gazette and as such has not been assigned a reference number or publication date.

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