1. **(b) Australia: Medicines: Suspensions of ranitidine-containing products from the ARTG**

The Therapeutic Goods Administration (TGA) announces that the following ranitidine-containing products from Arrow Pharma Pty Ltd, Apotex Pty Ltd, Sandoz Pty Ltd, Alphapharm Pty Ltd and Avallon Pharmaceuticals Pty Ltd will be suspended from the Australian Register of Therapeutic Goods (ARTG) starting from 16 Dec 2019 for 6 months to 16 Jun 2020. The products will be suspended because under subsection 29D(1)(b); it is likely there are grounds for cancelling this medicine from the ARTG under section 30(2)(a) on the basis that the quality of the goods is unacceptable.

Company	**Product Name**
Arrow Pharma Pty Ltd	- AUSRAN ranitidine 150mg (as hydrochloride) tablet bottle - AUSRAN ranitidine 300mg (as hydrochloride) tablet bottle - AUSRAN ranitidine 150mg (as hydrochloride) tablet blister pack - AUSRAN ranitidine 300mg (as hydrochloride) tablet blister pack
Apotex Pty Ltd	- TERRY WHITE CHEMISTS RANITIDINE ranitidine 150mg (as hydrochloride) tablet blister pack - CHEMMART RANITIDINE ranitidine 150mg (as hydrochloride) tablet blister pack - TERRY WHITE CHEMISTS RANITIDINE ranitidine 300mg (as hydrochloride) tablet blister pack - CHEMMART RANITIDINE ranitidine 300mg (as hydrochloride) tablet blister pack - APO-RANITIDINE ranitidine 150 mg (as hydrochloride) tablet blister pack - APO-RANITIDINE ranitidine 300mg (as hydrochloride) tablet blister pack
Sandoz Pty Ltd	- RANITIDINE GH ranitidine (as hydrochloride) 150 mg film-coated tablet blister pack - RANITIDINE GH ranitidine (as hydrochloride) 300 mg film-coated tablet blister pack - RANITIDINE SANDOZ ranitidine 150mg (as hydrochloride) tablet blister pack - RANITIDINE SANDOZ ranitidine 300mg (as hydrochloride) tablet blister pack - RANITIDINE SANDOZ ranitidine 50mg/5mL (as hydrochloride) concentrated injection ampoules
Alphapharm Pty Ltd	- RANI 2 ranitidine 300mg (as hydrochloride) tablet blister pack - RANI 2 ranitidine 300mg (as hydrochloride) tablet bottle - RANI 2 ranitidine 150mg (as hydrochloride) tablet bottle - RANI 2 ranitidine 150mg (as hydrochloride) tablet blister pack - RANITIDINE ALPHAPHARM ranitidine 150mg (as hydrochloride) tablet blister pack - RANITIDINE ALPHAPHARM ranitidine 300mg (as hydrochloride) tablet blister pack
Avallon Pharmaceuticals	- NOUMED RANITIDINE ranitidine (as hydrochloride) 150 mg tablet blister pack - NOUMED RANITIDINE ranitidine (as hydrochloride) 300 mg tablet blister pack

Pty Ltd	

Please refer to the following website in TGA for details:
http://www.tga.gov.au/medicines-suspensions-artg

In Hong Kong, the following ranitidine product is a registered pharmaceutical product:

- Ranital Tab 150mg (HK-34755; a Sandoz product currently not available for sale) registered by Novartis Pharmaceuticals (HK) Limited.

The other products mentioned in the news are not registered pharmaceutical products.

Currently, there are 67 registered pharmaceutical products containing ranitidine in Hong Kong. These products in the forms of oral preparations and injections are controlled as over-the-counter medicines and prescription-only medicines respectively. So far, the Department of Health (DH) has not received any case of adverse drug reaction related to ranitidine.

Related news on the detection of N-nitrosodimethylamine (NDMA) in ranitidine products was previously issued by various overseas drug regulatory authorities, and was posted on the Drug Office website since 16 Sep 2019, with the latest update posted on 20 Nov 2019. Letters to inform local healthcare professionals were issued by the DH on 18 Sep 2019. The DH has contacted the relevant overseas drug regulatory authorities for further information regarding the detection of NDMA in ranitidine products, and continues to remain vigilant on the update findings and investigation result announced by the authorities for consideration of any action deemed necessary.

The DH has contacted the certificate holders of all registered ranitidine products for follow up on the local impact of the issue; and to provide evidence that NDMA in the products are below the acceptable limit, and samples of ranitidine-containing products have been collected from the market for analysis. When any health risks are posed to the public, a press statement will be issued as soon as possible. The following are the main content of the press statements issued previously:

- On 24 Sep 2019, the DH endorsed a licensed drug wholesaler, GlaxoSmithKline Ltd, to recall all Zantac products (HK-42792, HK-42793, HK-30459, HK-42045) from the Hong Kong market as a precautionary measure due to the presence of NDMA in the products.
- On 25 Sep 2019, the DH endorsed licensed drug wholesalers Hind Wing Co Ltd and Top Harvest Pharmaceuticals Co Ltd to recall Apo-Ranitidine Tablets (HK-42273, HK-41873) and Zantidon Tablets 150mg (HK-64329) respectively.
- On 27 Sep 2019, the DH endorsed licensed drug manufacturer APT Pharma Limited and licensed drug wholesaler Eugenpharm International Limited to recall Amratidine Tablets 150mg (HK-53143) and Peptil H 150 Tablets 150mg (HK-65103) respectively.
- On 30 Sep 2019, the DH endorsed licensed drug wholesaler Vast Resources Pharmaceutical Limited to recall Weidos Tablets 150mg (HK-62210).
- On 11 Oct 2019, the DH endorsed licensed drug wholesaler Hind Wing Co Ltd to recall Epadoren Solution for Injection 50mg/2ml (HK-61752).
- On 1 Nov 2019, the DH endorsed licensed drug wholesaler Welldone Pharmaceuticals Limited to recall 6

ranitidine-containing products: Epirant Tab 150mg (HK-56826), Welldone Ranitidine Tab 150mg (HK-57473), Kin Pak Tab 150mg (HK-56824), Wah Tat Tab 150mg (HK-56823), Super Pro Tab 150mg (HK-56825) and Glo-Tac Tab 150mg (HK-57472).
- On 7 Nov 2019, the DH endorsed licensed drug wholesalers Healthcare Pharmascience Limited, Julius Chen & Co (HK) Limited and Atlantic Pharmaceutical Limited to recall 5 ranitidine-containing products: Raniplex 150 Tablet 150mg (HK-43456), Tupast Tablet 150mg (HK-50378), Wontac Tablet 150mg (HK-60085), Jecefarma Ranitidine Tablet 150mg (HK-64041) and Ratic Tablet 150mg (HK-61083).
- On 12 Nov 2019, the DH endorsed registration certificate holder Medreich Far East Limited to recall Ulticer Tab 150mg (HK-53488).

Patients who are taking ranitidine-containing products should not stop taking the medicines, but should seek advice from their healthcare professionals for proper arrangement, e.g. use of alternative medicines with similar uses.

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