TANZANIA FOOD AND DRUGS AUTHORITY

PRESS RELEASE

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SAFETY OF MEDICINES USED FOR MANAGEMENT AND TREATMENT OF HYPERTENSION AND HEART FAILURE CONTAINING VALSARTAN AS AN ACTIVE PHARMACEUTICAL INGREDIENT

1. Tanzania Food and Drugs Authority (TFDA) wishes to inform the public about safety and use of antihypertensive medicines for management and treatment of hypertension and heart failure containing Active Pharmaceutical Ingredient Valsartan either alone or in combination with other drug substances.

2. Valsartan containing medicines in tablet form have been in use in many countries for management and treatment of the conditions described above.

3. On 18th July 2018 World Health Organization (WHO) raised an alert regarding presence of a potentially carcinogenic impurity known as N-nitrosodimethylamine (NDMA) in the active pharmaceutical ingredient (API) namely Valsartan manufactured by the company named Zheijiang Huahai Pharmaceuticals Linhai based in China. However there are other manufacturers who produce Valsartan which is not contaminated by impurity NDMA.

4. The impurity was detected by the manufacturer Zheijiang Huahai Pharmaceuticals Linhai following which regulatory authorities and manufacturers worldwide were notified. The presence of impurity NDMA in Valsartan was thought to be related to changes in the manufacturing process of the API.

5. The review which has been conducted has shown that NDMA is a potential carcinogenic impurity.

6. Six (6) medicines containing Valsartan sourced from Zheijiang Huahai Pharmaceuticals Linhai were registered by TFDA as shown in the table below:

S/N	Brand Name	Name of API	Name of FPP Manufacturer	Dosage form
3.1	Valsar – Denk 80	Valsartan 80 mg	Denk Pharma GmBH & Co. KG – Germany	Tablets
3.2	Valsar – Denk 160	Valsartan 160 mg	Denk Pharma GmBH & Co. KG – Germany	Tablets
3.3	Valsar – Denk 320	Valsartan 320 mg	Denk Pharma GmBH & Co. KG – Germany	Tablets
3.4	CoValsar – Denk 160/12.5	Valsatartan 160 mg/Hydrochlorothiazide 12.5 mg	Denk Pharma GmBH & Co. KG – Germany	Tablets
3.5	CoValsar – Denk 80/12.5	Valsatartan 80 mg/Hydrochlorothiazide 12.5 mg	Denk Pharma GmBH & Co. KG – Germany	Tablets
3.6	CoValsar – Denk 320/12.5	Valsartan 320 mg/Hydrochlorothiazide 12.5 mg	Denk Pharma GmBH & Co. KG – Germany	Tablets

7. Based on the available information, TFDA has instigated the recall from the market of all medicines manufactured by Denk Pharma GmBH & Co. KG – Germany as listed in the table above and the manufacturer has been directed to recall the medicines within 14 days.

8. All patients using medicines containing Valsartan manufactured by Denk Pharma GmBH & Co. KG - Germany are required to stop using them and visit any nearby hospital or health facility for alternative options.

9. Healthcare providers are directed to stop prescribing the concerned medicines and should prescribe alternative brands which have been registered by TFDA.

10. All pharmacy owners are requested to return the above listed medicines to the distributor of those medicines.

11. It should also be noted that, TFDA has also registered other medicines containing the Valsartan sourced from other companies which can be used alternatively to treat hypertension and heart failure.

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