Most Immediate
Through Courier

F. No.13 - 38/2018-QC
Government of Pakistan
Drug Regulatory Authority of Pakistan
Ministry of National Health Regulation Services & Coordination
****

Islamabad, the 12th July, 2018

The Additional Director, Drug Regulatory Authority of Pakistan, **Islamabad.**	The Additional Director, Drug Regulatory Authority of Pakistan, **Karachi .**
The Additional Director, Drug Regulatory Authority of Pakistan, **Peshawar**	The Additional Director, Drug Regulatory Authority of Pakistan, **Lahore.**
The office incharge, Drug Regulatory Authority of Pakistan, **Quetta .**	

Recall Alert

Subject: **DRAP Reviewing Medicines Containing Valsartan From Zheijiang Huahai Following Detection Of Carcinogenic Impurity.**

I am directed to refer to subject cited above and to say that review was triggered by European Medicines Agency (EMA) and EMA detected an impurity, N-Nitrosodimethylamine (NDMA), in the valsartan active ingredient which the company supplies to manufacturers producing some of the valsartan medicines available in the EU including Pakistan.

2. **That NDMA is classified as a probable carcinogenic (a substance that could cause cancer) bases on results from laboratory tests**. The presence of NDMA was unexpected and is sought to be related to changes in the way the active substance was manufactured. The review is underway, National Authorities across the EU are recalling medicines containing valsartan supplied by **Zheijiang Huahai**. Valsartan medicines are used to treat patients with high blood pressure in order to reduce complications such as heart attack and stroke.

3. Keeping in view of above, you are requested **to implement the recall of the finished drugs containing valsartan manufactured by M/s Zheijhiang Huahai pharmaceuticals,**

OFFICE OF THE ... DRAP
Dy. No. 2646
Dated 12-07-18

China under sub section 3.7 of Section 3 of the Schedule B-II of the Drugs (Licensing, Registration &Advertising) Rules, 1976. It is also requested to direct the Federal Inspectors of Drugs for preparing inventory of the API of valsartan manufactured by **M/s Zheijhiang Huahai pharmaceuticals, China** and "not to dispose off" the same on prescribed form in the public interest till final decision by the Competent Authority.

4. The list of Manufacturers who imported the said API from **M/s Zheijhiang Huahai pharmaceuticals, China** is as under:

i. M/s Amarant Pharmaceuticals (pvt) ltd Karachi
ii. M/s Efroze Chemical Industries, Karachi.
iii. M/s High-Q Pharmaceuticals, Karachi.
iv. M/s PharmEvo(pvt). Ltd, Karachi.
v. M/s Safe Pharmaceuticals (pvt) ltd, Karachi.
vi. M/s Sami Pharmaceuticals pvt ltd, karachi.
vii. M/s Tabros Pharma(pvt). Ltd, karachi.
viii. M/s Searle Pharmaceuticals. Lahore
ix. M/s Genetics Pharmaceuticals. Lahore.

5. This recall shall also be implemented on all medicines containing valsartan (API) manufactured by **M/s Zheijhiang Huahai Pharmaceuticals, China** whether locally manufactured or imported but not included in above mentioned list.

6. All the health care professionals are requested to take necessary measures in the treatment of patients using valsartan products of the above mentioned manufacturers to protect patients from the complications of NDMA.

Zain Ul Abidin
Assistant Director (QC-V)

Copy for information and necessary action to:

i. The Chief Drug Controller/ Inspector, Punjab, Sindh, Baluchistan, KPK, AJK, GB and ICT.
ii. All stake holders (PPMA, Pharma Bureau, PPA, PMA, PCDA etc)
iii. PS to CEO, DRAP, Islamabad.
iv. The Additional Director, MIS Division(with the request to upload on DRAP'S website)
v. Office copy.

Zain 12-07-2018.