



# health

Department:  
Health  
REPUBLIC OF SOUTH AFRICA

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ATTENTION: Head of regulatory affairs, Pharmaceutical Industry

**RE: PRICING OF MEDICINE DELIVERY SYSTEMS POST THE PROCLAMATION  
ON 01 JUNE 2017 OF THE AMENDMENTS TO THE MEDICINES AND  
RELATED SUBSTANCES ACT 101 OF 1965.**

1. This communique serves to address implications to the pricing of medicine delivery devices post proclamation of the latest amendments to the Medicines and Related Substances Act 101 of 1965 (the Medicines Act).
2. Section 36 (2) provides for the Minister, upon recommendation of the Pricing Committee (PC), to exempt where applicable certain medicines and scheduled substances from Section 22 G provisions of the Medicines Act, as amended.
3. On 14 June 2017 the Pricing Committee made a recommendation for devices to be exempt for a period not exceeding 15 months and not beyond 30 September 2018. The intention is to publish a gazette by no later than end of December 2017 wherein inputs will be solicited from interested persons regarding the extension of this exemption beyond the aforementioned deadline.
4. In light of the above, devices such as cartridges, pen sets, prefilled syringes, insulin pens, inhalers, pumps, stents and disposable pens etc., which contain medicines and scheduled substances that are currently sold at Single Exit Price (SEP), must not be priced differently or amended on the basis of the aforementioned amendment, pending resolution by Minister and Pricing Committee.
5. The proclamation of the amendments to the Medicines Act on 1<sup>st</sup> June 2017 must therefore not be construed to suggest termination of supply of devices by



any manufacturer or importer especially in cases where a medicine or scheduled substance would otherwise be rendered ineffective without the delivery mechanism or device.

6. Stakeholders are deemed to be cognisant of the requirement to comply with all other provisions of the Act and to ensure not to read Section 36 (2), in isolation.
7. Further clarity on the communicate may be addressed with Ms Ntobeko Mpanza on the following contact details: email: [mpanzm@health.gov.za](mailto:mpanzm@health.gov.za); Tel: 012 395 8209/10.

**CLUSTER MANAGER: SECTOR WIDE PROCUREMENT**

**NATIONAL DEPARTMENT OF HEALTH**

**MR GAVIN STEEL**

  
**SIGNATURE:**

**DATE: 04 JULY 2017**