Dear Healthcare Professional,

SAFETY INFORMATION ON MEDICINES CONTAINING VALSARTAN FROM ZHEJIANG HUAHAI FOLLOWING DETECTION OF AN IMPURITY

The Food and Drugs Authority (FDA) has become aware of contamination of some medicines containing valsartan manufactured with active ingredient from Zhejiang Huahai Pharmaceuticals in Linhai, China. This is because the valsartan supplied by this manufacturer was found to contain an impurity, N-nitrosodimethylamine (NDMA), an organic chemical that is in a family of potent cancer causing agents.

The presence of NDMA was unexpected and is thought to be related to changes in the way the active ingredient (valsartan) was manufactured. A worldwide recall of about 2,300 batches from 22 countries of products manufactured by different companies for which the valsartan used was obtained from Zhejiang Huahai Pharmaceuticals, China is underway.

Available information indicates that batches of valsartan tablets manufactured by Dexcel Pharma Ltd and Actavis Group (now Accord Healthcare) are affected.

The FDA is carrying out further investigations to find out other products containing valsartan which may be affected and will provide updates as additional information becomes available.

Medicines containing valsartan are used to treat patients with high blood pressure in order to reduce complications such as heart attack and stroke. It is also used in patients who have had heart failure or a recent heart attack.

Information for Patients
- Do not stop taking your valsartan medicine unless you have been told to do so by your doctor or pharmacist because not all valsartan containing products contains the NDMA.
- Contact your doctor or pharmacist if you are taking products from Dexcel Pharma Ltd and Actavis Group (now Accord Healthcare).

Information for healthcare professionals
- Stop supplying all valsartan containing medicines from Dexcel Pharma Ltd and Actavis Group (now Accord Healthcare) and contact the FDA on Mobile: 024 4310 297 or Email: drug.safety@fdaghana.gov.gh.
Additionally, healthcare professionals and consumers are encouraged to be more vigilant when using such products and report any untoward effect to the National Pharmacovigilance Centre through the underlisted means:

- E-mail: drug.safety@fdaghana.gov.gh
- SMS Short code: 4015
- Telephone: 024 4310 297

Yours faithfully,

Signed

DELESE A. A. DARKO (MRS)
CHIEF EXECUTIVE OFFICER