SAHPRA
SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

Media Release

MEDICINES SAFETY COMMUNICATION

REASSURANCE ON THE SAFETY OF VALSARTAN-CONTAINING MEDICINES REGISTERED IN SOUTH AFRICA

To all Consumers and Healthcare Professionals

From: The Acting CEO of SAHPRA

Date: 20 December 2018

The South African Health Products Regulatory Authority (SAHPRA) would like to update and reassure the public on the status of valsartan-containing medicines in response to recent renewed concerns about valsartan. SAHPRA previously issued a press release regarding the recall of Pharma Dynamics Dynaval-Co range, containing the active ingredient, valsartan (23 July 2018). These medicines were recalled due to the detection of an impurity, N-nitrosodimethylamine (NDMA), in the valsartan active substance, manufactured by Zhejiang Huahai Pharmaceuticals, used to produce the Dynaval-Co Range. The key messages are:

- There are currently no affected products on the South African markets.
- The only amlodipine-containing products that were implicated in other countries were those that were available in combination with valsartan-containing products. Therefore amlodipine-containing products in South Africa are not contaminated with NDMA.
- The products that were affected (Dynaval-co range) have been recalled from the market and suspended from sale. Patients who are still on Dynaval-Co range of products should continue taking their medication but seek immediate medical attention as the risk of harm to patients' health may be higher if the treatment is abruptly stopped without an alternative treatment being initiated.
- Although there are other valsartan-containing products registered, most of them are currently not marketed, but all the manufacturers, including those with marketed products, have reassured SAHPRA that their products do not contain the implicated active pharmaceutical ingredient (API).
- SAHPRA is continuing to monitor the situation and would therefore like to reassure South Africans that if they are on any valsartan and/or amlodipine-containing medicines other than the Dynaval-Co Range, they can continue to use these without concerns of them being contaminated with NDMA.
- SAHPRA further reminds South Africans that if anyone is concerned about their blood pressure medication, they should see a doctor or pharmacist for further advice. Unsupervised changes to antihypertensive and heart medicines can be potentially dangerous to health.

Healthcare professionals in South Africa are urged to report any adverse reactions, particularly those associated with valsartan-containing medicines to SAHPRA Pharmacovigilance unit at (012) 395 9133 or to the National Adverse Drug Event Monitoring Centre at (021) 4471618 or using the reporting form which can be accessed at http://www.mccza.com/documents/14ed44a46.04_ARF1_Jul16_v4.pdf and e-mailed to adr@health.gov.za

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